Evaluation of alpha-adrenomimetic agents for gingival retraction: A randomized crossover clinical trial

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Abstract
Context: The displacement of the gingiva around the tooth allows proper access during preparation, precise impression taking, and cementation procedures that has a direct bearing on the health of the periodontium. Several methods and agents are used for this purpose.

Aims: The primary aim of the study was to clinically evaluate the efficacy of naphazoline as a gingival retraction agent. The secondary aim was to compare it with tetrahydrozoline and aluminum chloride.

Settings and Design: Fifteen patients participated in a randomized crossover clinical trial at the Army College of Dental Sciences, Secunderabad, Telangana, India.

Subjects and Methods: Preliminary maxillary impressions were made with irreversible hydrocolloid for all patients to fabricate custom trays. After that, baseline impressions and cast for control group measurements were prepared. Gingival displacement was carried out in the right maxillary central incisor for all, with retraction cord soaked in three agents, either, aluminum chloride, tetrahydrozoline, or naphazoline. These agents were used in all patients with a washout period of 14 days. Elastomeric monophase impressions and die stone casts were recorded for each group. The central incisors were sectioned, and gingival retraction was measured using a measuring stereomicroscope.

Statistical Analysis Used: The gingival displacement was statistically analyzed using one-way ANOVA and post hoc Bonferroni.

Results: Naphazoline had the highest retraction (138.160 µm) followed by tetrahydrozoline (136.039 µm) and aluminum chloride (130.759 µm).

Conclusions: Naphazoline, tetrahydrozoline, and aluminum chloride show a clinically and statistically significant amount of displacement when compared to control. Among the three agents, naphazoline showed maximum displacement and maybe a good alternative with fewer side effects.

Keywords: Gingival displacement; naphazoline; nasal decongestants; retraction cord; α-adrenomimetic agents

INTRODUCTION

The placement of finish lines along the gingival margin has a direct bearing on the fabrication of an indirect restoration and the subsequent health of periodontal tissues. The margins may be subgingival or equigingival, for esthetics, caries, to include the existing restorations and to provide additional retention. Marginal integrity is an essential aim of tooth preparation for indirect restorations.[1]

Gingival retraction is a procedure that involves the displacement of peripheral soft tissues around a tooth, mainly to allow proper access during preparation, precise impression taking, and cementation procedures. It enables
the flow of impression material apical to the finish line, thereby recording it precisely.\textsuperscript{[2]}

Several methods for gingival displacement are advocated, which include mechanical displacement, chemico-mechanical displacement, electrosurgery, and rotary gingival curettage.\textsuperscript{[3,4]} The chemico-mechanical method is standard. It employs the use of a retraction cord dipped in various chemical agents.\textsuperscript{[5,6]} The retraction cord mechanically displaces the gingival tissue and absorbs moisture in the gingival sulcus while the chemical agents control hemorrhage and retract the gingival tissues. The agents most often used are sympathomimetic vasoconstrictors such as 8% racemic epinephrine, astringents such as 100% alum, 5%–25% aluminum chloride, 13.3% ferric sulfate, and 8%–40% zinc chloride. Aluminum chloride and zinc chloride are caustic to gingival tissues and also interfere with the setting of impression materials.\textsuperscript{[7]} Ferric sulfate acts as a clotting agent and often results in discoloration of teeth.\textsuperscript{[8]}

Astringent compounds are chemically stable and active only at acidic pH. The acidic component may cause etching of hard tooth tissues, postoperative sensitivity in vital teeth and is also harmful to the gingival fibroblasts.\textsuperscript{[9,10]} Hence, their use has been restricted. Epinephrine, either supplied as a separate solution or incorporated into the retraction cord, has been widely used. In many patients, however, epinephrine produces undesirable side effects that may include tachycardia, increased respiratory rate, hypertension, nervousness, weakness in the extremities, frank apprehension, and postoperative depression.\textsuperscript{[3]}

The active ingredients in various over-the-counter (nonprescription) nasal or ophthalmic decongestants are vaso-active, that when used topically, provide local vasoconstriction with minimal systemic and cytotoxic effects. These imidazoline derivatives are sympathomimetic amines and are alpha-agonists. Among them, tetrahydrozoline and oxymetazoline, when used for gingival retraction, have shown promising results.\textsuperscript{[9]} Naphazoline, commonly used as a nonprescription nasal or ophthalmic decongestant with vasoconstrictive properties, has not been studied as a gingival retraction agent.

Hence, this study aims to compare and evaluate the gingival displacement produced by naphazoline and compare it to displacement by aluminum chloride and tetrahydrozoline.

**SUBJECTS AND METHODS**

**Selection of participants**
A randomized crossover clinical trial was conducted at the Department of Conservative Dentistry and Endodontics in Army College of Dental Sciences, Secunderabad, Telangana, India. The study protocol was approved by the Institutional Ethical Committee of Army College of Dental Sciences, Secunderabad, Telangana, India, and registered with the Clinical Trial Registry, India, with registration number-CTRI/2018/01/011613.

Fifteen participants were selected based on random sampling using the lottery method. The criteria for inclusion were individuals in the age group of 18–30 years, with healthy periodontium, following a Loe and Silness gingival index, and with the presence of the right maxillary central incisor. Exclusion criteria for the study were the presence of anterior malocclusion, teeth with gingival recession or undergoing orthodontic treatment, and allergy to agents such as tetrahydrozoline, aluminum chloride, and naphazoline. Pregnant and lactating mothers were also excluded from the study. Written informed consent was obtained from all participants.

**Impression for the fabrication of custom trays**
Preliminary maxillary impressions were made with irreversible hydrocolloids for the fabrication of custom trays for each participant.

**Gingival displacement and impression making**
The right maxillary central incisors were identified for gingival displacement. The schedule for displacement and impression making followed a Latin block design, given in Table 1.\textsuperscript{[11]} The patients were randomly allocated to the groups to receive the interventions in a phased manner.

On day 1, baseline impressions (Group I) were made with addition silicone, Type 2 medium body (Imprint 3 monophase, 3M, USA), and disinfected with 2% glutaraldehyde solution (Glutarex, 3M, USA).

The maxillary right central incisor was isolated with cotton rolls (Denmax, India) to maintain a dry working area. Ultrapak retraction cord of the required dimension sizes,
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#000, 0, 1, and 2 (Ultrapak, Ultradent products, USA), was selected based on gingival tissue biotype. Isolation was followed by gingival displacement with retraction cord and 10% aluminum chloride (Roeko, Coltene Whaledent) (Group II), tetrahydrozoline HCl 0.05% (Visine, Johnson and Johnson Health Care Products, USA) solution (Group III), and naphazoline HCl 0.025% (Naphcon A, Alcon Laboratories Inc., Texas) solution (Group IV). The cord was looped around the labial surface of the tooth and gently pushed into the sulcus with the gingival cord packer instrument (Hu-Friedy, USA). The retraction cord was left in situ for 10 min and then removed. Final impressions were made using the same protocol as for the baseline impressions.

After 14 days, the procedure was repeated for different agents based on the Latin block design. Overall, four impressions were recorded for each patient over 28 days.

Before displacement with each agent, the gingival index was verified as zero based on Löe H and Silness J gingival index.[12]

Pouring of impression and sample preparation
Each of the impressions was poured immediately with die stone (Kalabhai Ultrarock, India). Mesiodistal width of the right central incisor was measured with a digital Vernier caliper (Mitutoyo, Japan). The cast was positioned and stabilized on the platform of a die cutter. A first cut was made mesial to the maxillary right central incisor in the buccolingual direction through the entire length of the cast [Figure 1a]. A second cut was made distal to maxillary right central incisors along the whole length of the cast, and the incisor separated from the cast [Figure 1b].

Evaluation of the amount of displacement
For determining the amount of displacement, each sample was read under a measuring stereomicroscope (Carl Zeiss, USA). A perpendicular line drawn from the most prominent point of the crest of the marginal gingiva to the incisal edge of the maxillary central incisor gave measurement of displacement with the help of MIC 3.0 image analysing software. The gingival displacement was measured and recorded in micrometers and subjected to statistical analysis [Figures 2a and b]. The analysis was performed using one-way ANOVA and post hoc Bonferroni with a 95% confidence interval, and P < 0.005 was considered statistically significant.

RESULTS
The results suggest that all three displacement agents produced a statistically significant amount of retraction. The mean displacement with naphazoline was higher than the other two test groups, although not statistically significant.

The mean gingival displacement achieved by four groups of control, aluminum chloride, tetrahydrozoline, and naphazoline was 107.152 µm, 130.759 µm, 136.039 µm, and 138.160 µm, respectively, as shown in Table 2.

According to one-way ANOVA, there was a significant difference between the control and experimental groups. According to post hoc test, the difference between the experimental groups was not significant, as shown in Table 3.

DISCUSSION
A chemical agent used for gingival retraction should result in sufficient retraction to facilitate a proper impression of the gingival finish line of the prepared tooth and restoration of the cavity without being harmful to tissues. Commonly used displacement agents are 8% racemic epinephrine, 100% alum, 5%–25% aluminum chloride, 13.3% ferric sulfate, and 8%–40% zinc chloride. A clinical trial by Bowles et al. in 1991 suggested that the nasal and eye decongestants oxymetazoline hydrochloride, xylometazoline hydrochloride, and tetrahydrozoline gave superior tissue displacement in comparison to the conventional gingival retraction agents.[13]

Naphazoline, also a sympathomimetic agent, is an imidazoline derivative. It is a vasoconstrictor and is

Figure 1: Sectioning of cast. (a) Sectioning from the mesial aspect of the maxillary central incisor. (b) Section of the maxillary central incisor showing point of measurement of sulcus depth

Figure 2: Stereomicroscopic image of measured gingival sulcus. (a) Baseline impression. (b) Following gingival retraction
common as a nonprescription decongestant. Naphazoline has a faster onset, longer duration of action, and better decongestant effect than tetrahydrozoline.[14-16]

The pH of tetrahydrozoline and naphazoline being alkaline, they cause less damage to the gingival tissues as well as to the tooth structure.[17]

Hence, this study compared naphazoline to tetrahydrozoline and aluminum chloride.

A single-step technique was used for impression making to avoid discrepancies that may arise due to the use of two materials, tray positioning and the time lapse between the removal of the cord and impression. The method used in the present study is similar to the technique used by Bowles.[13]

Gingival displacement using a retraction cord is an economical and readily available method of tissue displacement and is associated with good-quality impressions. It may be used alone or in combination with chemical agents to achieve retraction. Hence, the same was employed in this study.[18-20]

Various instruments and methods are available to measure the depth and width of the gingival sulcus such as modified Boley’s gauge, low-power microscope, specifically designed dental endoscopic images, ultrasonographic periodontal probe, centrally rotating periodontal probe, remote-recording periodontal depth probe, manual periodontal probe, flexible strip, and stereomicroscopic images of the impression.[11,21-23] In this study, stereomicroscope was used to measure lateral gingival retraction on the impression using image analysis computer software. Linear measurements on dental casts were made, which are valid and reliable in comparison to other techniques stated.

Azzi et al.[24] in 1983, reported that the gingival tissues took around 14 days to heal after gingival retraction. Hence, in the present study, patients were recalled after a gap of 14 days between agents. Thereafter, the patients were observed at 3, 6, and 9 months for gingival health. No gingival recession was found with the right maxillary central incisor, as in the study by Azzi et al.

Results indicate effective reversible displacement of soft tissues with retraction cord presoaked with α-adrenomimetic agents. This displacement can be attributed to α-adrenergic activity resulting in vasconstriction comparable to astringents.[11] There was no statistically significant difference between tetrahydrozoline, naphazoline, and aluminum chloride.

Hence, both these α-adrenomimetic agents can be used successfully in the practice of esthetic and restorative dentistry.

CONCLUSIONS

The conclusions drawn from this study are naphazoline, tetrahydrozoline, and aluminum chloride show a clinically and statistically significant amount of displacement when compared to control. Among the three agents, naphazoline showed maximum displacement and may be a good alternative with fewer side effects.

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Conflicts of interest
There are no conflicts of interest.

REFERENCES

1. Gardner FM. Margins of complete crowns – Literature review. J Prosthet Dent 1982;48:396-400.
2. Trivedi SC, Talim ST. The response of human gingiva to restorative materials. J Prosthet Dent 1973;29:73-80.
3. Prasad KD, Hegde C, Agrawal G, Shetty M. Gingival displacement in prosthodontics: A critical review of existing methods. J Interdiscip Dent 2011;1:80-6.
4. Benson BW, Bomberg TJ, Hatch RA, Hoffman W Jr. Tissue displacement methods in fixed prosthodontics. J Prosthet Dent 1986;55:175-81.
5. Donovan TE, Gandara BK, Nemetz H. Review and survey of medicaments used with gingival retraction cords. J Prosthet Dent 1985;53:325-31.
6. Gardner FM, Walton JN. Gingival displacement techniques. In: Clinical Aspects of Dental Materials. Washington, DC: United States Army Institute of Dental Research; 1986. p. 165-75.
7. Gaurav Gupta G, Kumar S, Rao H, Garg P, Kumar R, Sharma A, et al. Astringents in dentistry: A review. Asian J Pharm Health Sci 2012;2:428-32.
8. Fischer D. Tissue management for making impressions. In: Restorative Techniques for Individual Teeth. New York, USA: Masson Publishing; 1981. p. 247-65.
9. Nowakowska D, Saczko J, Kubacka J, Choromanska A. Dynamic oxidoreductive potential of astringent retraction agents.
10. Kopac I, Batista U, Cvetko E, Marion L. Viability of fibroblasts in cell culture after treatment with different chemical retraction agents. J Oral Rehabil 2002;29:98-104.
11. Chaudhari J, Prajapati P, Patel J, Sethuraman R, Naveen YG. Comparative evaluation of the amount of gingival displacement produced by three different gingival retraction systems: An in vivo study. Contemp Clin Dent 2015;6:189-95.
12. Löe H. The gingival index, the plaque index and the retention index systems. J Periodontol 1967;38 Suppl: 610-6.
13. Bowles WH, Tardy SJ, Vahadi A. Evaluation of new gingival retraction agents. J Dent Res 1991;70:1447-9.
14. Butler K, Thompson JP, Yolton DP. Effects of non prescription ocular decongestants. Rev Optom 1978;115:49-52.
15. Abelson MB, Butrus SI, Weston JH, Rosner B. Tolerance and absence of rebound vasodilation following topical ocular decongestant usage. Ophthalmology 1984;91:1364-7.
16. Abelson MB, Yamamoto GK, Allansmith MR. Effects of ocular decongestants. Arch Ophthalmol 1980;98:856-8.
17. Nowakowska D, Saczko J, Kulbacka J, Choromanska A, Raszewski Z. Cytotoxic potential of vasoconstrictor experimental gingival retraction agents: In vitro study on primary human gingival fibroblasts. Folia Biol (Praha) 2012;58:37-43.
18. Beier US, Kranewitter R, Dumfahrt H. Quality of impressions after use of the Magic FoamCord gingival retraction system – A clinical study of 269 abutment teeth. Int J Prosthodont 2009;22:143-7.
19. Wöstmann B, Rehmann P, Trost D, Balkenhol M. Effect of different retraction and impression techniques on the marginal fit of crowns. J Dent 2008;36:508-12.
20. Phatle S, Marawar PP, Byakod G, Lagdive SB, Kalburge JV. Effect of retraction materials on gingival health: A histopathological study. J Indian Soc Periodontol 2010;14:35-9.
21. Kamansky FW, Tempel TR, Post AC. Gingival tissue response to rotary curettage. J Prosthet Dent 1984;52:380-3.
22. Stambaugh RV, Myers G, Ebling W, Beckman B, Stambaugh K. Endoscopic visualization of the submarginal gingiva dental sulcus and tooth root surfaces. J Periodontol 2002;73:374-82.
23. Lynch JE, Hinders MK, McCombs GB. Clinical comparison of an ultrasonographic periodontal probe to manual and controlled force probing. J Int Meas Confed 2006;39:429-39.
24. Azzi R, Tsao TF, Carranza FA Jr., Kenney EB. Comparative study of gingival retraction methods. J Prosthodont 1983;50:561-5.