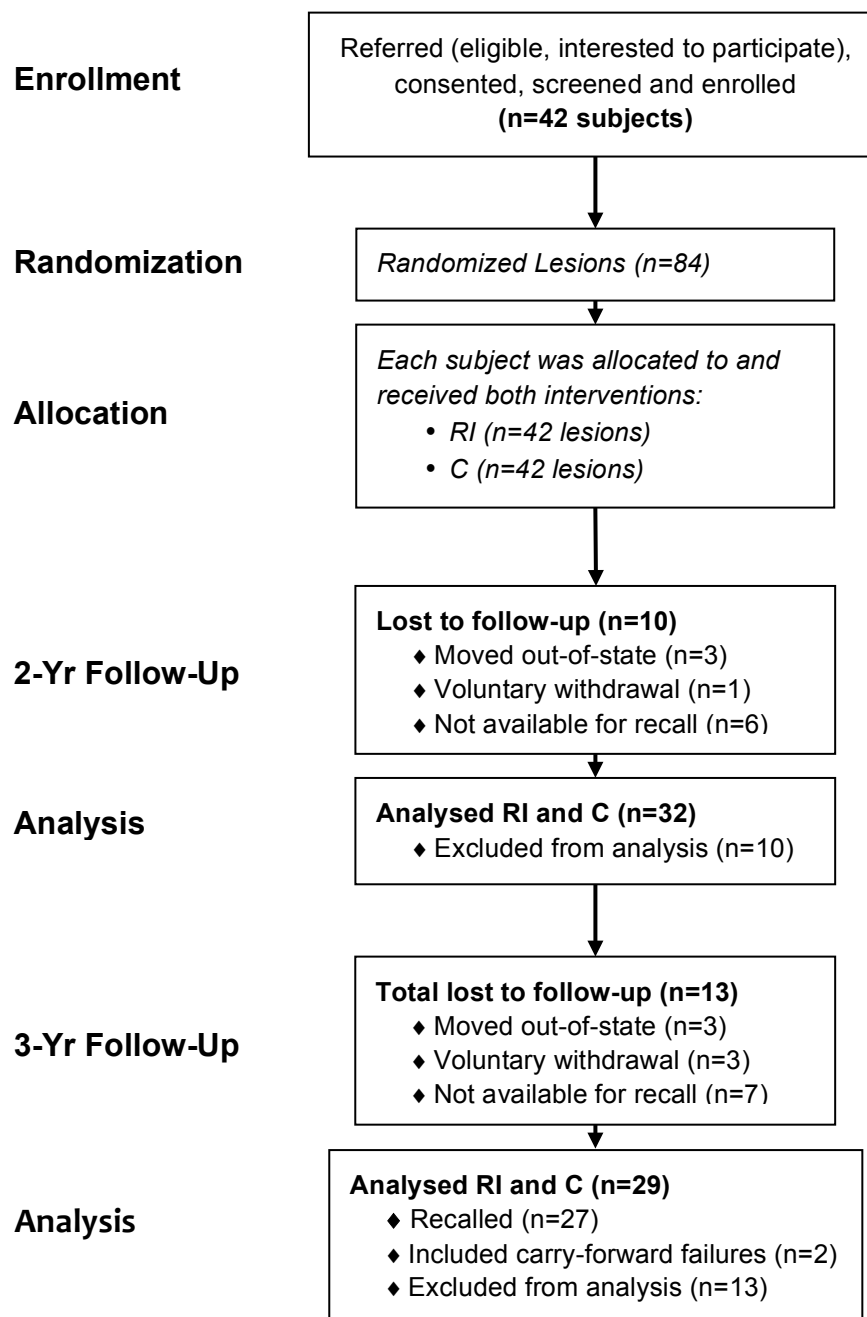


Efficacy of Proximal Resin Infiltration on Caries Inhibition: Results from a 3-Year Randomized Controlled Clinical Trial

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APPENDIX

CONSORT Flow Diagram



Appendix Figure 1. Study flow diagram of the within-person study design: 84 lesions were randomized in 42 subjects, each receiving both interventions infiltration (RI) and control (C).

ITT – Analyses

Appendix Table 1

LESION DEPTH	Impute1	Impute2	Impute3	Impute4	Impute5
One-sided P-value	0.1334	0.3872	0.1334	0.19385	0.1133

Three-year categorical depth scores (N=29) showed no difference between treatment groups (McNemar: $P = .172$). ITT-analysis: 5 imputed datasets showed all P-values $> .05$, confirming no difference between groups RI and C.

The Mantel-Haenszel odds ratio obtained from observed data is 0.4286 with 95% confidence interval from 0.1108 to 1.6573. The odds of lesion progression in treatment group RI were 57% less than that in treatment group C.

Appendix Table 2

PAIRWISE ASSESSMENT	Impute1	Impute2	Impute3	Impute4	Impute5
One-sided P-value	0.0176	0.01125	0.0384	0.0176	0.0327

At 3yr-recall, RI-lesions showed significantly less caries progression than C-lesions (McNemar: $P = .033$). ITT-analysis: 5 imputed datasets showed all P-values $< .05$, confirming a statistically significant difference between groups RI and C.

The Mantel-Haenszel odds ratio obtained from observed data is 0.2222 with 95% confidence interval from 0.0480 to 1.0285. The odds of lesion progression in treatment group RI were 78% less than that in treatment group C.

Appendix Table 3

CUMULATIVE PAIRWISE ASSESSMENT	Impute1	Impute2	Impute3	Impute4	Impute5
One-sided P-value	0.00115	0.00025	0.0022	0.00035	0.00635

Cumulative PW-data after 3 years revealed significantly less caries progression in infiltrated lesions (4 RI) than control lesions (14 C) (McNemar: $P < .003$). The P-values from 5 imputed datasets (ITT analysis) were all $P < .01$.

The Mantel-Haenszel odds ratio (OR) from observed data was 0.091 with 95% confidence interval (CI) from 0.012 to 0.704. The odds of 3yr-data being worse in RI-group were 91% less than those in group C.

Appendix Table 4

CUMULATIVE PW-ASSESSMENT of Baseline E2-lesions	Impute1	Impute2	Impute3	Impute4	Impute5
One-sided P-value	0.01955	0.0078	0.01955	0.00195	0.0625

For equal lesion pairs (N=17) both starting in enamel (E2), all RI-lesions were inhibited while 35.3% of C-lesions progressed (McNemar: $P < .016$). The P-values from 5 imputed datasets (ITT analysis) confirmed the significant difference between the groups by 4 out of 5 imputations to be $P < .05$.

A correction of 0.5 was used for the zero cell of discordant pairs to obtain a logit estimate of odds ratio. The estimated odds ratio from observed data is 0.1111 with 95% confidence interval from 0.0175 to 0.7051. For teeth with baseline E2-lesions, the odds of 3yr-data being worse in the RI-group were 89% less than that in the C-group.

Appendix Table 5

CUMULATIVE PW-ASSESSMENT of Baseline D1-lesions	Impute1	Impute2	Impute3	Impute4	Impute5
One-sided P-value	0.0625	0.03515	0.08985	0.08985	0.08985

For D1-lesion pairs (N=8), no difference was found between groups (McNemar: $P > .05$; confirmed by 4 out of 5 imputations showing P-values > 0.05 [ITT analysis]).

The Mantel-Haenszel odds ratio obtained from observed data is 0.25 with 95% confidence interval from 0.0279 to 2.2367. For teeth with D1-lesions at baseline, the odds of 3yr-data being worse in the RI-group were 75% less than in the C-group.