Clinical Efficacy of Hyaluronic Acid Gel Compared to Chlorhexidine Mouthwash in the Management of Plaque-Induced Gingivitis in Orthodontic Patients: A Clinical Trial

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Received: March 31, 2020; Published: April 25, 2020

Abstract

Aims and Objectives: Patients with fixed orthodontic appliances are at high risk of developing gingival and periodontal diseases. In general, mechanical plaque control is usually inadequate to control plaque and maintaining optimal oral health for long periods, therefore, incorporating chemical agents had shown better efficacy in controlling plaque-mediated diseases. This study aims to assess the impact of hyaluronic acid gel in improving gingival parameters by comparing the efficacy of hyaluronic acid gel (HA) and chlorhexidine mouthwash (CHX) in the management of plaque-induced gingivitis.

Study Design: Clinical trial.

Place and Duration of Study: Qassim University Female Dental Clinics, Qassim University Melida, Saudi Arabia, from November 2018 to January 2019.

Subjects and Methods: This clinical trial included 15 female patients wearing full-mouth fixed orthodontic appliances and having plaque-induced gingivitis, the age range was between 16 - 30 years old. Subjects were allocated into two groups; group A receiving hyaluronic acid gel and group B taking chlorhexidine mouth wash. Gingival health was evaluated using clinical indices; gingival index (GI), plaque index (PI), papillary bleeding index (PBI). Data were collected at baseline and after 3 weeks and were analyzed using Statistical Package for Social Sciences (SPSS) version 21.0.

Results: A total of 14 subjects have completed the trial. Intragroup comparison revealed a positive response to the treatment for group A and group B with clinical indicators; GI (P < 0.000), PI (P < 0.000), PBI (P < 0.000), and GI (P < 0.000), PI (P < 0.038), PBI (P < 0.010) respectively. Nevertheless, PI and PBL were lower in group A. Intergroup comparison demonstrated no significant difference between the groups, however, group B has reported some negative effects related to the use of chlorhexidine mouth wash.

Conclusion: The hyaluronic acid gel has shown a comparable effect to chlorhexidine mouthwash in the management of plaque-induced gingivitis in fixed orthodontic appliance patients. This study recommends considering hyaluronic acid gel as the first treatment option in controlling plaque-induced gingivitis.

Keywords: Gel; Gingivitis; Hyaluronan; Chlorhexidine; Orthodontic Brackets; Fixed Orthodontic Appliances

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Introduction

The main etiology of nearly all forms of the periodontal disease is a plaque. The most common form of periodontal disease is plaque-induced gingivitis affecting 50% to 90% of adults worldwide [1,2]. The prevalence of gingivitis among Saudi adult population in Riyadh region was 100% [3]. Gingivitis is a non-destructive periodontal disease and can be reversed with good oral hygiene. However, if not controlled or left untreated it can further progress into periodontitis, where the inflammation results in tissue destruction, alveolar bone resorption and eventually tooth loss. The painless nature of the gingival disease makes it difficult to be recognized by patients. Therefore, care must be given to gingivitis therapy as a strategy for preventing periodontitis [1].

The major etiologic agent for the initiation of gingivitis is dental plaque [4]. Roughly all fixed orthodontic appliance patients will have gingivitis at some point throughout the treatment [5]. Several studies revealed that orthodontic patients are at high risk of developing gingival and periodontal diseases because of orthodontic bands, brackets, ligatures wires and elastics which encourage the accumulation of microbial flora and food residues. Besides, the long time that orthodontic treatment takes can also contribute towards the initiation and progression of periodontal disease [6,7]. Moreover, oxidative stress and cytotoxic effects of materials in fixed appliances and bonding agents have been concerned as factors causing gingival inflammation [8,9].

Typically, gingivitis therapy is mainly directed at minimizing the etiologic factors to eliminate inflammation, thus allowing gingival tissues to heal. It can be managed with an effective plaque control program and debridement of tooth surfaces coupled with continued periodontal maintenance procedures to prevent re-initiation of inflammation [10]. Mechanical plaque control is usually insufficient to provide a level of plaque control consistent with oral health over long periods. Even after mechanical plaque control bacteria in the soft tissues can re-colonize the tooth surfaces [11]. Chemical agents with anti-plaque or antimicrobial activity incorporated into dental products have shown better efficacy in controlling plaque-mediated diseases [12]. CHX is one of the most effective topical anti-septics reported so far that has been used successfully for treating gingivitis and remains the superior quality of all chemical anti-plaque agents. However, patient compliance is limited due to CHX side effects of such as tongue and tooth staining, taste alterations, and mucosal erosions [13-15].

With the advances in the understanding of inflammatory mechanisms and wound healing process associated with periodontal diseases, numerous extracellular matrix components like hyaluronic acid, fibronectin, and chondroitin sulfate are identified as promoters of periodontal healing and regeneration [16]. HA is a naturally occurring linear polysaccharide of the extracellular matrix of connective tissue and other tissues. Its unique physicochemical and biological properties make it useful in the treatment of the inflammatory process in various medical areas. In the field of dentistry, HA has shown anti-inflammatory, anti-bacterial, and antioxidant effects in the treatment of periodontal diseases [17].

Because of its biocompatibility and non-toxicity, the use of exogenous HA-based biomaterials, applied topically to inflamed periodontal sites would provide beneficial effects in accelerating and modulating the host response [16].

A clinical trial was conducted by Sapna and Vandana [18] to evaluate the effect of topical application of hyaluronic acid gel shown to be an effective agent for treating gingivitis [18]. Further Eck., et al. [19] evaluated the application of HA containing gels in early wound healing after scaling and root planning. They concluded that adjunctive application of HA had positive effects on reduction of probing depth and may prevent recolonization by periodontopathogens [19]. Pilloni., et al. [20] trial showed an effect in reducing the gingival inflammation when HA gel used as an adjunct to mechanical home plaque control [20]. Additionally, Sahayata., et al. [21] have evaluated the therapeutic efficacy of HA gel in adjunct to non-surgical periodontal treatment in both clinical and microbiological parameters. It resulted in significant improvement in clinical parameters. Microbiologically it did not show any spastically significant results [21]. Although, Pole-palle., et al. [22] study showed that sub-gingival placement of HA along with scaling and root planning resulted in a significant improvement in both clinical and microbiological parameters [22]. In a study done by Batavia., et al. [23] on orthodontic patients. compared the effects of HA gel alone and in combination with scaling using clinical, microbial, and biochemical parameters. Their results supported the use of HA gel in adjunct to scaling [23]. None of the previous studies has reported any adverse effect associated with the local application

of HA gel.

**Materials and Methods**

**Ethical approval**

This study was approved by the Dental Ethics committee of Qassim University (#:EA/3005/2017). Participants received a letter describing the study and consent from all participants was obtained.

**Study population**

This clinical trial was conducted at female dental clinics at Qassim University. The adequate sample size was calculated with 21.38% margin of error and randomly allocated into study and control groups (Figure 1).

![Flowchart for the total study population](image)

*Figure 1: Flowchart for the total study population.*

Both groups received written and verbal oral hygiene instructions. Brushing was advised twice daily. All subjects were asked to refrain from all other unassigned forms of oral hygiene aids.

**Group A**

Patients were given 0.8% HA gel for home use application on the gingiva topically with the help of cotton bud applicator twice daily. The patients were advised to take a constant length of 1.5 cm gel which is equal to 1 ml of gel and place it in the inflamed area of the buccal and lingual gingiva twice daily. After application, the patients were instructed to avoid eating, drinking, or rinsing for 1 hour (Figure 2A).

**Group B**

Patients were given 0.12% CHX mouthwash. They were instructed to rinse with 15 ml of the solution for 30 seconds, twice daily (Figure 2B).

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Selection criteria

The subjects enrolled were female patients wearing full-mouth fixed orthodontic appliance with plaque-induced gingivitis, aging between 16 - 30 years, presenting good general health, having at least 24 natural teeth in the mouth excluding the third molars, exhibit a minimum of 30% bleeding on probing at qualifying sites, and probing depths not more than 3 mm. Exclusion criteria included:

- Syndromes or systemic diseases that could have contributed to inflammatory processes.
- Physical or mental handicap.
- Patients who had taken antibiotic therapy in the month prior to the commencement of the study.
- Periodontal therapy in the last 6 months before commencing the study.
- Smoking.
- Pregnant and lactating women.
- Periodontally compromised teeth.
- Active caries.
- Removable orthodontic appliances.

Instruments and measures

The indices assessed included clinical parameters; gingival index (GI), plaque index (PI) [24] and papillary bleeding index (PBI) [25]. These were recorded by the main investigator and were repeated on days 0 and after 3 weeks. A self-reported scale for evaluating subjective satisfaction ranged from 1 - 10, was collected from both groups after completing the treatment.
Data analysis

Data were collected during baseline and after 3 weeks and they were analyzed using Statistical Package for Social Sciences (SPSS) version 21.0. The statistical tests used were independent t-test for intergroup comparison and paired t-test for intragroup comparison.

Results

A total of 14 participants have completed the trial. The intraexaminer reliability test was performed on 10% of the sample size before active treatment took place using the Intraclass correlation coefficient test (ICC) (Table 1). The results had indicated a consistency of the data collection methods by the single examiner with ICC value above 0.7.

<table>
<thead>
<tr>
<th>Index</th>
<th>ICC</th>
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<tbody>
<tr>
<td>GI</td>
<td>0.845</td>
</tr>
<tr>
<td>PI</td>
<td>0.999</td>
</tr>
<tr>
<td>PBI</td>
<td>0.967</td>
</tr>
</tbody>
</table>

**Table 1: Intraexaminer reliability test for each index.**

Intragroup comparison has revealed a positive response to the treatment for both groups after assessing the clinical indicators within group A and group B; GI (P < 0.000), PI (P < 0.000), PBI (P < 0.000) and GI (P < 0.000), PI (P < 0.038), PBI (P = 0.010) respectively (Table 2A and 2B). However, PI and PBL were lower in group A after the treatment (Figure 3). Intergroup comparison demonstrated no significant difference between the groups neither before or after the treatment (Table 3). Nevertheless, group B have reported some negative effects related to the use of chlorhexidine mouth wash and demonstrate less satisfaction after the treatment. The self-reported scale for evaluating subjective satisfaction resulted in a mean of 9 for group A and a mean of 7.5 for group B (Figure 4A and 4B).

<table>
<thead>
<tr>
<th>Pair</th>
<th>Baseline Gingival Index</th>
<th>Mean ± SD</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Secondary Gingival Index</td>
<td>1.13483 ± 0.46127</td>
<td>0.000</td>
</tr>
<tr>
<td>2</td>
<td>Baseline Plaque Index</td>
<td>0.99446 ± 0.29321</td>
<td>0.000</td>
</tr>
<tr>
<td>3</td>
<td>Secondary Plaque Index</td>
<td>1.13442 ± 0.62827</td>
<td>0.001</td>
</tr>
</tbody>
</table>

**Table 2: Intragroup comparison.**

(A) paired t-test for group A assessment

<table>
<thead>
<tr>
<th>Pair</th>
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<th>Mean ± SD</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
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<td>Secondary Gingival Index</td>
<td>0.97233 ± 0.18772</td>
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<tr>
<td>2</td>
<td>Baseline Plaque Index</td>
<td>0.27583 ± 0.24091</td>
<td>0.038</td>
</tr>
<tr>
<td>3</td>
<td>Secondary Papillary Bleeding Index</td>
<td>0.58472 ± 0.35389</td>
<td>0.010</td>
</tr>
</tbody>
</table>

(B) paired t-test for group B assessment.

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<table>
<thead>
<tr>
<th>Measurement</th>
<th>Group 1</th>
<th>Group 2</th>
<th>Sig. P&lt;.05</th>
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</thead>
<tbody>
<tr>
<td>Baseline data</td>
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<td></td>
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<tr>
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<td>1.6875 ± 0.36105</td>
<td>1.6667 ± 0.11255</td>
<td>0.060</td>
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<tr>
<td>Plaque Index</td>
<td>1.5469 ± 0.35806</td>
<td>1.8310 ± 0.05807</td>
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<tr>
<td>Papillary Bleeding Index</td>
<td>1.7789 ± 0.47948</td>
<td>1.6980 ± 0.52159</td>
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<tr>
<td>Secondary data</td>
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<td></td>
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<td>Gingival Index</td>
<td>0.5527 ± 0.20990</td>
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<tr>
<td>Plaque Index</td>
<td>0.5525 ± 0.15426</td>
<td>0.5552 ± 0.20472</td>
<td>0.210</td>
</tr>
<tr>
<td>Papillary Bleeding Index</td>
<td>0.6445 ± 0.26106</td>
<td>1.1133 ± 0.30908</td>
<td>0.528</td>
</tr>
</tbody>
</table>

Table 3: Intergroup comparison using an independent t-test.

Figure 3: Bar chart comparing two study groups.

(A) One sample from group A

Discussion

Throughout orthodontic treatment with fixed appliances, the inflammatory reaction of gingival tissue can very often be observed at some point [5]. Furthermore, it has been stated that during orthodontic treatment periodontal problems may be primarily attributable to poor oral hygiene. Hence, if optimal oral hygiene is maintained, using mechanical and chemical aids, no harmful effects would result from orthodontic treatment with regard to periodontal health [10-12,26].

For a long time, CHX mouthwash remains the gold standard for treating gingivitis and has the superior quality of all chemical antiplaque agents [13-15]. Recently, exogenous HA, recognized to have an anti-inflammatory effect, was introduced for the treatment of gingivitis as a topical applicant. The topical application of high molecular weight, HA-based gel has been documented to have potential in inducing periodontal healing in patients with inflammatory periodontal diseases in several studies [17-23].

In the present study, a randomized, single-blind parallel study design in which a total of 14 patients was treated with two different agents and evaluated after 3 weeks. Scaling is usually the first treatment modality when managing gingivitis, however, this study has focused on evaluating the effect of both agents without scaling to ensure accurate evaluation of the chemical effect only. CHX group have shown a comparable result as Mendigeri., et al. [15] where they used CHX for orthodontic patients in comparison to different other anti-plaque agents, however, PBI had more significantly reduced in their study (p < 0.001) [15].

In Sapna., et al. [18] trial topical and intrasulcular application of HA gel was compared for reducing gingivitis in which they recommend both intrasulcular and extrasulcular application of HA gel for optimum results [18]. However, our trial has only evaluated the extrasulcular effect of HA gel. Consequently, the study subjects have shown a positive response to the treatment with HA. This analogues the findings of Batavia., et al. [26] who evaluated the microbial, and biochemical parameters through collecting plaque samples. Thus indicating advantageous use of HA gel in orthodontic patients; however, in their experiment HA gel was applied intrasulcularly with aid of disposable applicator [23]. Recently, Trombelli., et al. [27] have evaluated the use of CHX mouthwash containing HA and an anti-discoloration system.
compared to conventional CHX mouthwash in patients undergoing flap surgery. They found equivalent results in both groups with comparable tooth and tongue staining [27].

Another considerable aspect when dealing with orthodontic patients is the corrosion stability with use of antiseptic agents. It has been covered in Rincic Mlinaric., et al. [28] study where they found the biggest corrosion resistance in HA gel (Gengigel) compared to other antiseptic agents in both electrochemical impedance spectroscopy and cyclic polarization [28].

By comparing the two agents for managing gingivitis in orthodontic patients, an equivalent effect was established between the two groups involved. However, satisfaction was higher with using HA gel rather than CHX mouthwash. Bearing in mind the adverse effects of CHX and its time-related characteristics, it may best be indicated for acute/short-term usage, while HA gel can be considered as a first choice adjunctive aid for the orthodontic patient with mild to moderate gingivitis.

Conclusion

The hyaluronic acid gel has shown a comparable effect to chlorhexidine mouthwash in the management of plaque-induced gingivitis in fixed orthodontic appliance patients. This study recommends considering hyaluronic acid gel as the first treatment option in controlling plaque-induced gingivitis.

Financial Support and Sponsorship

Nil.

Conflicts of Interest

There are no conflicts of interest.

Bibliography

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**Volume 19 Issue 5 May 2020**
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