# Salivary Fluoride Concentration Following Toothbrushing with and without Rinsing: a Randomised Controlled Trial

Marwah M Albahrani , Asma Alyahya , Muawia A Qudeimat*, K Jack Toumba

Department of Developmental and Preventive Sciences, Kuwait University, Kuwait

## INTRODUCTION

Caries prevalence has declined significantly since the introduction of fluoridated toothpaste. There have been several developments regarding specific active fluoride ingredients but there is  not enough evidence to support one over the other. The purpose of this double-blind randomized controlled trial was to compare salivary fluoride concentrations of different fluoride formulations in the form of toothpaste with and without post-brushing water rinsing in adults.

## METHODS & MATERIAL

**Study Design:**

Figure 1 represents the Consolidated Standards of Reporting Trials (CONSORT) flow diagram of this randomised trial. The trial protocol was registered with ClinicalTrials.gov (NCT02740803).

**Sample Size Calculations and Participants' Allocation:**

Sample size calculations estimated that a sample of 3 participants was needed for each group. It was decided to increase the number of participants to 10 per group. Block randomisation was used to assign each participant to one of the 12 groups. To be included in the study, participants had to: 1. be adults with ASA grades I or II; and 2. have a resting salivary flow rate of ≥0.1 ml/min. Participants were excluded if they were: 1. edentulous; 2. allergic to any of the materials used in the study; 3. incapable of fasting for four hours; 4. unable to retain the toothpaste following brushing; or 5. if they had orthodontic braces.

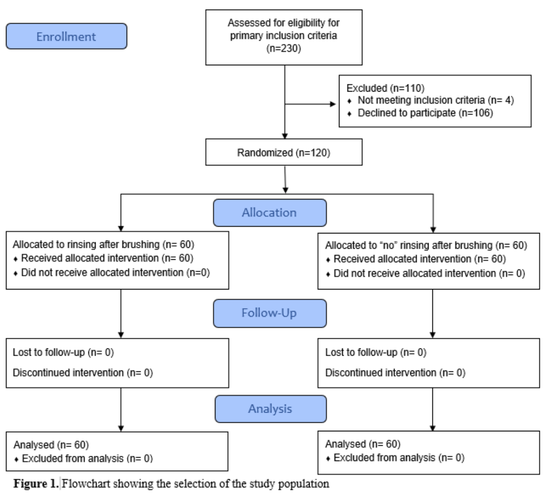


**Figure 1.** Flowchart showing the selection of the study population

The WHO criteria for DMFT, and DMFS scoring were followed. Teeth were also visually examined for the presence or absence of supra-gingival calculus. The interventions were to brush with one of the following six different toothpaste formulations: (1) fluoride-free (0 ppmF); (2) sodium fluoride (1450 ppmF); (3) sodium monofluorophosphate (1450 ppmF); (4) sodium fluoride and monofluorophosphate combined (1450 ppmF); (5) stannous fluoride and sodium fluoride combined (1450 ppmF); and (6) amine fluoride (1400 ppmF).

Participants were instructed to fast for at least two hours before the appointment, and refrain from brushing their teeth on the day of sample collection. At the start of the study, participants were asked to drool (unstimulated saliva sample) into a 15 ml sterile tube for two minutes. Then, participants brushed with 1.0 g of one of the six different toothpaste formulations either with or without post-brushing water rinsing. Saliva was collected at six different times (baseline and at 1, 15, 30, 60, and 90 min/s post-brushing). Samples were analysed using a fluoride ionspecific sensitive electrode.

## Statistical analysis

The predictor effects were considered to be statistically significant at ≤ 5% level. Mauchly's sphericity test was used to validate the repeated measures analysis of variance (ANOVA). Two-way mixed ANOVA with Tukey's post-hoc test and Bonferroni correction were used for the data analysis of fluoride concentrations within the different groups at different time intervals and within individual groups comparing rinsing and non-rinsing groups.

## RESULTS

- The demographic characteristics of the participants (Table 1) were not significantly different among the groups ($P > .05$).

Time, toothpaste formulation, and post-brushing rinsing routines had significant effects on saliva fluoride retention ($P < .05$).

- Amine fluoride-containing toothpaste was the only formula that showed statistically significantly higher concentrations of salivary fluoride at 90 min in both the rinsing and non-rinsing groups. Sodium monofluorophosphate toothpaste did not result in a significant difference compared to the control group at any time point, in both rinsing and non-rinsing groups (Table 2).

- Estimated marginal means of salivary fluoride concentrations (ppmF) for 12 groups (rinsing and non-rinsing) at different time intervals are presented in Figure 2.

| Variable | | Non-Rinsing Group | Rinsing Group | Total | *P* |
|---|---|---|---|---|---|
| Sex | Female (%) | 42 (70) | 37 (62) | 79 (66) | 0.22 |
| | Male (%) | 18 (30) | 23 (38) | 41 (34) | |
| | | | | | |
| Age | Range in years | 18- 58 | 18-60 | 18-60 | 0.96 |
| | Mean in years (SE) | 27.22 (1.03) | 27.28 (0.95) | 27.25 (0.70) | |
| | | | | | |
| Caries Experience (mean) | DMFT (SD) | 4.78 (5.47) | 4.70 (4.91) | 4.74 (5.18) | 0.93 |
| | DT (SD) | 0.60 (2.29) | 0.93 (1.73) | 0.77 (2.03) | 0.37 |
| | MT (SD) | 0.22 (1.18) | 0.12 (0.05) | 0.17 (0.08) | 0.53 |
| | FT (SD) | 3.97 (4.19) | 3.65 (3.75) | 3.81 (3.97) | 0.66 |
| | | | | | |
| | DMFS (SD) | 8.48 (16.89) | 7.62 (9.52) | 8.05 (16.66) | 0.73 |
| | DS (SD) | 0.73 (3.17) | 1.08 (2.23) | 0.91 (2.74) | 0.49 |
| | MS (SD) | 1.05 (5.65) | 0.57 (1.83) | 0.81 (4.19) | 0.53 |
| | FS (SD) | 6.70 (11.31) | 5.97 (7.55) | 6.33 (9.58) | 0.68 |
| | | | | | |
| Calculus | No (%) | 43 (72) | 44 (73) | 87 (72.5) | 0.50 |
| | Yes (%) | 17 (28) | 16 (28) | 33 (27.5) | |

**Table 1** Baseline demographic and clinical characteristics for each group

| Group | Rinsing Status | Mean fluoride concentration (SD) at each study interval | | | | | |
|---|---|---|---|---|---|---|---|
| | | Baseline | 1 minute | 15 minutes | 30 minutes | 60 minutes | 90 minutes |
| Control (fluoride-free) | Non-Rinsing | 0.106 (0.154) | 0.032 (0.193) | 0.050 (0.071) | 0.041 (0.053) | 0.039 (0.060) | 0.041 (0.056) |
| | Rinsing | 0.129 (0.120) | 0.037 (0.038) | 0.039 (0.049) | 0.023 (0.024) | 0.031 (0.048) | 0.020 (0.030) |
| | F-test | 0.135 | 0.120 | 0.178 | 0.892 | 0.133 | 1.085 |
| | *P*-value | .718 | .733 | .678 | .357 | .720 | .311 |
| Amine Fluoride (AmF) | Non-Rinsing | 0.173 (0.205) | 33.760 (17.507) | 2.784 (2.214) | 1.216 (1.044) | 0.500 (0.365) | 0.324 (0.221) |
| | Rinsing | 0.059 (0.058) | 16.865 (9.286) | 1.650 (1.169) | 0.561 (0.414) | 0.312 (0.295) | 0.174 (0.160) |
| | F-test | 2.900 | 7.268 | 3.395 | 3.133 | 1.614 | 3.040 |
| | *P*-value | .106 | **.015*** | .082 | .169 | .220 | .098 |
| Sodium Fluoride (NaF) | Non-Rinsing | 0.048 (0.025) | 35.500 (18.351) | 3.322 (2.504) | 0.787 (0.523) | 0.299 (0.229) | 0.158 (0.095) |
| | Rinsing | 0.063 (0.043) | 15.104 (9.497) | 1.701 (0.856) | 0.452 (0.210) | 0.213 (0.104) | 0.138 (0.096) |
| | F-test | 0.969 | 9.743 | 3.748 | 3.546 | 1.159 | 0.206 |
| | *P*-value | .338 | **.006*** | .069 | .076 | .296 | .655 |
| Sodium Monofluorophosphate ($Na_2FPO_3$) | Non-Rinsing | 0.172 (0.143) | 12.775 (4.871) | 1.905 (1.281) | 0.537 (0.371) | 0.180 (0.101) | 0.113 (0.062) |
| | Rinsing | 0.046 (0.043) | 8.976 (4.519) | 0.867 (0.578) | 0.260 (0.137) | 0.107 (0.058) | 0.058 (0.029) |
| | F-test | 7.109 | 3.269 | 5.461 | 4.896 | 3.961 | 6.705 |
| | *P*-value | **.016*** | .087 | **.031*** | **.040*** | .062 | **.019*** |
| Sodium Fluoride and Sodium Monofluorophosphate (NaF & $Na_2FPO_3$) | Non-Rinsing | 0.046 (0.023) | 18.118 (10.066) | 1.512 (1.452) | 0.369 (0.292) | 0.149 (0.104) | 0.105 (0.086) |
| | Rinsing | 0.078 (0.080) | 12.285 (6.486) | 1.356 (0.849) | 0.443 (0.459) | 0.186 (0.259) | 0.100 (0.120) |
| | F-test | 1.395 | 2.373 | 0.086 | 0.184 | 0.175 | 0.016 |
| | *P*-value | .253 | .141 | .773 | .673 | .681 | .900 |
| Stannous Fluoride and Sodium Fluoride ($SnF_2$ & NaF) | Non-Rinsing | 0.153 (0.117) | 21.919 (11.677) | 1.054 (0.673) | 0.272 (0.154) | 0.116 (0.058) | 0.071 (0.034) |
| | Rinsing | 0.087 (0.068) | 17.710 (9.433) | 2.245 (1.800) | 0.506 (0.342) | 0.175 (0.121) | 0.078 (0.042) |
| | F-test | 2.368 | 0.786 | 3.844 | 4.122 | 1.935 | 0.195 |
| | *P*-value | .141 | .387 | .066 | .057 | .181 | .664 |

* Statistically significant ($P \leq .05$)

**Table 2** Comparisons between the mean fluoride concentration (ppmF) at different time intervals between rinsing and non-rinsing groups

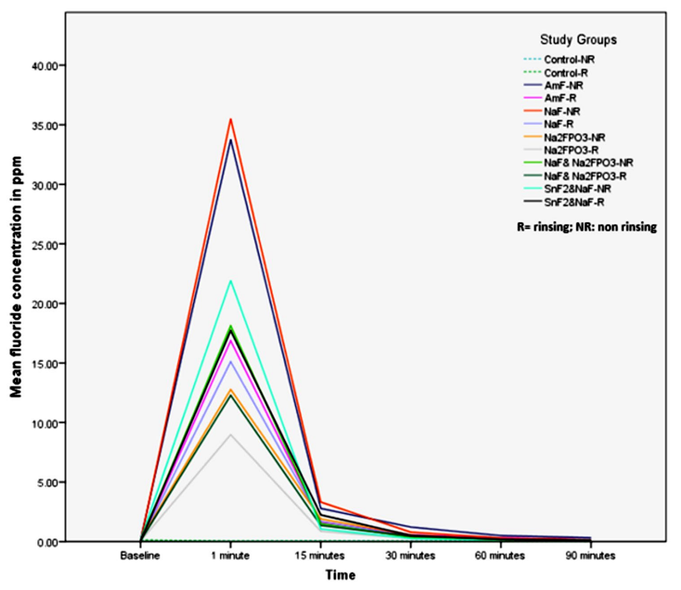


**Figure 1** Estimated marginal means of salivary fluoride concentrations (ppmF) for 12 groups at different time intervals with and without post-brushing rinsing

## CONCLUSION

1. Sodium monofluorophosphate containing toothpaste was the only formula that showed statistically significantly higher levels of fluoride in the non-rinsing group at 15-, 30- and 90-min time intervals compared to the rinsing group.
2. AmF-containing toothpaste was the only formula that showed statistically significantly higher concentrations of salivary fluoride at 90 min in both the rinsing and non-rinsing groups.

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