Evaluation of an alum-containing mouthrinse in children for plaque and gingivitis inhibition during 4 weeks of supervised use

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Abstract

Aluminum salts have demonstrated activity against oral bacteria and also have shown indications of inhibiting plaque and gingivitis. The aims of this clinical trial were to determine the effects of daily supervised rinsing with a specially formulated, alum-containing mouthrinse on existing plaque and gingivitis in children and to monitor its effect on the oral tissues and its acceptability to subjects. Using a double-blind, parallel design, 48 sixth-graders rinsed once daily for 30 sec under supervision with either a placebo or a mouthrinse containing 0.02 M alum while continuing their normal oral hygiene habits. Plaque and gingivitis were assessed and intraoral examinations were performed at 0, 2, and 4 weeks. The alum mouthrinse significantly ($P < 0.05$) reduced the amount of plaque relative to the placebo after both 2 and 4 weeks. Gingivitis and plaque thickness also were decreased, but the differences did not attain significance. No evidence of deleterious effects to the oral tissues was observed and the alum mouthrinse was well accepted by the children. This trial demonstrated that daily use of an alum-containing mouthrinse was safe and produced a significant effect on plaque that supplemented the benefits of daily toothbrushing. Thus, topically applied aluminum may have potential applications in preventive dentistry for controlling plaque. (Pediatr Dent 18:139–44, 1996)

Because traditional mechanical methods for controlling plaque have proven inadequate, research efforts have focused on chemotherapeutic agents for reducing or preventing plaque-induced oral diseases. Various metal salts, particularly polyvalent cations (e.g., Sn^{+2} and Zn^{+2}) that have been used widely in dental products, exhibit plaque inhibitory activity. Another polyvalent metal with a long history of oral use is aluminum (Al), primarily as the potassium sulfate salt, alum. In ancient times mouthrinsing with a mixture of alum, salt, and vinegar was advocated by Hippocrates for oral health, and during the 16th century — the first printed work devoted exclusively to dental therapeutics — a mixture of alum, vinegar, myrrh, and wine was recommended for washing the mouth after meals.[1] In modern times Al continues to be used for its astringent properties and only alum and zinc chloride were recommended by the Over-the-Counter Advisory Panel of the FDA as category I active ingredients in mouthwashes.[2] Also, Al salts remain popular as safe and effective gingival retracting agents.[3]

Al has demonstrated activity against oral bacteria. Early studies indicated that several Al salts inhibit growth of salivary bacteria.[4,5] More recently, using modern methods, Al showed antimicrobial activity against cariogenic streptococci[6] as well as normal oral flora and periodontal pathogens.[7] Al significantly reduced the ability of streptococcus microorganisms to colonize on enamel surfaces[8,9] and decreased the colloidal stability of oral bacteria.[10] However, in animal models, no significant effects were found in the composition of fissure plaque of rats that drank water containing 50 ppm Al for 14 days[11] or in the amount of plaque on the molars of rats that were topically treated with a mouthrinse containing 1000 ppm Al for 10 weeks.[12] Nevertheless, in humans, mouthrinsing with Al solutions has been shown to affect plaque accumulation and to alter the pathogenicity of established plaque. Twice-daily rinsing for 3 days with 0.02 M Al inhibited *de novo* plaque formation on clean teeth in young adults.[13] Al concentrations as low as 0.008 M inhibited phosphorolytic activity of several enzymes present in human plaque.[14] A 1-min rinse with 0.02 M $AlCl_3$ significantly reduced the acid-producing capability of plaque in adults for several hours.[15]

There are also indications that topically applied Al may be effective in reducing gingivitis. High concentrations (5-25%) of Al have been used traditionally as gingival retraction agents to reduce inflammation and bleeding following oral surgery.[16] Subgingival irrigation with 20% $AlCl_3$ significantly reduced plaque, gingivitis, bleeding, and probing pocket depth in adults

suffering from periodontitis.[17,18] A dentifrice containing Al lactate demonstrated activity against gingivitis.[19] Also, the Al salt of sucrose octasulfate, i.e. sucralfate, has been found to be useful in healing aphthous ulcers[20] as well as oral mucositis from radiation or chemotherapy[21,22] and stomatitis.[23]

Studies have established that Al also has cariostatic activity.[24] Recent animal studies[12,25,26] showed that Al in aqueous solution significantly reduced caries formation in rats. These findings suggest that regular rinsing with Al solutions may inhibit caries development in humans. However, due to natural astringency, Al solutions must be formulated into a compatible, palatable mouthrinse vehicle to be acceptable for daily use.[27]

The purpose of this clinical study was to examine the effect on existing plaque and gingivitis in children of daily supervised rinsing for a period of 1 month with a specially formulated, palatable mouthrinse containing 0.02 M (500 ppm) Al. Other objectives were to monitor its safety on the oral soft and hard tissues and patient acceptance of the mouthrinse.

Methods and materials

Experimental design

This investigation was a double-blind, stratified comparison of two parallel groups of children who used either a test mouthrinse or a placebo mouthrinse once daily under supervision for a 1-month period. Dental plaque and gingivitis were assessed at entry, 2 weeks, and 4 weeks. In addition, the subjects were questioned and an intraoral examination was performed at each visit to detect adverse or unusual reactions, such as desquamation, extrinsic staining, or unpleasant taste. The subjects were distributed randomly into two balanced groups using on-site frequency distribution graphs of the initial plaque and gingivitis average scores. A dental prophylaxis was not performed so that the subjects began the treatment regimen with their normal, existing level of plaque deposits.

Study population

Volunteers were recruited from the sixth grade of a parochial elementary school in Fort Wayne, Indiana. Signed consent forms were obtained from children and their parents after the nature of the study and possible risks were fully explained. Forty-eight subjects were accepted into the trial after completing a medical history questionnaire and receiving an oral examination. Subject selection was based on good oral health, no serious medical conditions or transmissible diseases, and absence of orthodontic appliances. Participants were not discouraged from receiving necessary dental treatment, but they were not allowed to have a dental prophylaxis during the course of the study. All subjects were instructed to continue their normal home oral hygiene procedures, except that use of mouthrinses other than those assigned was prohibited.

Clinical procedures

Clinical assessments were performed at the school site by two dental examiners using portable dental operatories and accepted methods of infection control. Supragingival plaque was scored by one examiner and gingivitis by a second examiner on the buccal and lingual surfaces of all natural teeth present except teeth with cervical restorations. The gingivitis examiner also performed the intraoral examinations. The examiners dictated the scores to assistants, who recorded them on individual case report forms. Separate forms were used for each examination and at no time were the examiners or recorders aware of the group assignment of any subject. The same examiners performed the clinical measurements at the same time of day throughout the study. Also, examination dates were not announced to the subjects in order to minimize a participation effect. The examiners had extensive experience in the use of the respective clinical indices. However, prior to each examination period, the examiners and clinical staff participated in a standardization session, which allowed the examining team to review the procedures and provided an opportunity for the examiners and principal investigator to review the diagnostic criteria for the clinical indices.

Dental plaque assessments

Supragingival plaque deposits on the teeth were scored using the Quigley and Hein[28] index as modified by Turesky et al.[29] Plaque was disclosed with fluorescein and scored using dichroic filtered light.[30] The facial and lingual surfaces of every tooth were assigned values according to the following criteria:

0 = No plaque
1 = Separate flecks of plaque at the cervical margin of the tooth
2 = A thin, continuous band of plaque (up to 1 mm wide) at the cervical margin
3 = A band of plaque wider than 1 mm, but covering less than one-third of crown
4 = Plaque covering at least one-third, but less than two-thirds of crown
5 = Plaque covering two-thirds or more of crown.

Plaque thickness was assessed using the fluorescein modification[30] for the Plaque Index system.[31,32] A visual estimate of thickness was based on the color intensity of disclosant in the plaque. Plaque thickness was scored for the facial and lingual surfaces of every tooth in each subject on a scale of 0 to 3.

For each plaque index an average score per subject was calculated by summing all scores and dividing by the total number of surfaces scored.

Gingivitis assessment

Gingivitis was scored using the Gingival Index.[33] The facial, lingual, mesial, and distal gingival segments of every tooth were scored according to the following criteria:

0 = No inflammation
1 = Mild inflammation characterized by slight change in color and texture, but no bleeding on probing

2 = Moderate inflammation characterized by moderate glazing, redness, edema, and hypertrophy accompanied by bleeding on probing

3 = Severe inflammation characterized by a marked redness, edema, and/or ulceration with a tendency to bleed spontaneously.

An average Gingival Index score was calculated for each subject by totaling the scores and dividing by the number of gingival segments scored.

Table 1. Demographic characteristics of study population

Mouthrinse Group	Number of Subjects			Age		
	Male	Female	Total	Mean ± SE*	Sig†	Range
Placebo	12	12	24	11.9 ± 0.1	—	11–13
Alum	11	13	24	11.6 ± 0.1	ns‡	11–13

* Mean age in years ± standard error of the mean; †Statistical significance between groups according to one-way ANOVA; ‡ns = not significantly different.

Intraoral examination

The intraoral examination included a visual inspection of the buccal, labial and sublingual mucosa, gingivae, tongue, hard and soft palate, oropharynx, floor of the mouth, lips, and teeth. The site, size, and severity of any lesions or aberrations and a tentative diagnosis, if possible, were recorded on the appropriate form. A judgment was made as to whether or not any abnormalities were attributable to the test materials.

Treatment regimen

Treatment consisted of once-daily supervised use of one of the following mouthrinses:

1. An experimental formulation containing 0.885% (0.02M) hydrated aluminum potassium sulfate, 3.0% Pluronic F127® (BASF Wyandotte Corp, Parsippany, NJ), 0.6% Tween 20® (ICI Americas Co, Wilmington, DE), and 0.1% sodium saccharin in a 10% glycerin/water base adjusted to pH 3.8.
2. A placebo formulation that was a vehicle control containing the same ingredients without aluminum potassium sulfate.

The two mouthrinses, which were citrus flavored (0.3%) and green (0.05%), were alcohol-free and were formulated to be as similar in taste and appearance as possible.

The subjects performed an oral rinse with the assigned product for 30 sec each day. The rinses were self-administered at school at a central location after the noon meal under the direct supervision of the clinical monitor. Using a calibrated pump dispenser, the monitor measured 10 ml of the mouthrinses into disposable cups, which were color-coded according to group and placed on separate trays. After rinsing, the subjects expectorated into the cups, placed them in a waste can, and returned to their classrooms. When school was not in session or a subject was absent, the rinses were self-applied at home under parental supervision. A sufficient supply of mouthrinse, a graduated dispensing cup, and directions were mailed to the parents of each participant at the start of the study.

Data analysis

Mean plaque and gingivitis scores for each group of subjects were calculated and the data were analyzed by means of a statistics program (SAS® version 6.08, SAS Institute Inc., Cary, NC). The statistical tests included analysis of variance for comparisons between groups and matched-pair *t*-testing for longitudinal comparisons within groups.

Results

Study population demographics

All 48 subjects who began the trial were present for the 2-week and 4-week examinations. The distributions of gender and age for each group in this study are presented in Table 1. The mean age for both groups was approximately 12 years and was not significantly different. The numbers of males and females were nearly equal in both groups.

Plaque data

Average plaque area scores for both the placebo and alum mouthrinses at baseline and after 2 and 4 weeks of use are provided in Table 2. As a result of the treatment assignment procedure, both groups were evenly balanced for average plaque area at the beginning of the study, and a statistical analysis demonstrated no significant difference. After both 2 and 4 weeks of daily use, the alum mouthrinse group had significantly less plaque than the placebo group with reductions of 15–17%. A similar effect was observed for plaque thickness data, which are also presented in Table 2. The groups were nearly equivalent for average plaque thickness at the baseline examination, and a statistical analysis showed no significant difference. At both the 2- and 4-week examinations, the alum group had lower plaque thickness scores than the placebo group, but neither reduction attained statistical significance.

Gingivitis data

Mean Gingival Index scores for the alum and placebo mouthrinse groups are presented in Table 2 for all three examinations. The group balancing procedure resulted in nearly equal mean baseline gingivitis scores that were not significantly different. At the subsequent examinations after 2 and 4 weeks of mouthrinsing, the GI scores of the alum group were approximately 6% lower than the placebo group, but the differences between the two groups were not significant. In addition, correlations were made between plaque area and gingivitis scores of all subjects. Significant correlation co-

Table 2. Plaque area, plaque thickness, and gingivitis scores at each examination

Mouthrinse Group	Baseline		2-Week		4-Week	
	Mean ± SE*	Sig†	Mean ± SE*	Sig†	Mean ± SE*	Sig†
			Plaque area			
Placebo	1.87 ± 0.09	—	1.51 ± 0.09	—	1.67 ± 0.11	—
Alum	1.84 ± 0.11	ns‡	1.25 ± 0.12	$P < 0.05$	1.42 ± 0.10	$P < 0.05$
			Plaque thickness			
Placebo	1.92 ± 0.12	—	1.50 ± 0.14	—	1.71 ± 0.11	—
Alum	1.94 ± 0.11	ns	1.35 ± 0.12	ns	1.58 ± 0.11	ns
			Gingivitis			
Placebo	1.35 ± 0.06	—	1.20 ± 0.05	—	1.24 ± 0.05	—
Alum	1.34 ± 0.05	ns	1.13 ± 0.03	ns	1.16 ± 0.04	ns

* Standard error of the mean (N = 24); †Statistical significance between groups according to one-tail t-test; ‡ns = not significantly different.

Table 3. Comparison of differences from baseline of 2-week and 4-week examinations for all clinical indices

Clinical Index	Mouthrinse Group	2-Week Exam		4-Week Exam	
		Δ*	Sig†	Δ*	Sig†
Plaque area	Placebo	0.36	$P < 0.01$	0.20	$P < 0.05$
	Alum	0.59	$P < 0.01$	0.42	$P < 0.01$
Plaque thickness	Placebo	0.42	$P < 0.01$	0.21	$P < 0.05$
	Alum	0.59	$P < 0.01$	0.36	$P < 0.05$
Gingivitis	Placebo	0.15	$P < 0.05$	0.11	$P < 0.05$
	Alum	0.21	$P < 0.01$	0.18	$P < 0.05$

* Difference from baseline examination mean; †Statistical significance between examinations according to matched pair *t*-test.

efficients of 0.58 ($P < 0.001$) and 0.44 ($P < 0.01$) were observed between the two indices at the baseline and final examinations, respectively.

Longitudinal effects

After 2 weeks of supervised mouthrinse use, statistically significant decreases in all clinical indices were observed in both the alum and placebo groups (Table 3). For both groups, all indices increased slightly from the 2- to 4-week examinations, but the differences from baseline were still significant. The fact that reductions in both plaque and gingivitis were observed for the placebo group indicates that a participation (Hawthorne) effect occurred during the study.

Adverse reactions

No adverse reactions were observed affecting either the hard or soft tissues during the 4-week study period. The 2- and 4-week intraoral examinations found no tissue changes from baseline for any of the subjects in either mouthrinse group.

Discussion

The results of this clinical trial demonstrated that a mouthrinse containing 0.02 M Al had a modest but significant effect on the amount of plaque present on children's teeth after 2 and 4 weeks of once-daily supervised use as an adjunct to normal oral hygiene procedures. In spite of several differences in methodology, these findings are in accordance with those of Skjörland et al.[13] who tested an aqueous solution containing the same concentration of 0.02 M Al. Our study was conducted with 12-year-old children and examined the effect of an Al mouthrinse on *existing* plaque during a period of 4 weeks, while their study used young adults who started with plaque-free teeth and participated for 3 days.

Our study was designed to simulate a realistic home treatment regimen in which the subjects rinsed for 30 sec once per day while continuing brushing and other routine oral hygiene practices. On the other hand, Skjörland et al.[13] utilized an accelerated plaque formation model in which the subjects enhanced plaque growth by eight daily rinses with a 15% sucrose solution and abstained from all oral hygiene procedures while rinsing twice per day for 60 sec. Based on these methodological differences, it is reasonable to assume that greater plaque inhibition might have been provided by the Al mouthrinse if the frequency and treatment time were doubled. Nevertheless, it is meaningful that a clinically significant effect was observed that complemented the benefits of daily toothbrushing.

Although no significant effect compared with the placebo was observed for the Al mouthrinse with regard to plaque thickness, it is noteworthy that the relationship between groups paralleled that observed for the plaque area findings. The lack of statistical significance appeared to be due to the greater variance associated with this plaque scoring method at all examinations.

The gingivitis findings were similar to those observed for plaque in that the subjects who were assigned the Al mouthrinse had lower mean scores after both 2 and 4 weeks of use; however, the differences were not significant. This was not surprising in light of the modest inhibitory effects noted for plaque in this study, and the fact that previously reported activity toward gingi-

vitis was accomplished with much higher concentrations of Al using a substantially different method of treatment application.[17,18] Still, it is possible that some gingival health benefits may be realized with topically applied Al by increasing the treatment application time and frequency or the concentration of Al.

Although the Al mouthrinse had only modest effects on plaque and gingivitis compared with the placebo, the data demonstrated that reductions in plaque correlated with reductions in gingivitis. Significant correlation coefficients indicated that subjects with greater amounts of plaque generally exhibited higher levels of gingivitis. This illustrates the well-established clinical relationship between plaque and gingivitis and shows that small plaque reductions can provide gingival benefits.

It is interesting that both groups of subjects in this study improved significantly with respect to plaque and gingival health after 2 and 4 weeks of participation. Significant reductions in plaque and gingivitis have been observed for control groups in other clinical trials as a result of the "Hawthorne Effect" in which the oral hygiene of the subjects improves solely as a result of participation in an experiment and anticipation of a forthcoming oral examination.[34] The fact that the plaque scores for both groups at the 4-week exam were higher than the 2-week exam indicates that the novelty of participating in the study was beginning to diminish, and the subjects were reverting to their normal oral hygiene habits. Similar phenomena have been observed in other dental studies[35] in which the "Hawthorne Effect" decreased as the clinical trial progressed. This participation effect is a confounding factor in determining the actual effectiveness of therapeutic agents. Although steps were taken to minimize the effect in our study by performing the 2- and 4-week exams unannounced, it is evident that a temporary behavioral change in oral hygiene habits nevertheless occurred. It is also possible that decreases in plaque and gingivitis from baseline were due to examiner drift, but this seems unlikely since the examiners were experienced in using the indices, standardization sessions were conducted, and the exams were performed during a relatively short time period of 1 month. Furthermore, both examiners observed the same relationship between groups.

In order to monitor potential adverse effects on oral tissues as a result of daily use of the Al mouthrinse, intraoral examinations were performed during every visit. In addition, for safety reasons, daily exposure was limited to a single 30-sec rinsing, and the study was designed to be discontinued at the 2-week assessment if there was evidence of adverse effects attributable to mouthrinse use. The study was completed without observing any indications of negative effects resulting from mouthrinse use, and the alum mouthrinse was well accepted by the children who took part in the experiment.

Salts of several metals (e.g. copper, iron, magnesium, tin, and zinc) have demonstrated plaque-inhibitory properties, but only stannous tin and zinc salts have found widespread use in dental products. Nevertheless, stannous-containing products have been associated with extrinsic stain formation, and both stannous and zinc salts have organoleptic problems that restrict the concentrations that can be used. A direct comparison of equimolar solutions of $AlCl_3$, $SnCl_2$ and $ZnCl_2$ in the study of Skjörland et al.[13] resulted in similar plaque reductions for all three salts. Although the antiplaque benefit of Al was moderate in this investigation, it is noteworthy that this benefit occurred in addition to the effects of daily toothbrushing when used just once daily for 30 sec. Because of Al's low toxicity, history of use in the mouth, and lack of adverse effects in this experiment, it appears to be safe for long-term oral use and is worthy of further study for potential applications in the practice of preventive dentistry.

Conclusions

1. When compared to a placebo mouthrinse, daily use for 30 sec of a mouthrinse containing 0.02 M alum significantly reduced existing dental plaque in children who followed normal oral hygiene habits including toothbrushing for a period of 4 weeks.
2. The alum mouthrinse also provided reductions in plaque thickness and gingivitis relative to the placebo, but these differences did not attain statistical significance.
3. No adverse effects to the oral hard or soft tissues were observed after using the Al mouthrinse for 4 weeks. The rinse was found to be palatable by the children who participated and appears to be suitable for use in long-term clinical trials.

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