# The impact of 0.24% hyaluronic acid gel on pain level and periodontal status following labial frenectomy

## *%0,24'lük hyalüronik asidin labial frenektomi sonrası ağrı düzeyi ve periodontal duruma etkisi*

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**Abstract**

**Aim:** The labial frenum is a mucosal fold that connects the upper lip to the alveolar ridge. Frenectomy involves the surgical removal of a mucosal fold. The traditional surgical technique utilizing a scalpel remains popular for performing a frenectomy. The study aims to examine the effectiveness of applying Hyaluronic Acid (HA) Gel after conventional frenectomy.

**Methods:** This research comprised 48 young patients (25 girls and 23 boys) aged 8 to 14. Participants were randomly divided into two groups. Group 1: Conventional Scalpel Surgery and Sterile Saline (SS) (n=24) and Group 2: Conventional Scalpel Surgery+HA (Aftamed, Child Gel 24% HA) (n=24). After measuring the participants' periodontal parameters, the frenectomy was performed. Postoperative pain levels were evaluated daily for one week utilizing a 10-point Visual Analog Scale. Before frenectomy, Plaque Index (PI), Gingival Index (GI), Pocket Depth (PD), Bleeding On Probing (BOP), Keratinized Gingival Width (KGW), Attached Gingival Thickness (AGT) values were measured and recorded. The periodontal parameters were assessed and analyzed after a 3-month follow-up period.

**Results:** VAS (Visual Analogue Scale) was assessed. The application of Although 0.24% HA gel caused less pain from days 1-3.6, there was no significant difference in pain levels between the HA gel and control groups (p>0.05). Pain levels were equal between groups on day 7. No significant changes in PI, GI, PD, BOP, KGW, or AGT values after three months of follow-up (p>0.05).

**Conclusions:** During the first week after a frenectomy performed with classic scalpel surgery, the application of 0.24% HA gel did not significantly reduce pain levels. It did not result in significant changes in other measured periodontal parameters after three months of follow-up.

**Keywords:** Conventional therapy; diastema; hyaluronic acid; labial frenum.

**Öz**

**Amaç:** Labial frenulum üst dudağı alveoler krete bağlayan bir kas dokusudur. Frenektomi işlemi bu kas dokusunun kaldırılmasını içerir. Frenektomi işlemi sırasında bisturi kullanılarak gerçekleştirilen geleneksel cerrahi teknik halen en popüler yöntemdir.Çalışmanın hedefi Hyalüronik Asidin (HA) konvansiyonel frenektomi sonrası etkisini incelemektir.

**Yöntemler:** Çalışmada yaşları 8-14 arasında değişen 48 genç hasta yer aldı (25 kız-23 erkek). Katılımcılar rastgele olarak 2 gruba ayrıldı. Grup 1: Konvansiyonel Cerrahi ve Steril Salin (SS) (n=24) ve Grup 2: Konvansiyonel Cerrahi+HA (Aftamed, Child Gel 24% HA) (n=24). Katılımcılara ait periodontal parametreler ölçüldükten sonra frenektomi yapıldı. Operasyon sonrası ağrı değerleri bir hafta boyunca günlük olarak 10 puanlık Görsel Analog Skala (VAS) ile değerlendirildi. Frenektomi öncesi Plak İndeksi (Pİ), Gingival İndeks (Gİ), Cep Derinliği (CD), Sondalamada Kanama (SK), Keratinize Diş Eti Genişliği (KDG), Yapışık Diş Eti Kalınlığı (YDK) ölçülüp kaydedildi. Periodontal parametreler 3 ay sonra tekrar ölçülüp değerlendirildi.

**Bulgular:** GAS (Görsel Analog Skala) skorları değerlendirildi. 1 ve 3. gün arası ve 6. günde HA grubunda ağrı düzeyi daha az olsa da, %0,24 HA jel uygulaması ağrı düzeyinde önemli bir farka yol açmadı (p>0.05). 7. günde ağrı düzeyleri eşitti. Pİ, Gİ, CD, SK, KDG, YDK değerlerinde 3 ay sonunda önemli bir fark yoktu (p>0.05).

**Sonuçlar:** Bir hafta sonunda topikal HA uygulamasının ağrı düzeyinde önemli bir farka yol açmadığı görüldü. Diğer periodontal parametrelerde üç aylık takip süresince yine HA uygulamasının önemli bir değişime yol açmadığı saptandı.

**Anahtar Sözcükler:** Diyastem; hyalüronik asit; konvansiyonel tedavi; labial frenulum

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## INTRODUCTION

Labial frenum mucosal fold consists of muscle fibers and connective tissue (1). As children develop, their frenum becomes shorter, and their maxilla continues remodeling. Many children have midline diastema until their permanent canines erupt due to the thick frenum structure despite any changes (2). Diastemas have multiple causes, but a hypertrophic frenum usually compounds the problem (3). While diastemas up to 1.6-2 mm between the teeth are considered normal until the permanent canines erupt, it has been stated that diastemas greater than 1.6-2 mm do not close spontaneously (2–4). To reduce the relapse rate in orthodontic treatments, the thick frenum causing diastema must be surgically removed (5).

Labial frenectomy is a surgical technique that separates the frenum attachment from the bone underneath it (1). There are four types of frenum classified based on their structure: mucosal attachment (42%) (6), gingival attachment (34%) (6), papillary attachment (20%) (6), and papilla penetrating attachment (4%) (7). Frenum with papillary or papilla-penetrating attachments can lead to pull syndrome. The pull syndrome occurs when lip movements detach the gingival papilla between teeth and marginal gingiva (1).

Following the surgical frenectomy procedure, the wound area is closed by suturing (8). Numerous wound care products have been introduced to minimize inflammation, reduce pain intensity, and take advantage of their potent antibacterial properties upon sealing the primary wound area. Hyaluronic Acid (HA) is a natural polymer synthesized exclusively by living organisms. HA degradation products exhibit pro-angiogenic effects. HA is known for its ability to bind water and create a beneficial matrix for wound healing (9). In recent years, HA has become a popular product in dentistry for wound healing. However, there are limited studies on its application after frenectomy, despite positive results from topical use (10).

This study examines how applying 0.24% HA affects pain levels in children during a week after undergoing a classical scalpel frenectomy procedure. It also evaluates bleeding on probing, gingival thickness, and gingival width parameters in the 3rd month after the frenectomy procedure. The study hypothesizes that the frenectomy group with 0.24% HA will have lower pain levels and higher gingival parameter values.

## MATERIALS AND METHODS

This study was performed after obtaining the approval of Afyonkarahisar University Clinical Research Ethics Committee (date: 14.06.2019, decision no: 2019-220). Children and adolescents between the ages of 8 and 14 were included in the study if they had parental written informed consent forms and were willing to participate. This research was conducted at the Department of Periodontology between August 2019 and May 2021. The number of study participants was determined using G-Power version 3.1. (Informer Tech Inc., Germany). The values for α and β were set at 0.05 and 0.2, respectively, and an effect size of 0.5 was considered (11). Based on the calculations, it was determined that each group should consist of 16 individuals for 95% power at a 5% significance level. Considering the exclusion criteria, it was decided to include additional patients in the study. The study included children who were systemically healthy and had not received medical treatment in the last three months.

48 patients were randomly divided into two groups. Group 1: Conventional Scalpel Surgery+Sterile Saline (SS) (n = 24), Group 2: Conventional Scalpel Surgery+HA (n = 24). The study included frenectomy treatments performed by researchers SSAD and CA. The researchers performed frenectomy treatments on the children without knowing which group they belonged to (control or HA). Each patient's controls and post-operative measurements were performed by a different physician, not the surgeon.

Before the frenectomy procedure, the patients' plaque index (PI), gingival index (GI), pocket depth (PD), bleeding on probing (BOP), keratinized gingival width (KGW), and attached gingival thickness (AGT) measurements were taken and recorded using a periodontal sond (HUF No:15, Hu-Friedy, Chicago, Illinois, USA). Measurements were taken independently for teeth number 11 and 21. PI, GI, and PD values were measured from 6 different points of each tooth: mesiobuccal, midbuccal, distobuccal, distopalatinal, midpalatal, and mesiopalatinal. Statistical analysis was conducted by averaging six values.

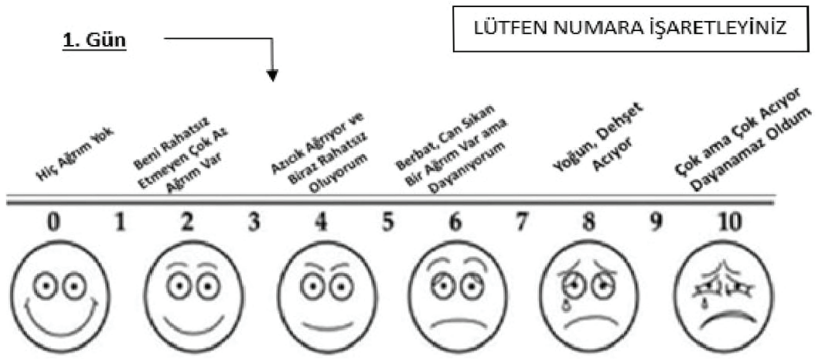
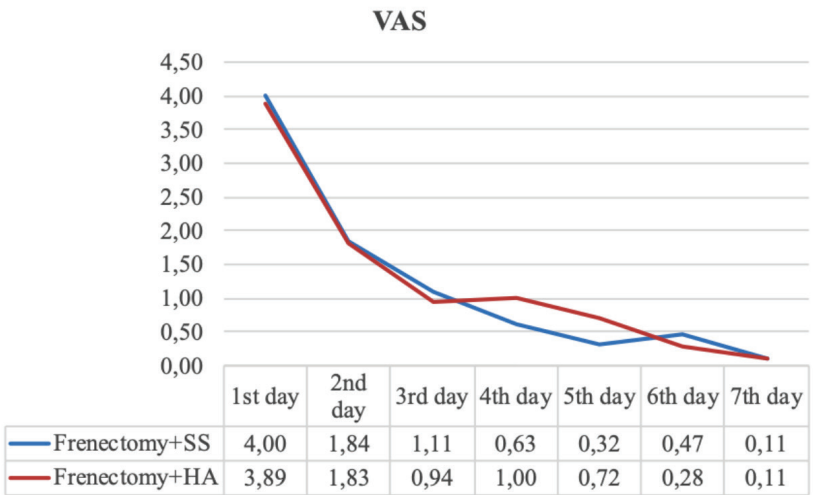



**Figure 1.** Visual Analog Scale




| | 1st day | 2nd day | 3rd day | 4th day | 5th day | 6th day | 7th day |
|---|---|---|---|---|---|---|---|
| Frenectomy+SS | 4,00 | 1,84 | 1,11 | 0,63 | 0,32 | 0,47 | 0,11 |
| Frenectomy+HA | 3,89 | 1,83 | 0,94 | 1,00 | 0,72 | 0,28 | 0,11 |

**Figure 2.** Changes in VAS over time for the Conventional Surgery+SS and Conventional Surgery+HA groups (VAS; Visual Analog Scale, SS: Sterile Saline, HA: Hyaluronic Acid)

Before undergoing the frenectomy procedure, all patients received oral hygiene training and professional dental cleanings. Local anesthesia was used for all frenectomy procedures. To ensure proper behavioral guidance, all patients were given topical anesthesia using Locanest spray, containing 10% lidocaine (Avixa İlaç San. Başakşehir, Istanbul). Each patient received local anesthesia using 2% articaine and 1:100.000 adrenaline. Injected one cc of local anesthetic solution on each side of the frenum. After achieving anesthesia, the frenum was clamped with a straight hemostat and removed by cutting from the upper and lower sides with a number 15 scalpel. After making a horizontal incision in the periosteum, the muscle attachments on the submucosal lateral walls were distally relieved and dissected away from the periosteum using a hemostat. The wound was closed using a 4-0 silk suture (DOGSAN, Turkey). Patients in the control group received seven days of SS injections using a 10cc syringe after the needle had broken. Patients in the HA experimental group were given seven blister disposable packages containing 0.24% HA. (Aftamed Child Gel, Aktident, Üsküdar, İstanbul, TURKEY).

Following the surgery, patients were advised to maintain proper hygiene and clean the incision site. Therefore, the control group (Conventional Scalpel Surgery+SS) was advised to irrigate the wound area with SS 3 times a day after meals. The participants in the experimental group were instructed to apply HA Gel to the wound area thrice a day after opening a new blister pack and refrain from eating or drinking for 10-15 minutes. Sutures were removed one week later.

A visual analog scale (VAS) was given to patients to rate their pain level each evening, including the night

**Table 1.** Comparing for three months changes between two groups using start-3 variables.

| Variables | | Conventional scalpel surgery+SS | Conventional scalpel surgery+HA | *p-value* |
|---|---|---|---|---|
| | No change | 17 (89,4) | 17 (94,4) | |
| **PI 11** | Decrease | 1 (5,3) | 0 (0,0) | *1,000[a]* |
| | Increase | 1 (5,3) | 1 (5,6) | |
| | No change | 17 (89,4) | 17 (94,4) | |
| **PI 21** | Decrease | 1 (5,3) | 1 (5,6) | *1,000[a]* |
| | Increase | 1 (5,3) | 0 (0,0) | |
| | No change | 15 (83,3) | 16 (88,9) | |
| **GI 11** | Decrease | 2 (11,1) | 2 (11,1) | *1,000[a]* |
| | Increase | 1 (5,6) | 0 (0,0) | |
| | No change | 14 (77,8) | 17 (94,4) | |
| **GI 21** | Decrease | 2 (11,1) | 1 (5,6) | *0,404[a]* |
| | Increase | 2 (11,1) | 0 (0,0) | |
| | No change | 18 (94,7) | 16 (88,9) | |
| **PD 11** | Decrease | 1 (5,3) | 0 (0,0) | *0,354[a]* |
| | Increase | 0 (0,0) | 2 (11,1) | |
| | No change | 18 (94,7) | 16 (88,8) | |
| **PD 21** | Decrease | 1 (5,3) | 1 (5,6) | *0,736[a]* |
| | Increase | 0 (0,0) | 1 (5,6) | |
| | No change | 15 (93,8) | 11 (84,6) | |
| **BOP 11** | Decrease | 0 (0,0) | 2 (15,4) | *0,192[a]* |
| | Increase | 1 (6,2) | 0 (0,0) | |
| | No change | 14 (87,5) | 10 (76,9) | |
| **BOP 21** | Decrease | 2 (12,5) | 3 (23,1) | *0,632[a]* |
| | Increase | - | - | |
| | No change | 13 (68,4) | 14 (77,7) | |
| **KGW 11** | Decrease | 5 (26,3) | 1 (5,6) | *0,229[a]* |
| | Increase | 1 (5,3) | 3 (16,7) | |
| | No change | 12 (63,2) | 15 (83,3) | |
| **KGW 21** | Decrease | 5 (26,3) | 1 (5,6) | *0,264[a]* |
| | Increase | 2 (10,5) | 2 (11,1) | |
| | No change | 15 (78,9) | 17 (94,4) | |
| **AGT 11** | Decrease | 0 (0,0) | 1 (5,6) | *0,105[a]* |
| | Increase | 4 (21,1) | 0 (0,0) | |
| | No change | 14 (73,7) | 15 (83,3) | |
| **AGT 21** | Decrease | 0 (0,0) | 2 (11,1) | *0,098[a]* |
| | Increase | 5 (26,3) | 1 (5,6) | |

SS: Sterile Saline, HA: Hyaluronic Acid, PI: Plaque Indeks, GI: Gingival Indeks, PD: Probing Depth, BOP: Bleeding On Probing, KGW: Keratinized Gingival Width, AGT: Attached Gingival Thickness, SD: Standard Deviation, Min: Minimum, Max: Maximum, a: Fisher-exact test.

of the frenectomy. According to this scale, 0 means I have no pain, and 10 means I have unbearably great pain (Figure 1). The researchers provided instructions to the patient and their parents on how to use the scale. Following a week, the patients accomplished the VAS scales and handed. All patients in the study were contacted for follow-up at the end of the third month.

### *Statistical Analysis*

The data was analyzed using the Statistical Package for the Social Science (SPSS) v21 program (SPSS, Chicago, USA). Quantitative variables were described using standard deviation and median (minimum-maximum). The Fisher exact test examines the relationship between two qualitative variables. The Repeated Mea-

sures Analysis of Variance test was used to compare the differences in measurements within each group. The statistical significance level was considered as 0.05.

## RESULTS

After conducting repeated VAS measurements for seven days in both the control group created with SS and the test group created with HA Gel, the study determined the days on which statistical significance was observed between the two groups. (p<0.001). The average Visual Analog Scale (VAS) score was at its peak on the first day and reached its lowest point on the seventh day. Upon examining the differences between pairs of days, it was observed that the following pairs had significant differences: first day-third day (p=0.039), first day-fourth day (p=0.002), first day-fifth day (p=0.001), first day-sixth day (p=0.001), first day-seventh day (p<0.001), second day-fifth day (p=0.013), and second day-seventh day (p=0.017). (Figure 2).

In the Conventional Scalpel Surgery+HA group, there was a significant difference in VAS measurements taken at seven different times (p<0.001). The mean VAS score was highest on the first day and lowest on the seventh day. After examining the variations between pairs of days, we have discovered that the following differences are significant: first day-second day (p<0.001), first day-third day (p<0.001), first day-fourth day (p<0.001), first day-fifth day (p<0.001), first day-sixth day (p<0.001), first day-seventh day (p<0.001), and second day-seventh day (p=0.004). (Figure 2).

Table 1 shows variable changes for both groups, but no significant differences were found (p>0.05). When looking at monthly changes, the Conventional Surgery+SS group had a 5.3% decrease and a 5.3% increase in PI values for tooth 11. An increase in PI value was only observed in 5.6% of patients in the Conventional Surgery+HA group for tooth 11 (p = 1.000). When analyzing three monthly changes, 5.3% of the patients in the Conventional Surgery+SS group had a decrease in PI value, while 5.3% had an increase in PI value for tooth 21. An insignificant reduction in PI value was found among only 5.6% of patients in the Conventional Surgery+HA group for tooth 21 (p = 1.000).

In the GI start-three months, it was found that among the patients in the Conventional Surgery+SS group, 11.1% experienced a decrease in GI value, and 5.6% had an increase in GI value on three monthly basis. However, in the Conventional Surgery+HA group, only 11.1% of patients experienced decreased GI value. The difference in results between the two groups was not statistically significant (p = 1,000) for tooth 11. In the GI start-3 month, it was found that among patients in the Conventional Surgery+SS group, 11.1% experienced a decrease in GI value, and 11.1% experienced an increase in GI value on three monthly basis. However, only 5.6% of patients in the Conventional Surgery+HA group experienced a decrease in GI value (p=0.404) for tooth 21, as shown in Table 1.

Pocket depth (PI) starting 3. months Considering three monthly changes, only 5.3% of the patients in the Conventional Surgery+SS group had a decrease in pocket depth value. In comparison, only 11.1% of the patients in the Conventional Surgery+HA group had an increase in pocket depth value (p = 0.354) for tooth 11 the pocket depth starts in three months. Considering the monthly change, only 5.3% of the patients in the Conventional Surgery+SS group had a decrease in pocket depth value. In comparison, 5.6% of the patients in the Conventional Surgery+HA group had a reduction in pocket depth value, and 5.6% had an increase in pocket depth value observed (p=0.736) for tooth 21 (Table 1).

For three months, 6.2% of patients in the Conventional Surgery+SS group experienced an increase in BOP value, compared to only 15.4% of patients in the Conventional Surgery+HA group who showed a decrease in BOP value (p = 0.192) for tooth 11. Over the initial three-month observation period, it was observed that patients in the Conventional Surgery+HA group experienced a decrease in BOP value at a rate of 23.1%. In contrast, only 12.5% of patients in the Conventional Surgery+SS group experienced a similar outcome. These findings are presented in Table 1 (p= 0.632) for tooth 21.

Within the Conventional Surgery+SS group, 26.3% of patients noted a monthly KGW value reduction, whereas 10.5% observed an increase. Conversely, the Conventional Surgery+HA group showed only 5.6% of patients experiencing a decrease, with 16% noting an increase in their KGW value. It's worth noting that seven patients experienced an increase in their

KGW value, though the statistical significance was not particularly strong (p=0.229) for tooth 11. Based on initial-3 data from KGW, there appears to have been a monthly shift in patients' KGW values. In the Conventional Surgery+SS group, 26.3% of individuals experienced a decline, while 5.3% observed an increase. In the Conventional Surgery+HA group, 5.6% noted a decrease, and 11% saw an increase. Furthermore, one patient experienced an increase in their KGW value (p=0,264) for tooth 21 (Table 1).

According to the findings of AGT start-3, it was observed that 21.1% of patients who underwent Conventional Surgery+SS treatment showed an increase in AGT value. In contrast, only 5.6% of patients who underwent Conventional Surgery+HA treatment experienced a decrease in AGT value on three monthly bases (p=0,105) for tooth 11. As per the findings of AGT start-3, a monthly variation in patients' AGT value was detected. Among the patients in the Conventional Surgery+SS group, 26.3% witnessed an increase in AGT value; in the Conventional Surgery+HA group, 11.1% experienced a decrease in AGT value, and 5.6% observed an increase (p = 0.098) for tooth 21.

## DISCUSSION AND CONCLUSION

This research introduces an approach to frenectomy in pediatric patients, utilizing 0.24% HA in conjunction with the conventional scalpel technique. The study examines the effects on periodontal parameters and pain levels during the first week and a three-month follow-up. The null hypothesis was rejected, revealing that a 0.24% HA dose did not significantly change pain values. It was determined that HA gel did not affect PI, GI, PD, BOP, KGW, or AGT parameters.

The frenum is a fold of mucosa that connects the upper lip to the mucosa, overlying the maxillary alveolar process (12). Abnormalities in the size and location of the frenum attachment cause midline diastema, restriction of lip movements during speaking and chewing, and aesthetic problems (2). In cases where the frenum needs to be removed, a surgical procedure called frenectomy is performed to excise it (6). Frenectomy should be performed early, particularly in cases where adequate oral hygiene is not achievable and there is a risk of early childhood caries (2). Relapse (13) and scar tissue formation18 after frenectomy operations performed at early ages are mentioned in the literature. Scalpel surgery was preferred to prevent both relapse and the formation of scar tissue (13), as well as to assist with orthodontic treatment, to assist in orthodontic treatment (4). It is recommended to use dental lasers to overcome these difficulties (10). It is preferred to trade with the scalpel method for fast operating time.

A visual analog scale was used to measure pain levels for patients who underwent frenectomy. Patients marked their pain level each evening. According to this scale, a score of 0 indicates no pain, while 10 signifies excruciating pain. As mentioned in the literature, the VAS scale is commonly used to assess pain levels in children (12–14). Since this study was conducted on pediatric patients, the VAS scale was used in conjunction with Wong-Baker pain scale images, unlike previous studies (15,16).

In children with oral injuries, concerns include retaining topically administered drugs in the wound, uncertain application dosage, and safety if ingested (17,18). High-viscosity HA gel has become increasingly popular among dentists, including treating gingivitis (9), periodontitis (9), oral aphthous ulcers (19), teething pain (20), and promoting wound healing after tooth extraction (9). Upon a search of the literature, only one study evaluated the healing effect of HA after frenectomy (10). However, that research used a diode laser and included adults. From this point of view, the findings of this study hold greater significance.

Before the frenectomy procedure, the participants' periodontal indexes, gum indexes, probing depths, bleeding on probing, keratinized gingiva width, and attached gingiva thickness values were measured before and three months after the treatment. No significant differences were found between the groups at either the first or second postoperative measurement time for any parameter. Upon examination of the literature, no other study resembling ours was found. However, in their studies evaluating similar parameters after classical scalpel technique and laser-assisted frenectomy procedures, Öztürk et al. (8) and Uraz et al. (21) found no significant difference in these parameter values.

There are certain limitations to this research. A larger sample size of patients with frenectomy indica-

tion would have improved the accuracy and clarity of the study results. Performing surgical operations on pediatric patients in a dental chair is difficult. Many patients had to be excluded from the study due to their treatment disrupting research standardization. One of our limitations is that we may not accurately apply topical medical treatments to pediatric patients. All patients who underwent frenectomy had HA administered by their parents. When evaluating research results, it's essential to consider the challenge of controlling children's eating and drinking habits after medical treatments. This study discontinued the monitoring of KGW and AGT parameters after three months. We suggest increasing the number of participants and extending the follow-up period in future studies to validate the obtained results.

After conducting the research, it was concluded that using 0.24% HA with high molecular weight did not effectively reduce postoperative pain in pediatric patients aged 8-14 who underwent frenectomy using classical scalpel surgery. There was no significant change in any measured periodontal parameters among the patients Our research will help to make for similar studies using HA gel with a higher percentage.

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### *Conflict-of-interest and financial disclosure*

The authors declare that they have no conflict of interest to disclose. The authors also declare that they did not receive any financial support for the study.

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