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CLINICAL EFFICACY OF CHLORHEXIDINE VERSUS HYALURONIC ACID AS A COATING ON ELASTOMERIC LIGATURES IN MANAGING GINGIVAL AND PERIODONTAL CONDITIONS DURING ORTHODONTIC TREATMENT

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ABSTRACT

Introduction: Keeping a healthy gingival and periodontal environment is an important concern during fixed orthodontic treatment. Chlorhexidine (CHX), being the gold standard, was compared to Hyaluronic acid (HA) which is thought, nowadays, to be a rising agent regarding the healing effects on human tissues, including gingival and periodontal tissues. **Aim:** The main objective of this trial was the assessment of efficacy of chlorhexidine versus hyaluronic acid as a coating on elastomeric ligatures in managing gingival and periodontal conditions during orthodontic treatment. **Materials and methods:** Chlorhexidine gluconate and hyaluronic acid 0.88 gels from the same manufacturer (EZ-Pac®) have been applied on plain elastomeric ligatures (Dentaurum®). Three groups of 57 cases in all were created (19 each). Group I received Chlorhexidine (CHX) coated elastomeric ligatures and was called CHX group. Group II received Hyaluronic acid (HA) coated elastomeric ligatures and was called HA group. Group III received plain elastomeric ligatures and was called control group. Recall visits were every month; T0 (pre-appointment assessment), T1 (after one month), T2 (after two months), T3 (after three months). Plaque.index (PI) and gingival.index (GI) have been measured at time intervals; T0, T1, T2 and T3 using Wiliams periodontal probe. **Results:** A statistically significant drop in PI (0.0381) and GI (P=0.024) was observed in HA than CHX and control group at T3. **Conclusion:** When compared to chlorhexidine, hyaluronic acid demonstrated a significant reduction in gingival index with a relatively weak correlation between PI and GI in HA group compared to CHX group.

INTRODUCTION

Historically, orthodontic treatment with old systems was thought to cause different problems in the gingival and periodontal conditions during the treatment procedure [(1)1].

Nowadays, due to development of new systems and multiple new innovations to decrease the hazardous effects of orthodontic appliances, it is thought now that orthodontic treatment has little hazards on the gingiva and periodontium and could even, in some instances, enhance their conditions [(2)].

Studies are still developing, and new trials are being made to enhance the hygienic effect of orthodontic appliances during treatment.

The concern to gingival and periodontal conditions and the microbial biofilm formation during orthodontic treatment is rising during the last few years and is considered to be one of the most important standards of a successful treatment [3].

Many trials have been made to study the effect of multiple agents that were thought to enhance gingival conditions during orthodontic treatment. Clinical trials studying the antimicrobial effects of many products and others measuring the periodontal parameters and gingival changes during orthodontic treatment using these agents and products [4].

For years, Chlorhexidine (CHX) was thought to be the gold standard for enhancing the gingival and periodontal conditions during dental treatment[5]. Studies and trials used to study the clinical and antimicrobial effects of chlorhexidine either by studying the clinical efficacy of CHX on microbial films[6], comparing different formulations and delivery shapes of CHX [7] or comparing CHX with other antimicrobial agents[8].

Hyaluronic acid (HA) is a promising agent dealing with healing and regenerative effects on different tissues of the human body. Likely, HA has healing and regenerative effects on the oral tissues[9]. It's believed that HA has a regenerative effect on the periodontium [10]. It's also thought that it has a plaque inhibitory effect [11].

Hence, the use of HA during orthodontic treatment is a rising innovation for managing gingival and periodontal conditions. Benefiting from its anti-plaque and regenerative effect, HA is thought to play an important role in successful orthodontic treatment with good gingival and periodontal health.

Comparing the beneficial effects of both agents, Hyaluronic acid and Chlorhexidine, in managing gingival conditions is main concern of this study.

MATERIALS AND METHODS

Study setting

This was a randomized clinical study which examined the periodontal health status in patients receiving orthodontic therapy by comparing chlorhexidine versus hyaluronic acid coatings on elastomeric ligatures. Computer-generated random numbers were used for randomization.

Sample size calculation

On the basis of previously treated clinical trial **Paschos et al.,** [2] (gingival index), Using the statistical program G Power version 3.1 (Franz Faul, Universität Kiel, Germany), a power analysis was performed. Based on an α of 5% and a power of 80% of an effect size = 0.4717317, the results showed that a minimum sample size of n = 48 samples, 16 samples for each group, was required.

F tests - ANOVA: Fixed effects, omnibus, one-way

Analysis: A priori: Compute required sample size

Input :	Effect size f	= 0.4717317
	α err prob	= 0.05
	Power (1-β err prob)	= 0.80
	Number of groups	= 3
Output:	Non-centrality parameter λ	= 10.681478
	Critical F	= 3.204317
	Numerator df	= 2
	Denominator df	= 45
	Total sample size	= 48
	Actual power	= 0.814826

MATERIALS

The materials used in the study were as following (Table 1):

Table (1) *Materials used in the Study*

Item	Composition	Manufacturer
1. Chlorhexidine gel	Chlorhexidine gluconate	EZ-Pac®, Alexandria, Egypt
2. Hyaluronic acid gel	Hyaluronic Acid 0.88	EZ-Pac®, Alexandria, Egypt
3. Elastomeric ligatures pack	Elastomeric ligature	Dentaurum®, Ispringen, Germany.

1. Methods: -

A total number of 57 cases in 3 groups (19 each) that met the inclusion criteria were examined.

A. Inclusion Criteria:

1) Patients' age range; 18-28 years.
2) Patients undergoing fixed orthodontic treatment.
3) Initial periodontal examination indicating good gingival and periodontal conditions.
4) Both genders.

B. Exclusion Criteria:

1) Patients with severe periodontal disease.
2) Pregnancy, lactation, menopause.
3) Smokers.
4) Patients with oral lesions.
5) Patients with any systemic diseases

2. Study design and procedures:

Chlorhexidine gluconate and hyaluronic acid 0.88 gels from the same manufacturer (EZ-Pac) have been applied on plain elastomeric ligatures and preserved for 10 days then thoroughly rinsed with distilled water and left to dry for 2 days (Fig.1, Fig. 2). Three groups of 57 cases in all (19 each) were created.

- **Group I** received Chlorhexidine (CHX) coated elastomeric ligatures and was called **CHX group**.
- **Group II** received Hyaluronic acid (HA) coated elastomeric ligatures and was called **HA group**.
- **Group III** received plain elastomeric ligatures and was called **control group**.

The patients were not aware of the agent they were receiving.

Fig. (1) Preparation of Chlorhexidine elastomeric ligatures

Fig. (2) Preparation of Hyaluronic Acid elastomeric ligatures

Recall visits were every month.

- **T0** (pre-appointment assessment),
- **T1** (after one month),
- **T2** (after two months),
- **T3** (after three months)

Periodontal parameters: **plaque.index (PI)** and **gingival.index (GI)** have been measured at time intervals; **T0**, **T1, T2** and **T3** using Wiliams periodontal probe.

a) **Plaque Index (PI**; Silness & Löe 1964): this index determines the thickness of plaque at the gingival margin; only this plaque contributes to the etiology of gingivitis. Teeth are air-dried to reveal plaque.

b) **Gingival Index (GI;** Löe & Silness 1963): assigns three categories of gingival inflammation. The chosen teeth are measured on oral, distal, mesial and facial aspects.

3. Ethics consideration:

The present research has been conducted after the approval, number 390/2021, of the Research Ethics Committee (REC) of the faculty of Dentistry, Suez Canal University, approval. It has been conducted on patients receiving orthodontic treatment. Before starting the study, the patients completed informed written consent forms outlining all clinical evaluations, procedures, and follow-up, and the researcher took ethical considerations pertaining to patient confidentiality and well-being into account.

Statistical analysis

The following appropriate statistical tests were used to calculate, tabulate, and statistically evaluate all of the data. The samples' normal distribution was examined using the Shapiro-Wilk normality test. The mean ± standard deviation (SD) was used to compute descriptive statistics. Nominal or categorical variables were compared using the Chi-Square test of independence.

More than two study groups were compared using Kruskal Wallis (Kw) (non-parametric variables).

Correlation coefficient was the determination between variables. Statistical significance is defined as a P value of less than 0.05. SPSS software for Windows version 26.0 (Statistical Package for Social Science, Armonk, NY: IBM Corp.) was used to conduct statistical analysis at significant levels ≤0.05 (P-Value).

RESULTS

Plaque Index

Comparison between groups at the same time for Plaque Index:

Statistical analysis showed a significant difference between groups at T3 (KW= 1.929, P=0.0381) while there is no significant difference between them at T0. T1 and T2. The percentage change from T0 to T3 increased with 57.04% in control group while the percentage change decreased with 19.89% in CHX group and 17.88% in HA group (Table 2**).**

Table (2) *Comparison between groups for Plaque Index changes at the same time and the percentage of change for each group*

Groups	T0		T1		T2		T3		%change T0-t3
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Control	1.42	0.51	1.44	0.70	1.58	0.84	2.23	0.92	57.04
CHX	1.76	0.62	1.67	0.69	1.52	0.83	1.41	0.85	-19.89
HA	1.79	0.42	1.94	0.25	1.63	0.76	1.47	0.77	-17.88
KW	5.12		2.282		0.295		1.929		
P value	0.077		0.320		0.863		0.0381 **		

***, means significant difference at P<0.05 using Kruskal Wallis (K.W) test at P<0.05*

Gingival Index

Comparison between groups at the same time for Gingival Index:

Statistical analysis showed significant difference between groups at T2 (KW= 21.45, P<0.001) and T3 (KW= 13.729, P=0.024) while there is no significant difference between them at T0 and T1. The percentage change from T0 to T3 decreased with 33.16% in CHX group and 65.29% in HA group while the percent change was increased with 57.47% in control group (Table 3).

Correlation between Plaque Index and Gingival Index for all groups at different time interval:

The results in (Table 4) showed the correlation coefficient between Plaque index and gingival index overall time interval. The correlation coefficient was significant and positive correlation (strong) in control group (r=0.767, P<0.001) and CHX group (r=0.615, P<0.001), while the correlation between Plaque index was positive but non-significant (weak) in HA group (r=0.229, P=437)

Table (3) *Comparison between groups for Gingival Index changes at the same time and the percentage of change for each group*

Groups	T0		T1		T2		T3		%change T0-t3
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Control	1.74	0.56	1.83	0.86	2.00	1.00	2.74	0.37	**57.47**
CHX	1.93	0.71	1.61	0.61	1.33	0.77	1.29	0.78	**-33.16**
HA	2.42	0.51	1.88	0.50	1.32	0.75	0.84	0.37	**-65.29**
KW	3.101		5.211		21.45		13.729		
P value	0.212		0.074		<0.001**		0.024**		

***, means significant difference at P<0.05 using Kruskal Wallis (K.W) test at P<0.05*

Table (4) *Correlation between Plaque Index and Gingival Index for all groups at different time intervals*

	Plaque Index					
	Control group		CHX		HA	
	R	P	R	P	R	P
Gingival Index	0.767	<0.001**	0.615	<0.001**	0.229	0.437

Correlation (R) is significant at the 0.05 and 0.01 level

DISCUSSION

The results of the study revealed that both plaque and gingival indices increased significantly and continuously from T0 to T3 for the sample cases of control group. These findings agree with those of the study made by **Ristic et al.**, [12]. These findings are likewise similar to those of the research conducted by **Sobouti et al.**, [13].

The increase in plaque index during fixed orthodontic treatment may be because of orthodontic attachments and ligatures that make it difficult to keep proper oral hygiene measures and impede toothbrushing severely ,according to **Jiang et al.**,[14].

The current study's findings indicate that both plaque and gingival indices decreased significantly along time intervals for the sample cases of CHX group. These results also suggest that the gingival index is directly related to plaque index. These findings coincide with those of **Karamani et al.**,[15] and **Hussain et al.**, [16].

The way that CHX controls plaque index is due to its anti-plaque effect by affecting the pellicle formation and due to its antibacterial effect; bacteriostatic and bactericidal, according to **Thangavelu et al.**, [17]. These effects are translated to anti-inflammatory effects on the gingiva and periodontium and therefore the control of gingival index.

Clinical findings in this study suggest that the periodontal changes and gingival index are highly dependent on plaque index and thus they are highly dependent on the preventive measures taken by the patient and the patient co-operation.

The study's findings showed that the sample cases in the HA group did not significantly differ in their plaque index. On the other hand, regarding to gingival index there was a significant difference at the time intervals from T0 to T3. This means that HA can improve gingival health regardless of the plaque amount on the affected teeth. Its physiochemical and biological characteristics, including its anti-inflammatory, hygroscopic, bacteriostatic, osteoinductive, and anti-edematous qualities, could be the cause of this "according to **Mehta et al.**, [18].

These results comes in a line with the results of the study made by **Pistorius et al.**, [19] where plaque index and other gingival indices were measured on Sixty patients with clinical signs of gingivitis, forty of them used HA-containing spray and twenty were the control group. The results showed improvement in all gingival measures and no significant difference in the plaque index between the two groups.

Another study made by **Pilloni et al.** [20] showed a decrease in plaque index for HA group more than that of the control group, but this decrease didn't reach a significant difference between both groups. Regarding to gingival index, there was a significant difference between both groups.

Also a study made by **Al-Shammari et al.**, [21] resulted in a significant difference in gingival index for the tested sites compared to the control sites, while there was no significant difference in plaque index between both sites.

According to the results of this study, the percentage of change of plaque index decreased with CHX more than that of HA (19.89% and 17.88% respectively). This may be due to several factors including the anti-plaque effects of both agents and the preventive oral hygiene measures' differences between individual patients themselves.

However, the percentage of change of gingival index decreased with HA than CHX (65.29% and 33.16% respectively). Furthermore, the correlation between PI and GI was stronger for CHX than HA. This means that the gingival enhancement mechanism of CHX is highly dependent on the plaque index of the patient. While for HA, the beneficial effect on gingiva is independent on the plaque index of the patient, but it is dependent on the effect of the agent itself.

This may be also due to the differences in the mechanism of action between the two agents. As for CHX, the mechanism of action is mainly an anti-inflammatory effect. However, the mechanism of action of HA depends mainly on the healing and regenerative effects besides its anti-inflammatory and anti-bacterial effects.

CONCLUSIONS

- Hyaluronic acid showed a relatively significant decrease in gingival index in comparison to Chlorhexidine.
- Although it's logic that gingival index is strongly dependent on plaque index, there was a relatively weak correlation between plaque index and gingival index for Hyaluronic Acid in comparison to Chlorhexidine. This may be due to the reparative and healing capacity of Hyaluronic Acid.

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