

# **Randomized clinical trial on root caries prevention among community-dwelling elders**

## **Authors:**

Li R<sup>1,2</sup>, Lo ECM<sup>1</sup>, Liu BY<sup>3</sup>, Wong MCM<sup>1</sup>, Chu CH<sup>1</sup>

<sup>1</sup>Faculty of Dentistry, University of Hong Kong, Hong Kong, China

<sup>2</sup>School of Stomatology, Shanghai Jiaotong University, Shanghai, China

<sup>3</sup>School of Stomatology, Zhengzhou University, Zhengzhou, China

## **Abstract**

Dental root caries is a common disease among elders. More efforts on preventing this disease are needed. Silver diammine fluoride (SDF) is known to be able to prevent dental caries in primary teeth. However, clinical evidence of its efficacy in preventing root surface caries is limited. This clinical trial aimed to compare the effectiveness of SDF in preventing root caries among elders in a water fluoridated area. A total of 323 elders who had at least five teeth with exposed root surfaces and had self-care ability were randomly allocated into 3 intervention groups as follows: Gp1 (placebo control) – annual application of tonic water; Gp2 – annual application of SDF solution; Gp3 – annual application of SDF solution immediately followed by potassium iodide (KI) solution. Oral hygiene instructions and fluoride toothpaste were provided to all subjects. Status of dental root surface was assessed every 6 months by the same independent examiner. After 30 months, 257 (79.6%) elders were reviewed. The mean numbers of root surface with new caries experience in the control, SDF, and SDF/KI groups were 1.1, 0.4, and 0.5 respectively (ANOVA,  $p < 0.001$ ). Scheffe's multiple comparison showed that elders who received placebo developed more new root caries lesions ( $p < 0.05$ ) while the difference between the SDF and SDF/KI groups was not statistically significant ( $p > 0.05$ ). Moreover, elders who had higher visible plaque index scores at 30-month examination (ANCOVA,  $p < 0.001$ ) and those who had higher baseline DMFT scores (ANCOVA,  $p = 0.005$ ) developed more new root caries. It is concluded that annual application of SDF or SDF/KI solution is effective in preventing root caries among community-dwelling elders in a fluoridated area. (Clinicaltrials.gov # NCT02360124)

## **Introduction**

Dental caries is common among dentate elders. As elders are having longer lifespan and keeping their teeth longer these days, dental caries has become an important dental public health issue in many places world-wide (Kassebaum et al. 2015). A recent survey in Hong Kong where water fluoridation has been implemented for over 50 years found that 94% of the community-dwelling adults aged 65-74 years were dentate, half of them had untreated dental caries and a quarter of them had root caries experience (Department of Health 2013). To reduce the possible harmful effects of dental caries, such as pain and tooth loss, World Health Organization (WHO) recommends countries to adopt methods to improve the oral health of elders (Petersen and Yamamoto 2005). Fluoride has been widely used in managing dental caries. Studies showed that fluoridated toothpaste and mouthwash could prevent dental root caries (Jensen and Kohout 1988; Nemes et al. 1991; Wallace et al. 1993) but few were conducted recently. More clinical trials are needed to provide good evidence for developing effective approaches to prevent dental root caries among elders.

Silver diammine fluoride (SDF) is an anti-caries agent available in some countries, including Australia, Brazil and Japan (Lo et al. 2012). It has been recommended for preventing and/or arresting dental caries in recent reviews (Rosenblatt et al. 2009; Peng et al. 2012; Shah et al. 2014). Although SDF has been used for decades, only two randomized clinical trial on using SDF to prevent root caries can be found in the literature. The trial conducted by Tan et al. (2010) showed that annual application of SDF solution was effective in preventing root caries among institutionalized elders. The other study, conducted among community-dwelling elders, found that the root caries preventive effect of annual application of SDF solution was not significantly different from that of providing individualized oral health instruction (OHI) alone (Zhang et al. 2013). However, that was the finding at 24-month follow-up and the test group subjects had only received two applications of SDF solution, one at baseline and one after 12 months. Although SDF seems to be a good choice for preventing root caries as it can also arrest active caries lesions, a concern is that SDF causes black stain on the arrested dentin caries lesions (Chu et al. 2002; Duangthip et al. 2016). This may be an aesthetic problem for adults. Knight et al. (2006) suggested that by applying saturated potassium iodide (KI) solution immediately after the application of silver fluoride, staining could be minimized while not affecting its effectiveness in preventing caries. However, this has not been tested in a clinical trial.

This study was conducted to promote dental health of community-dwelling elders in a water fluoridated area through preventing new root caries and arresting active root caries (Li et al. 2016). This paper reports on the effectiveness of annual application of SDF solution, with or without application of KI solution, in preventing root caries. The null hypothesis to be tested was that SDF application is not effective in preventing root caries when compared to a placebo control.

## **Materials and Methods**

This study was a randomized clinical trial using a parallel group design conducted from April 2012 to March 2015 in community centers for elders located in different districts in Hong Kong. Ethical approval was obtained from the Institutional Review Board of the University of Hong Kong and the trial is registered (clinicaltrials.gov # NCT02360124)

The study subjects were community-dwelling adults aged over 55 years. Information including the study purpose and procedures was sent to elderly centers. Elders who were interested and provided written informed consent received a free dental examination. The inclusion criteria of elders were: had 5 or more teeth with exposed root surfaces not indicated for extraction; no serious health problems; no cognitive problems in communication; and had self-care ability for normal daily activities. Elders whose salivary secretion had been significantly affected by disease, medication, or treatment were excluded.

Portable dental chairs, intra-oral LED lights, disposable dental mirrors, and CPI probes (405/WHO probe) were used by a trained dentist in the examinations. Teeth not indicated for extraction and had exposed root surfaces were assessed. Plaque and calculus obscuring visual inspection was removed using hand instruments and microbrush. Status of the mesial, distal, buccal and lingual root surfaces of each included tooth were classified using codes recommended by the International Caries Detection and Assessment System (ICDAS II) Coordinating Committee (2009). Both non-cavitated (code 1) and cavitated (code 2) root caries lesions were included. Activity of caries lesion was assessed through visual-tactile examination (Banting 2001). A caries lesion was recorded as active when dentin could be easily penetrated using a ball-ended probe with light force. Inactive caries was recorded when the lesion surface was hard and smooth. For caries lesions or fillings involving both tooth crown and root, only those with at least 1 mm extension beyond the cementum-enamel

junction was recorded as root lesion. A multi-surface root caries lesion or filling was recorded when it extended beyond the line angle to involve at least one-third of the adjacent tooth surface. Other clinical parameters recorded included: visible plaque (present/absent), greatest gingival recession (closest mm), close proximity (within 3 mm) to a removable partial denture (yes/no), and DMFT score. Information on the elder's demographic background, daily sweet snack intake, and frequency of tooth brushing was collected through an interview.

After baseline examination, subjects who fulfilled the inclusion criteria were randomly allocated into one of three study groups using block randomization with a block size of six. An assistant carried out the subject allocation according to combinations randomly generated by computer. Both the examiner and subjects were blinded to group assignment. Interventions were provided by another dentist (not the examiner). In Group 1, the control group, tonic water (placebo to mimic the bitter metallic taste of SDF) was painted onto all exposed tooth root surfaces using a disposable microbrush. In Group 2, 38% SDF solution (Saforide, Toyo Seiyaku Kasei Co. Ltd, Osaka, Japan) was painted. In Group 3, 38% SDF solution was painted on the root surface first and then immediately followed by painting a KI solution (2.36 mol/L). The KI solution was prepared in a laboratory with distilled water and KI powder (Sigma-Aldrich Co., St. Louis, USA). The elders were told not to rinse mouth, drink or eat after the intervention for at least 30 minutes. The interventions were repeated after 12 and 24 months. Besides, subjects received individualized OHI, including how to brush their teeth and clean their denture. A new toothbrush and a tube of fluoride toothpaste (1,450 ppm fluoride, Colgate, U.S.A.) were given to all study subjects at each follow-up. After the examination, the subjects were informed of the clinical findings and advised to seek appropriate treatment, as needed, from their own dentists.

Follow-up examinations were carried out at 12, 24, and 30 months after baseline by the same examiner using the same instruments and diagnostic criteria. The primary outcome was new root caries. A new lesion was recorded when a root surface recorded as sound at baseline was found to have a caries lesion or filling at follow-up examination. A random sample of 10% of the subjects were re-examined during each examination to monitor examiner reproducibility.

In sample size calculation, based on a previous clinical trial on root caries in Hong Kong (Tan et al. 2010), a mean 30-month increment of 2 new decayed root surfaces in the control group was anticipated. In order to show that a 50% difference in mean caries increment

between the highest and the lowest values in the three groups was statistically significant using one-way analysis of variance (ANOVA) at a 5% significance level and 80% power, a sample size of 80 subjects in each group was required. Allowing for a drop-out rate of 25% over 30 months, an initial sample size of slightly over 100 subjects in each group was planned.

### **Data analysis**

All collected data were input into computer and analyzed using the statistical software SPSS (Windows version 20, SPSS Inc., Chicago, USA) and SAS (University Edition, SAS Institute Inc., Cary, NC, USA). Intention-to-treat approach was used and subjects remained in the assigned study group regardless of whether they had received all the planned interventions. All available data at each time point were included in the analysis but there was no imputation of missing outcome measure data when a subjects did not attend a follow-up examination.

One way analysis of variance (ANOVA) was used to assess the differences in mean number of exposed sound root surfaces ( $ESS_{root}$ ), decayed root surfaces ( $DS_{root}$ ), filled root surfaces ( $FS_{root}$ ), and root caries experience ( $DFS_{root}$ ) among the three study groups at baseline. Number of root surfaces with new caries experience at 12-month, 24-month, and 30-month examinations were calculated. ANOVA with Scheffe's multiple comparison was used to assess the differences between the three groups in the number of new root caries surfaces. Analysis of covariance (ANCOVA) was used to assess the effects of the study interventions adjusted by elder's age, gender, baseline DMFT score, baseline root caries experience ( $DFS_{root}$ ), baseline VPI score, 30-month VPI score, denture wearing, snacking habit and tooth brushing frequency on the number of new root caries lesions developed over 30 months. Variables without statistically significant influence on the outcome measure were removed from the model one by one. Prevented fraction (PF), relative risk and number of root surfaces needed to treat (NNT) were calculated to assess treatment effects.

The data in this study were structured in two levels (level 1=subject, level 2=site). In consideration of clustering effect, generalized estimating equation (GEE) modeling was used in the multi-level logistic regression. The dependent variable was new root caries lesion found at the 30-month examination (yes/no). The independent variables included subject's age, gender, frequency of sweet snack intake, frequency of tooth brushing, tooth location (upper/lower jaw), tooth surface (mesial, buccal, distal, and lingual), plaque present or not at baseline, greatest gingival recession (in mm) at baseline, close proximity to a denture (yes/no),

and study group assignment. Interactions among independent variables were also considered. Statistical significance level for all tests was set at 5%.

## Result

Among the 544 elders who attended the baseline examination, 323 fulfilled the study inclusion criteria and participated in this study. There were 70 (22%) men and 253 (78%) women. Their mean age was 72.1 ( $\pm$  6.3) years. There were no significant differences in mean age (ANOVA,  $p=0.150$ ) and gender distribution ( $\chi^2$  test,  $p=0.922$ ) among the three groups. Most (86%) of the elders brushed their teeth at least twice daily, 21% took sweet snacks between meals every day, and 32% wore denture. Distributions of elders by tooth brushing frequency, snacking habits, and denture wearing were not significantly different among the three groups ( $\chi^2$  test,  $p>0.05$ ).

At baseline, the study elders had a mean of 41.2 exposed sound root surfaces and a mean DFS<sub>root</sub> score of 1.1. There were no significant differences (ANOVA,  $p>0.05$ ) among the three study groups regarding their mean baseline ESS<sub>root</sub>, DS<sub>root</sub>, FS<sub>root</sub>, DFS<sub>root</sub> and VPI scores (Table 1). Differences in these parameters between the elders who attended the baseline examination and those who remained after 30 months were not statistically significant (t-test,  $p>0.05$ ). There were also no significant differences among the three groups of elders who were followed for 30 months regarding their tooth brushing frequency, snacking habits, and denture wearing ( $\chi^2$  test,  $p>0.05$ ).

After 30 months, 257 (80%) subjects remained in the study (Fig 1). The subject drop-out rate of SDF group was lower than those of the other two groups (11% vs 25%) ( $\chi^2$  test,  $p=0.014$ ). Intra-examiner reproducibility in caries assessment was good (Kappa = 0.85-0.89). At the 30-month examination, there were 178 root surfaces with new caries or filling. The mean numbers of root surfaces with new caries experience were 1.1 in Group1 (control), 0.4 in Group2 (SDF), and 0.5 in Group3 (SDF/KI) (ANOVA,  $p<0.001$ ) (Table 2). Scheffe's multiple comparison showed both the SDF and SDF/KI groups developed fewer new root caries than the control group ( $p<0.05$ ) with a prevented fraction of 62% and 52%, respectively. Compared with the control group elders, the relative risk for developing new root caries at surface level was lower for elders in the SDF group (0.38; 95% C.I. 0.26-0.55) or in the SDF/KI group (0.48; 95% C.I. 0.33-0.68). The NNT (surfaces) of the SDF and SDF/KI groups were 60.2 and

71.9, respectively.

After adjusting for the significant confounding factors, elder's baseline DMFT score ( $p=0.005$ ) and 30-month VPI score ( $p<0.001$ ), results of ANCOVA showed that elders in the control group developed more new root caries than those in the two SDF groups ( $p=0.001$ ) (Table 3).

Results of the multi-level GEE logistic regression model (Table 4) indicate that being an upper tooth (OR=2.1,  $p<0.001$ ), distal surface (OR=247,  $p<0.001$ ), mesial surface (OR=86.4,  $p<0.001$ ), buccal surface (OR=83.6,  $p<0.001$ ), tooth brushing less than once daily (OR=3.5,  $p<0.001$ ), plaque present on root surface at baseline (OR=2.5,  $p<0.001$ ), and close proximity to a denture (OR=347,  $p<0.001$ ) were risk factors for developing new root caries, and application of SDF (OR=0.4,  $p<0.001$ ) or SDF/KI (OR=0.5,  $p=0.004$ ) was protective.

Only 19 (7%) elders raised a complaint about the interventions at the 30-month examination and half of them complained of black stain on the treated root surfaces. No harmful effects were reported and no injury to teeth or gums due to the application of study solutions was observed at any of the follow-up examinations.

## **Discussion**

This study used a parallel group design to provide high level clinical evidence. Self-reported information on sugar intake and tooth brushing frequency was collected. Information on xerostomia and medication history was not collected because elders with serious systemic diseases were excluded. Random allocation was carried out to balance the possible confounding effects in the three study groups. Although 20% of the elders were missing from the 30-month examination and the drop-out rate of SDF group was lower, the potential bias caused in the study outcome is probably not large because the baseline caries experience and oral health related behaviors were not significantly different between the elders who attended at baseline and those who remained after 30 months. Furthermore, there was still a balance of the investigated confounding factors among the three groups of elders examined after 30 months. Only 7% of the remaining elders in the two test groups did not received all three annual applications of SDF solution because they did not turn up at one of the annual follow-up visits. The impact of this on the study result is probably rather small.

The null hypothesis was not supported by the 30-month results. Elders who received the placebo developed more new root caries than the elders who received interventions in the SDF or SDF/KI group. This finding indicates that topical application of 38% SDF solution is effective in preventing new root caries and agrees with that of a previous study (Tan et al. 2010). This study found a higher prevented fraction for annual application SDF than that found in the study by Zhang et al. (2013), 62% vs 25%, though both studies were carried out among community-dwelling elders. The differences might be due to different study samples and the longer follow-up period in this study. It should be noted that the water in Hong Kong is fluoridated at an optimal concentration of 0.5 ppm and the elders in this study used fluoridated toothpaste, how effective is SDF solution in preventing root caries among elders living in non-fluoridated areas needs to be investigated in future clinical trials.

In the in-vitro study by Knight et al. (2007), it was found that treatment using silver fluoride followed by KI could inhibit biofilm formation on dentin, and reduce development of caries and the viability of *S. mutans*. In this study, the similar mean numbers of new root caries in the SDF and SDF/KI groups indicate that KI solution did not significantly affect the caries prevention effect of SDF solution. Yellowish solid particles was seen when KI solution was applied immediately after application of SDF solution. This compound should be silver iodide which precipitated on the root surface and could be washed away later. In a clinical setting, it is difficult to control the amounts of SDF solution and KI solution applied so that all of these compounds are consumed in the chemical reaction. It was likely that in this study, some silver ions or iodide ions were left on the root surface. Both silver and iodide ions are antiseptic, and silver ion has been shown to be able to inhibit formation of dental plaque (Morishita et al. 1998; Bürgers et al. 2009). These ions on the root surfaces may have helped to prevent new caries but the silver ions can become oxidized later to form a black stain.

In this study, the subject's past dental caries experience (baseline DMFT score), oral hygiene condition (VPI score, plaque presence, tooth brushing frequency), denture wearing and location of the tooth/surface were found to be associate with development of new root caries. The multi-level statistical analysis showed that clustering effect of tooth surfaces in the same mouth was significant and this was adjusted for in the modelling process. A recent study reported that having plaque on the root surface and denture wearing were risk factors of root caries, and upper teeth had a higher chance to develop root caries (Tan & Lo 2014). Previous studies found that wearing denture was significantly associated with new caries development



(Yeung et al. 2000; Christensen et al. 2015), and infrequent tooth brushing was a risk factor (Steele et al. 2001). In this study, it was found that proximal tooth surfaces had a higher chance to develop dental caries and this agrees with the results of a previous study (Demirci et al. 2010). An explanation is that these tooth surfaces are difficult to access for effective plaque control. Noting the information from this and the previous studies, more emphasis should be put on these risk factors during provision of oral health education to elders regarding prevention of dental caries.

Results of this randomized clinical trial support the use of annual application of SDF solution in preventing root caries. This intervention is simple to apply and the cost is low. Considering that the elders usually do not pay regular visits to dentists and have lower income, this intervention can be a good choice to prevent root caries among elders, especially for use in outreach dental services. Though SDF has a metallic taste and can blacken the arrested caries lesion, there were no adverse side-effect observed and few complaints from the subjects in this study. It seems that application of SDF solution could be generally accepted by elders.

It is concluded that topical application of either SDF solution or SDF/KI solution is effective in preventing new root caries among community-dwelling elders in a water fluoridated area. KI solution does not affect the effectiveness of SDF solution in preventing root caries. Annual application of SDF solution can be used in dental clinic or in outreach dental services to reduce the development of root caries among elders.

## **Acknowledgement**

This study was supported by the Hong Kong Research Grants Council (grant #HKU773711M). Authors had no conflict of interest and declare no potential interest with the products cited.

## **References**

- Bürgers R, Eidt A, Frankenberger R, Rosentritt M, Schweikl H, Handel G, Hahnel S. 2009. The anti-adherence activity and bactericidal effect of microparticulate silver additives in composite resin materials. *Arch Oral Biol.* 54(6):595-601.
- Banting DW. 2001. The diagnosis of root caries. *J Dent Educ.* 65(10):991-996.

- Christensen LB, Bardow A, Ekstrand K, Fiehn NE, Heitmann BL, Qvist V, Twetman S. 2015. Root caries, root surface restorations and lifestyle factors in adult Danes. *Acta Odontol Scand.* 73(6):467-473.
- Chu CH, Lo ECM, Lin HC. 2002. Effectiveness of silver diamine fluoride and sodium fluoride varnish in arresting dentin caries in Chinese pre-school children. *J Dent Res.* 81(11):767-770.
- Demirci M, Tuncer S, Yuceokur AA. 2010. Prevalence of caries on individual tooth surfaces and its distribution by age and gender in university clinic patients. *Eur J Dent.* 4(3):270-279.
- Department of Health. 2013. Oral Health Survey 2011. Hong Kong: Government Press. p.125-161.
- Duangthip D, Chu CH, Lo ECM. 2016. A randomized clinical trial on arresting dentin caries in preschool children by topical fluorides - 18 month results. *J Dent.* 44:57-63.
- ICDAS Coordinating Committee. 2009. International Caries Detection and Assessment System (ICDAS II). [accessed 2016 March 17] <https://www.icdas.org/uploads/ICDAS%20Criteria%20Document%20corrected%202013.pdf>.
- Jensen ME, Kohout F. 1988. The effect of a fluoridated dentifrice on root and coronal caries in an older adult population. *J Am Dent Assoc.* 117(7):829-832.
- Kassebaum NJ, Bernabe E, Dahiya M, Bhandari B, Murray CJ, Marcenes W. 2015. Global burden of untreated caries: a systematic review and metaregression. *J Dent Res.* 94(5):650-658.
- Knight GM, McIntyre JM, Craig GG, Mulyani. 2006. Ion uptake into demineralized dentin from glass ionomer cement following pretreatment with silver fluoride and potassium iodide. *Aust Dent J.* 51(3):237-241.
- Knight GM, McIntyre JM, Craig GG, Zilm PS, Gully NJ. 2007. Differences between normal and demineralized dentin pretreated with silver fluoride and potassium iodide after an in vitro challenge by *Streptococcus mutans*. *Aust Dent J.* 52(1):16-21.
- Li R, Lo ECM, Liu BY, Wong MCM, Chu CH. 2016. Randomized clinical trial on arresting dental root caries through silver diammine fluoride applications in community-dwelling elders. *J Dent.* 50:15-20.
- Lo ECM, Tenuta LMA, Fox CH. 2012. Use of professionally administered topical fluorides in Asia. *Adv Dent Res.* 24(1):11-15.
- Morishita M, Miyagi M, Yamasaki Y, Tsuruda K, Kawahara K, Iwamoto Y. 1998. Pilot study

- on the effect of a mouthrinse containing silver zeolite on plaque formation. *J Clin Dent.* 9:94-96.
- Nemes J, Banoczy J, Wierzbicka M, Rost M. 1991. Clinical study on the effect of amine fluoride/stannous fluoride on exposed root surfaces. *J Clin Dent.* 3(2):51-53.
- Yeung ALP, Lo ECM, Chow TW, Clark RKF. 2000. Oral health status of patients 5 to 6 years after placement of cobalt-chromium removable partial dentures. *J Oral Rehabil.* 27(3):183-189.
- Peng JJ, Botelho MG, Matinlinna JP. 2012. Silver compounds used in dentistry for caries management: a review. *J Dent.* 40(7):531-541.
- Petersen PE, Yamamoto T. 2005. Improving the oral health of older people: the approach of the WHO Global Oral Health Programme. *Community Dent Oral Epidemiol.* 33(2):81-92.
- Rosenblatt A, Stamford TC, Niederman R. 2009. Silver diamine fluoride: a caries "silver-fluoride bullet". *J Dent Res.* 88(2):116-125.
- Shah S, Bhaskar V, Venkatraghavan K, Choudhary P, Ganesh M, Trivedi K. 2014. Silver diamine fluoride: a review and current applications. *J Adv Oral Res.* 5(1): 25-35.
- Steele JG, Sheiham A, Marcenes W, Fay N, Walls AW. 2001. Clinical and behavioural risk indicators for root caries in older people. *Gerodontology.* 18(2):95-101.
- Tan HP, Lo ECM, Dyson JE, Luo Y, Corbet EF. 2010. A randomized trial on root caries prevention in elders. *J Dent Res.* 89(10):1086-1090.
- Tan HP, Lo ECM. 2014. Risk indicators for root caries in institutionalized elders. *Community Dent Oral Epidemiol.* 42(5):435-440.
- Wallace MC, Retiet DH, Bradley EL. 1993. The 48-month increment of root caries in an urban population of older adults participating in a preventive dental program. *J Public Health Dent.* 53(3):133-137.
- Zhang W, McGrath C, Lo ECM, Li JY. 2013. Silver diamine fluoride and education to prevent and arrest root caries among community-dwelling elders. *Caries Res.* 47(4):284-290.

## Legend

Fig. 1 Flow of subjects and root caries lesions in this clinical study

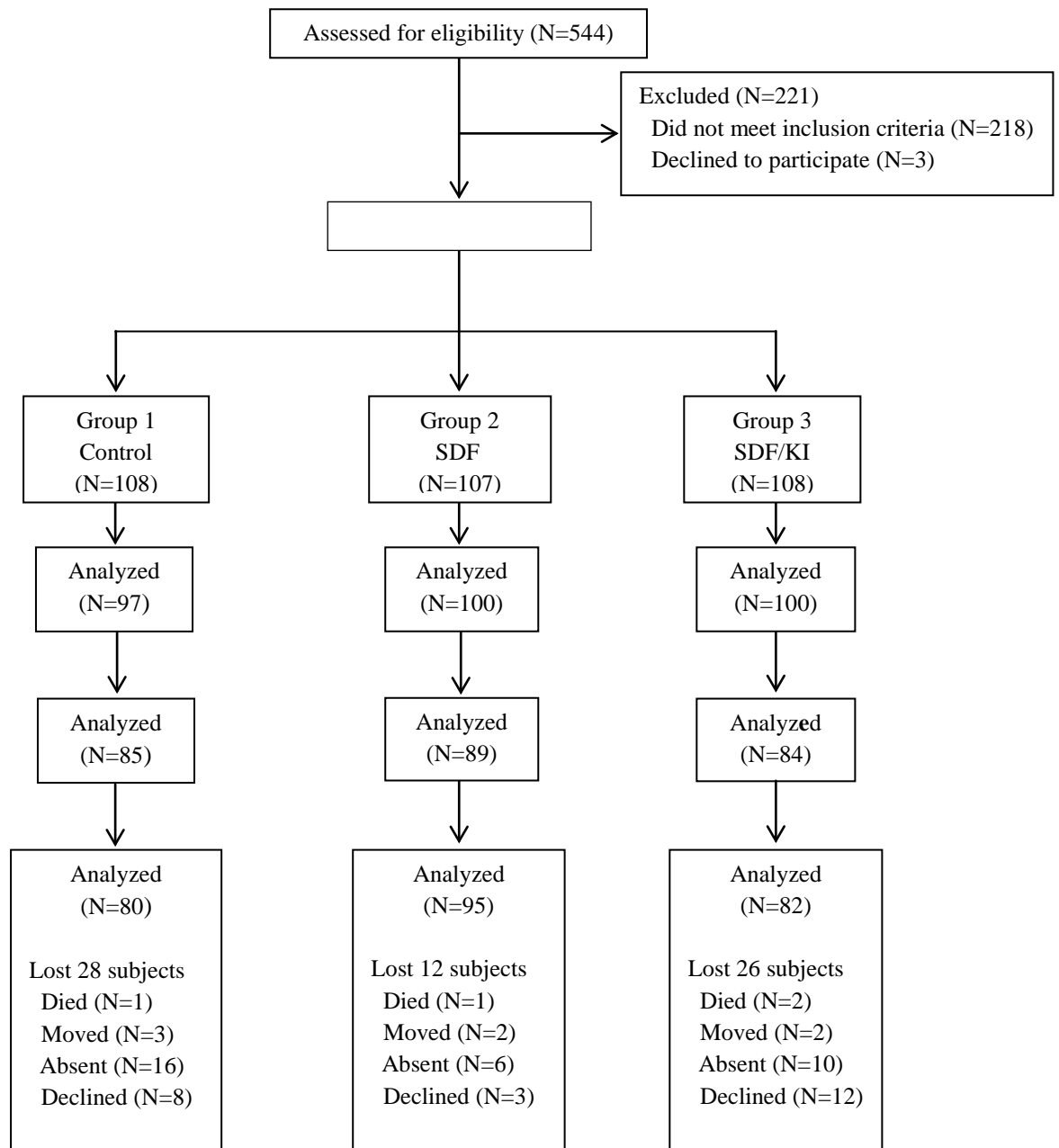


Fig. 1 Flow of subjects and root caries lesions in this clinical study

Table 1 Mean number (SE in parenthesis) of exposed sound root surfaces ( $ESS_{root}$ ), decayed root surfaces ( $DS_{root}$ ), filled root surfaces ( $FS_{root}$ ), root caries experience ( $DFS_{root}$ ), and visible plaque index (VPI) at baseline among all the subjects and those who remained in the study after 30 months

Study groups	All subjects						Subjects followed for 30 months					
	N	$ESS_{root}$	$DS_{root}$	$FS_{root}$	$DFS_{root}$	VPI	N	$ESS_{root}$	$DS_{root}$	$FS_{root}$	$DFS_{root}$	VPI
Control	108	40.2 (1.6)	0.6 (0.1)	0.4 (0.1)	1.0 (0.1)	28.6 (2.5)	80	42.7 (1.9)	0.5 (0.1)	0.5 (0.1)	1.0 (0.2)	28.1 (2.8)
SDF	107	41.7 (1.6)	0.6 (0.1)	0.4 (0.1)	1.0 (0.2)	26.6 (2.4)	95	41.7 (1.7)	0.6 (0.1)	0.4 (0.1)	1.0 (0.2)	26.0 (2.5)
SDF/KI	108	41.6 (1.6)	0.7 (0.1)	0.6 (0.1)	1.3 (0.2)	28.0 (2.7)	82	42.3 (1.9)	0.8 (0.2)	0.8 (0.2)	1.6 (0.2)	28.6 (3.0)
p-value		0.756	0.667	0.317	0.334	0.846		0.908	0.301	0.134	0.089	0.767

Table 2 Mean number (SE in parenthesis) of root surfaces with new caries lesions or fillings over 30 months

<b>Study groups</b>	<b>12-month N= 297</b>	<b>24-month N= 258</b>	<b>30-month N= 257</b>	<b>30-month PF</b>
Gp1 - Control	0.5 (0.1)	0.9 (0.1)	1.1 (0.2)	
Gp2 - SDF	0.2 (0.1)	0.4 (0.1)	0.4 (0.1)	62%
Gp3 - SDF/KI	0.2 (0.1)	0.4 (0.1)	0.5 (0.1)	52%
Significance	p=0.004	p=0.004	p< 0.001	
Scheffe' comparison	Gp1> Gp2, Gp3	Gp1> Gp2, Gp3	Gp1> Gp2, Gp3	

PF (prevented fraction) = (control mean – test mean)/control mean \*100%

Table 3 Results of Analysis of Covariance (ANCOVA) on the mean number of new root caries at 30-month examination (n=257)

<b>Independent variables</b>	<b>Estimate</b>	<b>SE (estimate)</b>	<b>p-value</b>	<b>Multiple comparison</b>
Study group			0.001	Gp2, Gp3 < Gp1
Gp3 vs Gp1	-0.475	0.139		
Gp2 vs Gp1	-0.394	0.134		
30-month VPI score	0.051	0.005	<0.001	
Baseline DMFT score	0.026	0.009	0.005	
Intercept	-0.138	0.141	0.329	

F-value = 48.45; df = 4, 252; p <0.001; R<sup>2</sup> = 0.426

Table 4 Final model of multi-level GEE logistic regression on new root caries experience at 30-month examination

<b>Factors</b>	<b>Odds ratio</b>	<b>95% CI</b>	<b>p-value</b>
Study group			
SDF/KI vs control	0.5	0.3 – 0.8	0.004
SDF vs control	0.4	0.3 – 0.7	<0.001
Tooth location			
upper vs lower	2.1	1.5 – 3.1	<0.001
Surface type			
distal vs lingual	247.2	62.3 – 980.6	<0.001
mesial vs lingual	86.4	20.6 – 362.1	<0.001
buccal vs lingual	83.6	19.9 – 351.3	<0.001
Tooth brushing			
<1/day vs $\geq$ 2/day	3.5	2.0 – 6.3	<0.001
1/day vs $\geq$ 2/day	1.3	0.6 – 2.7	0.548
Plaque present at baseline			
yes vs no	2.5	1.6 – 3.8	<0.001
Close proximity to a denture			
yes vs no	347.3	109.8 – 1098.4	<0.001

\*Exp(B) = Odds Ratio (OR)