

A Randomized Controlled Trial for Evaluation of the Effectiveness of Oral Irrigator and Interdental Floss for Plaque Control in Children with Visual Impairment

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ABSTRACT

Aim: To evaluate the effectiveness of oral irrigator and interdental floss as adjuncts to manual tooth brushing in 8–16 years old children with visual impairment.

Materials and methods: A three-arm, parallel-group randomized controlled trial with blinded outcome assessment was carried out with the inclusion of 90 institutionalized children with visual impairment of age 8–16 years. They were equally allocated to three groups: group I: tooth brushing along with interdental flossing, group II: brushing along with a powered oral irrigator, and group III: brushing alone (control). Baseline oral hygiene index-simplified (OHI-S), gingival index (GI), and plaque index (PI) scores were recorded for all the samples and compared with post-intervention scores at 14 and 28 days intervals. Repeated measures of analysis of variance (ANOVA), one-way ANOVA, and *post hoc* Tukey tests were used for statistical analysis.

Results: At 28 days interval, children in group II showed a highly statistically significant reduction in OHI-S (0.46; $p = 0.0001$), PI (0.16; $p = 0.0001$), and GI (0.24; $p = 0.0001$) scores compared to control group. They also showed a significant reduction in OHI-S (0.25; $p = 0.018$), PI (0.15; $p = 0.011$), and GI (0.15; $p = 0.0001$) scores compared to group I. There is no significant reduction in the scores of children of group I compared to control group except for the GI score (0.08; $p = 0.02$).

Conclusion: Oral hygiene maintenance using oral irrigator along with brushing was found to be more effective in visually challenged children. Interdental flossing, along with brushing and brushing alone was found to be less effective.

Clinical significance: This study underlines the fact that comprehensive oral hygiene care should include interdental cleaning aids for effective plaque control to prevent dental diseases in children with visual impairment. Since these children have less manual dexterity to perform good oral hygiene practices, electrically driven interdental cleaning aids like oral irrigator may help them to overcome the problem.

Keywords: Interdental floss, Oral hygiene, Oral irrigator, Randomized controlled trial, Visual impairment.

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INTRODUCTION

Maintenance of good oral health is essential for the quality of one's personal and social life. Unfortunately, oral health care remains the most unmet health care need in children with disability since general health is given priority.¹ Management of unmet dental treatment needs in children with disability poses greater challenges in terms of knowledge, special infrastructure in dental office, extra time, and competency levels of the clinician.

Complete visual impairment relates to a person's eyesight, which cannot be corrected to normal vision. These children routinely face many challenges in day-to-day life that include the maintenance of proper oral hygiene.^{2,3} When compared with normally sighted peers, children with visual impairment have poor oral hygiene.^{4,5} These children have decreased manual dexterity,⁶ which may lead to the accumulation of dental biofilm, gingival inflammation, and dental caries.⁷

The effectiveness of manual toothbrushes was limited to facial, lingual, and occlusal surfaces of the teeth.⁸ For complete oral hygiene maintenance, interdental cleaning aids are essential. Dental floss is the most commonly used and efficient interdental cleaning aid. However, flossing is technique sensitive, and it requires patient compliance.⁹ As children with visual impairment have less

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self-help skills,⁴ they are dependent on caretakers for performing oral hygiene.¹⁰

Another interdental cleaning aid used with ease is oral irrigator, which delivers a pulsating stream of water via controlled pressure. This is useful in the removal of interdental and subgingival plaque on tooth surfaces and reduces inflammation.¹¹ Oral irrigation is effective, easy to perform, less time taking, and even caretakers can maneuver.^{12,13} Hence, this clinical trial was carried out to evaluate

the effectiveness of oral irrigator and interdental floss as adjuncts to manual tooth brushing in children with visual impairment.

MATERIALS AND METHODS

A three-arm, parallel-group randomized controlled trial with blinded outcome assessment was carried out with the prior approval by the Institutional Review Board (VDC/IEC/2017/16), and the trial was registered with the Clinical Trials Registry-India (CTRI/2018/05/014171). The protocol is in compliance with the ethical standards of the human experimentation, Declaration of Helsinki.

Informed consent was obtained from the authorities of four selected residential schools in the Godavari districts of Andhra Pradesh. Background and protocol of the study were thoroughly explained to the school authorities. A total of 90 children with visual impairment aged 8–16 years were selected. Children with complete visual impairment having mild to moderate gingivitis (scores one and two of Loe and Silness GI) were included in the study. Children with syndromes, systemic diseases, periodontal abscess, gingival ulceration, and under medication (drugs associated with gingival hyperplasia) were excluded.

Study outcome is the evaluation of the effectiveness of oral irrigator and interdental floss as adjuncts to manual tooth brushing by comparing the baseline data with the post-intervention scores at 14 and 28 days intervals in children with visual impairment.

Sample Size and Allocation

The sample size was calculated using G*Power 3.1 software based on the data from the previous study.¹⁴ At a level of significance set at 5%, power of the study at 80%, and for an expected effect size of 0.75, it was calculated that 28 samples per group were required to perform the study. Assuming the 5% loss to follow-up, a sample size of 30 children was taken in each group.

A total of 90 children were randomly allocated to three groups: group I: manual tooth brushing along with interdental flossing ($n = 30$), group II: manual tooth brushing along with oral irrigator ($n = 30$), and group III: manual tooth brushing alone (control group, $n = 30$) using lottery method. Allocation details were noted on the cards and sealed in envelopes which were then numbered. Outcome assessor and data analyst were blinded to the allocation.

Baseline data of the oral hygiene status was recorded using OHI-S, PI, and GI by examining the children with diagnostic instruments under daylight. The principal investigator demonstrated the horizontal method of tooth brushing to visually challenged children using study models and toothbrushes by tell, feel, do technique. Investigator also demonstrated the use of oral hygiene irrigator with standard tip (Waterpik oral irrigator WP70EC, USA) and the multi-tufted, unwaxed interdental floss with holder (Younifloss-ICPA, Mumbai, India) to the caretaker. After a week, the same was repeated for both subjects and caretaker to reinforce the previous learning.

Two examiners were selected and trained to assess the post-intervention indices scores. They were standardized by allotting 10% of the sample size. Intraexaminer and interexaminer reliability was checked with kappa statistics and was found to be 0.88 and 0.83, respectively, indicating an almost perfect consistent agreement. Post-intervention scores at 14 and 28 days intervals were recorded and tabulated.

Statistical Analysis

The obtained data were subjected to statistical analysis using parametric tests. Repeated measures of ANOVA were used for intragroup comparison, one-way ANOVA for intergroup comparison, followed by *post hoc* Tukey test for intra and intergroup multiple comparisons.

RESULTS

Participation of the subjects through the study period is depicted in Consolidated Standards of Reporting Trials (CONSORT) flow diagram (Fig. 1). The mean age of the participants was 12.69 ± 0.96 years. The study sample consisted of 42 males and 48 females. Participants were recruited in March 2018 and followed up for 28 days. All the children were available for the follow-up without any dropouts.

Intragroup comparison of the mean baseline and post-intervention scores of all the indices was found to be highly statistically significant ($p = 0.0001$) in all three groups (Table 1).

On intragroup multiple comparisons of mean reduction in the indices scores, a statistically highly significant difference was observed between the baseline vs 14 and 28 days intervals ($p = 0.0001$) in both group I and group II as well as baseline vs 28 days in group III. However, the reduction at 28 days interval was found to be higher compared to 14 days interval in all the groups (Table 2).

On intergroup comparison of the mean baseline and post-intervention scores of the indices, a highly statistically significant difference ($p = 0.0001$) was found at 28 days interval in all the indices scores (Table 3).

At 14 days interval, children in group II showed a statistically significant reduction in OHI-S (0.31; $p = 0.01$), PI (0.18; $p = 0.001$), and GI (0.24; $p = 0.0001$) scores compared to group 3. There was no significant difference in the scores of the children of group II compared to group I except for the GI score (0.18; $p = 0.0001$). Also, no significant difference was observed in the children of group I compared to group III (Table 4).

At 28 days interval, children in group II showed a highly statistically significant reduction in OHI-S (0.46; $p = 0.0001$), PI (0.16; $p = 0.0001$), and GI (0.24; $p = 0.0001$) scores compared to group III. They also showed a significant reduction in OHI-S (0.25; $p = 0.018$), PI (0.15; $p = 0.011$), and GI (0.15; $p = 0.0001$) scores compared to group I. There was no significant difference in the scores of the children of group I compared to group III except for the GI score (0.08; $p = 0.02$) (Table 4).

DISCUSSION

Children with physical disabilities cannot perform appropriate oral hygiene measures on their own; they need assistance or supervision from parents or caretakers.¹⁵ The main barriers for access to oral health of an individual with a disability seem to be inadequate facilities, knowledge, cost, fear, and negative attitude towards dentistry.¹⁶ Children with visual impairment cannot perform oral hygiene practices better because they cannot spot and remove dental plaque.⁵ Hence, they are more likely to have gingival inflammation. The removal of debris and plaque from the surfaces of teeth needs a skill that can be mastered only when an individual has dexterity to manipulate the toothbrush.⁷ Unfortunately, they

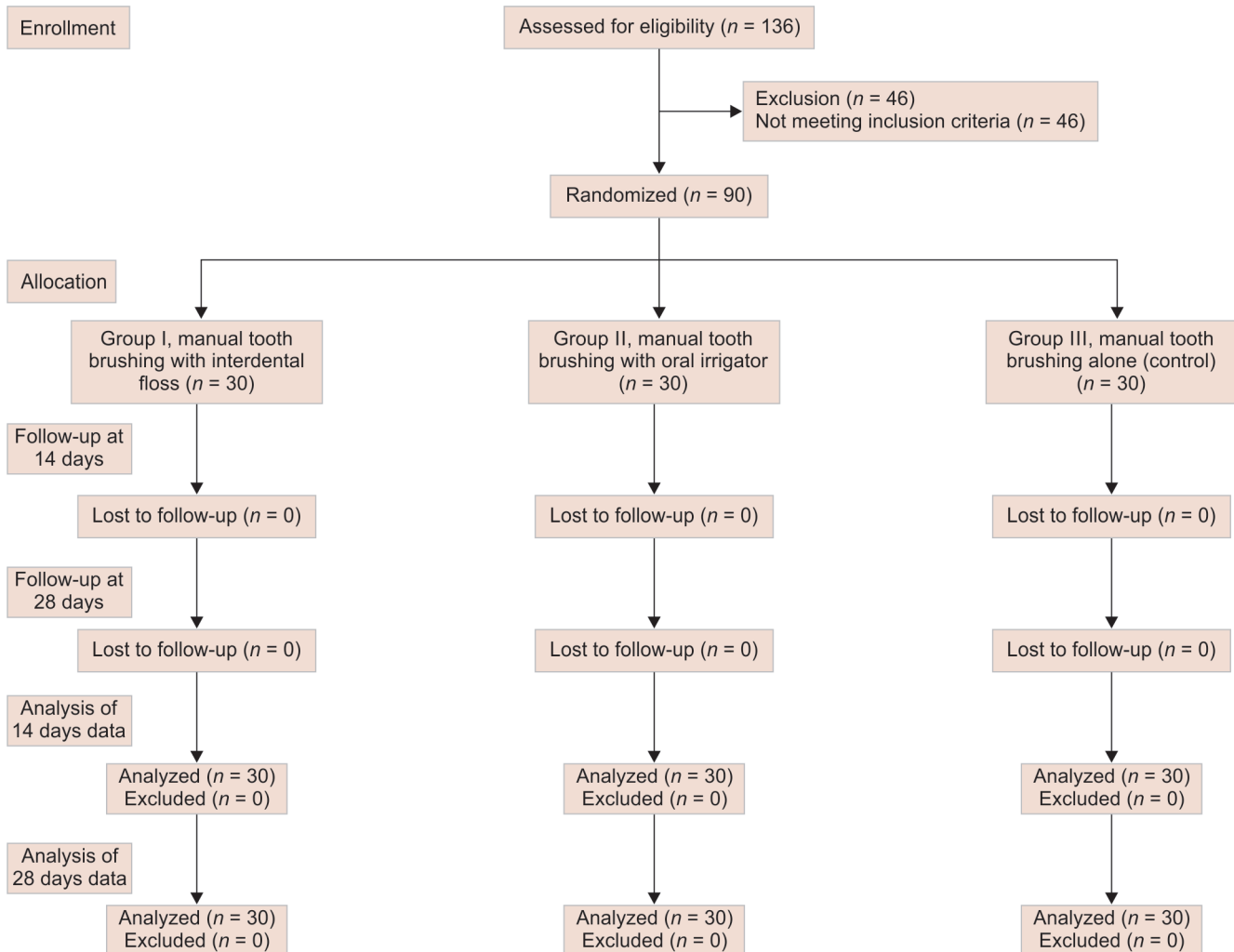


Fig. 1: CONSORT flow diagram

Table 1: Group-wise comparison of mean indices scores between the intervals

Groups	Time interval	OHI-S		PI		GI	
		Mean ± SD	p-value	Mean ± SD	p-value	Mean ± SD	p-value
Group I (brushing + flossing)	Baseline	2.94 ± 0.61	0.0001, HS	1.29 ± 0.15	0.0001, HS	1.03 ± 0.17	0.0001, HS
	14 days	2.30 ± 0.05		0.95 ± 0.11		0.86 ± 0.09	
	28 days	2.02 ± 0.07		0.83 ± 0.11		0.74 ± 0.07	
Group II (brushing + oral irrigator)	Baseline	2.93 ± 0.64	0.0001, HS	1.21 ± 0.21	0.0001, HS	0.98 ± 0.21	0.0001, HS
	14 days	2.24 ± 0.48		0.83 ± 0.24		0.62 ± 0.11	
	28 days	1.76 ± 0.33		0.71 ± 0.17		0.5 ± 0.13	
Group III (brushing alone)	Baseline	2.80 ± 0.39	0.0001, HS	1.21 ± 0.24	0.0001, HS	0.97 ± 0.19	0.0001, HS
	14 days	2.51 ± 0.39		1.03 ± 0.19		0.88 ± 0.14	
	28 days	2.19 ± 0.35		0.86 ± 0.15		0.79 ± 0.11	

Repeated measures of ANOVA; HS, highly significant

are deprived of the opportunity to learn by imitation⁵ and lack self-help skills.⁴

Tooth brushing is the most commonly practiced method for the mechanical control of dental plaque. However, brushing cannot efficiently clean interproximal surfaces. Interdental cleaning aids are recommended as adjunctive to regular tooth brushing for

effective plaque control. Among various interdental cleaning aids, floss is the most commonly used one, but it needs skill. Electrically driven interdental cleaning aids are employed for ease of use, and oral irrigator is one such interdental cleaning aid.

Oral irrigator removes plaque and soft debris through the mechanical action of jet stream of water directed through an

Table 2: Intragroup multiple comparison of the mean difference of indices scores between the intervals

Groups	Time interval comparison	OHI-S		PI		GI		
		Mean diff ± SE	p-value	Mean diff ± SE	p-value	Mean diff ± SE	p-value	
Group I (brushing + flossing)	Baseline vs	14 days	0.63 ± 0.11	0.0001, HS	0.34 ± 0.03	0.0001, HS	0.22 ± 0.03	0.0001, HS
		28 days	0.92 ± 0.11	0.0001, HS	0.47 ± 0.03	0.0001, HS	0.36 ± 0.03	0.0001, HS
	14 days vs	28 days	0.28 ± 0.11	0.046, S	0.12 ± 0.03	0.001, S	0.13 ± 0.03	0.001, S
Group II (brushing + oral irrigator)	Baseline vs	14 days	0.68 ± 0.12	0.0001, HS	0.37 ± 0.05	0.0001, HS	0.35 ± 0.04	0.0001, HS
		28 days	1.16 ± 0.12	0.0001, HS	0.49 ± 0.05	0.0001, HS	0.46 ± 0.04	0.0001, HS
	14 days vs	28 days	0.47 ± 0.12	0.001, S	0.12 ± 0.05	0.069, NS	0.11 ± 0.04	0.02, S
Group III (brushing alone)	Baseline vs	14 days	0.29 ± 0.10	0.012, S	0.18 ± 0.05	0.001, S	0.11 ± 0.44	0.032, S
		28 days	0.61 ± 0.10	0.0001, HS	0.31 ± 0.05	0.0001, HS	0.22 ± 0.44	0.0001, HS
	14 days vs	28 days	0.32 ± 0.10	0.001, S	0.13 ± 0.05	0.025, S	0.11 ± 0.44	0.033, S

Post hoc Tukey test; HS, highly significant; S, significant; NS, not significant

Table 3: Intergroup comparison of mean indices scores at different time intervals

Time interval	Groups	OHI-S		PI		GI	
		Mean ± SD	p-value	Mean ± SD	p-value	Mean ± SD	p-value
Baseline	Group I (brushing + flossing)	2.94 ± 0.61	0.58, NS	1.29 ± 0.15	0.142, NS	1.03 ± 0.17	0.17, NS
	Group II (brushing + irrigator)	2.93 ± 0.64		1.21 ± 0.21		0.98 ± 0.21	
	Group III (brushing alone)	2.80 ± 0.39		1.21 ± 0.24		0.97 ± 0.19	
14 days	Group I (brushing + flossing)	2.30 ± 0.30	0.029, S	0.95 ± 0.11	0.003, S	0.86 ± 0.09	0.0001, HS
	Group II (brushing + irrigator)	2.24 ± 0.48		0.83 ± 0.24		0.62 ± 0.11	
	Group III (brushing alone)	2.51 ± 0.39		1.03 ± 0.19		0.88 ± 0.14	
28 days	Group I (brushing + flossing)	2.02 ± 0.38	0.0001, HS	0.83 ± 0.11	0.0001, HS	0.74 ± 0.07	0.0001, HS
	Group II (brushing + irrigator)	1.76 ± 0.33		0.71 ± 0.17		0.51 ± 0.13	
	Group III (brushing alone)	2.19 ± 0.35		0.86 ± 0.15		0.79 ± 0.11	

One way ANOVA; HS, highly significant; S, significant; NS, not significant

Table 4: Intergroup multiple comparison of mean difference in indices scores at different time intervals

Time interval	Groups	OHI-S		PI		GI		
		Mean diff ± SE	p-value	Mean diff ± SE	p-value	Mean diff ± SE	p-value	
Baseline	Group I vs	Group II	0.01 ± 0.14	0.99, NS	0.08 ± 0.05	0.23, NS	0.05 ± 0.05	0.52, NS
		Group III	0.09 ± 0.14	0.8, NS	0.09 ± 0.05	0.17, NS	0.04 ± 0.05	0.62, NS
	Group II vs	Group III	0.08 ± 0.14	0.84, NS	0.05 ± 0.05	0.98, NS	0.05 ± 0.05	0.98, NS
14 days	Group I vs	Group II	0.06 ± 0.10	0.81, NS	0.11 ± 0.04	0.05, NS	0.18 ± 0.03	0.0001, HS
		Group III	0.24 ± 0.10	0.05, NS	0.06 ± 0.04	0.35, NS	0.06 ± 0.03	0.18, NS
	Group II vs	Group III	0.31 ± 0.10	0.01, S	0.18 ± 0.04	0.001, S	0.24 ± 0.03	0.0001, HS
28 days	Group I vs	Group II	0.25 ± 0.09	0.018, S	0.15 ± 0.03	0.011, S	0.15 ± 0.03	0.0001, HS
		Group III	0.21 ± 0.09	0.06, NS	0.05 ± 0.03	0.25, NS	0.08 ± 0.03	0.02, S
	Group II vs	Group III	0.46 ± 0.09	0.0001, HS	0.16 ± 0.03	0.0001, HS	0.24 ± 0.03	0.0001, HS

Post hoc Tukey test; HS, highly significant; S, significant; NS, not significant

orifice tip to the specific tooth surfaces, thereby reducing plaque formation.¹⁷ Various studies have demonstrated that oral irrigator significantly improves oral hygiene and gingival health.^{13,18} Irrigation devices are proven to be the effective means of reaching into the areas inaccessible to tooth brushing.¹⁷

In the present study, the use of oral irrigators along with tooth brushing was found to be more effective than brushing aided with flossing and brushing alone. Murthy et al. have demonstrated that modified oral irrigation device was more effective than manual tooth brushing alone in 6-year-old children, and it did not demand any special motor skill.¹² Reduction in gingival bleeding

and inflammation was observed when daily oral irrigation was practiced along with both powered and manual tooth brushing.¹¹ A systematic review summarized that oral irrigation has beneficial effects in reducing dental plaque and improving gingival health over regular oral hygiene or tooth brushing alone.¹⁹

In the present study, children who practiced tooth brushing along with flossing showed improved oral hygiene compared to the children who performed tooth brushing alone. A similar observation was noticed by Graves et al., where both brushing and flossing together had a greater impact on the reduction of gingival bleeding.²⁰ Daily flossing significantly reduced the

amount of interdental plaque compared to the manual brushing regimen alone.²¹

The probable reason for better results with flossing along with manual tooth brushing in the present study is it removes plaque from interproximal areas, thereby reducing the gingival inflammation and bleeding from the interdental region. Even though flossing has shown better results, it requires extra skill and dexterity, and is practically tedious and time-consuming.

Children who performed oral hygiene practice with tooth brushing alone have shown less improvement. This fact only underlines that comprehensive oral hygiene care should include interdental cleaning aids. Children with physical disabilities require more attention from their caregivers for the maintenance of oral health, which is an integral part of general health. Therefore, caregivers should have proper knowledge, skill, and patience for effective oral hygiene care in children with disabilities.

CONCLUSION

The use of oral irrigator along with tooth brushing was found to be more effective for oral hygiene care compared to interdental flossing with brushing and also tooth brushing alone. This study outcome underlines that regular oral hygiene practice with tooth brushing along with interdental cleaning is essential for effective plaque control to prevent dental diseases in children with visual impairment.

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