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High fluoride dentifrice for preventing and arresting root caries in community-dwelling older adults: A randomized controlled clinical trial

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ABSTRACT

Objective: Self-administered non-invasive therapies with high-fluoride dentifrices are an attractive alternative to traditional restorative management of root carious lesions (RCLs), but the available evidence is still scarce, particularly in community-dwelling elders. The aim of this randomized controlled trial (RCT) was to compare the effectiveness of toothbrushing with 5,000 ppm versus 1,450 ppm fluoridated dentifrice (F- dentifrice) on preventing and arresting RCLs, in community-dwelling elders.

Methods: A two years double-blinded RCT was carried out with 345 independently-living older adults, with at least one tooth with RCL. Participants were instructed to brush twice *per* day with either high-fluoride (5,000 ppm F) or the control dentifrice (1,450 ppm F). Incidence of new and arrested existing RCLs was recorded at two years and compared with the baseline data. Linear mixed regression model with repeated measures were used to test differences between groups ($p < 0.05$).

Results: The percentage of teeth with active lesions varied significantly at two years, but in opposite directions for both groups. While the control group significantly increased the mean percentage of RCLs activity from baseline to two years, from 24.32% to 40.52%, the intervention decreased the percentage of activity from 29.74% to 3.72%. The incidence of RCL was 93.5% and 35.2% in participants of the 1,450 ppm and 5,000 ppm in the F- dentifrice groups, respectively, with a relative risk (RR) of 0.10 [CI: 0.05 – 0.19].

Conclusion: Non-invasive treatment with 5,000 ppm F dentifrice is more effective than conventional dentifrices in preventing and arresting RCLs in community dwelling elders. ClinicalTrials.gov NCT02647203.

Clinical Significance: RCLs can be effectively prevented and arrested with the use of 5,000 ppm F dentifrice. Oral health programs directed to community-dwelling older adults might benefit from the inclusion of high fluoride dentifrice in their portfolio.

1. Introduction

Higher economic development along with more widespread access to fluoride are leading to increased tooth retention [1]. Although tooth retention may mean increased quality of life [2], it may originate niches for biofilm stagnation and the possibility of root caries lesions (RCLs). Epidemiological studies have shown a trend for a higher incidence of RCLs, in an age-dependent manner [3], including systemically healthy older adults [4].

Restorative management of RCLs is typically challenging, considering the difficulties in visibility, moisture control, access to the lesion, proximity to the pulp and to the gingival margin, and the high organic content of dentine [5]. Evidence for the choice of restorative materials for RCLs is neither abundant nor convincing, as studies have reported failure rates of up to 68% after 12 months [6–8]. When dentine is the only adherent substrate, as it is the case in many RCLs, retention of the restorative material can be compromised in the long term [9]. Hence, appropriate management of the lesions, either restoratively or non-operatively is highly desirable for patients and clinicians alike, especially in older adults.

Fluoridated products are the most extensively used agents for caries prevention and one of the main preventive measures for root caries in older adults [10]. Undisputed evidence has revealed that fluoride (F) is effective, not only in the prevention, but also in the arresting of RCLs [11]. The anti-caries effect of F is related to its ability to alter ionic saturation with respect to tooth mineral, thus, aiding remineralization

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and preventing demineralization. Likewise, at high concentrations it may interfere with bacterial metabolism and acid production [12]. Based on structural differences and arguably lower critical pH, dentin would be more susceptible to caries than enamel [13]. The differential risk between both tissues, along with the increasing rate of RCLs reported, has stimulated research, focused on the effects of F on root dentine and on RCLs [14,15]. Since fluoridated dentifrice are the major source of F in many communities, where water fluoridation is not available [16], regular toothbrushing using fluoridated dentifrice has been described as the most rational way to administer topical F [17]. The rationale for this statement derives from the fact that it puts in place two protective mechanisms; dental biofilm disruption and sustained F delivery. In the absence of the risk of fluorosis, there are potential benefits of high F dentifrice in older populations. A recent systematic review showed that the daily use of dentifrices containing 5,000 ppm F is more efficient in reducing active RCLs than dentifrices containing between 1,100 and 1,450 ppm F [18]. Although these promising findings, the authors concluded that there was a low number of clinical trials, with high risk of bias, meaning that the evidence to support a recommendation is limited. Furthermore, most clinical studies on RCLs with high F dentifrices have focused on older adults living in long-term care facilities [19–21], with few studies conducted on community-dwelling elders [22,23]. Independently-living people represent most of the older adult population worldwide. Large longitudinal studies following populations into ageing have shown that an increasing number of older adults are independently living, mobile and active in their communities [24–26]. Hence, new studies should be prioritized on this population. Thus, the hypothesis of this study was that self-administered 5,000 ppm F dentifrice is more effective in preventing and arresting root caries that conventional dentifrice in independent-living older adults.

2. Materials and methods

2.1. Study design

A double-blinded RCT with two parallel arms was conducted with participants recruited from community clubs of older adults from Talca, Chile. To be eligible, participants had to be 60-year-old or more, community-dwelling, living in areas with fluoridated water (0.7 ppm F) and independently-living according to the Functional Evaluation of Older Adults (EFAM for its abbreviation in Spanish) criteria [27], formally enrolled in community centers. The EFAM criteria comprise several psychological, biological and social items, that allow a comprehensive view on the functionality of the older adult. According to Chilean regulation and WHO criteria, the age of 60 years old is used to distinguish elderly people. Intraorally, participants had to have at least five remaining teeth and one tooth with an active RCL [28,29]. Participants with cognitive impairment or alcoholism were excluded from the study, using the Short Mini-Mental State Examination (MMSE-SF) [30] and the Alcohol Use Disorders Identification Test (AUDIT-C Test), respectively [31].

The study and the informed consent form were approved by the Ethics Committee of the University of Talca (number:2013-047). The study coordinator explained the nature of the study and invited the participants to voluntarily take part of the RCT. All participants signed an informed consent form. If the lesions progressed during follow-up, they received professional treatment by the research team, including Atraumatic Restorative Treatment (ART) restorations. This RCT complies with the CONSORT (Consolidated Statement Of Reporting Trials) statement [32]. This trial is registered at ClinicalTrials.gov under the number NCT02647203.

Sample size was calculated with the software GRANMO (Institut Municipal d'Investigació Médica, Barcelona, Spain), for the comparison of two means (arrested RCLs) in independent populations considering a previous study [19]. Thus, accepting an alpha error of 0.05 and beta error of 0.2 in a two-sided test, the common standard deviation was assumed to be 1.11 with an estimated drop-out rate of 20 percent, a total of 304 participants was necessary (n = 152 *per* group) to recognize as statistically significant a difference greater than or equal to 0.4 units. Following simple randomization procedures through a computer-generated list of random numbers prepared by an investigator with no clinical involvement in the trial, participants were randomly assigned to one of the two treatment groups: Control group: 1,450 ppm F- dentifrice as NaF (Colgate Total®); and Intervention group: 5,000 ppm F- dentifrice as NaF (Colgate Duraphat® 5,000 Plus). Both dentifrices were available in the Chilean market, by the time of the investigation, and were covered with color-coded opaque tape and saved in numbered containers until allocation. At each control, participants had to bring the tube, so researchers could verify they had not removed the tape.

2.2. Intervention

Oral and written instructions were given to participants to toothbrush twice *per* day, after breakfast and before bedtime. To increase F concentration and retention, participants were also instructed not to rinse with water after brushing and to only eliminate the excess of the dentifrice by spitting out. The amount of dentifrice to be used had to be about the size of a pea. Toothbrushing duration was standardized, recommending a sweeping technique for two minutes, without formal training. By tape-covering the tubes, neither the patients nor the study principal investigator knew the type of dentifrice the participants were using. Additional toothbrushes and dentifrices were provided to the volunteers every three months and adherence to treatment was checked by returning the used dentifrices and toothbrushes to the investigators.

2.3. Clinical examinations at baseline and follow-up

Primary outcomes, regarding effectiveness of fluoridated dentifrices on RCLs, was the incidence of RCLs *per* root after two years, detected by ICDAS [33] and lesion inactivation or arrest, using Nyvad criteria for lesion activity *per* root, also after two years [28,29] (Table 1). Only few teeth presented with more than one RCL *per* root. In those cases, the

Table 1
Nyvad criteria for differentiating active and inactive RCLs. Adapted from: [28,29,64].

	Nyvad Criteria	
	Active Lesion	Inactive Lesion
Visual Appearance	Typically, yellowish or light-brown and brownish discoloration.	Typically, brownish or black.
	Dull/matte	Shiny smooth
	Typically covered by biofilm	Often not covered by biofilm
	Usually close to the gingival margin	Distant from the gingival margin
Tactile Features	Feels soft, sticky/leathery on gently probing.	Feels hard on gentle probing
	Whit/without localized/manifest cavitation	Cavity formation may be rough/uneven
	Margins of cavity are sharply demarcated	Margins of cavity are smooth

most severe lesion was recorded. Baseline and follow-up clinical examinations were performed by a single calibrated examiner. The examiner (SL) had a theoretical training before the beginning of the study and examined patients from the undergraduate dental clinic. She examined at least 20 patients in two separate days to calibrate and the intra-examiner Kappa was calculated. This calibration was repeated at the one-year follow-up visit. Intra-examiner kappa obtained prior to the beginning of the study was 0.81 and 0.83 at one year. Dental mirrors and graduated (in mm) periodontal probes were used during the examinations in a conventional dental clinical setting. At baseline, professional prophylaxis, consisting in the removal of supragingival calculus by scaling and polishing, was carried out in each participant and then every six months, followed by the RCLs assessment. Root surfaces were scored during the baseline and the follow-up examination as sound, inactive (arrested) or active. Root that showed new RCLs or that were restored or lost throughout the follow-up period were also registered in a root odontogram, that included RCLs detection and activity assessment. Other variables included were age, sex and socio-economic status (SES). SES was classified as lower when the respondent declares that family income is not enough to afford the most basic items in a month and upper when family income is enough.

2.4. Statistical analysis

Sociodemographic information of patients was described by groups at baseline and compared using Chi squared test (χ^2). Descriptive analyses included the calculation of the lesion type frequency distribution and the number of teeth with RCLs, both active and arrested, *per* patient. The percentage of caries activity *per* patient was calculated by the following formula (number of teeth with active lesions/number of total teeth) x 100. Mean and standard deviation were compared by groups using *t*-test accompanied by bootstrapping techniques, as normality assumption was not met. Any patient that developed new active RCLs during the study period was identified to calculate the incidence and the Relative Risk (RR), using z test. Linear mixed model with repeated measures (i.e., baseline and two-year assessment) were performed to evaluate the main effect of age, sex, SES and treatment upon percentage of RCLs activity. Statistical analyses were performed using the statistical SPSS v25 (IBM, NY, USA).

3. Results

A total of 355 participants were initially invited to be part of the study and assessed for eligibility. While all accepted the invitation, 10 were excluded because they did not meet all the inclusion criteria. Thus, a final sample of 345 participants, 258 (74%) females and 87 (26%) males, were randomized to the control or to the intervention groups. Recruitment and clinical examinations took place at the School of Dentistry of the University of Talca, Talca, Chile, from July 2014 to November 2016. Age of the respondents ranged between 61 and 88 years (mean 69.63 ± 6.25). After two years, 65 individuals were lost to follow-up; 34 from the control and 31 from the intervention group (Fig. 1), who contributed with 426 teeth with RCLs. Final data correspond to the 280 participants who completed the two years of follow-up. At baseline, there were no significant differences between groups regarding sex, age, SES and educational level (Table 2). However, the 5,000 ppm F- dentifrice group had higher number of teeth with lesions, with 1,422, and higher number of active lesions with 1,016, compared with the control, that had 1,119 RCLs and 683 active RCLs ($p < 0.001$) (Table 2).

3.1. Fate of the baseline lesions after 2 years, by activity status

After excluding those who were lost to follow-up (n = 65), there were 2,115 teeth with RCLs in 280 participants, at the baseline examination. The fate of each of those lesions during the follow-up is depicted in Table 3, showing whether the lesions changed or remained active or inactive (arrested) during the duration of the study. Of the teeth with active RCLs at baseline in the intervention group 699 out of 804 became inactive, whereas only 234 of 589 were inactivated in the control group (1,450 ppm). In the case of the inactive lesions, while 196 out of 363 became active in the control group at two years, only 12 out of 359 transformed from inactive to active in the intervention (5,000 ppm). Very few of the baseline teeth with RCLs were extracted or restored during the two-year follow up (Table 3).

3.2. Activity status of the total number of teeth with RCLs at 2 years

At the final examination, a total number of 2,628 teeth with RCLs were identified in the 280 participants who completed the study. A higher total number of teeth with RCLs were detected in the control (n = 1,440) than in the intervention group (n = 1,188). Of those, there was an increase in the number of teeth with active RCLs (from 589 to 915) and with inactive RCLs (from 363 to 525) in the control group. In the intervention group there was also an increase in the number of teeth with inactive RCLs from the baseline data (from 359 to 1,094), but a great decrease in the number of total teeth with active RCLs (from 804 to 94) (Table 3).

3.3. Mean number of teeth with RCLs, by activity status

When comparing the average number of teeth with RCLs, both active or inactive (arrested) (Table 4), there was a higher mean number of teeth with RCLs after 2 years in the control group (6.98 vs 10.43), but no differences were detected in the intervention group (8.19 vs 8.36). On the other hand, the mean number of teeth with inactive RCLs was statistically different for both treatments. Thus, there was an increase for the control group (2.63 vs 3.80) and also in the intervention arm (2.53 vs 7.70). For the mean number of teeth with active lesions, while the control group showed an increase (4.27 vs 6.63), there was a significant reduction in the group treated with 5,000 ppm dentifrice (5.66 vs 0.66) The percentage of active lesions also varied significantly at two years in both groups (Table 4), albeit with different directionality. Whereas there was higher percentage of active lesions in the control group over the 2 years of the study (24.32 vs 40.52), the opposite trend was observed in the intervention group, with a significantly substantial reduction (29.74% vs 3.72%).

3.4. Incidence of RCLs during the observation period

The incidence of patients developing new RCLs was statistically different between both treatments (Table 5). In the control group 93.5% of patients developed new RCLs compared only with the 35.2% of patients in the high-F dentifrice group. The RR for the intervention group was 0.10 [95% CI: 0.05 – 0.19] ($p < 0.001$). Thus, participants exposed to the intervention group have 90% less likelihood of having teeth with new RCLs than those in the control group. The number needed to treat (NNT) was 1.71, that is, it would be necessary to treat only about 2 patients with high-F dentifrices, to avoid a new RCL. This NNT value is considered to be a very effective treatment with large improvement over control.

3.5. Linear mixed regression model for the percentage of activity per patient

The linear mixed model confirmed that the type of treatment had a statistically significant effect upon the percentage of activity. Treating RCLs with 1,450 ppm dentifrices increased the mean percentage of activity *per* patient ($p < 0.001$). There was also an increase in the percentage of activity with age ($p < 0.001$). Sex and SES failed to show a significant effect on the percentage of activity (Table 6).

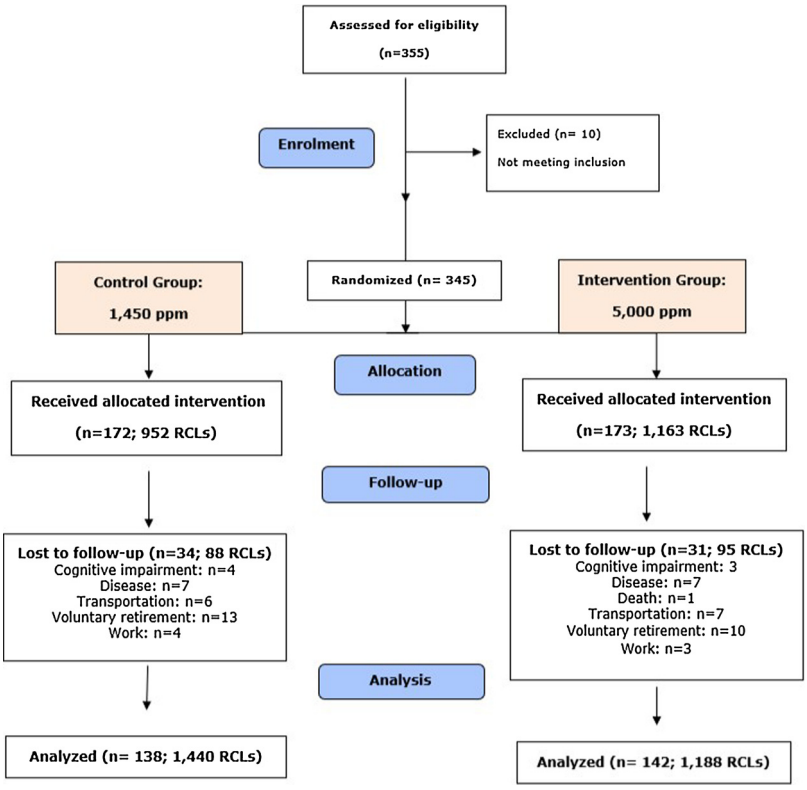

Fig. 1. Flow diagram.

4. Discussion

Only few RCTs have been conducted on RCLs prevention using high-fluoride dentifrices. Despite promising results, evidence is still blurry to be conclusive that 5,000 ppm F- dentifrices are effective on preventing and/or arresting existent RCLs in older adults [34], including frail and vulnerable people [19,20]. To the best of our knowledge, no study of this type has been conducted with community-dwelling elders. Unlike institutionalized older adults, community-dwelling elders do not depend on others for oral care. Our results, therefore, are only attributable to the adherence of the participant to self-administration of the treatment and not to the compliance of a caregiver or a third party. Since effectiveness of high-F doses in lesion arresting may be the result of the combined effects of abrasion and mineral re-deposition on the surface layer of root dentin, appropriate oral hygiene is key to achieve clinical success, verified as reversal of active lesions. Studies have shown that under favorable conditions and when the root surface is readily available to toothbrushing, even those lesions with a distinct cavity extending deep into dentin can be controlled and inactivated [35].

Our results clearly demonstrated that it is possible to prevent and arrest RCLs using self-administrated and non-invasive therapies with 5,000 ppm F- dentifrice in independent-living, community dwelling older adults. It was interesting to observe that despite a higher mean number of teeth with RCLs in the intervention group than in the control group at baseline, the results showed dramatically lower caries activity for the experimental intervention. These results may be explained by F enrichment of the oral environment, i.e., saliva and the dental biofilm after using a 5,000 ppm F dentifrice, twice *per* day. The bioavailability of F allows the formation of CaF_2 on the tissues, all of which may hamper biofilm formation and reduce the levels of putative cariogenic

Table 2
Socio-demographic and clinical characteristics of the study population at baseline and comparisons between treatment group.

			1,450 ppm F^-		5,000 ppm F^-		
	Variable	Category	n	%	n	%	p value (χ^2)
Socio-demographic n = 345 participants	Sex	Men	45	(26.2)	42	(24.3)	p = 0.68
		Women	127	(73.8)	131	(75.7)	
	Age	60 a 69	92	(53.5)	88	(50.9)	p = 0.62
		70 or +	80	(46.5)	85	(49.1)	
	Socio-economic status	Upper	112	(65.1)	109	(62.6)	p = 0.68
		Lower	60	(34.9)	64	(37.4)	
	Educational level (years)	≤ 8	51	(29.7)	42	(24.3)	p = 0.32
		9-12	57	(33.1)	70	(40.5)	
		> 12	64	(37.2)	61	(35.2)	
Clinical n = 345 participants	Number of Teeth examined (n = 6478)	Sound	1958	(49.7)	1979	(50.3)	p < 0.001*
		With RCLs	1119	(44.0)	1422	(56.0)	
	Number of Teeth with RCLs (n = 2541)	Active	683	(40.2)	1016	(59.8)	p < 0.001*
		Inactive	436	(51.7)	406	(48.3)	

RCLs: Root caries lesions.
* Statistical significant difference by Chi-square test.

Table 3
Data at baseline and after two years by lesion (tooth).

Groups	Baseline*			After two years						
	Teeth with active RCLs	Teeth with inactive RCLs	Total number of teeth with RCLs	Fate of baseline active RCLs	Fate of baseline inactive RCLs	New active RCLs	New inactive RCLs	Total active RCLs	Total inactive RCLs	Total RCLs
1,450 **ppm** **n = 138 participants**	589	363	952	290 active 234 inactive 34 filled 31 extracted Total = 589	196 active 147 inactive 14 filled 6 extracted Total = 363	429	144	915	525	1,440
5,000 **ppm** **n = 142 participants**	804	359	1,163	45 active 699 inactive 33 filled 27 extracted Total = 804	12 active 314 inactive 14 filled 19 extracted Total = 359	37	81	94	1,094	1,188
Total **n = 280 participants**	722	1,393	2,115			466	225	1,009	1,619	2,628

RCLs: Root caries lesions.
* Data represents only those participants that completed the study: n = 280; 2,115 RCLs. 65 participants were lost to follow up, representing 426 RCLs.

bacteria, such as *S. mutans* and *Lactobacillus* [36]. The dentifrice used in this study contains sodium fluoride (NaF), which along with sodium monofluorophosphate (NaMFP) are the most commonly used fluoridated agents in dentifrices [37,38]. Regardless of the salt used, F contained in dentifrices are attributed to act through precipitation of a low acid-resistant calcium fluoride (CaF_2)-like layer on the tooth surface, forming a "mechanical barrier", by the formation of bioavailable reservoirs within the dental biofilm. Alternatively, a microbiological effect has been reported, whereby there would be a formation of intercellular or intracellular Ca "bridge" with fluoride at fixed bacterial sites [39]. CaF_2 formation and the effect of F on the dental biofilm and on its remineralizing capacity has been reported to be dose-dependent, which may be why the dentifrice of the experimental group performed substantially better than the conventional F concentration counterpart [40]. High-F varnishes also act by forming CaF_2 reservoirs in the dental biofilm [41], and the repeated application or longer retention time warrants better remineralizing potential [42]. Some studies suggest that by using high-F dentifrices (5,000 ppm F, for example), concentrations of about 800 ppm F are reached in saliva within 2 min of toothbrushing, which is about 7 times higher than the 100 ppm required to create CaF_2 [36]. Others have also reported this dose-dependency for the effect of F-dentifrices on RCLs. An experimental study showed that 5,000 ppm F-dentifrice was more effective for controlling RCLs formation and progression than a fluoride concentration of 1,300 or 1,500 ppm [43]. Dentifrices containing higher F concentrations (5,000 ppm F and 2,800 ppm F) seem to enhance acid resistance of bovine root dentine [44] and to increase F concentration in saliva [45–48]. Likewise, a RCT showed that 5,000 ppm F- dentifrice controlled RCLs progression more efficiently among elders than regular dentifrices of 1,000 ppm to 1,450 ppm fluoride [19]. Large variations in the effect of a 5,000 ppm F dentifrice was described among participants of a multi-center clinical trial [22]. Despite the existent clinical evidence for the efficacy of the 5,000 ppm F- dentifrices, a pilot in situ study indicated that a

Table 5
Incidence of RCLs. Teeth with new RCLs by participants.

Groups	With new RCLs n (%)	Without new RCLs n (%)	Total n (%)
1,450 ppm	129 (93.5)	9 (6.5)	138 (100)
5,000 ppm	50 (35.2)	92 (64.8)	142 (100)

RR = 0.10; 95% CI = 0.05 – 0.19; z test = 6.99; p value < 0.001; NNT = 1.71.
ppm parts per million; RCLs root caries lesions; RR relative risk; CI Confidence interval; NNT number needed to treat.

Table 6
Linear mixed regression model for percentage of active lesions.

Variables		Estimates	SE	p value	95% CI
Group	*1,450 ppm*	14.22	1.50	< 0.001*	11.26 – 17.18
Sex	*Female*	−1.63	1.78	0.36	−5.13 – 1.87
SES	*Low SES*	0.85	1.63	0.60	−2.30 – 4.05
Age	*In years*	0.51	0.12	< 0.001*	0.27 – 0.75

SE standard error; CI confidence interval; SES socio-economic status; ppm parts per million.
* = p < 0.05.

Table 4
Average number of teeth with RCLs and percentage of active lesions per treatment group, analyzed by patient at baseline and after 2 years.

	Group			
	1,450 ppm		5,000 ppm	
	Baseline	2 years	Baseline	2 years
Number of teeth with RCLs (mean ± SD)**	6.98 ± 4.04^	10.43 ± 4.69^	8.19 ± 4.19	8.36 ± 4.21
Number of teeth with inactive RCLs (mean ± SD)*	2.63 ± 2.59^	3.80 ± 3.58^	2.53 ± 2.50^^	7.70 ± 4.02^^
Number of teeth with active RCLs (mean ± SD)**	4.27 ± 3.35^	6.63 ± 4.20^	5.66 ± 3.52^^	0.66 ± 2.36^^
% of active lesions (mean ± SD)**	24.32 ± 16.66^	40.52 ± 23.30^	29.74 ± 18.44^^	3.72 ± 12.32^^

** Independent *t*-test p value < 0.05 for 1,450 ppm vs 5,000 ppm, at baseline and 2 years.
* Independent *t*-test p value < 0.05 for 1,450 ppm vs 5,000 ppm, at 2 years only.
^ Paired sample *t*-test for 1,450 ppm group between baseline and 2 years, p value < 0.05.
^^ Paired sample *t*-test for 5,000 ppm group between baseline and 2 years, p value < 0.05.

concentration of 1,100 ppm F- dentifrice was enough to reduce root dentine demineralization in a highly cariogenic environment, albeit with a relatively small sample size [49]. Other studies have shown that the combined use of acidulated phosphate F (APF) gel (12,300 ppm F) and 1,100 ppm F dentifrices or 22,600 ppm F varnish with 1,450 ppm F dentifrice were not as effective as a 5,000 ppm F- dentifrice, in inhibiting and arresting dentin caries lesions [20,50]. On the other hand, it has been argued that the effect of fluoridated products on RCLs could not be attributed only to the effect of F, but also to the application mode [51]. Indeed, alternative causal explanations for the positive results obtained with 5,000 ppm F, over the control dentifrice is the synergistic effect of the brushing and the periodical application of F on the tissues and its penetration within the dental biofilm forming CaF_2, as above mentioned [17].

In the present study, it was decided to instruct patients not to rinse after brushing and perform oral hygiene with toothbrushing in the morning and at night. This recommendation supposes an interesting discussion, as this is a controversial topic, for which there is not agreement either among clinicians or researchers. The rationale behind this recommendation is two-fold; on the one hand, there is some evidence showing variations in the concentration of F in saliva, relative to the circadian rhythm. In fact, higher F concentrations have been detected early in the morning and late at night than those found during the day [47]. Circadian cycles could induce lower flow rates of saliva, concentrating F in the morning and at night [52]. On the other hand, refraining from rinsing after brushing, supposes higher F retention for longer times in contact with the hard-dental tissues and the ubiquitous dental biofilm. In fact, a study showed a two-fold increase in salivary F when young people using dentifrices of 5,000 ppm F were instructed to refrain from rinsing after brushing [45]. Moreover, it has been stated that if the F concentration in the dental plaque reaches levels of around 10 ppm, F can interfere with bacterial metabolism [12]. While brushing with conventional 1,450 ppm F- dentifrices reaches levels around 10 ppm F in the dental biofilm, a 5,000 ppm F dentifrice increases salivary F up to approximately 14 ppm [45,46]. Interestingly and potentially an explanation for our results, it was reported that pH drop in response to a 10% sucrose rinse was less pronounced when participants had brushed with 5,000 ppm than when they had used 1,450 ppm F dentifrice [48,53]. High F concentrations may alter the biofilm cariogenic potential, decreasing the levels of acid-producing microorganisms [48].

The effectiveness of F dentifrices is not only determined by F concentration, but also by the frequency of use. F should be constantly available in the oral fluids to maximize its effect. An in situ study demonstrated a positive correlation between the frequency of use and the reduction of root dentine demineralization, although no significant association was found between the frequency and the remineralization of existing carious lesions [54]. A recent systematic review [18] showed that RCLs can be controlled by daily brushing with fluoridated dentifrices. In addition to high-F dentifrices, active carious lesions can be inactivated using other forms of professionally applied F, including varnishes or gels. Based on our findings and other similar studies, it would be possible to recommend that only active RCLs that cannot be accessed by toothbrushing should be surgically removed and then restored using minimally invasive techniques [34]. Otherwise, professionally applied non-invasive or, as in this case, self-applied therapies should be preferred, unless other considerations are in place, like aesthetics.

The relative risk (RR) for the onset of new RCLs in the intervention group was 0.10 (95% CI: 0.05–0.19), which would provide 90% reduction, as compared with older adults using a regular dentifrice. Similar studies for the treatment of RCLs using non-invasive approaches have reported similar, but lower RR for this type of intervention. Indeed, Ekstrand et al. [20], reported a 0.65 RR, Lynch et al. [55] a 0.72 RR, Baysan et al. [56] found a 0.85 RR (95% Cl, 0.52–0.80) and Ekstrand et al. [19], a 0.41 RR (95% CI, 0.33–0.50). A systematic review including the studies of Baysan and Ekstrand (2013), pooled 315 RCLs for the experimental and 321 for the control group, obtaining a 0.49 RR (95% CI, 0.42–0.57) [18]. There is another RCT reported [22], but the RR cannot not be calculated. In general, most of the studies on non-invasive management of RCLs with F dentifrices report RR of around 0.5, which implies that the risk is reduced to half when using dentifrices with higher F concentration. In our study, RR was much higher, reaching a 90% reduction, probably because it was a 2-year follow-up, unlike the other studies, where follow-up is much shorter, reducing the opportunity to reach all the beneficial effect of F in remineralizing the lesions. Additionally, during the first period after the beginning of the intervention, both groups may be motivated with the study, maximizing toothbrushing. This enhanced mechanical effect may blur the differences between groups, derived from the F- dose. Thus, a short-term assessment may find results as those reported in the literature. Conversely, the two-year follow up in this study might exclude the motivational initial effect, minimizing the mechanical and preserving mostly the chemical activity of F-.

Consistent with other studies [57], the linear mixed model confirmed that the type of treatment and older age had a statistically significant effect upon the percentage of RCLs activity (Table 6). Lesions created by the carious process and their consequence (fillings and extractions) are mostly irreversible, in terms of caries experience, so it is expected that age was associated with RCLs. There seems to be a higher caries risk with age, due to many putative factors acting together at that age, as it has been reported [58–60]. Less investigated, immune senescence may be an interesting contributor to root caries and lesion progression [59,61]. Importantly, age impacts on physical and cognitive impairment, as well as on a reduced access to care [58]. These other factors may also become part of the complex mix of protective/risk factors acting during aging. Neither sex nor SES had an effect on the results of the non-invasive therapy. Given that this RCT provided with dentifrice and toothbrush, independent of the SES, results were not affected by this variable. In a real-life setting, it is possible that SES plays an important role in the outcomes of an intervention like this. Although it could be of interest, education level was not included as a variable to avoid variability and uncontrolled factors beyond the treatment itself, but also because in Latin American countries like Chile, education is used as a proxy for SES.

Interestingly, the control group showed an overall increase in the number of active lesions after the follow-up (Table 3). We believe this may be because this group was not substantially intervened. Participants in this arm had active lesions before, and the study did not affect their incidence rate, so a natural increase in activity was observed as a consequence of their previous caries risk and the natural progression of the disease.

We acknowledge some limitations of the study design. No brushing assessment before the beginning of the study was done. We could have included an arm without any intervention, keeping previous oral hygiene regimes and the type of toothpaste they used. However, in the Chilean market, almost all conventional toothpastes are formulated with 1,450 ppm F [62], so this arm would have complicated the design with a modest scientific value added. Furthermore, individuals with better motor skills could have entered the study with dissimilar initial conditions. We believe these limitations could have been ameliorated due to the large sample and to an even distribution of the participants between both study arms, nonetheless. Another source of bias could have been the lack of dietary control. Both limitations may have converted this RCT into a rather pragmatic randomized clinical trial [63], that is, a study conducted under real-world circumstances. This makes our study closer to the reality of community-dwelling elders, who are autonomous and do not require assistance to perform daily oral care.

5. Conclusion

Self-administered non-invasive therapy with high-F dentifrices

appears to be highly effective in arresting active RCLs and in reducing the onset of new lesions in community-dwelling elders. Treatment with a 5,000 ppm F- dentifrice appears to be an attractive alternative to traditional restorative treatment for older adults, allowing expanded access to care, at a much lower cost and suitable for non-clinical settings. The increasing prevalence of RCLs can be significantly controlled by simple and efficient treatment approaches like this. Public and private practices should consider including this type of treatment in their routine clinical protocols.

Declaration of competing interest

None.

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