

Randomized Control Trial Evaluating the Efficacy of TCP-Fluoride Varnish vs. Fluoride Varnish

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BACKGROUND

- White spot lesions (WSLs) can significantly detract from an esthetic orthodontic outcome and the health of teeth.
- Any treatment that causes carbohydrates and bacteria to become trapped around the teeth, such as fixed orthodontic treatment, may cause an increase in WSLs.
- Demineralization is a common finding after orthodontic treatment, with one study reporting a 97% prevalence (Ogaard, 1989).
- Although it is accepted that fluoride treatments can reduce demineralization, there is insufficient evidence regarding how effective they are in preventing WSLs during orthodontic treatment.
- The purpose of this study was to compare the effectiveness of tricalcium phosphate (TCP)-containing fluoride releasing varnish to a control fluoride releasing varnish without TCP in preventing early enamel demineralization during orthodontic treatment.



Table 2. White spot lesions following orthodontic treatment

METHODS

- 10 patients between the age of 10-80 years old undergoing comprehensive orthodontic treatment at the University of Colorado School of Dental Medicine who required two or more extractions of premolars in any combination were enrolled.
- A single application of either a control 5% NaF varnish or 3M 5% TCP-containing NaF varnish was completed after bracket bonding onto premolars planned for extraction. The teeth were randomized to each intervention in a 1:1 ration using the split-mouth design.
- The teeth were extracted after at least 1 month and subsequently analyzed. The provider, outcome assessors and patients were blinded to the intervention.
- The primary outcome was demineralization depth of enamel measured by the Canary System. The Canary System is a highly accurate and sensitive method for evaluating tooth demineralization in vitro compared to conventional methods (Jan, 2016).
- A secondary outcome was lesion location and pattern on the extracted teeth.

RESULTS

Table 1. Characteristics of the study sample

Variable	Overall (N=10)
Age	
Mean (SD)	21.3 (10.78)
Median [Min, Max]	17.5 [12, 44]
Gender	
Male	3 (30%)
Female	7 (70%)
Race	
Hispanic	4 (40%)
White	1 (10%)
Black	5 (50%)

Table 2. Summary statistics based on Canary numbers

	Canary Number	
	Varnish A (N=7)	Varnish B (N=7)
Average	28.071	25.464
SD	7.212	6.491
Paired Statistics		
Δ Varnish A – B (N=7)		
Average (SD)	2.607 (6.450)	
Paired p	0.3260	
Power	0.1484	
n (80%/0.05)	50	

Figure 1. Varnish A vs. Varnish B Canary Numbers

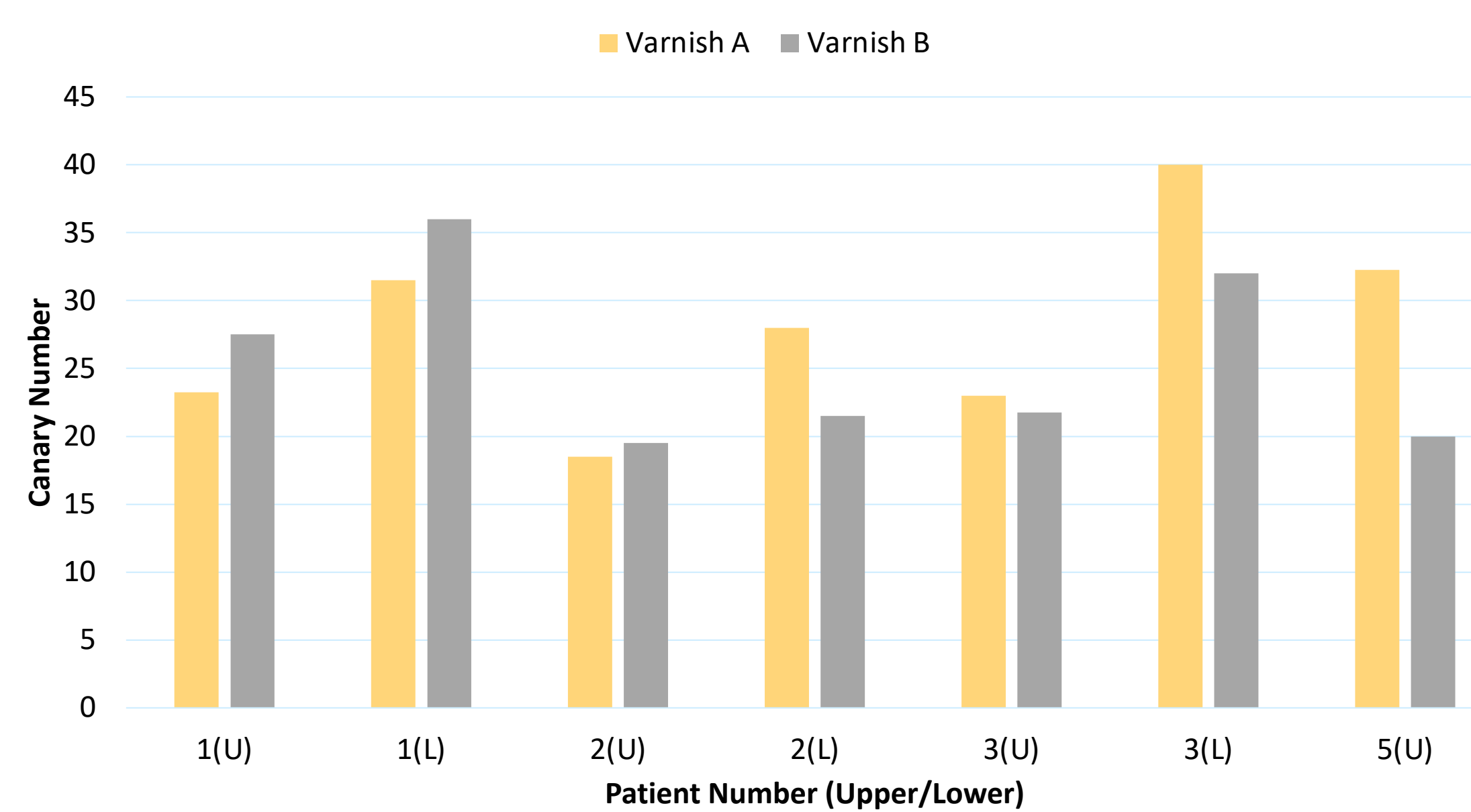


Table 3. Summary statistics of upper vs lower comparisons

Jaw		Canary Number	
		Varnish A	Varnish B
Upper (N=4)	Average	24.25	22.19
	SD	5.76	3.67
Lower (N=3)	Average	33.17	29.83
	SD	6.17	7.49
Upper vs. Lower	t-test	0.1061	0.1297
	Paired t-test	0.0514	0.1103

CONCLUSIONS

- Due to the blinded nature of this trial design and ongoing data collection, it is not possible to disclose the identity of Varnish A and Varnish B.
- The small sample size of 4 participants at the present time resulted in a p value of p=0.326. The results do not hold statistical significance and prevent any reports of conclusive data.
- There were no adverse outcomes reported for this study.
- Preliminary data revealed (1) Varnish A had a higher average Canary number than Varnish B which was not statistically significant (2) Demineralization scores were consistently higher for lower teeth which contradicts findings from previous studies.
- The early results of this study suggest that there is no significant difference between the two groups regarding enamel demineralization during orthodontic treatment.
- Other additives to fluoride-releasing varnish such as CPP-ACP-NaF may have a greater effect on prevention of white spot lesions (Lekht, 2019).

IMPLICATIONS

- More research is needed to determine the significance of TCP in reducing enamel demineralization during orthodontic treatment.

DISCLOSURES

- The authors have nothing to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation.