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ORIGINAL ARTICLE

Interdental papilla loss: treatment by hyaluronic acid gel injection: a case series

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Abstract
Objectives The purpose of this prospective clinical trial was to examine the clinical and patient outcomes following esthetic reconstruction of interdental papilla loss in anterior teeth, using an injectable, non-animal-based, hyaluronic acid gel.
Materials and methods Ten systemically healthy adults, with at least one anterior site with class I or II interdental papilla loss, were recruited. Following local anesthesia, ~0.2 ml of hyaluronic acid gel was injected directly into the base of the papilla. The injection was repeated twice 21 days later. Patients were seen monthly for follow-up. Lost papilla surface area was calculated from digital clinical photographs taken at baseline and at 4 and 6 months postoperatively. Differences in lost papilla surface area between baseline and postoperative time points were statistically analyzed. Participants completed questionnaires (satisfaction surveys).
Results Seventeen sites (13 maxillary, 4 mandibular) were treated in 9 females who completed the study. The lost inderdental papilla area at baseline and at the 4- and 6-month postoperative visits was 1.2 ± 1.8 mm^2 (mean ± SD), 0.6 ± 0.9 mm^2, and 0.7 ± 0.7 mm^2, respectively. Differences between baseline and postoperative visits were statistically significant ($p < 0.0001$). Two thirds of the patients would choose to undergo the procedure again.
Conclusions Use of hyaluronic acid gel to treat interdental papilla loss resulted in significant improvement at 6 months. Patients expressed satisfaction with the obtained improvement and dissatisfaction with the associated procedure discomfort.
Clinical relevance Treatment of interdental papilla loss (black triangle) by hyaluronic acid gel injection appears a promising modality to address this esthetic patient concern.

Keywords Esthetics, Dental · Gingiva · Hyaluronic acid · Incisor · Injections · Surgical procedures, minimally invasive

Introduction

The interdental papilla, i.e., the interdental portion of the free gingiva, represents only a small percentage of the visible surface area of oral hard (teeth) and soft (gingiva, alveolar mucosa) tissues [1] and has distinct anatomical, histological, and molecular characteristics [2]. Although small from an anatomic perspective, this part of the gingiva has disproportionately large significance from an esthetic perspective, especially in the anterior dentition, because it is almost universally displayed during smile [3, 4]. The significance of the interdental papilla to smile esthetics can be gleaned from the level of esthetic concern generated either by changes in papilla dimensions [5, 6] or, more importantly, by loss of the papilla ("black triangle" formation) [7]. Loss of interdental papillae and the resulting open gingival embrasures can be attributed to several different factors, such as age, periodontal disease, crown form, root angulation, and interproximal contact position [8, 9].

The esthetic significance of the interdental papilla has stimulated efforts to prevent papilla loss following intraoral surgical procedures by using incision designs that spare or preserve existing papillae [10–13]. It has also led to the development of various non-surgical and surgical/invasive approaches to

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restore lost papillae [9, 14, 15]. Despite the elegance and sophistication of surgical techniques proposed for papilla reconstruction, their predictability remains to be demonstrated [9, 15]. Furthermore, as with other periodontal plastic surgery procedures, patient-reported outcomes are lacking.

Among invasive approaches proposed for papilla reconstruction, the injection of various fillers [16–18] and biological preparations [19] has been investigated either with [17] or without [16, 18, 19] concomitant access flap. Hyaluronic acid gel preparations, long used as dermal fillers [20–22], have been recently used to treat interdental/interimplant papilla loss [16, 18]. Hyaluronic acid is a polysaccharide (glycosaminoglycan) present in body tissues, such as skin and cartilage, and under physiologic conditions it binds to water and swells when in gel form, resulting in smoother/fuller tissue contours [22, 23]. Hyaluronic acid is a high molecular weight ($\geq 10^5$ Da) polymer consisting of disaccharide repeats of *N*-acetylglucosamine and glucuronic acid, with several thousand sugar molecules in the backbone [22, 23]. The viscosity of hyaluronic acid solutions increases with increasing concentrations, and its unique rheological properties make it an ideal lubricant in the biomedical realm [22, 23].

Chemical modification (cross-linking) of hyaluronic acid preparations results in a material that degrades more slowly (because of decreased water solubility) [22, 23]. Hyaluronic acid preparations used as fillers have been manufactured from bacterial or animal sources, and their clinical effects typically last 6–12 months [22]. The purpose of this prospective clinical trial was to examine the clinical and patient outcomes following non-surgical reconstruction of interdental papillae in the anterior teeth, using a non-animal-based hyaluronic acid gel.

Materials and methods

Patient population Patients were recruited among the population seeking treatment in the clinics of the Dental College of King Saud University. Eligibility criteria were as follows: adults (≥18 years old), systemically healthy, with at least one maxillary or mandibular anterior interdental space exhibiting class I or II [24] interdental papilla loss (Fig. 1a). Exclusion criteria were as follows: history of allergic reaction to injectable filler, smoking, pregnancy and lactation, medications affecting the gingiva or wound healing, periodontal surgery in the last 12 months, carious lesions or fixed restorations on study teeth, periodontitis, and poor plaque control (visible plaque present, full mouth plaque score >20 % [25]). The study protocol and associated questionnaires, data collection, and consent forms were approved by the Ethics Committee of the Dental College of King Saud University. Eligible and interested patients were given detailed information about the study procedures and the informed consent form to read at their leisure. All participants provided signed informed consent.

Study procedures Oral hygiene instructions were given to all participants and, when necessary, supragingival debridement prior to study procedures. Subsequently, participants had alginate impressions made of the arch including the study teeth. Impressions were used to prepare stone casts. Digital clinical photographs were taken of study teeth sextants (frontal view), and participants completed questionnaires.

For treatment purposes, patients were given local anesthesia and then approximately 0.2 ml of the cross-linked hyaluronic acid clear gel [1] was injected directly into the middle of the papilla, 2–3 mm apical to the tip of the papilla, using a 23-gauge needle (Fig. 1b). Injection was followed by gentle massage of the area for 1 min. After this initial treatment, the hyaluronic acid injection was repeated at 21 days and then at 42 days. After each treatment session, patients were given postoperative instructions that included (a) a 24-h abstinence from mechanical plaque control in the area, (b) the use of soft toothbrush after the first 24 h, and (c) resumption of routine mechanical oral hygiene after 2 weeks. Patients were seen monthly for follow-up. Clinical photographs were repeated at 4 and 6 months after the first treatment session. All procedures were performed by one operator, who also served as the examiner (i.e., performed measurements as described below).

Clinical photographs were obtained with the same digital single-lens reflex camera (resolution 24.2 megapixel) using a fixed focal length (80 mm) under the same lighting conditions and camera settings. The patients were sitting upright, looking directly ahead (Frankfort plane parallel to the ground), and the camera was held with the lens axis horizontal (parallel to the ground).

Clinical photographs were used to measure the surface area of the lost papilla, using the image analysis software (NIH image J software). Images were imported into the software and calibrated using the crown dimensions measured on the stone cast. The area of interest (in mm^2) was calculated at baseline (prior to the injection) and at 4 and 6 months. Papilla loss area was calculated by measuring the surface area of the visible black triangle using the formula area = 0.5 × height (mm) × base (mm). The percent reduction in black triangle area was calculated by the formula (baseline area − postoperative area) × 100/baseline area. All measurements were executed by a sole calibrated examiner, whose reliability (81 % accuracy within 0.1 mm^2 for class I sites) was assessed by performance of duplicate measurements on four randomly chosen cases.

Data analysis Individual papillae were the unit of analysis. Descriptive statistics were calculated and are reported as mean ± SD and median, interquartile range (IQR). Data normality was tested by Shapiro-Wilks test. Because of the lack

[1] Hyadent BG®, BioScience Gmbh, Germany

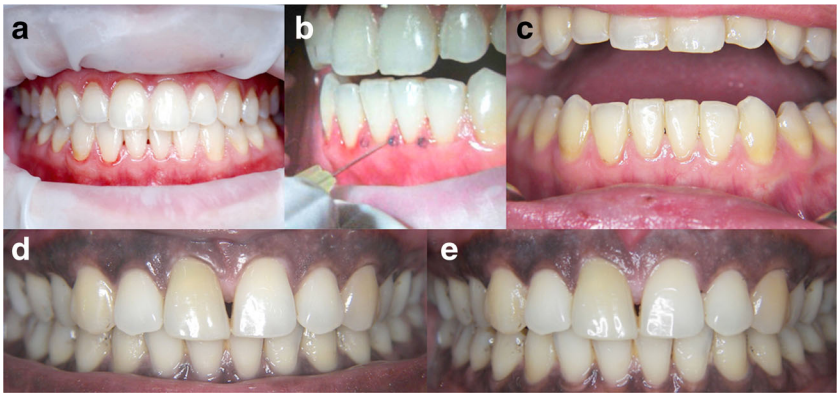

Fig. 1 Clinical images of two representative cases: case 1 (**a**, **b**, **c**) and case 2 (**d**, **e**). **a** Case 1. Immediate pre-operative view; note interdental papilla loss in mandibular anterior teeth. **b** Case 1. Injection of filler. **c** Case 1. Postoperative appearance at 6 months. **d** Case 2. Immediate pre-operative view; note interdental papilla loss in maxillary anterior teeth. **e** Case 2. Postoperative appearance at 6 months.

of normal distribution, differences over time were analyzed by Wilcoxon signed-rank test. Statistical significance was set at $\alpha = 0.05$.

Results

Ten female patients were enrolled in the study and nine completed all study procedures and appointments. One patient was excluded after the third visit, when she revealed she was a smoker. The nine patients whose data were collected and analyzed had an average age of 36.4 years (age range 22–55 years) and 17 anterior sites (13 maxillary, 4 mandibular) with interdental papilla loss. Of the 17 sites, 4 maxillary sites were classified as class II and 13 sites (9 maxillary, 4 mandibular) were classified as class I.

Hyaluronic acid injections were uneventful. Temporary localized effects, such as limited swelling and tenderness at the injection site, were observed/reported and typically lasted for the first 2–3 postoperative days.

The results of the interdental papilla loss area measurements are presented in Table 1 and representative cases are shown in Fig. 1. Differences between baseline and 4 or 6 months were statistically significant ($p < 0.0001$), while there was no statistically significant difference ($p > 0.12$) between the two postoperative time points. The changes from baseline to 4 and 6 months represent an average 62 and 41 % reduction in black triangle area, respectively. At 4 months, 13 sites had ≥50 % reduction in black triangle area with 2 of these sites having complete papilla fill, while at 6 months the corresponding numbers were 8 and 3 sites.

Two of the patients expressed dissatisfaction with the procedure in terms of pain/discomfort during the first postoperative week, while many of the patients (5/9) rated the postoperative discomfort the worst part of the overall experience. About half of the patients (5/9) rated the 1st injection as being worst, while the remaining patients (4/9) rated all injections the same. Patient satisfaction survey outcomes are presented in Table 2. Although patient satisfaction with their smile and the amount of space between the teeth improved post-treatment (Table 2), only 66 % of the patients would choose to undergo the procedure again.

Discussion

The present case series assessed the clinical and patient outcomes after esthetic reconstruction of interdental papilla loss in anterior teeth, using a non-animal-based, injectable hyaluronic acid gel. The results indicate that papillary fill can be obtained, although there is great variability in outcomes and complete fill of the lost papilla area is uncommon (less than 20 % of treated sites). The present study is the first one to document patient-reported outcomes following hyaluronic acid gel injection for inderdental papilla loss. Discomfort following the injections was the primary patient complaint associated with this procedure, while two thirds of the patients would choose to undergo the procedure again.

The potential therapeutic uses of hyaluronic acid, a naturally occurring polysaccharide, in ophthalmology, surgery, and wound healing have been explored since the 1970s [26]. However, the non-surgical use of a hyaluronic acid gel to treat interdental/interimplant papilla loss has only recently been investigated [16, 18]. Becker et al. [16] assessed the effects of a similar hyaluronic acid preparation injected 2–3 times in 14 sites (11 patients) after 6–25 months of follow-up; they reported 100 % improvement in 3 sites and 88–97 % improvement in 8 sites; one site adjacent to an implant had only 57 % improvement. Only 4 of the sites treated by Becker et al. [16] were between natural teeth; the remaining sites were mixed (between natural teeth and implants). Differences in outcomes between the present study and the one by Becker et al. [16]

Table 1 Clinical outcomes

Interdental papilla loss (black triangle area; in mm^2)							
Patient #	Site #	Jaw	Class[†]	Baseline	4 months	6 months	Reduction[#]
1	1	Max	I	0.22	0.00	0.06	72.7
2	2	Mand	I	0.38	0.09	0.00	100
2	3	Mand	I	0.21	0.03	0.00	100
3	4	Max	I	0.05	0.00	0.00	100
4	5	Max	II	2.30	1.30	2.24	2.6
5	6	Max	II	7.71	3.80	2.48	67.8
5	7	Max	I	3.10	1.45	1.40	54.8
6	8	Max	I	0.38	0.18	0.16	57.9
6	9	Max	I	0.34	0.24	0.16	52.9
7	10	Max	I	0.67	0.67	0.67	0
8	11	Max	II	0.47	0.18	0.46	2.1
8	12	Max	II	0.63	0.14	0.57	9.5
8	13	Mand	I	0.84	0.20	0.77	8.3
8	14	Mand	I	1.00	0.22	0.92	8
9	15	Max	I	0.78	0.25	0.60	23.1
9	16	Max	I	0.86	0.28	0.56	34.8
9	17	Max	I	1.11	0.73	1.08	2.7
	Mean ± SD			1.24 ± 1.84	0.57 ± 0.93*	0.71 ± 0.74*	41 ± 37
	Median, IQR			0.67, 0.70	0.22, 0.58	0.57, 0.89	35, 65

Mand mandible, *max* maxilla, *IQR* interquartile range, *SD* standard deviation

[†] Papilla loss classification according to Nordland & Tarnow [24]

[#] Percent reduction at 6 months, compared to baseline

*Significantly different from baseline ($p < 0.0001$)

may relate to differences in the product used or the variable and more extended follow-up in the latter study. The results of Becker et al. [16] suggest that improvements in papilla fill achieved after injection of a hyaluronic acid gel can be

Table 2 Patient satisfaction survey responses

Question and response options	Time point	
	Pre-treatment ($n = 9$)	Post-treatment ($n = 9$)
How satisfied are you with your smile?		
Not at all satisfied	1 (11 %)	1 (11 %)
Slightly satisfied	1 (11 %)	1 (11 %)
Somewhat satisfied	5 (55 %)	1 (11 %)
Very satisfied	2 (22 %)	6 (67 %)
Extremely satisfied	–	–
How satisfied are you with the black space showing between your teeth?		
Not at all satisfied	3 (33 %)	–
Slightly satisfied	6 (67 %)	2 (22 %)
Somewhat satisfied	–	7 (78 %)
Very satisfied	–	–
Extremely satisfied	–	–
Having had this overall experience, would you choose to have the injection procedure again?		
Definitely would not		2 (22 %)
Probably would not		1 (11 %)
Probably would		4 (44 %)
Definitely would		2 (22 %)

maintained for periods of up to 2 years. Mansouri et al. [18] used an unidentified hyaluronic acid gel preparation to treat 21 sites (11 patients) with 3 and 6 months follow-up and reported that the average improvement was 47 % at 6 months (43 % of sites had 50 % improvement at 6 months). Despite possible differences in material used, treatment, and follow-up protocols, the results of the Mansouri et al. study [18] (at 6 months 43 % of cases had >50 % improvement) and of the present study (47 % of sites had >50 % improvement at 6 months) are similar. A common limitation among the present and previous studies [16, 18] is the relatively small number of patients/sites treated and the use of 2-dimensional analysis, which does not provide information on the obtained volume changes.

Besides the present study, only Mansouri et al. [18] reported longitudinal assessment of patients after hyaluronic acid treatment for papilla loss. Although the results of the two studies are similar at 6 months (see paragraph above), the apparent course over time is opposite. Mansouri et al. [18] reported improvement over time, while in the present study there was relapse between 4 and 6 months. Such disparities may relate to the specific material used and the apparent difference in size of the treated defects.

The results of the present study revealed that, from a patient's perspective, the worst aspect of this procedure was the postoperative discomfort while the procedure improved the esthetics of the smile and the papillary space. Two thirds of the patients reported they would likely undergo the procedure again. Future randomized clinical trials, which might include a placebo group, should help ascertain whether the reported discomfort is material specific or related to the procedure itself (intrapapillary injection).

The material used in the present study is a non-animal-based, clear gel, composed primarily of low molecular weight hyaluronic acid, which has been successfully used as a filler to address facial wrinkles, unsatisfactory lip fullness, and other consequences of inadequate soft tissue volume [27]. The use of a non-animal product minimizes the possibility of allergic reactions [28]. "Black triangles," i.e., the loss of interdental gingival papillae, represent a unique esthetic concern originating from reduced intraoral soft tissue volume. The use of a non-immunogenic filler with excellent benefit-risk profile, such as a hyaluronic acid gel [21], is a promising non-surgical approach in the management of lost interdental papillae.

As mentioned previously, injection of hyaluronic acid is just one of the many methods used in an effort to restore or reconstruct lost interdental papillae [9, 14, 15]. The various approaches to manage a black triangle can be categorized as non-invasive and invasive. The non-invasive approaches include orthodontic tooth movement and/or interproximal enamel reduction (stripping) [9, 29], restorative treatment [9], and non-surgical periodontal instrumentation [30]. The invasive approaches can be categorized as non-surgical and surgical. The local injection [16, 18, 19] of fillers and other materials comprises the non-surgical or minimally invasive approaches. The surgical approaches reported in the literature vary from limited, localized flap procedures [31] to flaps combined with biological preparations [17, 32] or soft tissue grafts [33–36] to soft tissue grafts applied by microsurgical techniques [37] and to flaps combined with both hard and soft tissue grafts [38, 39]. The more invasive approaches are typically accompanied by greater morbidity, while they possibly provide more stable results on long-term scale. However, the limitation of all reported techniques is the lack of proven predictability, of strong clinical evidence, and of patient-reported outcomes. Therefore, a great need remains for robust clinical trials to properly assess the various approaches for papilla reconstruction, in order to provide clinicians with the means to predictably solve this esthetic problem.

In conclusion, the use of a commercially available hyaluronic acid gel for the treatment of esthetic interdental papilla deficiency was somewhat effective, when assessed up to 6 months post-treatment, and was associated with promising levels of patient satisfaction. Future studies are needed to ascertain long-term outcomes and determine the appropriate time period for re-treatment, identify pre-treatment determinants of positive outcomes and patient satisfaction, as well as perform comparisons between different available materials.

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Compliance with ethical standards

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Conflict of interest The authors declare that they have no competing interests.

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