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Research Article

Efficacy of a Rinse Containing Tetrapotassium Pyrophosphate and Sodium Tripolyphosphate on Calculus Formation in a Group of Adults

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ABSTRACT

Objectives: To evaluate a mouth rinse containing tetrapotassium pyrophosphate and sodium tripolyphosphate on supragingival calculus formation in a group consisting initially of forty adults seeking periodontal treatment at a Canadian dental school.

Methods: The extent of supragingival calculus in relation to the lingual surfaces of the lower anterior teeth was measured using the Volpe-Manhold Calculus Index (VMI). In addition, The Plaque Index (PI) was used to evaluate plaque scores while the presence or absence of gingival bleeding index (GBI) was used to determine gingival health. At the completion of the hygiene appointment (baseline), the PI, GBI and VMI was assumed to be zero and the subjects were randomly assigned to test (rinsed twice a day with the anticalculus mouthwash) or control groups (only used regular dentifrice) and appropriate instructions provided. After a 60-day trial period, the test and control subjects were recalled, and the clinical measurements were conducted using the indices indicated above.

Results: There were no statistically significant differences in the overall reduction in the mean VMI scores between the test and control groups.

Conclusion: Within the limitations of the study, rinsing with tetrapotassium pyrophosphate and sodium tripolyphosphate for sixty days did not affect the formation of supragingival calculus in the present cohort of adults.

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Introduction

It is well established that plaque biofilm initiates gingival inflammation and dental caries. Within 2 to 14 days after initial plaque formation, it undergoes a pathologic mineralization process becoming calculus [1]. Phosphate and calcium ions in the saliva are responsible for mineralizing plaque into calculus [2]. The composition of the crystal form of calculus is approximately, "hydroxyapatite 58%, magnesium whitlockite 21%, octacalcium phosphate 12%, and brushite 9%" [3]. Supragingival calculus forms in the presence of biofilm, a relatively low salivary pH and a concomitantly high calcium to phosphorus ratio in saliva [4].

On average, plaque mineralizes about 50% in 2 days and between 60-90% in 12-20 days [5]. Complete mineralization can occur between 12 and 20 days because plaque mineralizes at different rates in different people [2]. Some aspects which can influence the formation of calculus include oral hygiene, diet, smoking, diabetes, medications, tooth anatomy and time since last oral hygiene appointment [6]. Supragingival calculus has an adverse effect on oral health because it acts as a reservoir for more plaque biofilm to accumulate on its rough surface, impeding its efficient removal and thereby furthering the disease progression. Supragingival calculus is white or light yellow and occurs commonly on the lingual surface of mandibular anterior teeth and the buccal surface of maxillary molars [1]. Calculus has strong adhesive properties and cannot be removed with regular brushing and flossing. It must be removed with

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hand, sonic or ultrasonic instruments, procedures which are labor and time consuming and costly. Consequently, there has been considerable interest in formulas, mostly incorporated in dentifrices, containing zinc citrate, chlorhexidine, bisphosphonates, pyrophosphates, triclosan, polymers and copolymers attempting either to inhibit or retard the formation and accumulation of calculus [6-11]. These agents appear to reduce the formation of supragingival calculus by 30-50%, the variance probably due to differences in study design [12].

Recently an anticalculus oral rinse containing tetrapotassium pyrophosphate ($\text{Na}_4\text{P}_2\text{O}_7$) and sodium tripolyphosphate ($\text{Na}_5\text{P}_3\text{O}_{10}$) as its main ingredients, has become available commercially. Several studies appear to indicate that preparations containing pyrophosphates do reduce the formation of calculus [11, 13-17]. It has been proposed that tetrapotassium pyrophosphate binds to calcium and magnesium in the saliva resulting in insufficient calcium to form into calculus [18]. It also binds to the enamel and the hydroxyapatite layer of calculus which prevents protein binding which in turn reduces the formation of new calculus on top of these layers [18]. The tetrapotassium pyrophosphate is also intended to prevent mineralization of the unbound biofilm, so it is unable to bind to the calculus already present on the tooth surface. Sodium tripolyphosphate binds the calcium in the saliva to slow down the mineralization process of the plaque. Since there is a paucity of clinical studies attesting to the efficacy of this product containing tetrapotassium pyrophosphate and sodium tripolyphosphate as its main two ingredients, the aim of the present study was to ascertain its efficacy on supragingival calculus formation in a group of adults seeking periodontal treatment at a Canadian dental school [19].

Materials and Methods

A total of 40 patients were pre-selected in order to have 80% of power at 5% significance for a mean difference of 0.3 from baseline measurement (0) with a 0.2 standard deviation. To be included in the study the subjects had to be dentate, have measurable amount of supragingival calculus on the lingual surfaces of their lower anterior teeth, be reasonably healthy and ambulatory, and an anticipated ability to attend a follow up visit. Exclusion criteria included a significant medical condition (including but not limited to, poorly controlled diabetes mellitus, rheumatic heart disease or clinically significant heart murmur), pregnancy, smoking, current orthodontic treatment and a recent history of, or ongoing antibiotic therapy. The study was conducted in full accordance with ethical principles and with the approval of the University of Saskatchewan, Biomedical Research Ethics Board. Participants signed an informed consent form and were free to withdraw from the trial at any time.

The experiment was designed as a randomized, single-blind study in which the subjects were randomly divided into two groups of 20 with group (A) being the test and group (B) the control. The name and the unique identification number of each subject was only known to one investigator (JH) throughout the study. The clinical examinations were conducted at the Dental Clinic, College of Dentistry, University of Saskatchewan, Saskatoon, Canada by one of the investigators (KY) an experienced registered dental hygienist, who remained blind throughout the study period. This examiner was trained and calibrated to ensure the accuracy of the recordings. The calibration was done on five randomly selected adult subjects not involved in the study.

The following clinical parameters were recorded. Plaque biofilm (PI) was assessed on the distal, mesial, and lingual surfaces of each of the six mandibular lower teeth and the overall plaque score for the six mandibular anterior teeth (if all six were present) was obtained by adding the scores for each surface and dividing by eighteen [20]. Likewise, the presence or absence of gingival bleeding on gentle probing of the sulcus (GBI) was used to determine gingival health on the above-mentioned surfaces [21]. The extent of supragingival calculus in relation to the lingual surfaces of the lower anterior teeth was measured using the Volpe-Manhold Calculus Index (VMI). The linear extent of the calculus was determined to the nearest 0.5 mm by placing a William's periodontal probe at the most inferior visible border of the calculus in three directions bisecting the lingual surface, mesio-incisal angle and disto-incisal angle, thereby measuring three surfaces on each of the six designated teeth. The VMI for each tooth was the sum of the scores from the mesial, lingual and distal planes. The subject's total VMI comprised the sum of the tooth scores [22, 23].

After receiving a verbal description of the study, each subject indicating a willingness to participate and meeting the inclusion/exclusion criteria and demonstrating a minimum VMI of 7 was recruited into the study. Thereafter, a written description of the study was provided and a signed consent obtained. All subjects then received a full mouth scaling and root planning using hand or ultrasonic instruments by senior dental students supervised at all times by licensed registered dental hygienists. Plaque control instructions were given before, during and at the end of the phase one treatment. At the completion of the hygiene appointment (baseline), the PI, GBI and VMI was assumed to be zero and the subjects were randomly assigned to test or control groups. The control group (B) participants were requested to maintain standardized oral health practices for the duration of the experiment in which they were required to brush their teeth for two minutes using the Modified Bass technique, twice per day with the provided dentifrice (having no anticalculus agents) and floss once daily using the spool method. Since the product was packaged in sachets in the powder form, Group A (test group) participants were requested to mix the contents of the provided anticalculus agent (as per the manufacturer's instructions) in 1/2 cup (118 ml) of water and swish the solution in the mouth for 20 seconds, expectorate and repeat until solution was gone - once in the morning and once before bed.

Rinsing was to be followed by tooth brushing with the same brand of dentifrice provided to the control group and flossing as described above. Written instructions on the rinsing technique was also given to each test subject. Participants in both groups were advised not to use any other oral hygiene products including antiseptic rinses and to inform the investigators immediately if prescribed oral or systemic antibiotics of any kind or had a reaction to the anticalculus agent, during the period of study. All verbal information was provided by KH or AH. After a 60-day trial period, the test and control subjects were recalled, and the clinical measurements were conducted as described above.

Statistical analyses was conducted using SPSS version 27 (IBM Corp. Released 2020. IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY: IBM Corp.). Descriptive Statistics, mean and standard deviation reported for continuous variables and for categorical variables frequency and percentage (%) was reported. Changes from the baseline for the three indices (PI, BOP and VMI) and for different surfaces

(mesial, mid lingual and distal) were calculated taking the difference between the scores at baseline (0) and after the 60-day trial period for both control and test groups. The observed data, test scores (those who used the anticalculus rinse) and control scores (those who did not use the test rinse) was assumed to be sampled from populations with a normal distribution. Hence, the mean differences between test and control group's changes in mean scores were analysed using two independent samples t-test and p values were reported. The level of significance was set at α (alpha) = 0.05.

Results

A total of forty consenting adults were originally recruited to participate in the study. However, during the trial period, several either did not show up for their 60-day examination or after arriving for the examination, admitted that they were not able to comply with the study protocol and hence, were eliminated from the study. New subjects fulfilling the

inclusion and exclusion criteria had to be recruited to replace those who had been rejected, thereby extending the duration of the study. The experiment was concluded due to time limitations when thirty-five adults (20 males and 15 females) eventually completed the study and claimed that they abided with the given instructions. The mean age was 58.50 ± 14.16 years (Table 1). The effect on the formation of supragingival calculus on the lingual surfaces of the mandibular teeth of rinsing the mouth with a solution containing tetrapotassium pyrophosphate and sodium tripolyphosphate for sixty seconds, twice a day for sixty days is shown in (Table 2). There was no statistically significant difference in the overall change from baseline in relation to the overall mean plaque scores, gingival bleeding scores or the VMI when compared with the control group (Table 3). However, there was a statistically significant reduction in bleeding on the mesial surfaces and supragingival calculus formation on the distal surfaces in the test subjects.

Table 1: Demographics of test and control group by age group and sex.

Variable	Test Group (n=17)			Control group (n=18)		
Age in years	Male	Female	Total	Male	Female	Total
20-29	1	0	1 (5.9%)	1	0	1 (5.6%)
30-39	1	1	2 (11.8%)	0	1	1 (5.6%)
40-49	0	1	1 (5.9%)	1	0	1 (5.6%)
50-59	3	2	5 (29.4%)	2	1	3 (16.7%)
60-69	2	2	4 (23.5%)	6	3	9 (50.0%)
70-79	2	2	4 (23.5%)	1	2	3 (16.7%)
Total	9 (52.9%)	8 (47.1%)	17	11 (61.1%)	7 (38.9%)	18
Mean age \pm SD years	56.00 \pm 17.33	59.13 \pm 12.88	57.47 \pm 15.0	57.64 \pm 14.19	59.86 \pm 15.13	58.50 \pm 14.16

Table 2: Mean Scores and Standard deviation of PI, BOP, and VMI by group (Test vs Control) and comparative assessment of clinical parameters of groups.

Score	Test Group (n=17)	Control group (n=18)	Test-Control Difference	t value	P- value
PI	1.28 \pm 1.16	1.85 \pm 1.79	-0.56	-1.094	0.282
BOP	0.13 \pm 0.22	0.38 \pm 0.59	-0.25	-1.641	0.110
VMI	2.97 \pm 1.65	4.23 \pm 2.71	-1.26	-1.649	0.109

Results are not significant at 5% significance level.

Table 3: Mean Scores and Standard deviation of PI, BOP, and VMI by group (Test vs Control) and comparative assessment of clinical parameters of groups.

Score	surface	Test Group (n=17)	Control group (n=18)	Test-Control Difference	t value	P- value
PI	Mesial	0.48 \pm 0.44	0.72 \pm 0.66	-0.24	-1.275	0.211
	Mid Ling	0.36 \pm 0.44	0.53 \pm 0.65	-0.17	-0.911	0.369
	Distal	0.44 \pm 0.39	0.59 \pm 0.60	-0.14	-0.857	0.398
BOP	Mesial	0.04 \pm 0.11	0.18 \pm 0.23	-0.14	-2.316	0.029
	Mid Ling	0.03 \pm 0.06	0.08 \pm 0.20	-0.05	-1.058	0.298
	Distal	0.06 \pm 0.14	0.11 \pm 0.24	-0.05	-0.796	0.432
VMI	Mesial	1.18 \pm 0.82	1.63 \pm 1.14	-0.46	-1.350	0.186
	Mid Ling	1.02 \pm 0.54	1.23 \pm 0.86	-0.21	-0.857	0.397
	Distal	0.77 \pm 0.62	1.37 \pm 0.97	-0.59	-2.173	0.038

Significant differences at 5% significance level marked in bold.

Discussion

The purpose of the present study was to ascertain the effect on supragingival calculus formation of a solution containing tetrapotassium pyrophosphate and sodium tripolyphosphate among a group of adults who, at the time of seeking treatment, had measurable amount of supragingival calculus (VMI of 7 or greater) on the lingual surfaces of the lower anterior teeth. The VMI technique was chosen as it has been used in several clinical trials to assess calculus and shown to be a reliable representative of the actual tooth surface covered with calculus. Barnett *et al.* confirmed the suitability of this index by objectively measuring the mean calculus area in 40 subjects with a wide range of calculus deposition, using computer-assisted planimetry. They reported a statistically significant ($p < 0.05$) correlation coefficient of 0.93 indicating a strong correlation between the VMI and the mm^2 calculus area [24].

There exists very little clinical data on the efficacy of rinses containing tetrapotassium pyrophosphate and sodium tripolyphosphate on the formation of supragingival calculus and the reported results are mixed. Other studies involving the use of pyrophosphate have either been carried out *in vitro* or incorporated in dentifrices, gels or whitening strips [11, 13-16]. We have attempted to compare the results of the present study with the limited published information on the effect of pyrophosphate containing rinses only.

The results of the present study did not indicate any significant differences in the formation of supragingival calculus as measured using the Volpe-Manhold Calculus Index, between the two groups when the three surfaces (distal, lingual and mesial) were considered as a whole, nor were there any significant differences in biofilm formation and bleeding on gentle probing between the groups. However, when the surfaces were analysed separately, the distal surface of the lower anterior teeth seem to form significantly less calculus while the mesial surfaces demonstrated less bleeding in the test group. The reason for the positive outcome on these isolated surfaces is not understood and cannot be explained.

Saini (2015) employing a protocol similar to the present study on a total of sixty subjects attending a dental teaching institution in India, concluded that the test subjects demonstrated a decline in VMI score from 3 months to six months by 23.12% compared to the control group where there was a continuous increase in VMI score of 22.16% from the third to the sixth month [18]. Kokovic and Tattan investigating the effects of an oral rinse containing tetrapotassium pyrophosphate and sodium tripolyphosphate in subjects with zirconium dioxide and titanium dental implants concluded a clinically significant reduction in calculus formation when the test participants used the rinse twice daily for 6 months as an adjunct to toothbrushing [19]. Cantore *et al.* in a 3-day plaque accretion model study reported that an oral rinse with the similar constituents as above has an equivalent plaque inhibitory effect as chlorhexidine [25]. Tandelilin *et al.* (2018) assessing the efficacy of an anticalculus rinse in a group of 40 participants indicated that though the rinse was effective in lowering all the clinical scores both with and without any professional intervention the optimal results were however achieved when combined with professional scaling [26].

Rajnic and Radnai (2017) conducted an *in vitro* pilot study by collecting calculus samples from a group of patients attending a Hungarian Dental school. They reported that subjecting the pulverized sample of calculus to a solution containing tetrapotassium pyrophosphate and sodium tripolyphosphate for several hours, helped increase the rate of dissolution of Ca^{2+} ions thereby softening the hard calculus. Based on their findings they concluded that soaking removable dentures overnight in a solution comprising of the above chemicals, could help patients in cleaning their dentures by softening the calculus thus facilitating easy removal by mechanical means [27].

However, Tham (2015) investigated 53 systemically healthy subjects in the USA reported no significant difference in visible calculus between the test subjects who used a rinse consisting of tetrapotassium pyrophosphate and sodium tripolyphosphate for a period of 90 days compared to the control subjects [28]. It was not clear as to how the formation of calculus was evaluated. Likewise, in a more recent study carried out among 37 patients with a history of rapid calculus formation, in Valencia, Spain, the test subjects used a mouth rinse which contained pyrophosphate-based formula (0.85% Tetrasodium Pyrophosphate decahydrate; 0.5% Sodium Hexametaphosphate; 0.5% Sodium Tripolyphosphate 0.5%; 0.05% Sodium Fluoride [226 ppm of F ions] for a period of three months [29]. The authors reported that the pyrophosphate-based mouth rinse did not show any anticalculus effects or any positive effects on saliva flow or saliva composition when the test and control groups were compared [29].

Limitations of the present study included the comparatively small sample size, the relatively short trial period of two months and possibly compliance issues within the test subjects who rinsed with the product at home and hence were unsupervised. The subjects were supplied packets containing the ingredients in a powder form to take home and were expected to dissolve the contents in water and rinse twice a day and repeat the same for sixty days. It is possible that some of test subjects did not adhere to the expected protocol. Although written and verbal directions were provided, it is also likely that some individuals may not have rinsed their mouth for the required twenty seconds as per instructions. Further, the time restraints (the study was conducted during the school term) and the cost involved to conduct the study using a larger sample size for an extended period also limited the sample size and the duration of the study.

Conclusion

The results of the present study, within the limitations as described above, appear to indicate no statistical difference in the prevention of supragingival calculus when a solution containing tetrapotassium pyrophosphate and sodium tripolyphosphate was used in the form of an oral rinse for a period of sixty days. However, further research using larger sample sizes with a longer follow up periods must be conducted before any decisions could be made concerning the role of pyrophosphates incorporated in an oral rinse as a preventive agent for supragingival calculus.

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Conflicts of Interest

None.

Author Contributions

The authors have contributed equally to this work by making significant contributions to the commencement and design, acquirement of, and analysis and interpretation of data as well as being involved in drafting of the manuscript. All authors read and approved the final manuscript.

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