

Salivary pH changes under the effect of stainless steel versus elastomeric ligatures in fixed orthodontic patients: A single-center, randomized controlled clinical trial

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Abstract

Background

Fluctuations in pH of saliva during a prolonged treatment course influences the enamel demineralization progress, which is one of the complications of fixed orthodontic treatment. This randomized clinical trial aimed to evaluate and compare the short-term effect of stainless steel (SS) versus elastomeric (EM) ligatures on salivary pH in patients scheduled for fixed orthodontic treatment.

Methods

Seventy participants were enrolled in the study (54 females, 16 males) aged 19–36 who met specific inclusion criteria. They were randomly selected and allocated into two equal groups through a computer-generated randomization. All patients received fixed orthodontic treatment using conventional brackets. Two commonly used archwire ligature methods were used: stainless steel and elastomeric modules. An unstimulated (resting) salivary sample was collected before tying of the ligatures at T0 (baseline), 2 weeks, 6 weeks and 12 weeks. Salivary pH was measured using a digital pH meter. The level of significance was set at p value < 0.05 .

Results

The salivary pH level was stable between T0 and T1 (6.72 ± 0.14), then significantly and progressively increased from T1 to T2 (6.78 ± 0.13) and from T2 to T3 (6.81 ± 0.14) with ($P < 0.05$) in the SS group. In the EM group, the salivary pH level was significantly decreased in all follow-up periods; T0 (6.77 ± 0.16), T1 (6.72 ± 0.14), T2 (6.67 ± 0.13) and T3 (6.64 ± 0.13).

Conclusion

EM ligature showed a significant decrease in salivary pH to an unfavorable level, which increased the risk of enamel demineralization. Therefore, EM as ligature material is not recommended in patients with high caries index or inadequate oral hygiene.

Trial Registration

ANZCTR.org. (ACTRN12618001647224). Registration Date: 5/10/2018, "Retrospectively registered"

Background

Malocclusion is considered as the third oral problem following dental caries and periodontal diseases.^{1,2} Most malocclusions are treated by fixed orthodontic appliances as a second phase following orthopedic treatment or as a comprehensive treatment after cessation of growth or as a preparatory stage for orthognathic surgery.³ Treatment of malocclusion with fixed orthodontic appliances is estimated to last from 18 to 36 months.^{4,5} As they are termed "fixed appliances," they are fitted permanently to the teeth

creating plaque-retentive areas around the bracket wings. This increases chances for plaque accumulation and bacterial colonization. The main formed colonies are of specific interest as are the acid-producing bacteria (*Streptococcus mutans* and *Lactobacilli*).⁶⁻¹¹

Plaque harboring around the brackets is also influenced by the archwire ligation material.^{7,10,12-14} Stainless steel (SS) and elastomeric modules (EM) are the most commonly used materials to secure archwires to the bracket slots.¹⁴ They have different properties including surface topography.

SS ligatures demonstrated less plaque retention compared to EM, and is, therefore, better for oral hygiene maintenance.¹⁴ Higher levels of acidogenic bacteria are detected with EM ligatures, most noticeably *Streptococcus mutans* and *Lactobacilli*.^{10,15} This contributes to the drop in salivary pH levels during orthodontic treatment.^{16,17} The choice to use either ligation method has been shown to be a matter of personal preference of the practitioner and is influenced by the patient choice.

Salivary pH is one indicator of caries susceptibility of the individual patient. The risk of enamel demineralization is increased if salivary pH drops below the critical value (pH = 5.5).¹⁸⁻²⁰ This drop contributes to the formation of white spot lesions reported to occur in around 50% of orthodontic patients.²¹⁻²⁴

The effect of the fixed orthodontic appliances on salivary pH has been investigated in previous studies without reporting which type of archwire ligation material was used. In an observational study, Zogakis et al.²⁵ demonstrated a significant decrease in pH of saliva six weeks after fitting the appliance. Different results were presented by Peros et al.²⁶ who reported an increase in salivary pH at 6, 12 and 18 weeks from therapy. Bonetti et al.¹⁶ reported that no changes in salivary pH values occurred under the effect of fixed orthodontic treatment. To our knowledge and in the available literature, no randomized clinical trial (RCT) evaluated the effect of SS and EM ligation materials on pH of saliva.²⁷

Specific objectives

The aim of this trial was to evaluate and compare the short-term effects of SS and EM ligatures on salivary pH in patients treated with fixed orthodontic appliances.

Methods

Trial design

This investigation was a two-arm parallel-group Randomized Controlled Clinical Trial. No changes were introduced to the trial following commencement.

Participants, eligibility criteria, and settings

The following selection criteria were: subjects requesting orthodontic treatment, aged from 19 to 36 years, with good oral hygiene and periodontally healthy (plaque index ≤ 1). Patients with habits (mouth breathing, smoking, or any chewing habits), chronic or systemic disease and chronic medication intake were excluded. Deterioration of oral hygiene level after recruitment was considered an exclusion criterion.

Patients were recruited from the Department of Biological and Preventive Sciences, College of Dentistry, University of Science and Technology. Consecutive patients were examined by the primary researcher. Those meeting the selection criteria were invited to participate. Informed consent was signed after the nature of the study was explained.

Intervention

This study follows the guidelines of the Consolidated Standards of Reporting Trials statement.²⁸ Ethical approval was obtained from the ethics committee of the University of Science and Technology (Registry No: EAC/UST126). All participants received a standard protocol of oral hygiene instructions and motivation (Bass technique) using tooth paste containing fluoride.

All subjects were treated with straight wire appliances using MBT bracket system (SIA, Italy). Leveling and alignment was initiated with round nickel-titanium archwires and treatment proceeded as required for each patient.

The sample consisted of two groups, each including 35 subjects. They received archwire ligation (SIA, Italy) with either SS (Group A) or EM (Group B) based on the randomization technique followed. The ligations were replaced every four weeks during follow-up visits.

Saliva collection

Unstimulated (resting) whole salivary samples were collected according to the protocol derived from the World Health Organization/International Agency of Research²⁹ as follow; The samples were obtained in the morning between 9 a.m. and 12 p.m. using the passive drooling method. The subject was seated in the dental chair and instructed to allow saliva to pool in the mouth passively for five minutes, then drool it into a graduated plastic sterile tube. These samples were immediately transferred into a reservoir container and sent to the laboratory for salivary pH measurement. The laboratory technician received the salivary samples that were coded and labeled without any indications of intervention details.

Outcomes

The outcome of this study was to measure the pH of the salivary samples collected from the patients at four points in time. The baseline value was measured before placement of ligature materials (T0). T1, T2 and T3 were measured at 2, 6 and 12 weeks from T0. The purpose was to evaluate and compare the change in salivary pH values with the introduction of two different types of ligatures in two randomly assigned groups.

Measurements were performed in the laboratory of Drugs and Medicine, College of Pharmacy, University of Science and Technology. A digital handheld pH meter with incorporated automatic temperature compensation (3510, JENWAY, UK) was used. The procedure was conducted according to the manufacturer's instructions and included the following steps: (a) Calibration was done by freshly prepared standard buffer solutions at pH 7 and 10; (b) For pH measurement, the probe sensor was fully immersed inside the sample for 30 seconds to get a stable final reading, and (c) Disinfection was achieved by washing the meter under running water to remove any remnants. It was then cleaned with alcohol and allowed to dry.³⁰

Sample size calculation

The required number of participants were calculated using G power software. By hypothesizing a mean difference of 0.1 unit change in pH and ± 0.14 standard deviation (SD) with a power of 80% and $\alpha = 0.05$, a minimum number of 35 participants was required for each group.³¹

Randomization (random number generation, allocation concealment, implementation)

A total of 70 participants (54 females and 16 males) from 19 to 36 years were randomly selected with a 1:1 allocation ratio. Randomization was accomplished with random permuted blocks of 70 participants with the allocations concealed in sequentially numbered, opaque, sealed envelopes. The clinic assistant was responsible for generating the allocation sequences, preparing the enclosed envelopes in sequence numbers, enrolling the participants, and assigning them into their groups.

Blinding

Blinding of the patients and investigator to the intervention was not implemented. It was applied to the laboratory technician and the statistician.

Statistical analysis

The data were statistically analyzed using statistical software (version 25; SPSS, Armonk, NY: IBM Corp). Data included age, gender, type of archwire ligature (SS or EM), and salivary pH at T0, T1, T2 and T3. The Shapiro-Wilk test was applied to verify the normality of distribution of the examined variable. The t-test for independent samples was applied for the comparison between groups of archwire ligation. Intra-group difference comparisons between T0 and T1, T2 and T3 were carried out with the t-test for paired samples. Repeated measure ANOVA was used to make comparisons between T0, T1, T2 and T3, and the level of significance was set at p value < 0.05 .

Results

Baseline data

Recruitment started in January 2018 and ended in March 2019. Baseline demographic and clinical characteristics for each group are shown in (Table 1.) The data relative to salivary pH was normally distributed.

Participant flow

The flow of participants throughout the trial is demonstrated in the flowchart (Figure.1). Eight participants did not receive the allocated intervention for various reasons, including lack of follow-up and discontinuation of treatment.

Outcomes and estimation

Significant changes in salivary pH values were observed ($P < 0.05$) for both ligation materials compared to the baseline values (T0). The EM group showed a significant decrease of salivary pH value in all assessment time points. Regarding the SS group, a significant increase of salivary pH value was observed at 6 (T2) and 12 weeks (T3) (Table 2). Repeated ANOVA measured for multiple comparisons revealed a significant difference in salivary pH value between T0, T2 and T3 (Table 3).

Harm

No serious harm was inflicted upon the participants other than moderate marginal gingivitis associated with fixed orthodontic treatment.

Discussion

Limitations

Blinding of the investigator and participants was not feasible. Short-term follow-up for 3 months during levelling and alignment stage was conducted, since only brackets, archwire and ligature utilized excluding other confounding's like; elastics, power chain, coils or others.

Generalizability

Applicability of the above findings to other populations is possible. The average salivary pH values range from 6.5–7.5 with no difference between communities and populations.^{30,32}

Interpretation

The importance of preservation of enamel integrity during orthodontic treatment urges orthodontists and researchers to improve the appliances used to decrease the chances for plaque accumulation and subsequent enamel demineralization.

Freitas et al.³³ in a systematic review reported that fixed orthodontic appliances affect the quality and quantity of oral microbiota with a significant increase of acid producing bacteria, particularly

Streptococcus mutans and Lactobacilli, which contributes to the drop in salivary pH level during the course of treatment.

No previous study has evaluated the effect of archwire ligation materials on salivary pH. Comparison of the current study's findings with previous studies was not possible. Several previous studies evaluated the effect of fixed orthodontic appliance on salivary pH. They compared the changes before and after treatment without specifying which type of ligature materials were used.^{12,16,17,25,31,33-40} The effect of archwire ligation materials (SS and EM) have been previously evaluated on oral biomarkers other than salivary pH, including plaque, gingival, bleeding indices, and microbial colonization with a split mouth design.^{10,13-15}

The EM group demonstrated a significant decrease in salivary pH level in all stages. By comparison, the SS group showed an increase after T1. The current study findings agree with the results of Forsberg et al.¹⁴ that demonstrate a higher level of Streptococcus mutans and Lactobacillus on EM ligature compared to SS for 12 orthodontic patients. They recommended that EM should be avoided for patients with inadequate oral hygiene.

Türkkahraman et al.¹⁰ at the early stages of orthodontic treatment evaluated the microbial colonization between two archwire ligatures with split-mouth study for 21 orthodontic patients at three different times. They reported that EM ligature had slightly more microbial colonization of Streptococcus mutans and Lactobacilli compared to SS. However, the difference was not significant.

Alves de Souza et al.¹³ conducted a study to evaluate microbial colonization using polymerase chain reaction analysis of two archwire ligations, EM and SS before fixed orthodontic appliance and after 6 months for 14 patients with split mouth design. They reported that EM ligatures were associated with higher scores of microbial plaque index than SS ligatures.

Sukontapatipark et al.,⁸ by comparison, conducted an experimental study by scanning electron microscopy evaluated microbial colonization on two types of archwire ligation, EM and SS, for 20 patients at three time intervals over a period of three weeks. They demonstrated that the ligation material did not influence the microbial morphotypes.

Elastomeric modules are considered an organic material in their composition that would be more favorable for bacterial colonization than stainless steel, which is an inorganic material with inert metal surfaces.^{41,42} The differences in surface topography and structural characteristics of elastomeric and steel ligature wires may also be a factor that enhances the bacterial colonization on the organic and porous surfaces of EM. These are diminished with SS, which has inorganic and smooth surfaces.^{43,44} The discrepancies may be attributed to the difference in study design and duration, sample size, methods of saliva collection, and tools for measuring pH.

Females' participants most often apply for orthodontic than males⁴⁵; they are more attendance and commitment to orthodontic clinics and treatment instructions. Unstimulated (resting) saliva was specified for collection, it is the long-lasting oral secretion in contact with teeth rather than stimulated saliva.

The clinically significant of study results lies on that, via a short-term evaluation EM is a cause of drop in salivary pH which in itself constitute a risk indicator for enamel demineralization throughout the treatment with fixed orthodontic appliances, and subsequently on enamel demineralization and formation of whit spot lesions, as orthodontic treatment is a long-term treatment course.

Preventive approaches relating to changes in the oral environment in orthodontic patients were established. Checking the pH of saliva can be valuable as part of an overall clinical assessment especially for patients with high caries index.

Conclusion

Early in orthodontic treatment, EM had a significant effect on salivary pH compared with SS ligature, lowering it to unfavorable levels. Therefore, the EM as ligature material is not recommended in orthodontic patients with high caries index or inadequate oral hygiene.

Abbreviations

EM Elastomeric Modules

SS Stainless steel

RCT Randomized Clinical Trial

Registration: This trial was registered at ANZCTR.org. (ACTRN12618001647224)

<http://www.anzctr.org.au/ACTRN12618001647224.aspx> (A Retrospective registration)

Competing Interests: The authors declare that they have no conflict of interest.

Declarations

Ethics approval and consent to participate

Ethical approval was obtained from the ethics committee of the University of Science and Technology, Sana'a – Yemen (Registry No: EAC/UST126). A form of the approval was submitted as a sperate document.

Every participant was signed an Informed consent after the nature of the study was explained. A form of the informed consent was submitted as a sperate document.

Consent for publication

We hereby submitting the manuscript for publication in “BMC oral health Journal” titled “Salivary pH changes under the effect of stainless steel versus elastomeric ligatures in fixed orthodontic patients: A single-center, randomized controlled clinical trial” We assure that this manuscript is an original work has neither been published in any other journal nor submitted for publication in any other journal.

A form of the Authors approval and signatures was submitted as a sperate document.

Availability of supporting data

Any of the supporting data in this manuscript are available in any time.

Competing interests

We, as authors declare that “No competing of interest” regarding this work.

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Authors' contributions

Hend Abulkareem Abdullah Nasher Al-Haifi

(primary investigator, corresponding author)

Ramy Abdulrahman Ali Ishaq (Co – supervisor)

Maged Sultan Abdullah Al-Hammadi (Main – supervisor)

Both co and main supervisors were approved every step in the study in details and supervised all the steps of work and revised the primary and final version for manuscript writing.

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Tables

Table.1: Baseline demographic characteristics data for participants in both groups

Study characteristics	Stainless Steel	Elastomeric	Total
Number of participants (who received the allocation intervention)	31	31	62
Age (y) – Mean (SD)	20.45 ± 4.26	20.48 ± 3.92	20.47± 4.60
Gender distribution (Male / Female)	6/25	6/25	12/50

Note: (y): years, (SD): standard deviation.

Table.2: Longitudinal Changes in Salivary pH values for each group from T0 to T3

pH value at	T0		T1		T2		T3		Significance between		
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	T0-T1	T0-T2	T0-T3
Ligature											
Stainless Steel	6.72	0.14	6.72	0.14	6.78	0.13	6.81	0.14	NS	*	*
Elastomeric	6.77	0.16	6.72	0.13	6.67	0.13	6.64	0.13	*	*	*

T0, baseline; T1, 2 weeks, T2, 4 weeks and T3, 12 weeks from T0, NS: indicates nonsignificant

* indicate significant p value < 0.05

Table.3: Multiple Comparison for Salivary pH Mean difference from T0 to T3

Time	T1	T2	T3	Significance between		
Comparison	T0 -T1	T0 -T2	T0 -T3	T0-T1	T0-T2	T0-T3
Mean difference	0.03	0.02	0.02	NS	*	*
P- value	0.70	0.02	0.04	NS	*	*

T0, baseline; T1, 2 weeks, T2, 4 weeks and T3, 12 weeks from T0,

NS: indicates nonsignificant, * indicate significant p value < 0.05

Figures

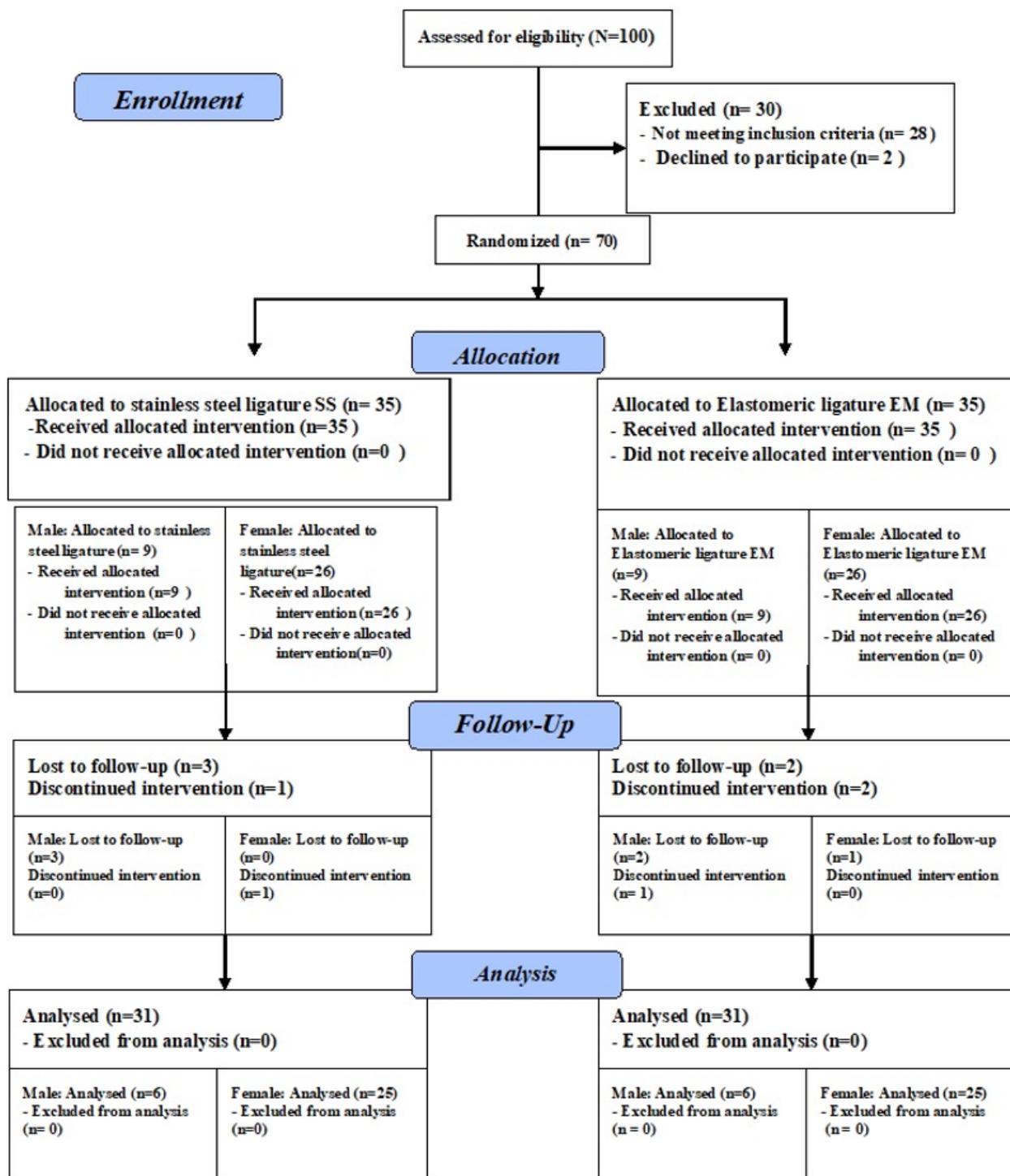


Figure 1

represent the CONSORT flow chart diagram for the follow up of participants throughout the trial.