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IP International Journal of Periodontology and Implantology

Journal homepage: https://www.ijpi.in/

Original Research Article

Efficacy of hyaluronic acid dermal filler for soft tissue augmentation around dental implants- A clinical study

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ARTICLE INFO

Article history:
Received 03-09-2024
Accepted 28-10-2024
Available online 14-12-2024

Keywords:
Dental implant
Hyaluronan
Dermal filler
Papillary height
Interdental papillary deficiency

ABSTRACT

Introduction: The success of dental implant is based on direct contact between supporting alveolar bone and implants. Traditional surgical approaches to manage soft tissue discrepancies have shown initial good results, but virtually there is a significant reduction of tissue that may occur as soft tissue matures often. Minimally invasive procedures such as dermal fillers may be suitable alternative to correct soft tissue discrepancies.

Aims & Objectives: The aim of our study is to clinically evaluate efficacy of hyaluronic acid dermal filler for soft tissue augmentation around dental implants in Seibert's class I/II ridges with minimal soft tissue deficiency.

Materials and Methods: A total of 5 (1 female and 4 males) systematically healthy implant patients with single/ partially edentulous site in maxillary/mandibular region with minimal soft tissue deficiency were randomly selected and treated for soft tissue augmentation with 1% hyaluronic dermal filler. All the patients were evaluated for soft tissue parameters of soft tissue thickness, keratinized tissue width, papillary soft tissue horizontal width, papillary recession depth and papillary index score at baseline, 45th and 90th day after soft tissue augmentation.

Results: At 45^{th} day width of soft tissue (Mesial Papilla, Mid buccal point and distal papilla), Width of keratinized mucosa, soft tissue horizontal width (buccal and lingual point), papillary recession depth, showed statistically significant difference but no significant difference seen between 45 days and 90 days.

Conclusion: Injecting hyaluronic acid helped in improving various parameters but for a short period of time only.

1. Introduction

The introduction of dental implants over the past years has expanded the therapeutic options in various clinical situations. In order to achieve predictable long-term tissue stability; functional, biological and aesthetic considerations need to be made. A variety of clinical and radiographic parameters have been identified to predict and evaluate long-term success from biologic and aesthetic (subjective and objective parameters) perspective which include papilla height, biologic width, soft tissue level, amount of soft tissue and width of keratinized mucosa.[1] Tissues adjacent to a dental implant should be in harmony with adjacent teeth or implants and present with minimal to an absence of soft tissue deficiencies between the implant and adjacent natural teeth.[2] The amount of soft tissue volume can influence the aesthetic outcome and may even partly compensate for missing bone on the buccal side of the dental implants.[3]

In the aesthetic zone, the level of crestal and interproximal bone as well as the quality and quantity of soft tissue surrounding pre- existing teeth may be a critical factor for the success, and therefore must be considered

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https://doi.org/10.18231/j.ijpi.2024.040

in the treatment planning stages.[3] Thicker band (>2 mm) of keratinized mucosa (KM) renders the gingiva more resistant to recession with respect to soft tissue volume augmentation. Only a limited number of studies have been reported thus rendering a weak level of evidence.[3]

Historically, the methods to augment keratinized mucosa included an apically positioned flap (APF), APF/vestibuloplasty, APF/ vestibuloplasty plus autogenous tissue/allogenic soft tissue substitute/collagen matrix. The disadvantages of using autogenous tissues are mainly due to harvesting procedure, prolonged healing time and patient morbidity.[4] There is a need for development of alternative techniques and materials that fulfils the demands of soft tissue volume augmentation but reduces morbidity, increases reliability and eliminates the need for autogenous tissue.

Recent advances have highlighted the clinical use of hyaluronic acid (HA) in the dental implantology for soft tissue healing and osseointegration. Hyaluronic acid has also been successfully used to reconstruct lost interdental papilla around implants.[2] It is a naturally occurring non-sulphated glycosaminoglycan found in connective tissue, synovial fluid of joints and vitreous humor of the eye. It has unique hygroscopic, rheologic and viscoelastic properties, that affects cellular behavior by modulating the macro and micro-environment around the cells. It has functions like cell proliferation, recognition and loco-motion that contributes to its tissue healing properties.[5]

Bioengineered hyaluronic acid derivatives provide safe, effective soft tissue augmentation in non-surgical facial rejuvenation but in the field of dentistry**,** these clinical results need to be further strengthened by controlled clinical trials. Hyaluronic acid may be tried as non-invasive treatment for soft tissue augmentation around dental implants. However, limited clinical trials report the use of hyaluronic acid dermal fillers to enhance keratinized mucosa around dental implants.[6,7]

Therefore, in the light of above facts, this study was conducted to evaluate the efficacy of hyaluronic acid dermal filler for soft tissue augmentation around dental implants in Seibert's class I/II ridges with minimal soft tissue deficiency.[8]

2. Materials and Methods

2.1. Study population

For the proposed study, a total of 5 systemically healthy implant patients were selected from the Outpatient Department of National Dental College and Hospital, Dera Bassi, Punjab after being tested negative for allergy to hyaluronic acid. An ethical approval for the study was obtained from the Institutional Ethical Board Committee at National Dental College and Hospital, Dera Bassi, Punjab**.** Each patient signed the consent form prior to commencement of the study. Before starting the study, ethical approval from the institutional review board of National Dental College, Dera Bassi was obtained for conducting the study.

2.2. Inclusion criteria

Patients were included in the study if they were healthy adults between 20-60 years of age irrespective of gender, having Single/ partially edentulous site in maxillary/ mandibular region with minimal soft tissue deficiency (Seibert's class I/II classification system), with the esthetic concern and healthy, sufficient and stable soft tissue architecture.

2.3. Exclusion criteria

Patients were excluded if they had any systemic disease, known allergy to hyaluronic acid, Pregnant and lactating women. The patients who had regular intake of medicines such as steroids which may affect the connective tissue metabolism.

2.4. Methodology

In the present clinical trial, a total of 5 implant patients in the age were selected and treated for soft tissue augmentation with 1% hyaluronic acid dermal filler (MCCM Hyaluronic Acid 1% Professional)(Figure 1). A surgical stent was made with holes at three sites, mesial papilla, distal papilla and mid buccal point around 2 mm apical to the tooth surface. 0.2 ml hinjected at eachsite, was repeated after a week.(Figure 2A,B)(Figure 2A,B)

Figure 1: MCCM hyaluronic acid 1% professional

Clinical parameters were recorded at baseline, 45^{th} day and 90^{th} day. All patients underwent a full mouth scaling using ultrasonic scalers and hand instrumentation.

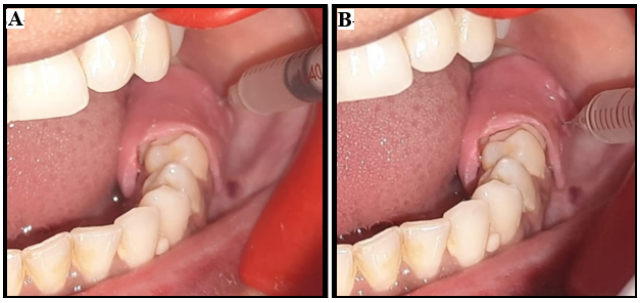

Figure 2: A: Hyaluronic injection at baseline (Case 1); **B:** Hyaluronic injection after 1 week (Case 1)

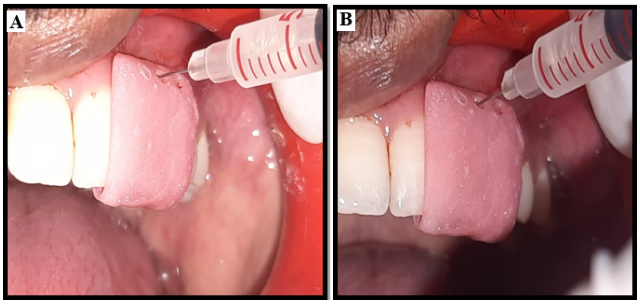

Figure 3: A: Hyaluronic injection at baseline (Case 2); **B:** Hyaluronic injection after 1 week (Case 2)

2.5. Assessment of clinical parameter

The clinical parameters were tabulated and put to statistical analysis.

2.6. Clinical parameters

All the clinical parameters were recorded and evaluated at base line, 45th day and 90th day after soft tissue augmentation. Parameters were recorded with UNC-15 probe.

1. Soft tissue thickness**:** It was measured at the base of mesial and distal papilla and at the mid buccal point using standardized acrylic stent.
2. Width of keratinized mucosa (ktm)**:** It waws measured from most apical gingival margin to the mucogingival junction and the location will be determined using Lugol's iodine solution.
3. Soft tissue horizontal width**:** It was measured at most prominent buccal and lingual point on the ridge using vernier caliper
4. Papillary recession reduction**:** The distance from the tip of the papilla to the base of contact point was measured to the nearest millimeter using UNC 15 probe. It was recorded on 90th day.
5. Papillary recession depth**:** It was measured as a distance between the base of the contact point to the tip of the papilla in between the dental implant and adjacent natural tooth (CP-GM)
6. Papillary index score (pis) jemt's classification (1997)**:** It was clinically measured and recorded at 45th day and 90th day

2.7. Statistical analysis

The parameters were tabulated and put to statistical analysis. The data for the present study was entered in the Microsoft Excel 2007 and analyzed using the SPSS statistical software 23.0 Version. The descriptive statistics included mean, standard deviation frequency and percentage. The intragroup comparison for the different time intervals was done using Paired t-tests to find the difference between the individual time intervals. The level of the significance for the present study was fixed at 5%. The intergroup comparison for the difference of mean scores between independent groups was done using the one-way ANOVA and Post Hoc Tukey Analysis.

3. Results

The present study was conducted on 5 patients (1 female and 4 males) with single/ partially edentulous site in maxillary/mandibular region with minimal soft tissue deficiency were randomly selected and treated for soft tissue augmentation with 1% hyaluronic dermal filler.(Table 1)

3.1. The soft tissue thickness results

The soft tissue thickness was measured at three points mesial papilla, mid buccal point and distal papilla.

When the thickness of all the three points, Mesial Papilla, Mid buccal point and distal papilla were compared between baseline and at 45^{th} day, there was statistically significant difference with ($p < 0.05$) and it was also significant when compared between baseline and at 90^{th} day. But when the thickness was compared between 45 days and 90 days, the mean thickness did not differ significantly and at different intervals of time as well, no significant change was observed ($p => 0.05$). (Figure 4)

This showed that after injecting HA gel into the interdental papillary area, the thickness of the soft tissues changes clinically and statistically when compared from baseline to 45 days and baseline to 90 days. (Figure 5)

3.2. Width of keratinized mucosa (ktm)

The statistical results for width of keratinized Mucosa showed significant difference when compared between baseline and after 45 days as well as between baseline and 90 days, the mean value was significant ($p< 0.05$) and ($p0.05$) respectively.(Figure 6) However, the comparison between 45 days and 90 days, the mean width did not differ significantly ($p > 0.05$) yet signficant changes were observed when width of Keratinized mucosa was compared

Table 1: The compiled results of the study were tabulated

Table: Descriptive statistics										
Particulars		**N**	**Mean**	**±SD**	**SE**	**95% Confidence Interval for Mean**		**Minimum**	**Maximum**	**P-Value**
						Lower Bound	**Upper Bound**			
Soft tissue thickness										
Mesial papilla	Baseline	5	5.600	3.209	1.435	1.615	9.585	3.000	10.000	
	45 days	5	7.000	3.742	1.673	2.354	11.646	4.000	12.000	0.659
	90 days	5	7.700	3.931	1.758	2.820	12.581	4.500	12.000	
Distal papilla	Baseline	5	7.100	2.460	1.100	4.046	10.154	3.500	10.000	
	45 days	5	8.000	2.151	0.962	5.330	10.670	4.500	10.000	0.625
	90 days	5	8.500	2.179	0.975	5.794	11.206	5.000	10.500	
Mid buccal point	Baseline	5	6.300	1.718	0.768	4.167	8.433	3.500	8.000	
	45 days	5	7.400	1.949	0.872	4.980	9.820	4.000	9.000	0.441
	90 days	5	7.800	1.891	0.846	5.452	10.148	4.500	9.000	
Width of keratinized mucosa	Baseline	5	2.800	0.274	0.122	2.460	3.140	2.500	3.000	
	45 days	5	4.000	0.707	0.316	3.122	4.878	3.000	5.000	0.006*
	90 days	5	4.300	0.758	0.339	3.359	5.242	3.000	5.000	
Soft tissue horizontal width										
Buccal point	Baseline	5	4.300	0.274	0.122	3.960	4.640	4.000	4.500	
	45 days	5	5.400	0.418	0.187	4.881	5.919	5.000	6.000	0.001*
	90 days	5	5.400	0.418	0.187	4.881	5.919	5.000	6.000	
Lingual point	Baseline	5	3.900	0.224	0.100	3.622	4.178	3.500	4.000	
	45 days	5	5.100	0.224	0.100	4.822	5.378	5.000	5.500	0.001*
	90 days	5	5.100	0.224	0.100	4.822	5.378	5.000	5.500	
Papillary reduction (PRR)	recession	5	1.600	0.548	0.245	0.920	2.280	1.000	2.000	0.1
Papillary index score (PIS)	Baseline	5	1.400	0.548	0.245	0.720	2.080	1.000	2.000	
	45 days	5	1.800	0.447	0.200	1.245	2.355	1.000	2.000	0.1
	90 days	5	2.000	0.000	0.000	2.000	2.000	2.000	2.000	
Papillary recession depth (PRD)	Baseline	5	3.500	1.414	0.632	1.744	5.256	2.000	5.000	
	45 days	5	2.700	1.304	0.583	1.081	4.319	1.000	4.500	0.035*
	90 days	5	2.300	1.304	0.583	0.681	3.919	1.000	4.000	

at different intervals of time. (Figure 7)

3.3. Soft tissue horizontal width

The soft tissue thickness was measured at two points, Buccal point and Lingual point. When the thickness of both the points was compared between baseline and at 45^{th} day, there was statistically significant difference with ($p < 0.05$) The mean width of buccal point increased to 5.400 after 90 days from 4.300 at baseline, while It was 5.400 at 45 days and the mean width increased to 5.100 after 90 days from 3.900 at baseline, and for the lingual point, it was 5.100 at 45 days The mean width increased to 5.100 after 90 days from 3.900 at baseline, while it was 5.100 at 45 days.

3.4. Papillary recession reduction

Papillary recession reduction when observed between baseline and after 90 days, The stastical results were non-significant (p=0.1 i.e. < 0.05).

3.5. Papillary recession depth

No signficant change was observed when the papillary recession depth (PRD) was compared at different intervals of time whereas the papillary recession depth (PRD) when compared between baseline and after 45 days, the mean value showed a significant difference ($p< 0.05$). It also showed a significant difference ($p< 0.05$) when there was comparison between baseline and after 90 days however when the papillary recession depth (PRD) was compared between 45 days and after 90 days, the mean value did not differ significantly (p= 0.909 i.e.p> 0.05).(Figures 8 and 9)

3.6. Papillary index score (PIS) jemt's classification (1997)

No significant change was observed when the Papillary index score (PIS)(p=0.100) was compared at different intervals of time. It was non-significant ($p > 0.05$) when compared between baseline and after 45 days, also non-significant (p> 0.05) between baseline and after 90 days,

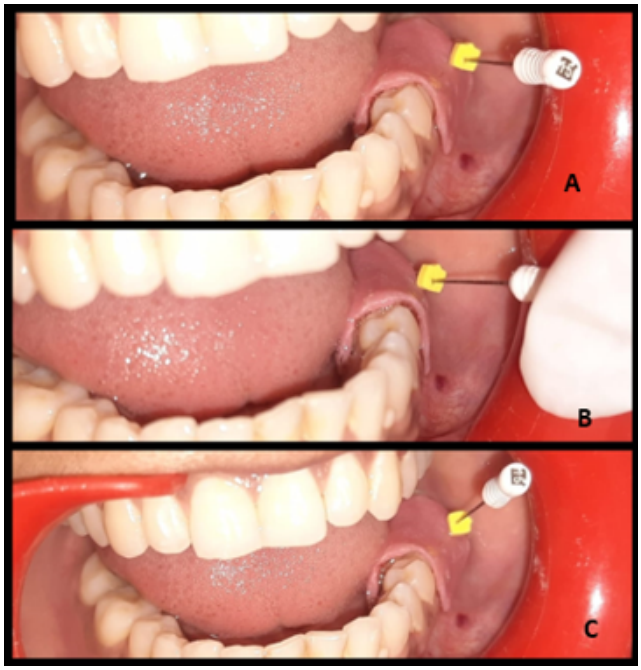

Figure 4: (Case-1) Measurement of soft tissue thickness using an Endodontic file; **A:** At baseline; **B:** After 45 days; **C:** After 90 days

Figure 5: (Case-2) Measurement of soft tissue thickness using an Endodontic file; **A:** At baseline; **B:** After 45 days; **C:** After 90 days

Figure 6: (Case-1) Measurement of width of keratinized mucosa using Lugol's iodine solution; **A:** At baseline; **B:** After 45 days; **C:** After 90 days

Figure 7: (Case-2) Measurement of width of keratinized mucosa using Lugol's iodine solution; **A:** At baseline; **B:** After 45 days; **C:** After 90 days

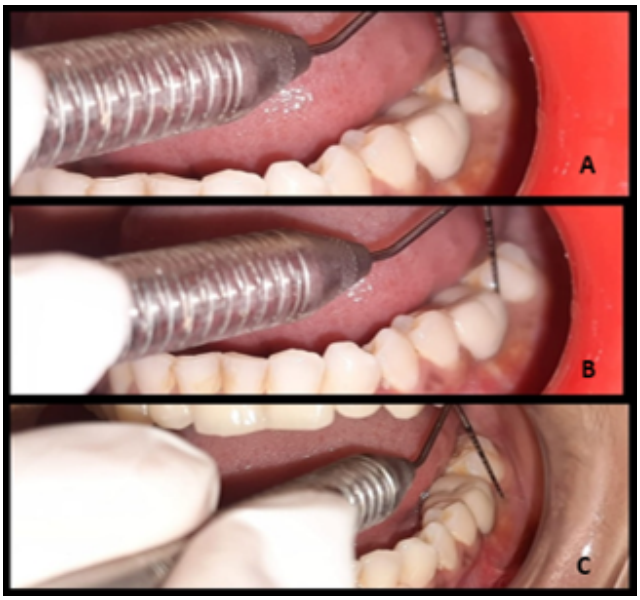

Figure 8: (Case-1) Measurement of Papillary recession depth using UNC-15 probe; **A:** At baseline; **B:** After 45 days; **C:** After 90 days

Figure 9: (Case-2) Measurement of Papillary recession depth using UNC-15 probe; **A:** At baseline; **B:** After 45 days; **C:** After 90 days

furthermore the PAPILLARY INDEX SCORE (PIS) when compared between 45 days and after 90 days, the mean score did not differ significantly (p=0.374 i.e.p> 0.05).

4. Discussion

This study aimed to assess the effect of injection of HA gel compared for the reconstruction of soft tissue deficiency around the implant. This was presented as the change in soft tissue thickness, keratinized tissue width, papillary soft tissue horizontal width, papillary recession depth and papillary index score at baseline, 45^{th} and 90^{th} day and Papillary recession reduction after 90 days.

Hyaluronic acid has been successfully used as a filler to address facial wrinkles, lip fullness, and other consequences of inadequate soft tissue volume. It is one of the most hygroscopic molecules known in nature. When HA is incorporated into aqueous solution, hydrogen bonding occurs between adjacent carboxyl and N‑acetyl groups; this feature allows HA to maintain conformational stiffness and to retain water. One gram of HA can bind up to 6 L of water. As a physical background material.[9]

The current study was initiated on the basis of promising results presented in a recent case series report by (Becker et al. 2010).[8] In this report, it was described that 2– 3 HY injections of cross-linked HY (a different product than the one used herein) in interdental and interproximal papillae at implants (i.e., 4 and 10 papillae, respectively) resulted in significant closure of the "black triangles." In almost 1/3 of the cases, complete closure was observed, while in half of the cases, closure was between 94 and 97%; only one case showed a limited closure of about 60%.

Whereas a study conducted by (Bertl et al. 2016),[10] did not show much promising results. In this study, twenty-two patients with a deficient papilla in the anterior maxilla next to an implant supported crown were randomly assigned to receive twice either HY (test) or saline solution (control) injection. The following parameters were recorded prior to injection (baseline) and 3 and 6 months after injection: distance between the papilla tip and contact point (PT-CP),[11,12] modified papilla index score (MPIS),[13] and standard clinical periodontal parameters.[13,14] Pain level after injection was recorded on a visual analogue scale (VAS). The deficient area was evaluated on clinical photographs, and the esthetic appearance was recorded on a VAS. Differences in mucosal volume were assessed after 3 months by intraoral scans. The bone level was assessed on periapical radiographs. The results showed no differences between groups, neither at baseline nor at 3 and 6 months post-treatment. Mean PT-CP,[15] ranged between 1.8 mm and 2.3 mm without significant differences between groups or over time within groups; MPIS was 2 for all patients at all-time points. Similarly, insignificant differences between groups or time points were observed for deficient area, gingival volume changes, bone level,

and esthetic appearance. There were no differences in pain level between groups during injection, but discomfort after injection lasted longer in the test group. While comparing it, our present study also did not show any significant change in the papillary recession depth (PRD)[16] at different intervals of time whereas when it was compared between baseline and after 45 days, the mean value showed a significant difference (p=0.035 i.e. < 0.05). It also showed a significant difference (p=0.004 i.e. < 0.05) when there was comparison between baseline and after 90 days however, when the papillary recession depth (PRD) was compared between 45 days and after 90 days, the mean value did not differ significantly (p= 0.909 i.e. p> 0.05). Similarly, there was no significant change observed when the Papillary index score (PIS)(p=0.100) was compared at different intervals of time. It was non-significant (p=0.178 i.e. p> 0.05) when compared between baseline and after 45 days, also non-significant (p=0.07 i.e. p> 0.05) between baseline and after 90 days and it did not show any significant difference (p=0.374 i.e. p> 0.05) between 45 days and after 90 days as well.

In a study conducted by Alhabashneh et al. 2020[17] there was a statistically significant decrease in black triangle height measurements over the 6 months periods following HA injections. HA injection showed a clinically demonstrable reduction to black triangle height of about 8%, 39%, and 29% at 3 weeks, 3 and 6 months, respectively. From the third to sixth months, the black triangle height increased significantly by 0.21 mm (10%) but it was still significantly lower than the baseline measurements. This can be explained by the fact that HA degrades naturally in the body, and therefore, the duration of maintenance of the injectable HA gel is critical.[17] The patient should be aware of the duration of improvement with such protocol before commencing treatment and this should be included in the informed consent.

5. Conclusion

Within the limitations of this study, it can be concluded that the use of commercially available Hyaluronic acid dermal filler for the soft tissue augmentation around implant is a procedure with promising results over the first 45 days after injection. The maximum improvement in various parameters was at 45^{th} day after injection with a not much improvement between 45^{th} day and 90^{th} day. This trial paves the way for future studies to determine the most appropriable protocol of HA injection yet long- term follow-up with more sample size will further establish HA as minimally invasive technique for soft tissue augmentation around implant.

6. Source of Funding

None.

7. Conflict of Interest

None.

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Cite this article: Kaur H, Kaur G, Kaur N. Efficacy of hyaluronic acid dermal filler for soft tissue augmentation around dental implants- A clinical study. *IP Int J Periodontol Implantol* 2024;9(4):195-202.