Received: 30 April 2024 | Revised: 26 May 2024 | Accepted: 28 May 2024

DOI: 10.1111/cid.13353

ORIGINAL ARTICLE

WILEY

Volumetric assessment of volume stable collagen matrix in maxillary single implant site development: A randomized controlled clinical trial

Ahmed Hamdy[1] | Suzan Seif Allah Ibrahim[2] | Dalia Ghalwash[1] | Doaa Adel-Khattab[2]

[1]Periodontology and Diagnosis, Faculty of Dentistry, The British University in Egypt, Cairo, Egypt

[2]Oral Medicine, Periodontology and Oral Diagnosis, Faculty of Dentistry Ain Shams University, Cairo, Egypt

Correspondence
Doaa Adel-Khattab, Oral Medicine, Periodontology and Oral Diagnosis Department, Faculty of Dentistry, Ain Shams University, Cairo, Egypt.
Email: dr.doaa.adel-khattab@dent.asu.edu.eg

Abstract

Introduction: The stability of soft tissue volume around dental implants is an important factor for the final esthetic outcome. The main objective of this study was to compare volume stable collagen matrix (VCMX) versus connective tissue graft (CTG) in the augmentation of soft tissue profiles in single implant sites with a class I Siebert ridge defect.

Materials and Methods: Twenty patients (14 females and 6 males) were enrolled in the present study. After implant placement and augmentation of the buccal defect by VCMX or CTG, post-operative evaluation of the volumetric changes at the augmented implant site was carried out at 3, 6, and 9 months as primary outcome, clinical and radiographic soft tissue thickness were carried out at baseline and 9-month intervals, visual analog scale (VAS) and oral health impact profile-14 (OHIP14) were recorded 2 weeks after the surgery.

Results: A statistically significant difference in soft tissue volume was found between baseline and 3, 6, and 9 months postoperatively in both groups with the highest value at 9 months (136.33 ± 86.80) (mm^3) in VCMX and (186.38 ± 57.52) (mm^3) in CTG. Soft tissue thickness was significantly increased in both groups at 9 months in comparison to baseline. However, there was a significantly higher increase in soft tissue thickness at 9 months in CTG (3.87 ± 0.91) than in VCMX (2.94 ± 0.31). Regarding the radiographic soft tissue thickness, there was a statistically significant increase in both groups at 9 months in comparison to baseline. However, there was a statistically higher increase in the radiographic soft tissue thickness at 9 months in CTG (3.08 ± 0.97) than in VCMX (2.37 ± 0.29). VAS showed a statistically lower value in VCMX (0.4 ± 0.7) than CTG (2.8 ± 1.48). The OHIP recorded lower values in the VCMX group than the CTG group with no statistical significance. In addition, there was no difference in the PES between the two groups.

Conclusion: The present study showed that CTG and VCMX were both effective in soft tissue augmentation around implants in the esthetic zone. However, CTG proved more efficient in increasing peri-implant soft tissue volume and mucosal thickness

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around single implants at a 9-month follow-up period. VCMX was associated with less pain or discomfort and reduced patient morbidity, as reflected by the significantly reduced VAS value in the VCMX group.

KEYWORDS
connective tissue graft, volume stable collagen matrix, volumetric assessment

Summary box

What is known

- A recent systematic review of patient-reported outcomes showed that soft tissue grafting can improve patient satisfaction and aesthetics compared to non-grafted sites,[1] but to the best of our knowledge, no systematic review was conducted on collagen membrane regarding the amount of volume gain and stability of the results, so further individual multi-center randomized controlled studies with appropriate sample sizes are still needed to further confirm these findings.

What this study adds

- Despite successful clinical applications, there is little knowledge about the long-term behavior of grafts in the augmented region regarding volumetric stability.
- Accordingly, the present investigation was performed to evaluate the volumetric changes of soft tissues at implant sites with Siebert class I ridge defect after augmentation with a volume stable collagen matrix (VCMX) in comparison with connective tissue grafting (CTG) as the primary objective, and to evaluate esthetic outcome and patient satisfaction as a secondary objective.

1 | INTRODUCTION

Following tooth extraction, the alveolar process begins to remodel and reshape itself, particularly the bundle bone at the buccal side. These remodeling and reshaping processes typically take place within the first few weeks after extraction, resulting in a considerable amount of volume loss, particularly in the buccal segment of the ridge.[2,3] In order to make up for the volume loss, a variety of surgical interventions may be required. Volume can be obtained on the hard tissue level either through primary bone augmentation prior to implant placement or at the same time as implant placement.[4]

A common complication occurring after GBR procedures is loss of initially gained volume. Many patients experience a lack of volume following a GBR procedure.[5] Particularly in esthetically challenging areas, this may result in an unattractive outcome. To gain additional volume, soft tissue augmentation may be the treatment of choice. Soft tissue augmentation following implant placement is a common surgical procedure performed primarily prior to abutment connection and is estimated to contribute up to 43% of the final volume according to clinical data.[6] When sufficient bone is present for implant installation, the gold standard for this procedure is the use of a subepithelial connective tissue graft (SCTG) harvested from the patients' palate and placed into a pouch on the buccal-facing aspect of the placed implant.[7]

Clinical studies have shown that buccal soft tissue volumes remain stable between permanent crown placement and 1- or 3-year follow-up.[7–9] Despite the clinical effectiveness of CTG, its main drawback is the need for a second surgical site for tissue collection. This can lead to complications such as palatal bleeding, pain, swelling, infection, and necrosis.[10,11] Graft dimensions and harvesting methods have been shown to influence patient symptoms.[12] A thick CTG may cause postoperative pain but is unavoidable when large buccal depressions need to be eradicated. Soft tissue augmentation results are therefore influenced by the amount of soft tissue that can be harvested from the donor site.[13]

To overcome the above limitations of autologous CTG, a volume stable cross-linked porcine-derived collagen matrix (VCMX) was developed. VCMX contains a single porous layer that enhance the process of angiogenesis, fibroblasts' growth, matrix biosynthesis, and tissue integration.[14] On the other hand, while a collagen matrix could normally be used in an open environment, a VCMX needs submerged healing. Several preclinical and clinical studies inspecting VCMX have yielded promising outcomes in terms of volume gain, with no considerable adverse sequelae noted.[8,14,15] Despite successful clinical applications, there is little knowledge about the behavior of grafts in the augmented region regarding volume stability. Therefore, the main objective of this study was to compare VCMX versus CTG in a randomized controlled trial in augmentation of soft tissue profiles in single implant sites with a class I Siebert ridge defect (Figure 1).

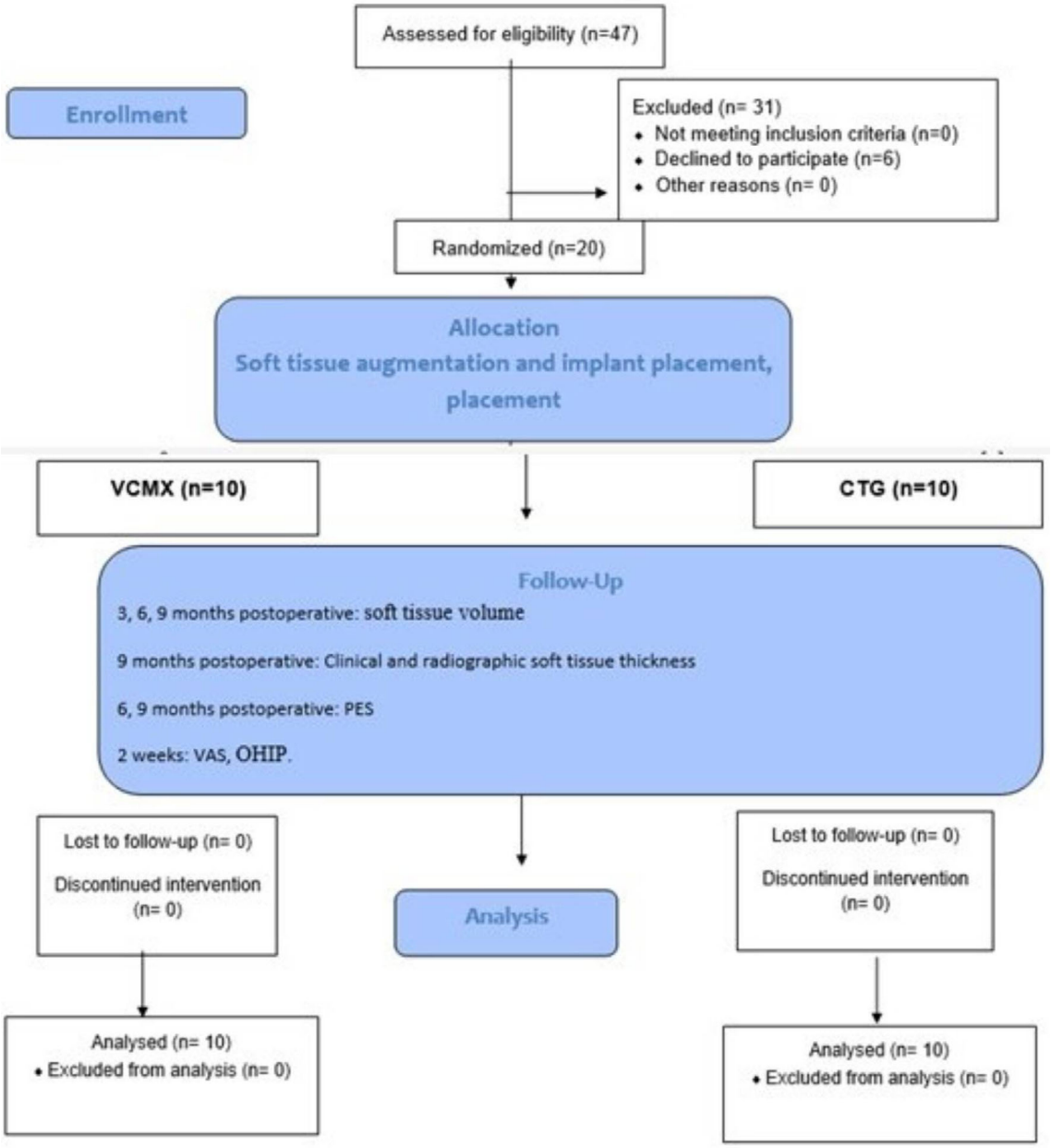

FIGURE 1 Consort checklist diagram.

2 | MATERIALS AND METHODS

The present study included 20 patients (14 females and 6 males) with partially edentulous dentition requiring restoration of missing teeth in the maxillary esthetic zone (Figure 2A,J), they were recruited from the outpatient clinic of Oral Medicine, Periodontology, Oral Diagnosis and Radiology Department, Faculty of Dentistry, Ain Shams University. The purpose of this study was explained to all patients and an informed consent was signed before the study was conducted. The Faculty of Dentistry Research Ethics Committee reviewed and accepted the proposal in February 2021 with number (FDASU-RecID021817), phone +20 222 601 221, Email ethicscommitte.fdasurec@gmail.com, in line with the Helsinki Declaration of 1975. In addition, the study was registered in a clinical trial registration site (NCT04873830).

2.1 | Eligibility criteria

Patients were selected according to certain inclusion criteria (healthy adult patients, age ranged from 20 to 50 years old, Siebert class I ridge defect).[16] On the other hand, smokers (>10 cigarettes/day), pregnant females, and patients with poor oral hygiene or not willing to perform oral hygiene measures were excluded from the study.

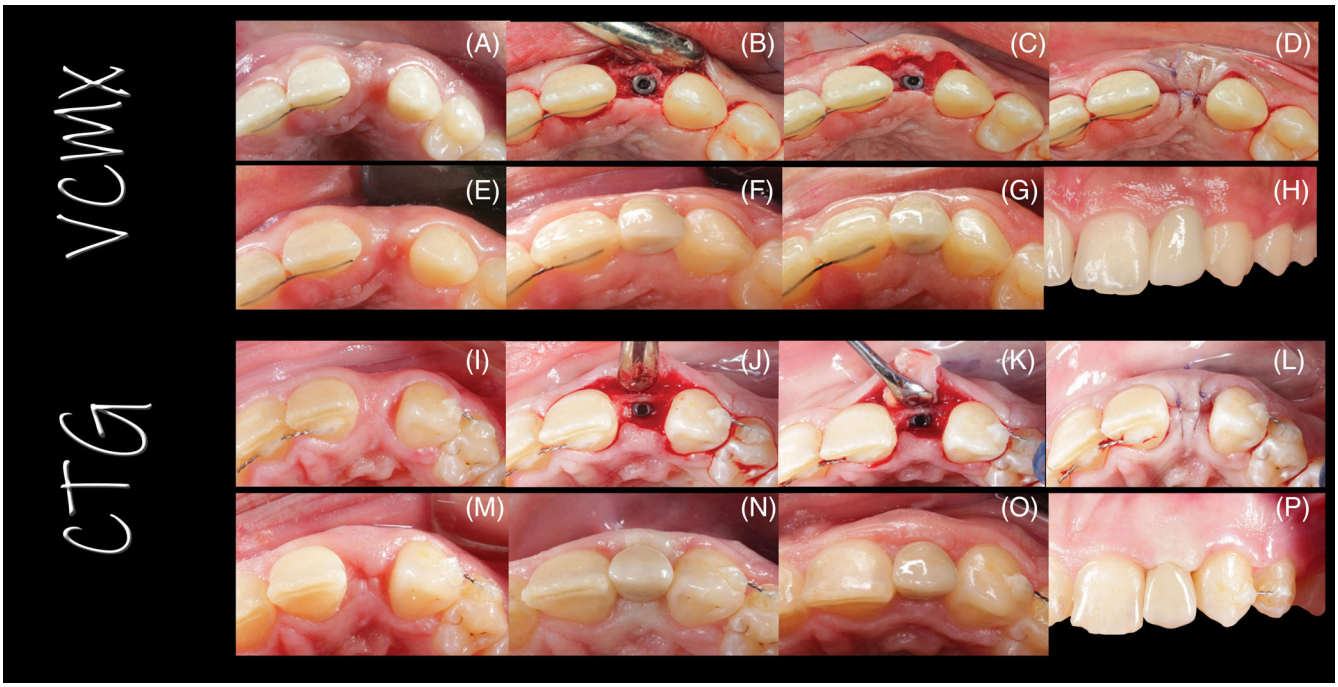

FIGURE 2 (A): Preoperative occlusal view showing horizontal ridge deficiency around the edentulous space, (B): Flap reflection and placement of dental implant, (C): VCMX was placed into the buccal envelope and fixed with a single suture, (D): Primary flap closure using simple interrupted sutures, (E): Postoperative occlusal vieat 3 months follow-up, (F): Postoperative occlusal view at 6 months follow-up, (G): Postoperative occlusal view at 9 months follow-up, (H): Postoperative frontal view, (I): Preoperative occlusal view showing horizontal ridge deficiency around the edentulous space, (J): Flap reflection and placement of dental implant, (K): CTG was placed into the buccal envelope and fixed with a single suture, (L): Primary flap closure using simple interrupted sutures. (M): Postoperative occlusal view at 3 months follow-up, (N): Postoperative occlusal view at 6 months follow-up, (O): Postoperative occlusal view at 9 months follow-up, and (P): Postoperative frontal view.

2.2 | Randomization

Patients who met the eligibility criteria were randomly allocated using computer assisted randomization (www.randomizer.org) through numbered sealed envelopes into two treatment modality groups: 10 patients were assigned to Group I (VCMX) and 10 patients were assigned to Group II (control). After implant placement and augmentation of the buccal concavity by VCMX and CTG in both the test and control groups, respectively, post-operative evaluation of the volumetric changes at the augmented implant site was carried out for each patient at 3, 6, and 9 months postoperative.

2.3 | Masking/blinding

Blinding of the participants and operators was not applicable, the outcome assessor and the biostatistician were blinded.

Clinical and radiographic soft tissue thickness were assessed at baseline and 9-month intervals. The pink esthetic score was evaluated after crown delivery at 6- and 9-month intervals along with (PROMs) including the visual analog scale (VAS) and oral health impact profile-14 (OHIP14) which were recorded 2 weeks after surgery.

2.4 | Sample size calculation

A power analysis was designed to have adequate power to apply a two-sided statistical test of the null hypothesis that no difference would be found between different tested groups regarding soft tissue thickness. By adopting an alpha (α) level of 0.05, a beta (β) level of 0.2 (i.e., power = 80%), and an effect size (d) of 1.46 calculated based on the results of a previous study,[17] the predicted sample size (n) was a total of 19 cases (i.e., 9 cases per group). The sample size calculation was performed using G*Power version 3.1.9.7.[19]

2.5 | Treatment protocol

A field block of Articaine HCL 4%[1] containing epinephrine at a concentration of 1:100000 was given buccally and palataly at surgical sites. The surgical approach consisted of a mid-crestal incision down to bone and sulcular incisions around the neighboring teeth to help in complete elevation of the flap. After the crestal incision, full thickness elevation of the flap was done at the crest ensuring a denuded bone surface to accept the implant preparation step, and then a partial thickness flap was reflected toward the buccal side.[19] This study

utilizes the (4C) implant placement protocol according to Gallucci et al.[20] Following a complete reflection of the combined full/partial thickness flap, dental implant[2] with a suitable diameter and height according to the site was placed in the right position. Cover screw[3] was placed over the implant and secured with a screwdriver to its final position (Figure 2B, K).

For the test group, VCMX[4] with an initial dimension of 15 × 20 × 6 mm was used. Graft thickness was adapted to the defect with a scalpel as deemed appropriate by the surgeon. A sterile saline solution was applied to the graft and slight compression was made. The graft was further trimmed with scissors to arrive at the ideal dimensions.[13] Following a superficial incision to release muscle tension, the graft was brought into the buccal envelope and fixed with single sutures[5] onto the buccal mucosa (Figure 2C). Then the flap was sutured in its original place using simple interrupted sutures (Figure 2D). For the control group, a free (de-epithelialized) gingival graft was harvested by basic surgical techniques previously described by Zucchelli et al.[13] Following a superficial incision to release muscle tension, the graft was tucked into the buccal envelope and fixed with single sutures onto the buccal mucosa (Figure 2L). Then the flap was sutured in its original place using simple interrupted sutures (Figure 2M).

Postoperatively, all patients received antibiotics for 1 week (amoxicillin + clavulanic acid 1000 mg b.d.s)[6] and an anti-inflammatory drug (Ibuprofen 400 mg b.d.s).[7] Patients were instructed to pass the first 24 h and to start rinsing twice daily with a 0.12% chlorhexidine digluconate[8] mouth rinse and to avoid mechanical plaque control at the site of surgery for 15 days. The sutures were removed after 2 weeks for both groups and patients were instructed to use the Bass technique for tooth brushing. At 3 months, all patients were recalled for the final crown fabrication. Patients in both groups were followed up at 6- and 9-month intervals. The follow-up period included oral examination and plaque removal, when necessary.

2.6 | Outcome measure

Clinical measurements were recorded, and models were scanned at 0. 3-, 6- and 9-months' intervals in both control and intervention groups. The STL files obtained from each model were subsequently transferred to a digital shape sampling and processing software for re-elaboration of 3D models from the 3D scan data (Medit design, © Medit Corp). (Figure 3). After superimposition, the marked superimposed implant sites were isolated and volumetric changes (the primary outcome) between digitalized superimposed casts were measured using blender 4dental software according to Akcali et al.[21] Additionally, linear measurements were assessed, a cross-sectional cut at the center of the implant crown was selected to represent contour of the buccal peri-implant tissues. Horizontal measurements were carried out at 1 and at 3 mm below the buccal mucosal margin. The differences between the two measurements at baseline and 9-month follow-up represented the changes of the tissue thickness over time.[22]

Clinical and radiographic soft tissue thickness were assessed at baseline and 9-month intervals. Clinically, soft tissue thickness was measured using an anesthetic needle with a rubber stopper to pierce the gingiva mid-buccally, 1.0 mm coronal to the MGJ and perpendicular to the long axis of the tooth until bone contact (Figure 4). The part of the instrument penetrating into soft tissue was measured in mm.[23] The radiographical assessment was done using CBCT at baseline and 9-month follow-up.

The pink esthetic score was evaluated.[24] Moreover, VAS and OHIP14 were recorded 2 weeks after surgery. The VAS score was recorded through the pain score reported by the patient directly (from 0 to 10. 0: no pain, 1: minimal pain, 5: moderate pain, and 10: severe pain).[25] The OHIP14 questionnaire was used to assess limitations of function, pain, discomfort, social, psychological, physical disability, and general satisfaction. The OHIP-14 utilizes a scale with five categories (1 = never, 2 = hardly ever, 3 = occasionally, 4 = often, and 5 = very

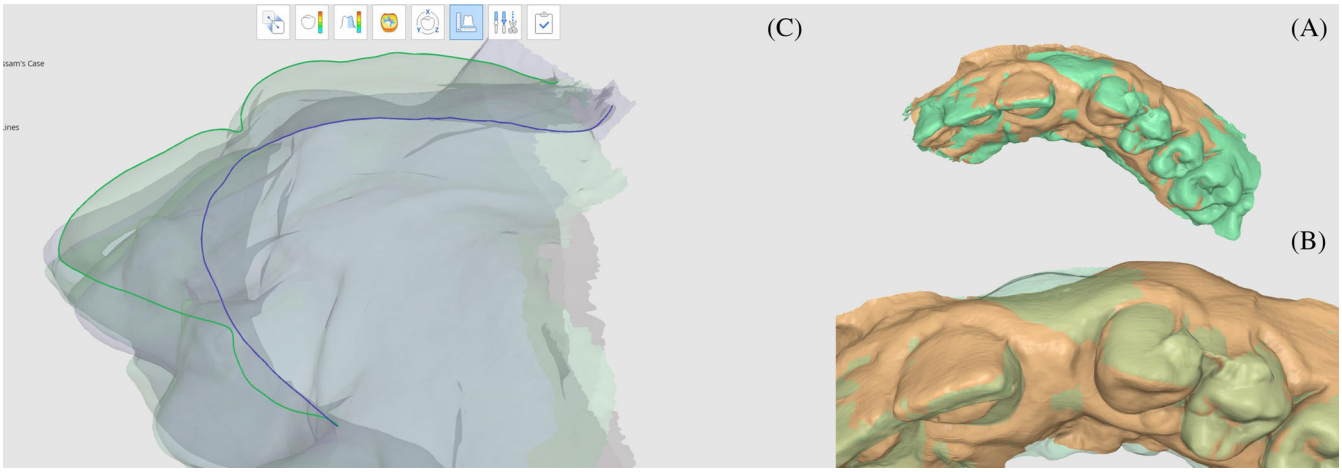

FIGURE 3 (A, B): Digital model showing superimposition of scanned models of two-time intervals and (C): Contour lines showing dimensional change between two-time intervals.

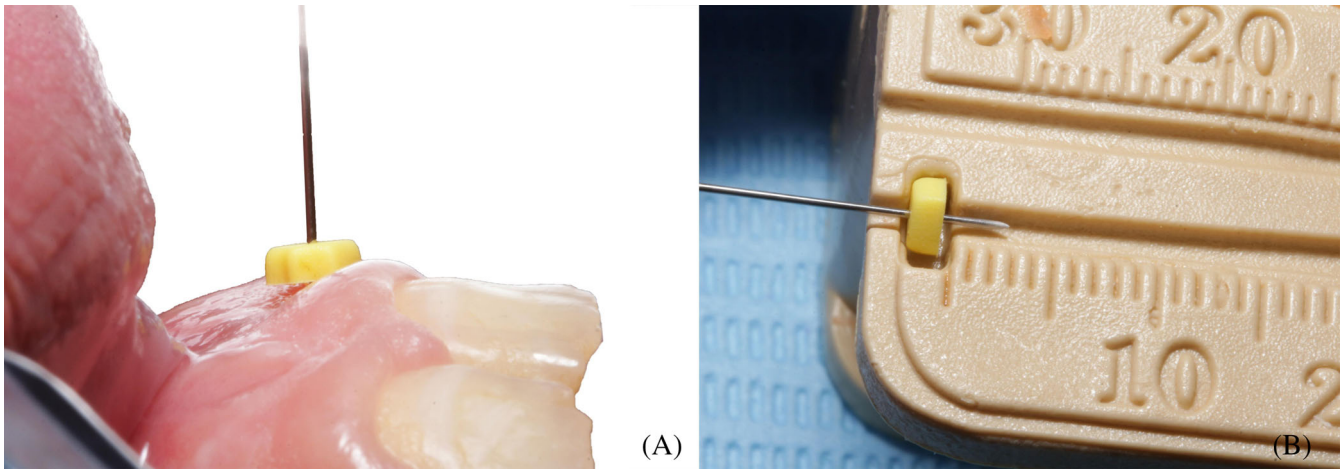

FIGURE 4 (A): Measurement of soft tissue thickness clinically using anesthetic needle with a rubber stopper and (B): Measurements were recorded in mm using endodontic ruler.

TABLE 1 Intergroup comparison and summary statistics for demographic data in VCMX and CTG groups.

Parameter		VCMX	CTG	*df*	Test statistic	*p*-value
Gender *n* (%) (Chi square test)	Male	2 (20.0%)	4 (40.0%)	1	0.95	0.329
	Female	8 (80.0%)	6 (60.0%)			
Age (Mean ± SD) (years) (Independent *t*-test)		32.00 ± 8.42	35.90 ± 7.98	18	1.06	0.302

Abbreviation: df, degrees of freedom.

often). A lower score in any of the five categories indicates higher satisfaction.[26] All the previous data were collected and statistically analyzed.

2.7 | Statistical analysis

Categorical data was presented as frequency and percentage values and was analyzed using the chi-square test. Numerical data was presented as mean and standard deviation values. They were analyzed for normality using the Shapiro–Wilk test. Parametric data were analyzed using the independent *t*-test for intergroup comparisons and repeated measures ANOVA followed by a Bonferroni post-hoc test for intragroup comparisons. Non-parametric data were analyzed using the Mann–Whitney U test for intergroup comparisons and Friedman's test followed by Nemenyi post-hoc test for intragroup comparisons. Correlation analysis was done using Spearman's rank order correlation coefficient. The significance level was set at $\mathbf{p} < 0.05$ within all tests. Statistical analysis was performed with R statistical analysis software version 4.3.1 for Windows.[9]

3 | RESULTS

Twenty patients fulfilling the eligibility criteria were enrolled in the present study, there were 2 males and 8 females in the VCMX group and 4 males and 6 females in the CTG group. The mean age of cases in the VCMX group was (32.00 ± 8.42) years and (35.90 ± 7.98) years in the CTG, there were no significant differences between both groups regarding gender ($p = 0.329$) or age ($p = 0.302$) (Table 1).

Regarding the soft tissue volume in groups VCMX and CTG, there was a statistically significant difference between baseline and 3, 6, and 9 months postoperatively, with highest value at 9 months (136.33 ± 86.80) (mm^3) in the VCMX and (186.38 ± 57.52) (mm^3) in the CTG. However, there was no statistically significant between both groups throughout all time intervals. Regarding the linear measurement, there was a statistically significant difference between VCMX and CTG groups at 3 mm (0.65 ± 0.31) in VCMX and (1 ± 0.4) in CTG. However, there was no statistical significance difference between both groups at 1 mm or within each group between 1 and 3 mm (Table 2).

The soft tissue thickness had a statistically significant increase in both groups at 9 months in comparison to baseline. However, there was a statistically higher increase in soft tissue thickness at 9 months in CTG (3.87 ± 0.91) than in VCMX (2.94 ± 0.31) ($p = 0.007$). Regarding the radiographic soft tissue thickness, there was a statistically significant increase in both groups at 9 months in comparison to baseline. However, there was a statistically higher increase in the radiographic soft tissue thickness at 9 months in CTG (3.08 ± 0.97) than in VCMX (2.37 ± 0.29) ($p = 0.04$) (Table 2).

There was no statistically significant difference in soft tissue volume between baseline to 9 months postoperative, 26.2 ± 10.2 and 43.3 ± 30.9 in VCMX and CTG, respectively. On the contrary, the soft tissue thickness difference from baseline to 9 months postoperatively

TABLE 2 Inter, intragroup comparisons, mean and standard deviation (SD) for soft tissue volume (mm^3), clinical and radiographic soft tissue thickness in VCMX and CTG groups.

	Soft tissue volume (mm^3) (Mean ± SD)				
Time	**VCMX**	**CTG**	***df***	**Test statistic (Independent *t*-test)**	***p*-value**
Baseline	110.12 ± 86.41[B]	143.00 ± 56.00[B]	18	1.01	0.326
3 months	131.49 ± 87.99[A]	173.52 ± 56.58[A]	18	1.27	0.220
6 months	135.68 ± 82.37[A]	180.60 ± 56.74[A]	18	1.42	0.173
9 months	136.33 ± 86.80[A]	186.38 ± 57.52[A]	18	1.52	0.146
dfn	3	3			
dfd	27	27			
Test statistic (Repeated measures ANOVA)	31.36	31.36			
p-value	0.012*	<0.001*			

	Linear measurement (mm) (Mean ± SD)			
Time	**VCMX**	**CTG**	**Test statistic (Independent *t*- test)**	***p*-value**
1 mm	0.63 ± 0.37	0.73 ± 0.29		0.47
3 mm	0.65 ± 0.31	1 ± 0.4		0.03*
Test statistic (Paired *t*-test)				
p-value	0.07	0.87		

	Clinical soft tissue thickness (mm) (Mean ± SD)				
Time	**VCMX**	**CTG**	***df***	**Test statistic (Independent t- test)**	***p*-value**
Baseline	2.10 ± 0.32	2.10 ± 0.32	18	0.00	1
9 months	2.94 ± 0.31	3.87 ± 0.91	18	3.05	0.007*
df	9	9			
Test statistic	7.52	7.39			
p-value (Paired *t*-test)	<0.001*	<0.001*			

	Radiographic soft tissue thickness (mm) (Mean ± SD)				
Time	**VCMX**	**CTG**	***df***	**Test statistic (Independent *t*- test)**	***p*-value**
Baseline	1.50 ± 0.26	1.64 ± 0.54	18	0.74	0.468
9 months	2.37 ± 0.29	3.08 ± 0.97	18	2.21	0.040*
df	9	9			
Test statistic (Paired *t*-test)	8.21	8.23			
p-value	<0.001*	<0.001*			

Abbreviations: df, degrees of freedom; dfn, degrees of freedom numerator; dfd, degrees of freedom denominator.
*Significant ($p < 0.05$).

had a statistically higher significance in CTG 1.77 ± 0.76 than in VCMX 0.84 ± 0.35 ($p = 0.002$). The same was true in the radiographic soft tissue thickness that had a statistically higher significance difference from baseline to 9 months postoperative CTG 0.887 = ± 0.34 than VCMX 1.44 ± 0.55 ($p = 0.013$) (Table 3). In addition, there was a strong correlation between clinical and radiographic soft tissue thicknesses ($p < 0.001$) (Figure 5).

VAS showed a statistically lower value in VCMX (0.4 ± 0.7) than in CTG (2.8 ± 1.48) ($p < 0.001$). The OHIP recorded lower values in the VCMX group than the CTG group with no statistical significance. In addition, PES had no statistical significance between both groups and between baseline and 9 months postoperatively in both VCMX and CTG (Table 4).

4 | DISCUSSION

The stability of soft tissue volume around the dental implant is an important factor affecting the final esthetic outcome.[27] Furthermore, increased soft tissue thickness could mask the color of the underlying restoration, which might otherwise be unsightly.[28,29] The augmented soft tissue volume also enhances and maintains peri-implant tissue condition in the long term.[1,30] That is why much more attention has been paid recently to soft tissue augmentation around dental implants.[31,32]

When sufficient bone is present for implant installation, the gold standard is the use of a subepithelial connective tissue graft (SCTG) to increase the mucosal thickness at implant sites.[23,33] However,

TABLE 3 Intergroup comparison, mean and standard deviation (SD) for change in soft tissue volume (mm^3), clinical and radiographic soft tissue thickness in VCMX and CTG groups.

	Soft tissue volume difference (mm^3) (Mean ± SD)			
Interval	**VCMX**	**CTG**	**Test statistic (*t*-test)**	***p*-value**
Baseline- 3 months	21.37 ± 9.65	30.52 ± 17.75	70.00	0.140
3–6 months	4.19 ± 11.31	7.08 ± 20.95	46.50	0.821
6–9 months	0.65 ± 5.57	5.78 ± 7.18	70.00	0.140
Baseline-9 months	26.20 ± 10.28	43.38 ± 30.92	67.00	0.212

	Clinical soft tissue thickness difference (mm) (Mean ± SD)				
Interval	**VCMX**	**CTG**	***df***	**(Independent *t*-test)**	***p*-value**
Baseline- 9 months	0.84 ± 0.35	1.77 ± 0.76	18	3.52	0.002*

	Radiographic soft tissue thickness difference (mm) (Mean ± SD)				
Interval	**VCMX**	**CTG**	***df***	**Test statistic**	***p*-value**
Baseline- 9 months	0.88 ± 0.34	1.44 ± 0.55	18	2.77	0.013*

Abbreviation: df, degrees of freedom.
*Significant ($p < 0.05$).

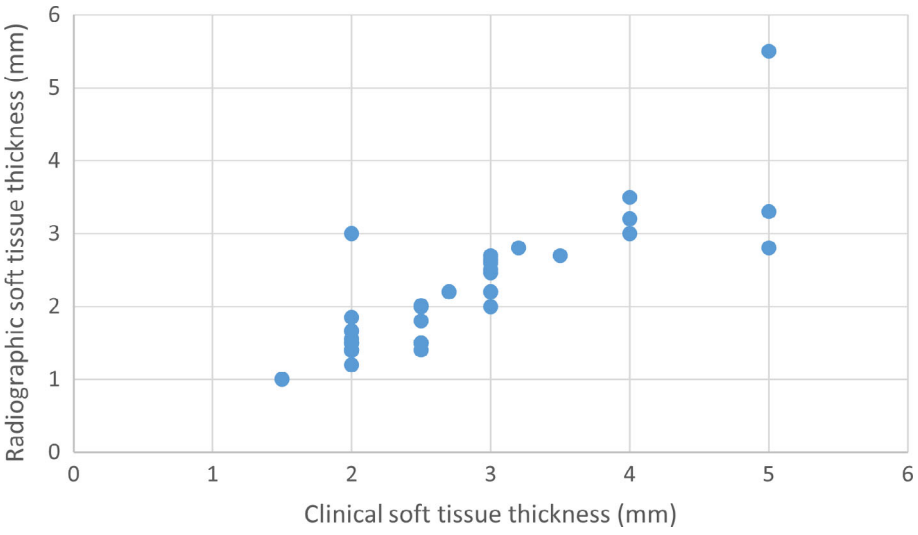

FIGURE 5 Scatter plot showing the correlation between clinical and radiographic soft tissue thicknesses.

transplantation of autogenous tissue is always accompanied by patient morbidity stemming from the donor site, which has been a focus of several clinical trials lately.[1,34] Aiming to decrease patient morbidity resulting from autogenous soft tissue graft harvesting, attempts have been made to develop products that can replace the autogenous graft.[34,35] These soft tissue substitutes (matrices) made of porcine-derived collagen have been clinically tested, reporting highly promising results.[36,37] According to histological evidence, these collagenous matrices are incorporated by the host tissues, remodeled, and replaced by connective tissue.[37–39] This enables the increase of soft tissue volume in areas where it is lacking and the maintenance of that over time.[15,39]

Despite successful clinical applications, there is little knowledge about the behavior of grafts in the augmented region regarding volumetric stability. Accordingly, the present investigation was performed to evaluate the volumetric changes of soft tissues at implant sites with Siebert class I ridge defects after augmentation with volume stable collagen matrix in comparison with connective tissue grafting as the primary objective, and to evaluate esthetic outcome and patient satisfaction as a secondary objective.

Analysis of soft tissue volume measurements revealed a significant increase in soft tissue volume measured at different intervals compared to baseline for both VCMX and CTG groups demonstrating the greatest soft tissue volume increase at 9 months. CTG recorded more gain in soft tissue volume (30.52 mm^3) than VCMX (21.37 mm^3) from baseline to 3 months as well as the overall volume gain from baseline to 9 months where the greatest volume gain of 43.38 mm^3 was registered in CTG group relative to overall volume gain of 26.20 mm^3 in VCMX group. These results are in line with clinical profilometric studies using CTG at single implants confirming the increase in buccal soft tissue profile 3 months after the augmentation procedure.[9,18,39,41,42]

TABLE 4 Inter, intragroup comparisons, mean and standard deviation (SD) for VAS, OHIP, and PES in VCMX and CTG groups.

VAS (Mean ± SD)			
VCMX	**CTG**	**Test statistic (*t*-test)**	***p*-value**
0.40 ± 0.70	2.80 ± 1.48	94.50	<0.001*
OHIP (Mean ± SD)			
VCMX	**CTG**	**Test statistic**	***p*-value**
8.30 ± 0.48	9.40 ± 2.22	57.00	0.605
	PES (Mean ± SD)		
Time	**VCMX**	**CTG**	**Test statistic (Mann–Whitney)**	***p*-value**
6 months	8.40 ± 0.70	8.80 ± 0.79	38.00	0.345
9 months	9.10 ± 0.32	9.10 ± 0.74	49.00	0.963
Test statistic	0.00	0.00		
p-value (Signed rank)	0.126	0.149		

*Significant ($p < 0.05$).

On the contrary, the present study demonstrated a noticeable stability of soft tissue volume gained all through the 9-month study period with no loss of the initially gained volume which is consistent with an earlier single-center study by cosyn et al.,[43] reporting a relatively stable soft tissue volume gain in both study groups during the one-year follow-up period after soft tissue augmentation.[42,43] Similarly, this is in line with recent studies reporting a stable profilometric outcome following SCTG augmentation owing to the verified stability of autogenous CTG,[15,42,44] which remains the gold standard for volume augmentation.[45]

Several studies have indicated that soft tissue grafting procedures can lead to improved clinical and radiographic outcomes.[30,46] In the same context clinical and radiographic soft tissue thickness analysis in the current investigation demonstrated a strong positive correlation and revealed a significant improvement of soft tissue thickness at 9 months in both VCMX and CTG groups. Whereas intergroup comparison revealed a significantly greater soft tissue thickness improvement in CTG (3.87 mm) than VCMX (2.94 mm) at 9 months. This was closely related to results of an earlier investigation reporting more improvement in tissue thickness of 3.4 mm in the CTG group compared to 3.0 mm thickness in CM at 6 months post-surgical.[8]

Moreover, in the present results, CTG showed a significantly greater gain of 1.77 mm in clinical soft tissue thickness compared to 0.84 mm in VCMX with a significantly higher percentage change. This was in accordance with prior research reporting more significant gain in gingival thickness (1.17 mm) obtained using CTG than that obtained using collagen matrices (0.81 mm),[39] and another relevant study which reported a mucosal thickness gain of 1.2 mm for the CTG group and 0.9 mm in VCMX.[23] Furthermore, Huber et al.,[44] a reported an increase in buccal soft tissue profile of 1.15 mm in CT group and 0.85 mm in CM group after 3 months of follow-up.[44] In contrast to these results, other preceding studies did not find significant difference in soft tissue thickness increase while using collagen matrix or autogenous connective tissue graft.[36,40,47–49] Additionally, when linear measurements were carried out, it seems that the augmentation outcome is concentrated at the 3 mm measure point regardless of the graft type used which corresponds to the area where the augmentation focus was concentrated. The horizontal contour mean gain in the present study ranged from 0.65 to 1 mm in favor of the CTG group over time.[50]

In addition to assessment of the customary clinical parameters, the current investigation focuses on aesthetics and patient-reported outcomes. Since patients' opinion may be different than the objective signs of successful implants and esthetic outcome. Thus, it would be highly valuable to assess the therapeutic modalities based on patient-reported outcomes measures (PROMs). Several indicators have been developed to objectively evaluate the post operative esthetic outcome such as the Pink Esthetic Score which is a widely used index that also showed good reproducibility in other studies.[24,51–53]

As it has been suggested that a PES >7 was clinically acceptable, in the present study PES revealed very favorable esthetic outcome in both groups, as indicated by a mean PES of greater than 9. This is consistent with other studies reporting high esthetic outcomes after soft tissue augmentation.[53] This is also in line with a preceding study declaring that application of a collagen matrix provides soft tissues volume increase that is comparable to a connective tissue graft both esthetically and functionally.[16,45,54]

Even though patient-reported outcomes are not standardized in terms of patient reporting, visual analogue scales (VAS) are most often implemented to evaluate post operative patients' symptoms of pain or discomfort.[55] In the current investigation mean VAS value were significantly reduced in VCMX group (0.40) than CTG group (2.80) indicating that soft tissue augmentation using VCMX is associated with less amount of pain or discomfort and reduced patient morbidity; an important factor to consider during clinical decision-making. This is in line with earlier research reporting significantly higher VAS score values when autogenous grafts were used than when xenografts were used.[37,45,55]

The significantly reduced VAS scores in VCMX group revealed in the present results are also in line with a recent systematic review and meta-analysis showing the ability of soft tissue alternatives such as VCMX to significantly reduce the perception of pain when compared to autogenous soft tissue grafts.[15] In the same line, Sanz et al.,[32] and Tavelli et al.,[14] established that the patients in collagen matrix group perceived less pain and needed fewer anti-inflammatory drugs, and did not present pain 30 days after surgery, while patients who received autografts still presented "minor pain".[1,32] Although collagen matrix was the best rated, there were no statistical differences in patient-reported outcome measures (PROMs) according to Thoma et al.[8] On the contrary, only Cie'slik-Wegemund et al.[40] reported greater pain in patients treated with collagen matrix.

CTG is associated with longer chair-time and greater morbidity than CM, as patients receiving CTG experience significantly higher post-surgical pain and consume more anti-inflammatory drugs.[22,56–61]

One of the benefits of using collagen matrix instead of connective tissue is reducing intraoperative duration, a reduction of analgesic consumption and a higher final patient satisfaction.[23,45,59]

The validated and standard Oral Health Impact Profile (OHIP-14) questionnaire has been also used in the present study to assess the impact of oral health on the overall well-being of individuals[55,59] and it showed satisfactory results with no major difference between VCMX and CTG therapeutic approaches for soft tissue augmentation reflecting success for the overall treatment from the patient's point of view. Similar results were reported in recent investigations comparing soft tissue augmentation using CTG and collagen matrix.[9,16]

Therefore, although CTG recorded the greatest gain of soft tissue volume and mucosal thickness, the morbidity of a second surgical site is a major limiting factor. In some instances, patients' preference of less painful procedures may override the superior effect of CTG in soft tissue volume gain at implant site. Taking into consideration that VCMX also achieves successful soft tissue augmentation.

5 | LIMITATIONS

It is undeniable that there are some limitations in our study. First, the sample size was relatively small, which might diminish the power to detect subtle differences between groups. Additionally, although the 9-month follow-up results could fairly demonstrate the efficacy of VCMX on augmenting the alveolar ridge defects. More well-designed RCTs with long-term follow-up are encouraged to provide valuable information about the long-term stability of XCM in the future.

6 | CONCLUSION

Within the limitations of this study, the present study showed that CTG and VCMX were both effective in soft tissue augmentation at implant sites in the esthetic zone. However, CTG proved more efficient than VCMX in increasing peri-implant soft tissue volume and mucosal thickness around single implants at 9-month follow-up period. VCMX was associated with less amount of pain or discomfort and reduced patient morbidity as reflected by the significantly reduced VAS value in VCMX group than CTG group, thus supporting the detrimental effect of harvesting procedure on patient reported outcomes. Further studies are recommended with larger sample size, and longer follow-up duration on using VCMX in alveolar ridge augmentation around implants that could provide more obvious clinical and radiographic results. A cone beam radiographic evaluation for crestal bone stability around implants is recommended also to assess hard tissue response in between CTG and VCMX.

AUTHOR CONTRIBUTIONS

Ahmed Hamdy: Concept/Design, Surgical intervention, Data collection/interpretation, Drafting article; Suzan Seif Allah Ibrahim: Concept/Design, Drafting article, Critical revision of article, Approval of article; Dalia Ghalwash: Concept/Design, Drafting article, Critical revision of article; Doaa Adel-Khattab: Concept/Design, Data analysis/interpretation, Statistics; Drafting article, Critical revision of article, Approval of article.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ORCID

Dalia Ghalwash https://orcid.org/0000-0003-2541-7243
Doaa Adel-Khattab https://orcid.org/0000-0002-0254-0890

ENDNOTES

[1] Septodont LTD, Septanest 1:100000.

[2] Jdental care – Italy.

[3] Jdental care – Italy.

[4] Fibroguide.Geistlich Pharma AG (Wolhusen, Switzerland).

[5] (Vicryl® 5.0) Polyglactin 910, Ethicon, Johnson & Johnson, Edinburgh, UK.

[6] Amoxil MUP Egypt.

[7] Amoun Egypt.

[8] Antiseptol Kahira Pharm Egypt.

[9] R Core Team (2023). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL https://www.R-project.org/.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Hamdy A, Ibrahim SSA, Ghalwash D, Adel-Khattab D. Volumetric assessment of volume stable collagen matrix in maxillary single implant site development: A randomized controlled clinical trial. *Clin Implant Dent Relat Res*. 2024;1-12. doi:10.1111/cid.13353