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Evaluating socket management with clot-retaining collagen: A single-blind randomized clinical trial

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Abstract

Objective: The present single-blind split-mouth randomized clinical trial aimed to evaluate the effect of socket management with clot-retaining collagen (Collacone®) on post-extraction socket healing.

Methods: Sixteen participants (20 pairs of sockets) were included, and underwent bilateral premolar extraction using an atraumatic extraction technique. For each patient, one socket remained empty, whereas Collacone® was placed on the contralateral side. Both sockets were sutured, and buccolingual (BL) and mesiodistal (MD) socket widths were measured. Furthermore, pain, comfort, bleeding, and swelling levels were recorded at baseline and two and four weeks after extraction. Data were analyzed with the repeated measures ANOVA (α=0.05).

Results: The study included 11 females and five males with an average age of 32±5 years. The MD and BL widths of the extraction sockets decreased significantly in the experimental and control groups over 4 weeks (P<0.001). The BL and MD width of the extraction sockets were comparable between the groups at all time points (P>0.05). No significant differences were found in pain, comfort, bleeding, and swelling levels between the groups at 2 and 4 weeks post-extraction (P>0.05).

Conclusions: The application of Collacone® following atraumatic tooth extraction does not offer any advantages in preserving socket dimensions and reducing patients' pain, comfort, bleeding, and swelling levels in healthy young individuals.

Keywords: Alveolar ridge augmentation, Bone regeneration, Collagen, Immediate implant loading, Tooth extraction, Tooth socket

Introduction

Following tooth extraction, the alveolar bone undergoes significant morphological alterations, which are more prominent between 4 and 6 weeks after tooth removal (1). During the first six months after extraction, post-extraction socket healing results in an average horizontal bone loss of 3.8 mm and vertical bone loss of 1.2 mm (2). This process is mainly characterized by significant buccal bone degradation due to the limited blood supply to the thin bone plate. Bone loss continues slowly and alters ridge morphology (3).

Bone resorption post-extraction frequently impedes conventional prosthetic treatments and complicates optimal dental implant placement due to insufficient hard and soft tissue volumes (4). Insufficient bone volume may also reduce the primary stability and long-term prognosis of the implant (5). Therefore, effective socket management strategies have been suggested to mitigate these challenges (2).

Socket preservation immediately after tooth extraction can increase keratinized gingiva and improve the esthetic, function, and prognosis of future implants (1, 2). Bone substitutes, including autografts, allografts, xenografts, and alloplastic materials, are commonly used for alveolar ridge preservation. These materials reduce soft and hard tissue alterations but may not completely prevent bone resorption (2).

Collacone® (Botiss Biomaterials Co, Berlin, Germany) is a resorbable collagen sponge derived from animal sources, making it a type of xenograft. Xenografts are biocompatible and act as osteoconductive scaffolds.

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Collacone® is composed of 75–96% natural absorbable collagen and is specifically designed to facilitate post-extraction healing by promoting blood clot formation, stabilizing the socket, and accelerating soft tissue and hard tissue regeneration. Collacone® is completely absorbed within 2–4 weeks, which ensures effective integration without additional removal procedures (6). Collacone® sponges absorb tissue exudate, adhere gently to wounds, maintain moisture, and protect against mechanical damage and bacterial infections (7-9). Therefore, Collacone® may be suitable for socket preservation (10).

Previous studies have demonstrated the benefits of alveolar ridge preservation following tooth extraction. For instance, Walker et al. (11) found that alveolar ridge preservation significantly prevented the loss of buccal ridge height compared to natural healing, although ridge width loss remained similar across groups. A systematic review reinforced these findings, highlighting the effectiveness of alveolar ridge preservation in mitigating vertical bone loss, albeit with variability in horizontal bone preservation (12).

While Collacone® has shown promise in promoting socket repair and hemostasis (13), its efficacy in preserving alveolar dimensions and reducing postoperative sequelae after conservative tooth extraction has not been sufficiently explored. This study aimed to evaluate the effectiveness of Collacone® for socket preservation after conservative tooth extractions.

Materials and method

Participants

This split-mouth, single-blind clinical trial was approved by the ethics committee of Shahid Beheshti University of Medical Sciences (IR.SBMU.RIDS.REC.1396.458) and registered in the Iranian Registry of Clinical Trials (IRCT code: IRCT20241204063947N1).

Sixteen patients with 20 pairs of sockets were included in this study. The sample size was determined according to the findings of Walker et al. (11), considering α=0.05 and β=0.8. Participants were selected from those referred to the Department of Oral and Maxillofacial Surgery at Shahid Beheshti University of Medical Sciences for bilateral premolar extraction. Exclusion criteria were systemic diseases, medications including antibiotics and immune-suppressor drugs, smoking, carious teeth, periodontal diseases, infection history, or periapical pain. The goals of the study were explained to the patients or their parents, and written informed consent was obtained from the participants.

Intervention

Teeth were anesthetized (Persocaine-E; Daroupakhsh, Tehran, Iran), and periodontal ligaments were detached using a periosteal elevator. Conservative bilateral extractions were performed in one session with a pair of universal extraction forceps (Aesculap Co, USA) under vertical and rotational pressure. Two patients required bilateral extraction of mandibular premolars. The mandibular extractions were performed two weeks after the extraction of the maxillary teeth for these patients.

One socket was randomly selected via a random numbers table and served as the study group for each patient. Following extraction, a collagen sponge (Collacone®) was placed in the socket on the experimental side. The opening was then sutured with a horizontal mattress using 4-0 polyglactin absorbable sutures (Vicryl, Ethicon, Johnson & Johnson, NJ). The contralateral socket (control group) was sutured similarly without adding the collagen material.

Postoperative care instructions were provided, including oral hygiene guidance and dietary recommendations. If the patients had severe pain, they were recommended to take Gelofen (Daana Pharma, Iran). Sutures were removed one week postoperatively.

Variable measurements

Immediately after the extraction, the mesiodistal (MD) socket width was measured using a caliper. The buccolingual (BL) width was assessed with a Williams probe (Hu-Friedy Co., USA). The BL and MD widths of the extraction sockets were measured again two and four weeks after the procedure.

The following items were also evaluated at the follow-up visits:

- Pain level: The patient's pain level was evaluated using a 10-cm visual analog scale (VAS), where 0 indicates no pain, and 10 signifies the highest pain level.
- Comfort level: The patient's comfort level was evaluated using the visual analog scale (VAS), where 0 indicates total discomfort and 10 signifies complete comfort. This index was assessed postoperatively, considering the comfort level of patients in activities, such as chewing, speech, sleep, and other routine activities.
- Oozing: In this study ‘oozing’ was defined as the slow, continuous leakage of a small amount of

Table 1. Mean±standard deviation (SD) of mesiodistal and buccolingual socket widths in the study groups at different time points

Time point	Mesiodistal width			Buccolingual width		
	Experimental Mean±SD	Control Mean±SD	P value	Experimental Mean±SD	Control Mean±SD	P value
Baseline	5.70 ± 1.08^{A}	5.50 ± 1.00^{A}	0.67	7.75 ± 1.21^{A}	7.90 ± 1.52^{A}	0.073
2 Weeks	3.05 ± 0.99^{B}	2.85 ± 0.81^{B}	0.48	3.70 ± 0.87^{B}	3.80 ± 1.15^{B}	0.75
4 Weeks	1.65 ± 0.93^{C}	1.45 ± 0.69^{C}	0.44	2.05 ± 1.10^{C}	2.10 ± 1.21^{C}	0.89
P value	<0.001*	<0.001*		<0.001*	<0.001*	

*Values less than 0.05 represent a significant difference between the groups according to repeated measures ANOVA.
In each column, different uppercase letters represent a significant difference between the groups according to theBonferroni test.

blood from the extraction site. This mild bleeding typically occurred within the first 12 to 48 hours after the procedure and did not require medical intervention. The presence or absence of oozing (mild bleeding) from the extraction site was recorded in the patient's form.

- Swelling: The presence or absence of swelling was recorded in the patient's form.

Statistical analysis

Data normality was assessed using the Kolmogorov-Smirnov test (P>0.05). Changes in socket dimensions were analyzed by repeated-measures ANOVA. A paired t-test was used to compare the pain and comfort levels between the study groups. Data analysis was performed using SPSS 26.0 (IBM Inc., Armonk, NY, USA). Values less than 0.05 were considered statistically significant.

Results

The study included 20 dental sockets for 16 patients (11 females and five males). The mean age of participants was 32 ± 5 years. No complications were observed following conservative extraction, and all patients' healing processes were acceptable. However, two patients were excluded since they did not attend follow-ups.

Table 1 shows the MD and BL widths of the extraction sockets in the study groups. Regarding MD socket width, the mean on the experimental side at baseline was 5.70 ± 1.08 mm, which decreased to 3.05 ± 0.99 mm after 2 weeks and 1.65 ± 0.93 mm after 4 weeks. On the control side, the baseline mean value was 5.50 ± 1.00 mm, which decreased to 2.85 ± 0.81 mm after two weeks and 1.45 ± 0.69 mm after four weeks. On both sides, the MD socket width decreased significantly over time (P<0.001), with a significant difference between all intervals (P<0.05).

Regarding BL socket width, the mean on the experimental side at baseline was 7.75 ± 1.21 mm, which decreased to 3.70 ± 0.87 mm and 2.05 ± 1.10 mm after two and four weeks, respectively. On the control side, the baseline value was 7.90 ± 1.52 mm, which decreased to 3.80 ± 1.15 mm and 2.10 ± 1.21 mm after two and four weeks, respectively. On both sides, the MD socket width decreased significantly over time (P<0.001), with a significant difference between all intervals (P<0.05).

Between-group comparisons revealed that the MD and BL widths were comparable between the groups at all intervals (P>0.05; Table 1).

Table 2 shows the pain and comfort level of patients on both sides. The VAS score for pain decreased, and the patient's comfort increased over the experiment. No

Table 2. Mean±standard deviation (SD) of pain and comfort levels among the study groups at different time points

Timepoint	Pain			Comfort		
	Experiment Mean±SD	Control Mean±SD	P value	Experiment Mean±SD	Control Mean±SD	P value
2 Weeks	3.80 ± 1.64	3.35 ± 1.50	0.37	7.00 ± 2.15	7.10 ± 1.83	0.87
4 Weeks	1.00 ± 0.00	1.00 ± 0.00	-	10.00 ± 0.00	10.00 ± 0.00	-

significant difference was found in pain or comfort level between groups at two or four weeks (P>0.05; Table 2).

Table 3 shows the frequency of oozing and swelling in the study groups. At the 2-week interval, 100% of patients reported the occurrence of oozing after tooth extraction, whereas only 5% reported the experience of localized swelling on both sides. No patient reported the occurrence of bleeding and swelling at the 4-week follow-up.

Discussion

This study assessed the effects of Collacone® on the extraction socket closure and postoperative pain, comfort, bleeding and swelling levels following atraumatic tooth extraction. The participants of the present study were orthodontic patients, in whom socket preservation is generally unnecessary. However, including orthodontic patients in this study aimed to evaluate the effect of Collacone® on the healthy alveolar ridge while reducing the risk of confounding variables. The split-mouth design of the present research reduced the risk of potential heterogeneity caused by patient-related factors, including the environmental and genetic factors that affect wound and bone healing (1, 2).

In the present study, the mesiodistal width of the socket showed 71% and 74%, decreases in the experimental and control groups, respectively. Furthermore, the BL width decreased by about 73% in both groups. The reduction in socket width was significant in both groups over the experiment, but no significant between-group differences were found at any interval. Therefore, using Collacone® was not more effective than no intervention in preventing bone loss in extraction sockets. This implies that Collacone® placement after tooth extraction could not provide socket preservation in healthy individuals.

The outcomes of this study are in agreement with the results of Anderud et al. (14), who found no significant difference in bucco-palatal bone loss between sockets treated with Collacone® (1.15 mm) and the control group (0.57 mm). Tutuş et al. (15) reported that placing a type-1 collagen cone into an extraction socket did not significantly improve extraction socket healing and postoperative sequelae after the third molar extraction. The authors assessed the plaque index, gingival index, clinical attachment level, and pocket probing depth of the second molars. However, they did not evaluate the MD and BL widths of the extraction site.

The outcomes of this study disagree with the findings of Velasquez et al. (16), who reported that collagen wound dressings and soft tissue graft substitutes aid in healing extraction sockets. Schnutenhaus et al. (2) showed that using a collagen membrane and a collagen cone (PARASORB Sombrero®, Resorba, Nuremberg, Germany) provided a slightly higher value of osteogenic factors, although vascularization and bone metabolism were comparable to those without socket preservation (2). In an animal study in rats, using collagen sponges to protect the extraction socket reduced the incidence of bisphosphonate-related osteonecrosis of the jaw (BRONJ) (17).

Tooth extraction occasionally results in complications such as pain, swelling, and bleeding. In the present study, the patient's pain and comfort levels were comparable in both groups. In contrast, Tsai et al. (18) reported that using type 1 collagen in the third molar extraction socket decreased pain intensity, discomfort duration, and mouth opening restriction compared to no socket augmentation. The difference between the results of these studies might be attributed to the extraction method: surgical extraction of the impacted third molars in the study of Tsai et al. (18) versus simple conservative extraction of premolars in the present study. Another study by Zirk et al. (19) reported that using Collacone® after atraumatic tooth extraction prevented severe bleeding in patients with coagulation problems. However, their study lacked a control group.

The comparable socket closure, pain, comfort, oozing, and swelling levels between the groups in the present study might be attributed to atraumatic tooth extraction. Atraumatic extraction techniques reduce soft tissue damage and decrease postoperative bleeding (20). Furthermore, it has been reported that patients undergoing atraumatic extractions experience lower

Table 3. The percentage of extraction sides that showed bleeding and swelling in the study groups

Timepoint	Bleeding		Swelling	
	Experimental	Control	Experimental	Control
	%	%	%	%
2 Weeks	100%	100%	5%	5%
4 Weeks	0%	0%	0%	0%

pain levels and other complications, which contributes to a more stable healing environment (21). Some studies revealed that atraumatic extraction combined with a socket preservation method could maintain bone dimensions and reduce horizontal resorption compared to spontaneous healing (21, 22). Another reason for the insignificant results between groups in this study may be that the suturing was done on both sides. It is important to note that suturing of premolar extraction sites is not routinely performed. However, in the present study, sutures were placed on the control side to maintain group similarity, which could affect patient pain, comfort levels, and other variables. Furthermore, the patients in this study were young and healthy, implying that healing is expected to occur fast and without considerable complications in such cases (23).

One limitation of this study was that comparisons between different age groups were impossible due to the limited sample size and the fact that the participants were young orthodontic candidates. Future studies should include a larger sample size and encompass various age groups. Furthermore, it is necessary to evaluate the effect of Collacone® in wound healing and postoperative sequelae in patients with systemic diseases and patients who undergo complicated extractions. Additionally, long-term follow-up studies are needed to evaluate the effect of Collacone® on alveolar ridge preservation and soft tissue stability following tooth extraction.

Conclusions

Collacone® did not preserve the BL and MD dimensions of the sockets after premolar extractions. Furthermore, Collacone® did not affect pain and comfort levels or the occurrence of bleeding and swelling in patients who underwent premolar extractions. Therefore, the application of Collacone® does not offer any advantages for socket preservation following atraumatic tooth extraction in healthy young individuals.

Acknowledgments

None.

Conflict of Interest

The authors have no conflicts of interest.

Ethical Considerations

This clinical trial was approved by the ethics committee of Shahid Beheshti University of Medical Sciences (IR.SBMU.RIDS.REC.1396.458) and registered in the Iranian Registry of Clinical Trials (IRCT code: IRCT20241204063947N1).

Author Contributions

H.M. and M.K. contributed to the design and conceptualization of the study. N.D. contributed to the data collection and data analysis. F.B., F.M., and Z.B. contributed to manuscript preparation and data analysis. All authors read and approved the final manuscript.

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