



AIM

To compare the effectiveness of two 5% NaF varnishes containing CPP-ACP or TCP to the conventional 5% NaF varnish in preventing ECC in high caries-risk preschool children.

METHODS

- Registered: www.clinicaltrials.gov (NCT04274569)
- Ethical clearance: IRB from University of Hong Kong/Hospital Authority Hong Kong West Cluster (UW18-054)
- Double-blinded, randomized controlled trial with three parallel arms, (2019-2021) in 25 kindergartens, selected by convenient sampling
- Inclusion criteria: 3-4 years old children with at least one carious lesion (pre-cavitated or cavitated)
- Data collected:
 - Completed structured questionnaire
 - Clinical examination through ICDAS-II and VPI
- Intervention (quarterly application):
 - Group 1- 5% NaF (Duraphat®, Colgate-Palmolive Ltd, UK)
 - Group 2- 5% NaF with TCP (Clinpro™ White, 3M ESPE, USA)
 - Group 3- 5% NaF with CPP-ACP (MI Varnish™, GC corp., Japan)
- Outcome measure:
 - Primary- Incidence of new cavitated lesion
 - Secondary- Increment of both cavitated and non-cavitated lesions

RESULTS

- No significant difference in baseline sociodemographic and oral health characteristics of children remaining at the final follow-up among 3 groups
- Total varnish applications received: 3-6, no significant difference ($p=0.630$) in its distribution among 3 groups
- No statistically significant difference in caries incidence and increments among different number of fluoride applications in each group

Figure: Flow Diagram of the study design

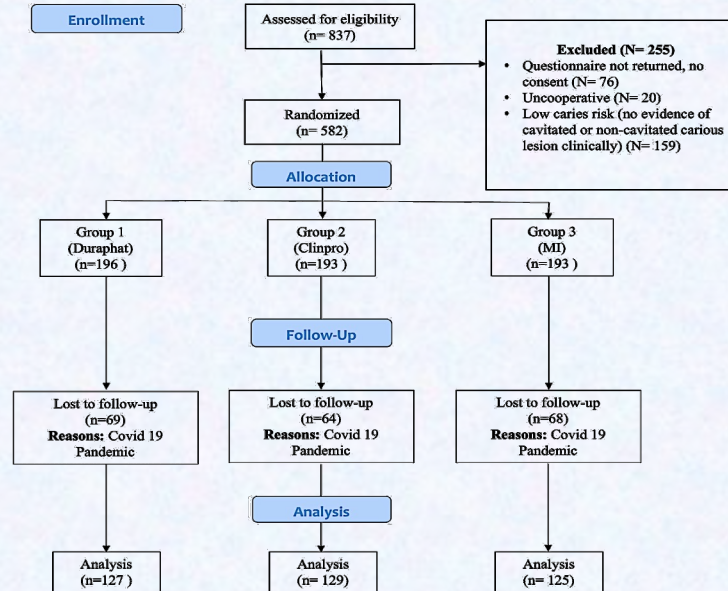


Table 1: Caries incidence and increment in 3 groups

	Group 1 (Duraphat) (n=127)	Group 2 (Clinpro) (n=129)	Group 3 (MI) (n=125)	p-value
Caries incidence: n (%)	84 (66.1%)	84 (65.1%)	74 (59.2%)	0.466 [†]
Cavitated lesions increment Mean (SD)	3.21 (4.06)	2.80 (3.28)	2.99 (4.01)	0.714 [‡]
Non-cavitated lesions (WSLs) increment Mean (SD)	-1.54 (3.86)	-0.95 (3.93)	-1.90 (4.05)	0.223 [‡]

[†]Pearson Chi-square test; [‡]Independent-Samples Kruskal Wallis Test

Abbreviations: NaF- Sodium fluoride; CPP-ACP- Casein phosphopeptide amorphous calcium phosphate; TCP- Tricalcium phosphate; ECC-Early childhood caries; ICDAS- International Caries Detection and Assessment System; VPI- Visible plaque index; SD- Standard deviation; CI- Confidence interval; SE- Standard error; dmfs- decayed, missing, filled surfaces; WSLs- White spot lesions.

Table 2: Negative binomial regression for cavitated lesions increment

Parameters	Odds ratio	S.E.	95% CI	p-value
Intervention group				0.662
Group 1 (Duraphat)	1	-	-	
Group 2 (Clinpro)	0.89	0.13	0.67, 1.19	0.439
Group 3 (MI)	0.88	0.14	0.65, 1.21	0.439
Number of Fluoride applications	0.91	0.07	0.79, 1.06	0.239
Baseline dmfs	1.07	0.01	1.05, 1.08	<0.001
Number of non-cavitated lesions (WSLs) at baseline	1.08	0.02	1.05, 1.11	<0.001

Table 3: Binary logistic regression model for caries incidence

Parameters	Odds ratio	95% CI	p-value
Intervention group			0.421
Group 1 (Duraphat)	1	-	-
Group 2 (Clinpro)	0.77	0.41, 1.44	0.411
Group 3 (MI)	0.66	0.35, 1.24	0.196
Number of Fluoride applications	1.02	0.75, 1.39	0.908
Fed after brushing			0.028
No	1	-	-
Yes	1.83	1.07, 3.15	0.028
Baseline dmfs	1.50	1.30, 1.72	<0.001

Table 4: General linear model for non-cavitated lesions increment

Parameters	Estimate	S.E.	95% CI	p-value
Intervention group				0.194
Group 1 (Duraphat)	0 [†]	-	-	-
Group 2 (Clinpro)	0.59	0.33	-0.05, 1.22	0.072
Group 3 (MI)	0.23	0.33	-0.41, 0.88	0.476
Number of fluoride applications	0.10	0.16	-0.23, 0.42	0.556
Number of non-cavitated lesions (WSLs) at baseline	-0.84	0.04	-0.91, -0.76	<0.001
Baseline VPI percentage	0.03	0.01	0.01, 0.05	0.014

CONCLUSIONS

- Two calcium- and phosphate-containing NaF varnishes showed similar caries-preventive effect and the potential to arrest/remineralize the initial non-cavitated lesions as compared to the conventional NaF varnish in high-risk preschool children.
- Past caries experience was significantly associated with the development of new caries and increment of cavitated and non-cavitated carious lesions.