Evaluation of Gingival Displacement with Aluminum Chloride and Naphazoline Hydrochloride: A Randomized Controlled Trial

Keywords

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ABSTRACT

The objective of this study was to evaluate the use of naphazoline hydrochloride in comparison with aluminum chloride for vertical gingival displacement. The inclusion criteria were: patients with a good general systemic condition; periodontal health; and thick gingival biotype. Moreover, the exclusion criteria were: smoking individuals; canine teeth or central incisors with carious lesions, abrasion, erosion, prosthetic abutments or unsatisfactory restorations; patients with periodontal disease; and users of continuous medication. 72 teeth were included and the Square Block Design was used to randomize the samples. Three measures were obtained from each tooth, and mean vertical gingival displacement was calculated. A descriptive analysis of the average displacement was performed. The normality test used was the Lilliefors' Test and for comparison between treatments, the Kruskal-Wallis Test was used. The Bartlett's Test for homogeneity of variances was used and a 5% ($p < 0.05$) significant level was considered. Thus, the Aluminum Chloride and Naphazoline Hydrochloride showed no statistically amount of gingival retraction than the control group ($p = 0.3822$). The average of gingival vertical displacement in all groups were less than 0,5 mm. The technique used did not allow any amount of horizontal displacement on obtained models.

INTRODUCTION

Prosthetic procedures have been performed by dentists to treat patients who need functional and aesthetic rehabilitation, mainly when teeth lose anatomical structure due to carious disease or trauma. In addition, the good quality of a prosthetic restoration depends essentially on a mechanical and biological integration through a precise pillar tooth adaptation.[1] The gingival displacement is important to expose the entire terminal line, allowing a precise adaptation and long-term healthy tissues around teeth who received those rehabilitations.[2,3,4,5,6] However, prosthodontic procedures required for the fabrication of fixed prostheses can negatively affect the biological tissue status like procedures such as crown preparation and gingival displacement during the impression.[1,7,8,9,10,11]

The sulfate astringents and aluminum chloride ($AlCl_3$) are the most commonly used chemical astringents,[12,13,14] however aluminum chloride has been commonly used in the literature for comparative studies because

it's has minimum negative interaction with impression materials and soft tissues.[15] The aluminum chloride is usually compared to other substances, like tetryzoline hydrochloride[16,17] and also compared with retraction cords free of chemical substances The tetryzoline hydrochloride is a substance used for eye drops and nasal sprays and it has been suggested as an alternative for gingival displacement.[16,17] Nevertheless, tetryzoline hydrochloride could be difficult to find on the market and naphazoline hydrochloride (eye drops) has also been suggested as a substitute for tetryzoline. In general, tetryzoline and naphazoline act on adrenergic receptors, with no effect on beta-adrenergic receptors, generating constriction of the vascular bed.[18]

Moreover, there are some studies comparing soft tissue management with chemical astringent cords[4,15,19] and despite the number of published papers, there is still more to learn about the chemicals agents for gingival management, mainly aluminum chloride and naphazoline hydrochloride, especially it's interaction with impression materials[20] and soft tissue phenotype.[21] Thus, this study seeks to evaluate the possibility of using these substances as a chemical medium to the gingival displacement and if these substances are important during procedures of the gingival displacement.

Hence, the objective of this clinical study was to evaluate Vertical Gingival Displacement (VGD) using threads embedded with Naphazoline hydrochloride and Aluminum chloride, comparing threads without any chemical infiltration. The null hypothesis of this investigation is that no difference could be observed between the tested groups.

MATERIAL AND METHODS

This study followed the CONSORT Guidelines[22] for randomized clinical studies.

ETHICAL ASPECTS

This study was carried out in private practice from February 2015, in accordance with all ethical principles involved in research with human beings established through the Declaration of Helsinki.[23] The project of this research was submitted to the Ethics Committee of the State University of Maringa, which obtained a favorable opinion with the number of the Consubstantiated Opinion of the CEP: 1.515.263, and the CAAE: 53153116.6.0000.0104. All participants in this study signed an informed consent form (IC).

PARTICIPANTS

Inclusion criteria were: patients with a good general systemic condition; periodontal health; and thick gingival biotype. The gingival biotype was selected by applying the transparency method[24] of the periodontal probe by probing the gingival margin of the teeth selected for the study. Exclusion criteria were: smoking individuals; canine teeth or central incisors with carious lesions, abrasion, erosion, prosthetic abutments or unsatisfactory restorations; patients with periodontal disease; and users of continuous medication. 24 patients were included in the study, each one was submitted to the 3 groups, in three different teeth. The teeth sample size calculation was performed through the software (Gpower® 3.1).[25]

TRIAL DESIGN AND ALLOCATION

Teeth 13, 21 and 23 of each patient were selected for the procedures (N = 72) based on the easiest operational access and better humidity control. Each tooth was randomly assigned to one of the experimental treatments: Group 1 received gingival cords impregnated with Aluminum chloride (Hemostop®); Group 2 with Naphazoline hydrochloride (Legrand Collirium®); and Group 3 (control) without any chemical substance. In order to ensure homogeneous distribution among patients, randomization was performed based on a Square Block Design[26] which subjects are divided into groups (blocks) of like subjects and a random assignment is done within each block separately, *(Table 1)* where treatments for each tooth were previously defined. Before the procedures, the participants were properly oriented and trained to carry out appropriate and effective oral hygiene. The patients were not blinded to the procedures.

INTERVENTIONS

Initially, the relative isolation with cotton rollers was performed at the areas corresponding to the involved teeth. After cleaning with dental floss and cotton ball soaked in 2% chlorhexidine gluconate (Riohex®), the teeth were washed and dried. A photopolymerizable gingival protector layer (Top-dam®) was applied to the surfaces of teeth 13, 21 and 23 at the level of the cervical margin of the gingival sulcus to record the

Table 1. Square Block Design used in the study.

Subject	13	21	23
1	1	2	3
2	2	3	1
3	3	1	2
-	-	-	-
-	-	-	-
-	-	-	-
22	2	3	1
23	3	1	2
24	1	2	3

Treatment: (1) Aluminum Chloride; (2) Naphazoline Hydrochloride; (3) Control Group

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initial positioning *(Figure 1*). After removing all excess of the gingival contour with the aid of a probe, the gel was polymerized 20 seconds by a light-curing unit (Valo®).

Furthermore, it was used a double gingival cord technique.[3,25] The gingival displacement cord (Ultrapak®) was positioned on the experimental teeth *(Figure 2*). The gingival cords No. 000 and No. 1 was used for gingival spacing. Strands No. 1 from Experiment Groups 1 and 2 were soaked in Naphazoline Hydrochloride and Aluminum Chloride respectively, for 20 minutes[27,28] before being applied to the teeth. The placement of the threads for gingival displacement No. 1 obeyed the randomization of treatments previously established. Initially, the gingival displacement strands No. 000 were positioned inside the gingival sulcus of the buccal surface of each tooth. Thereafter, the threads for gingival displacement No. 1 were positioned on the first thread *(Figure 2*). After a period of four minutes, the gingival threads were removed from the gingival sulcus, the area was rinsed and dried with air jets and the molding was performed by a polyvinylsiloxane (3D®). All impression procedures were made by following the manufacturer specifications.

OUTCOMES

After two hours, the impression was leaked with a special plaster type IV (Herostone®). The models were cut into small blocks, and from these, 72 pictures (one image for each tooth treated with gingival displacement) have been captured by a Stereomicroscope SZ-STS (Olympus®) coupled to a magnifying glass (x20). The images were analyzed through the software (Image-pro Plus® 4.5) to measure the distance between the gingival protector layer (that marks the previous position of the gums) and the level of the gingival margin after the displacement, in three points of tooth's buccal face, a point on the medium line, a mesial point to this and distal point, being that a ruler was used to measure between the distances, thence standardized *(Figure 3*). To determine intraobserver reproducibility, 30 randomly chosen teeth were measured twice within a 24-hour interval. The intra-class correlation coefficient was >0.8, indicating good intra-examiner agreement. All measures were carried out by a single examiner blind to the procedures.

STATISTICAL ANALYSIS

The data obtained from the gingival displacement were tabulated and submitted to non-blinded statistical analysis, for comparison between the groups. The presented data were obtained from the three measures performed on the buccal face of each tooth. To quantify the entire displacement, the average between these three measures was considered and the results were used to compare the treatment between the groups.

In this study, each patient received the three proposed treatments and it was provided observations for the three interest groups. It is important to know that the sample units under analysis were teeth (13, 21 and 23) and the choice of these three units in each subject was made due reduce the influence among the treatments. Therefore, it is reasonable to assume that the samples obtained are independent. Descriptive analysis for the average displacement was performed considering the three types of treatments. The normality test used to verify the data distribution was the Lilliefors' test. For comparison between treatments, the Kruskal-Wallis test was used. Finally, Bartlett's Test for homogeneity of variances was used to evaluate that variances are equal for all treatments. All these tests were carried out through R Software® and a 5% ($p < 0.05$) significant level was considered.

Figure 1: Application of the Topdam® light-curing gingival protector

Figure 2: The Gingival displacement thread (Ultrapak®) were positioned on the experimental teeth. The threads No. 000 and No. 1 were used.

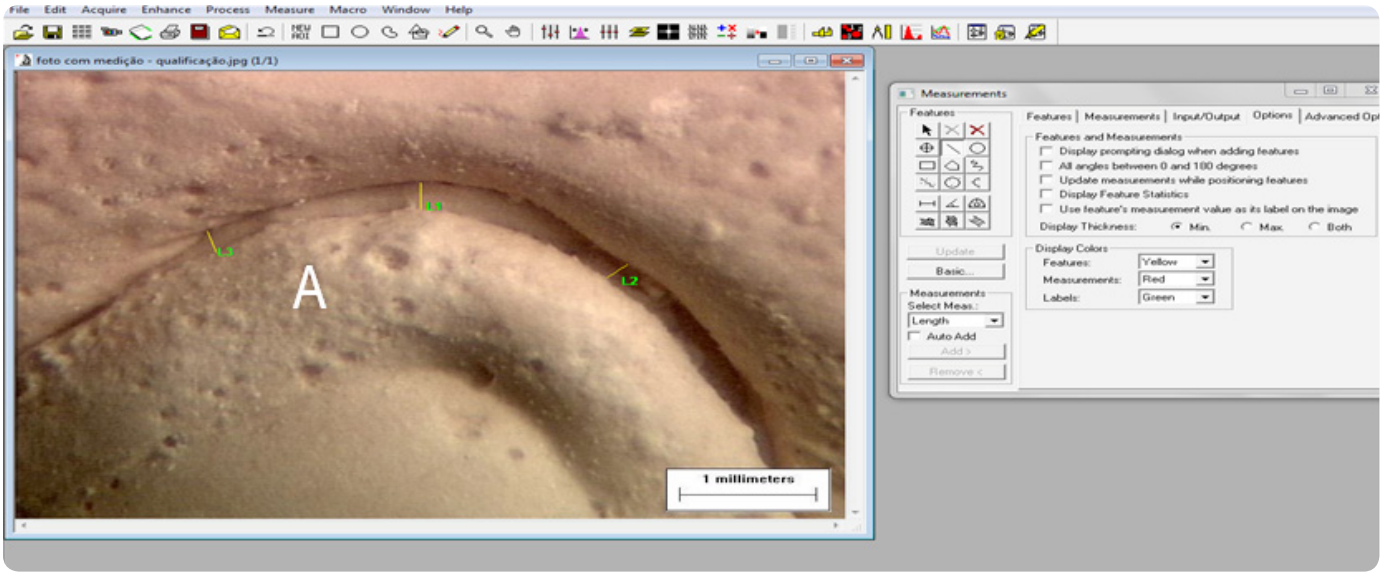

Figure 3: Gingival displacement measurement on Image Pro Plus® 4.5. (A) The edge of the photopolymerizable gingival protector layer (Topdam®) marks the initial position of the gingival tissue. L1 (medial line buccal aspect), L2 and L3 (mesial and distal buccal points) marks the distance between the layer and the margin of the soft tissue after gingival displacement.

RESULTS

The sample was composed of 24 individuals, being 13 women (54.16%) and 11 men (45.83%), aged between 17 and 59 years old. Moreover, the frequency distribution *(Figure 4.)* shows a global characteristic of the data. The mean value, indicated by the red line, is 0.215 millimeters. The right tail of this histogram shows the occurrence of extreme values in the sample.

Furthermore, *(Figure 5.)* shows the gingival displacement by treatment. However, these differences are not statistically significant according to Bartlett's test (p = 0.1443). The presence of outliers was detected in Aluminum Chloride and Control groups. Data from the group "without substance" resembles the data of the group "Naphazoline", which is one of the treatments to be analyzed. In addition, Table 2 represents the mean, standard deviation, and median values of the VGD obtained for each treatment.

Data analysis indicates that there is no significant statistical difference between the treatments (p = 0.3822). As a result, no patient experienced bleeding or any inflammatory exudate during procedures, resulting in a homogenous group.

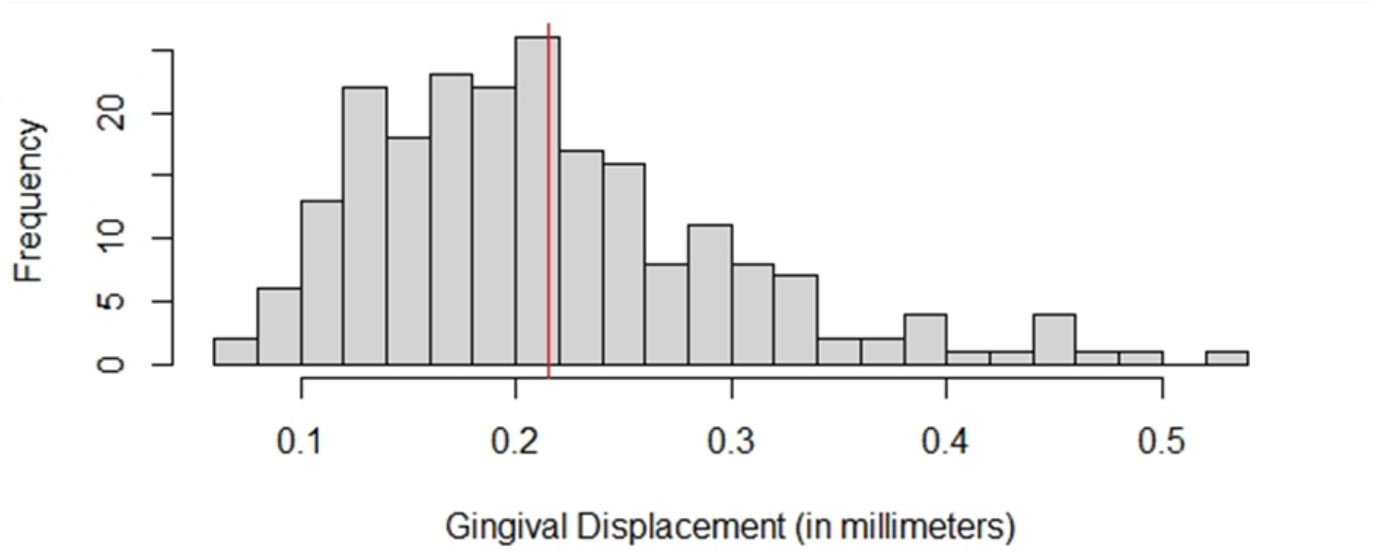

Figure 4: The frequency distribution shows a global characteristic of the data.

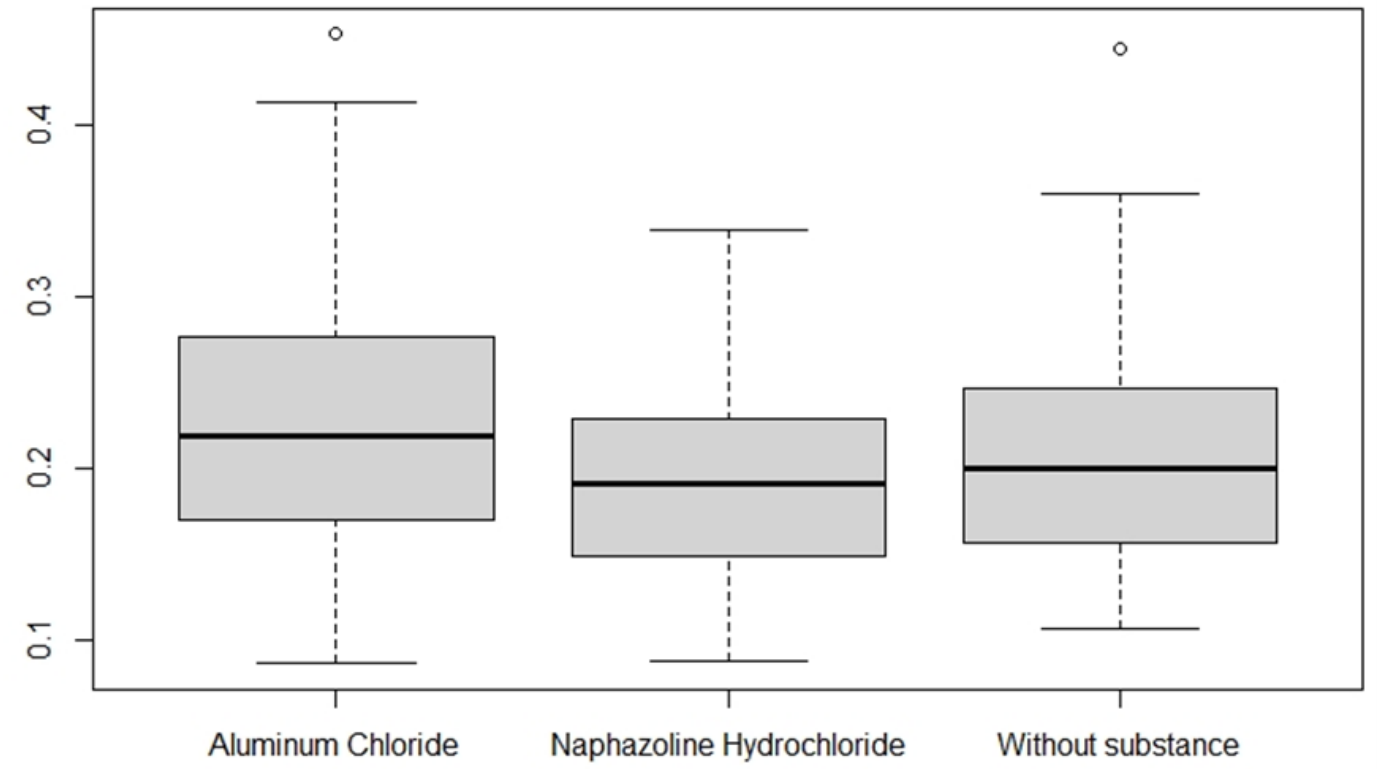

Figure 5: Box-plot representing the numeric variation between the groups

DISCUSSION

Fixed prosthodontics is a procedure that involves treating patients who need functional and aesthetic rehabilitation, mainly when their teeth lose anatomical structure through carie disease or trauma. It is important to know that the mechanical and biological integration through a precise pillar tooth adaptation is a fundamental knowledge to a good quality of prosthetic restoration. The gingival displacement is a basic and fundamental role that promotes the vertical and lateral tissue movement and exposes the margin restoration, allowing a precise adaptation between the pillar and the restoration and long-term healthy tissues around the teeth that received those rehabilitations.[2,3,4,5,6] However, prosthodontic procedures required for the fabrication of fixed prostheses, such as gingival retraction, crown and restoration margin preparation can negatively affect the biological tooth status.[1,7,8,9,10,11] The VGD reached 0.23 ± 0.09 millimeters for threads impregnated with aluminum chloride, 0.19 mm ± 0.06 for threads impregnated with naphazoline and 0.21 ± 0.08 millimeters from threads

Table 2. Mean and standard deviation (SD) results of the gingival displacement, considering the three interest groups after treatment.

Groups	Mean	Median	SD
G1	0.235	0.219	0.0929
G2	0.198	0.191	0.0611
G3	0.212	0.200	0.0809

G1 (Aluminum Chloride); G2 (Naphazoline Hydrochloride); G3 (Without substance - control group)

without any chemical substance. Every group presented results of less than 0.5 millimeters. In other words, this clinical study demonstrated that threads soaked in naphazoline hydrochloride produced a vertical gingival displacement (VGD) similar to the threads with aluminum chloride and the threads without chemical substance, supporting the no rejection of the null hypothesis. The results mentioned above were similar to some results in the literature where the cord displacement technique generate a retraction of 0.28 with aluminum chloride,[29] and also it is important to observe and compare in the literature other data of gingival displacement achieved by the mechanical (0.19 to 0.23 mm) and chemo mechanical (0.02 to 0.46 mm)[30] methods, where the results were similar to the results in the present study.

The discuss regarding the use of just mechanical-chemical gingival displacement procedures is also present in the literature. A study[16] evaluated the gingival displacement between three methods and two of them were aluminum chloride and tetryzoline hydrochloride. The authors concluded that the most successful displacement method was aluminum chloride. Despite the results, no information about the mechanical (free astringent threads) technique was provided in the study.

Although the exact dimensions of the supracrestal tissue attachment can be different from person to person, it is widely accepted that preparation for prosthetic restorations should not extend beyond 0.5 to 1.0 millimeters in the gingival sulcus.[2,31] Also, restorative considerations can dictate the position of restorations margins.[32] Despite the values of previous papers in the literature, it is a concern about the necessity of making indirect restorations margins subgengivally.[1] None of the models demonstrated horizontal displacement possibility of being measured and the gingival horizontal displacement was not took into consideration in this study because the methodology does not allow this data to be obtained.

To the best of our knowledge, this is the first clinical study that compares aluminum chloride and naphazoline hydrochloride. Most of the studies cited here analyzed tetryzoline hydrochloride and aluminum chloride, and both naphazoline and tetryzoline are used in medicine with similar mechanisms.[18,33,34] Moreover, there is a lack of evidence to provide knowledge about the behavior of naphazoline hydrochloride compare to the threads free of substances in procedures of gingival displacement.

Regarding the periodontal status (phenotype), the data of gingival displacement was obtained after the periodontal assessment. However, the gingival displacement procedures were carried out in different anatomic areas (canines and the upper central incisor) in the same patient, which may be a bias. Although in this specific situation, the patients presented thick healthy soft tissue around the teeth and presented no post-operative complications. In addition, the two threads were removed before the impression procedure, allowing the gum shifted during the polymerization of the molding material. Despite that, the small number of teeth per patient may not influence the time of material insertion during the procedure. Thusly, new randomized clinical trials are needed to evaluate the behavior of naphazoline hydrochloride and the amount of impression material that penetrates beyond the prosthetic margin position, and the quantity of gingival retraction in a vertical and horizontal orientation around teeth and dental implants.

CONCLUSION

Taking into considerations the limitations of the present study, the results demonstrated that the Aluminum Chloride and Naphazoline Hydrochloride showed no statistically amount of gingival displacement than the control group. In another words, this study concludes that gingival displacement can be performed without any astringent substances. The average of gingival vertical retraction in all groups were less than 0,5 mm, therefore, insufficient to expose the prosthetic margin. The technique used did not allow any horizontal displacement on obtained models.

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The authors report no conflicts of interest to this paper. Also, the authors claim to have no financial support and financial interest, either directly or indirectly, in the products or information listed in the article.

MANUFACTURERS DETAILS

- Gpower® 3.1 (Universitat Kiel, Germany)
- Aluminum Chloride (Hemostop®, Dentsply, São Paulo, SP, Brazil)
- Naphazoline Hydrochloride (Legrand Collirium®, Campinas, SP, Brazil)
- 2% chlorhexidine gluconate (Riohex® 2%, Rioquímica, São José do Rio Preto, SP, Brazil)

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- A Topdam® (FGM, Joinville, Santa Catarina, Brazil)
- Valo® (Ultradent, South Jordan, Utah, USA)
- Ultrapak® (Ultradent, South Jordan, Utah, USA)
- Polyvinylsiloxane 3D® (Angelus, Londrina, PR, Brazil)
- Special plaster type IV Herostone® (Vigodent, Rio de Janeiro, RJ, Brazil).
- Olympus® SZ-STS (Lehigh, Pennsylvania, USA)
- Image-pro Plus® 4.5 (Rockville, Maryland, USA)
- R Software® (The R Foundation, Auckland, New Zeland)

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