



Radiographic Survival of 0.05% Oxymetazoline Used in Primary Pulp Therapy

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Introduction

Deep caries excavation can result in pulpal exposure. In normal pulps or those with reversible pulpitis, a pulpotomy is indicated and involves the partial removal of the pulp tissue in order to treat and save a tooth with extensive decay or infection in a primary tooth or a young permanent tooth.

Traditional secondary hemostatic agents used following primary clotting (hemostasis from pressure), such as ferric sulfate (FS), have been used to manage radicular bleeding by occluding damaged blood vessels through a Fe-protein complex. Other agents that cause hemostasis via other mechanisms have been explored. This includes oxymetazoline which is a common active ingredient found in over-the-counter nasal decongestants. Its imidazolin derivatives works as an alpha-adrenergic agonist to achieve hemostasis, relieve nasal congestion, or to manage ophthalmic inflammation.

A Nasal Spray containing 0.05% oxymetazoline (NS-OXY) is found in most anesthesia carts that support pediatric dental procedures in hospital.



Purpose

The purpose of this retrospective clinical study was to assess the radiographic survival of an NS-OXY used in primary pulp therapy by:

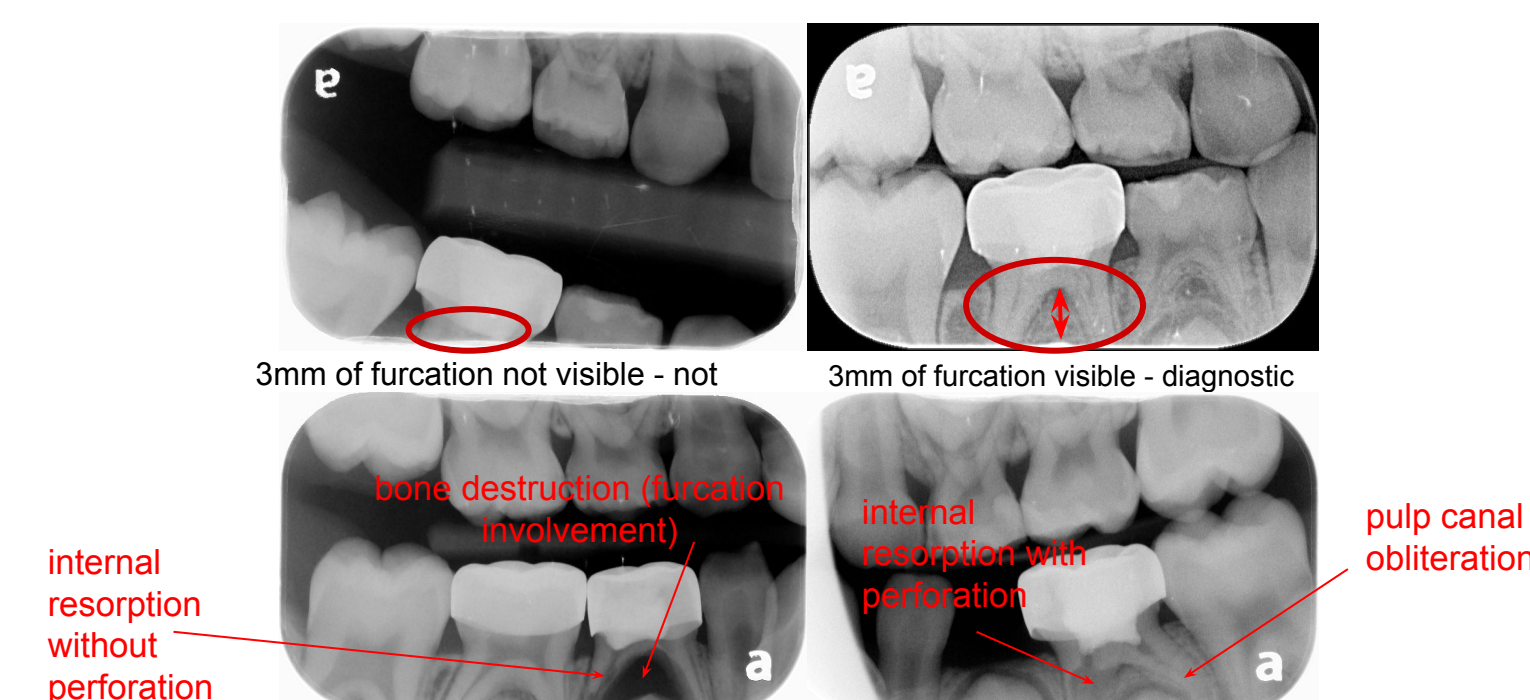
1. Identifying the predictor variables that affect the survival of teeth treated with pulpotomies
2. Comparing the survival time of teeth hemostatically managed with NS-OXY with those managed by FS

Method

After IRB review, pulpotomy treatment (CDT code D3220) performed at the UM Pediatric Dental Clinic from 2018-2022 were reviewed.

- Inclusion criteria: pulpotomies done on a single primary tooth per patient that used ferric sulfate (FS) or nasal spray with 0.05% oxy (NS-OXY) and restored with a stainless steel crown.
 - Treated teeth from the same patient were randomly selected so that only one tooth was included from each patient.
- Exclusion criteria: teeth with
 - no follow up appointment after treatment
 - no pre-op x-rays
 - no post-op radiographs or the radiographs were not diagnostic
 - no clinical failure within 3 months of the treatment and no post-op radiographs older than 3 months to the treatment.
 - Teeth with preop spontaneous pain were also excluded for data analysis.

A total of 173 cases were included for data analysis.



Radiographs interpretation was blinded by two examiners. Radiographic findings were recorded as

- Radiographic survival: (1) within normal limits, (2) near exfoliation, (3) apical root resorption, (4) lateral root resorption, (5) pulpal canal calcification,
- Radiographic failure: (1) internal root resorption without perforation, (2) internal root resorption with perforation, (3) bone destruction

Log-rank test and restricted Mean Survival Time to 30 months were used to compare the survival curves for the significant variables found from multivariable cox regression analysis.

Results

Two variables were included in the Cox Regression model, but neither behavior (uncooperative vs compliant, $P=.19$, 95% CI [0.08-1.63]) nor the use of different hemostatic agents (NS-OXY vs FS, $P=.13$, 95% CI [0.03-1.56]) were found to be significant predictors of radiographic failure (Table 1).

Covariate*	coefficient	P	Hazard ratio	95% CI
Behavior (Frankl 1-2 vs Frankl 3-4 +OR)	-0.99	.19	0.37	0.08-1.63
Hemostatic Agent	-1.56	.13	0.21	0.03-1.56

Table 1. Variables included in Cox Regression Analysis.
*Variables were removed from the analysis if $P > .2$; Variables not included in the model were Age, Gender, Location (Clinic vs OR), Capping materials (MTA vs IRM), Tooth location (Maxillary vs Mandibular).

The estimated RMST up to 30 months was 28.1 months (SE: 0.48, 95% CI: [27.17-29.05]) for FS and 29.3 months (SE: 0.64, 95% CI: [28.10-30.60]) for NS-OXY (Figure 1).

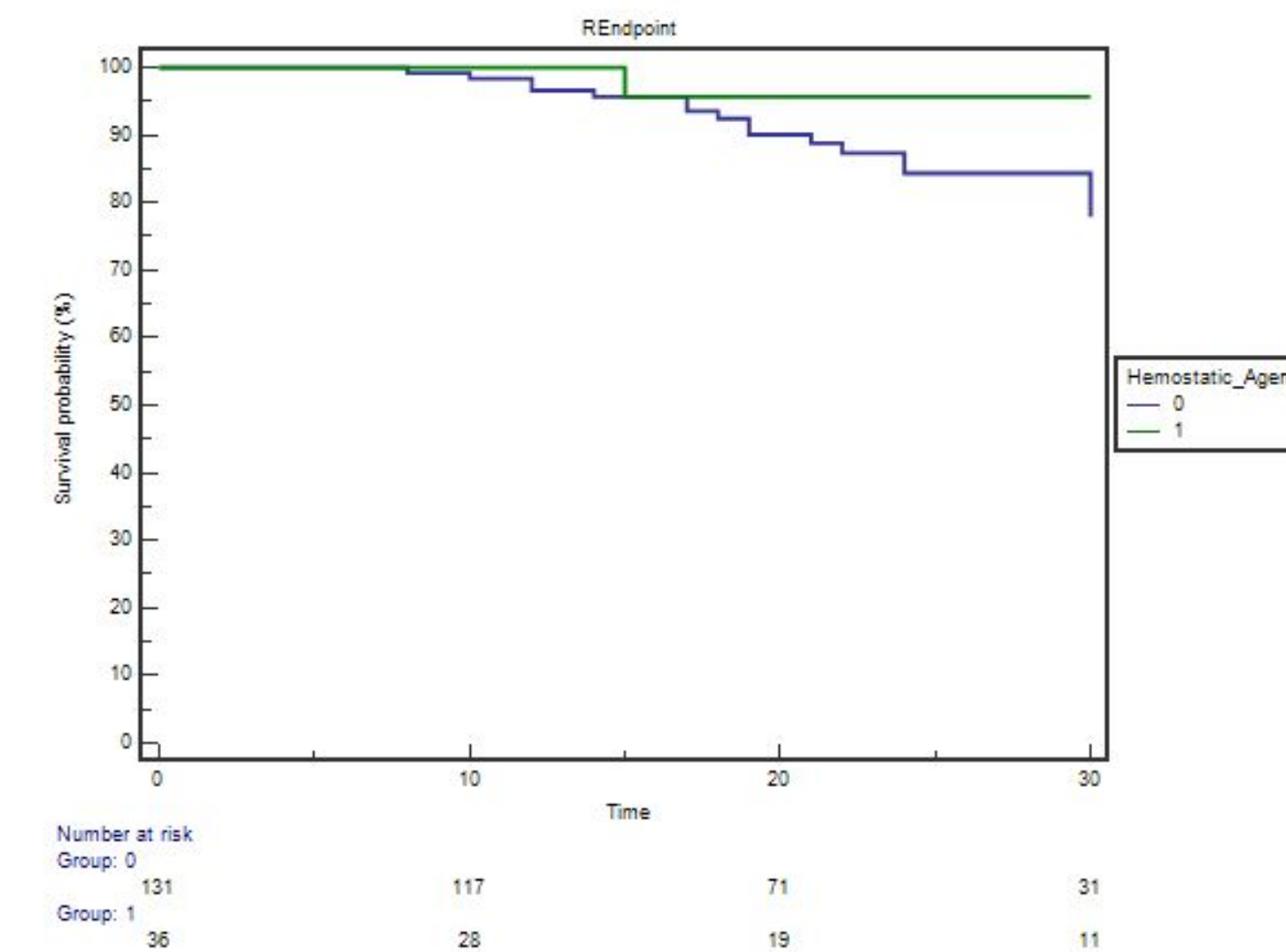


Figure 1. Survival curve of Ferric sulfate was blue (0), of NS-OXY was green (1).

Capping material confounds the analysis. The overall success rate of IRM was 86% and of MTA was 100%. MTA cases all survived. The RMST up to 30 months of IRM was 28.3 months (SE: 0.43, 95% CI [27.43-29.10]) and of MTA was 30.0 months. MTA had a significant improvement of 2 months over IRM up to 30 months ($P=.0001$).

Discussion

FS and NS-OXY showed comparable results of primary teeth pulp therapy. The mean survival time for the FS group was 44.4 months, for NS-OXY was 49.4 months. However, the estimated RMST up to 30 months showed only 1.2 months difference between FS and NS-OXY. The overall success rate up to 30 months of pulpotomy done with FS was 83.97%, and with NS-OXY was 97.22%.

The survival curves for hemostatic agents were also not significantly different ($P=.06$). Capping material, though not included in the cox regression model as all MTA cases survived, showed a confounding effect to the analysis.

The difference of mean survival time and RMST showed the effect of censored data (patient had no follow up visits) and the assumptions about the distribution beyond the last recall. The difference between the overall success rate of FS and NS-OXY indicates that the use of survival rate at the end time as descriptive statistic may not be appropriate.

Conclusion

Both FS and NS-OXY were effective hemostatic agents to be used for pulp therapy, and the two agents showed comparable treatment outcome. This pilot study suggest that the safety profile of NS-OXY supports further investigation.

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