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# Changes in Peri-Implant Soft Tissue Dimensions Following Soft Tissue Contour Augmentation: A 3-Year Follow-Up of a Multi-Center RCT

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## ABSTRACT

**Aim:** To assess 3-year changes of peri-implant tissues following previous soft tissue (volume) augmentation (STA) with a volume-stable collagen matrix (VCMX) or connective tissue (SCTG) at single-implant restorations.

**Material and Methods:** In a non-interventional follow-up observation, peri-implant tissues were evaluated with regard to buccal mucosal thickness (MT) and contour, peri-implant conditions: probing depth (PD), bleeding on probing (BOP), plaque (PI), mucosal margin level/crown height (CH), and clinician-reported esthetics (PE and PES). Patient- and clinician-reported satisfaction was recorded at 3 years (VAS). Mixed-effects models were used to compare the groups.

**Results:** Fifty-six patients (age: 48.0 ± 15.5 years) were followed. MT changes over time did not differ between groups [3.9 ± 1.4 mm to 2.6 ± 1.1 mm for VCMX; 3.8 ± 1.3 mm to 2.9 ± 1.2 mm for SCTG]. The estimated intergroup mean difference (VCMX–SCTG) was 0.2 mm ($p = 0.587$). Mucosal recession was minimal in both groups [0.2 ± 1.0 mm (VCMX) and 0.2 ± 0.6 mm (SCTG)]. At 3 years, intergroup differences in PE scores amounted to 0.5 at mesial ($p = 0.06$) and distal sites ($p = 0.023$) in favor of SCTG. PES scores were high in both groups (VCMX = 10.8; SCTG = 10.9) with no significant differences between the groups ($p = 0.580$). Patient-reported satisfaction with overall esthetics was high (VAS: SCTG = 9.5; VCMX = 9.6) with no significant intergroup differences. Clinician-reported satisfaction was significantly higher for SCTG (VAS: 8.5) compared with VCMX (VAS: 7.4; $p = 0.04$).

**Conclusion:** Both VCMX and SCTG maintained stable peri-implant soft tissues with minimal contour changes 3 years after implant loading. Clinician-reported outcome—esthetics overall—favored SCTG; however, patient-reported outcomes did not support this finding.

Daniel S. Thoma and Irena Sailer equally contributed to this work.

## 1 | Introduction

A healthy and esthetically pleasing smile along with patient comfort has become a key outcome and is of prime concern when replacing missing anterior teeth with implants.

It is well known how buccal bone thickness affects facial contour/esthetic outcomes and the risk of biological complications (Monje et al. 2019; Nohra et al. 2018; Schwarz et al. 2012; Farronato et al. 2020). Even with adequate bone, esthetic changes may still be evident in patients with thin soft-tissue phenotypes, so soft-tissue management is important. Connective tissue grafting (CTG) or soft tissue augmentation should be considered to improve the final contour, mask minor bone changes, and hide the prosthetic abutment when the soft tissue is thin (Farronato et al. 2020; Bienz et al. 2022). Besides, the soft-tissue phenotype has a significant impact on the risk of peri-implantitis, as indicated by recent systematic reviews (Tavelli and Barootchi 2025; Monje et al. 2025).

Surgical techniques for soft tissue augmentation (STA) have been developed, as a sufficient amount of soft tissue volume around the osseous support of the implant, the abutment and marginal areas of the restoration is needed to improve esthetic outcome and functional restoration. These procedures aim for an adequate zone of non-mobile tissues with close adaptation to the emerging implant structure as a prerequisite for a healthy and harmonious relationship with the adjacent teeth (Bienz et al. 2022). Notably, a reduced keratinized tissue width is associated with an increased prevalence of peri-implantitis, plaque accumulation, soft-tissue inflammation, mucosal recession, marginal bone loss, and greater patient discomfort (Ramanauskaite et al. 2022). Moreover, a recent systematic review (Bressan et al. 2023), has indicated that initial soft tissue thickness seems to influence marginal bone loss.

Phenotype modification can be an important component for the esthetic outcome of implant-supported restorations (Tavelli et al. 2021; Thoma et al. 2023). Subtle parameters that report on tissue appearance, texture and color seem to be relevant and have already been incorporated into professional scores for root coverage procedures at natural teeth (Cairo et al. 2009). Efforts to incorporate a professional assessment of esthetics after peri-implant plastic procedures have been made and scores given by clinicians and patients having received SCTG were higher compared with non-augmented implant sites (Wiesner et al. 2010).

Mucosa thickness is a crucial factor in terms of discoloration caused by different restorative materials: the thicker the mucosa, the lesser the chances of tissue discoloration (Jung et al. 2007). Therefore, the efficacy of soft tissue reconstructive surgical interventions and maintaining stable outcomes is a key component for clinical decision-making.

Several systematic reviews have highlighted the predictability of soft tissue volume gain by increasing its quantity and quality, and there is growing evidence pointing to effective augmentation procedures with either connective tissue grafts and/or collagen matrices (Thoma et al. 2018). Both treatment modalities (grafts or replacement grafts) have shown beneficial effects on soft tissue phenotype modification and marginal bone level stability (Tavelli et al. 2021, 2022; Valles et al. 2022).

The rationale for the use of replacement grafts/soft tissue substitutes is based on reduced patient morbidity and a shorter surgery time (Lorenzo et al. 2012; Thoma et al. 2016; Zeltner et al. 2017). The latter study (Zeltner et al. 2017) comparing a recently introduced volume-stable collagen matrix (VCMX) to autogenous subepithelial connective tissue grafts (SCTG) reported a gain of mucosal thickness similar to the gold standard (SCTG). These short-term benefits were substantiated by a follow-up analysis RCT (Thoma et al. 2020) assessing mid-term clinical, radiographic and profilometric outcomes. The authors concluded that only minimal changes in the tissue contour as well as soft tissue occurred at implant sites previously grafted with VCMX or SCTG. However, that study was single-centered and included only a small number of patients.

More robust evidence from multi-center, prospective evaluations of longer-term tissue stability and of clinician- and patient-reported esthetic outcomes of soft tissue augmentation at implants is desirable. Therefore, the aim of this study was to investigate the changes in peri-implant soft tissues with regard to buccal mucosal thickness, contour, peri-implant health, esthetics and patient satisfaction over 36 months following soft tissue augmentation at single-implant reconstruction.

## 2 | Materials and Methods

### 2.1 | Study Design

The present study was designed as a non-interventional follow-up observation of patients who had participated in a multi-center, multinational, randomized clinical trial (Hammerle et al. 2023) (Trial registration: DRKS00005944), performed according to ISO 14155:2011 (clinical investigation of medical devices for human subjects—Good clinical practice), and to national laws in the respective country (Switzerland: Verordnung über die Humanforschung mit Ausnahme der klinischen Versuche (Humanforschungsverordnung, HFV) vom 20. September 2013 (Stand am 1. Januar 2014) gestützt auf das Bundesgesetz über die Forschung am Menschen (Humanforschungsgesetz, HFG) vom 30. September 2011 (Status 1. Januar 2014); Germany: Medical Device law (MPG) und Verordnung über klinische Prüfungen von Medizinprodukten (MPKPV) (13. Mai 2010); Spain: in accordance with the conduct of clinical trials (Real Decreto 223/2004, de 6 de febrero)).

Ethical approval had been obtained by the competent local authority for each center (CH: KEK Zurich, Basec 2018–00775; DE: Bonn Ethics Committee-Nr. 094/18; ES: CEIC Hospital Clínicos San Carlos, Nr. 19/365-O_P).

Prior to his/her entry into the non-interventional 36 months prospective observation, the subjects provided informed consent and the study was performed according to the declaration of Helsinki (64th WMA General Assembly, Fortaleza, Brazil, October 2013) on experimentation involving human subjects. The study was initiated in May 2018 and ended in July 2021. Reporting follows the STROBE checklist for observational studies.

## 2.2 | Inclusion Criteria

- Successful participation and implant restoration in the original study (Hammerle et al. 2023).
- Ability to fully understand the nature of the proposed follow-up observation and ability to sign the informed consent form.

## 2.3 | Exclusion Criteria

- Second soft tissue augmentation since completion of the original RCT study (Hammerle et al. 2023).
- Severe trauma to implant site.

Details of the inclusion and exclusion criteria of the original study, randomization and allocation concealment have been previously reported (Hammerle et al. 2023).

## 2.4 | Clinical Procedures

### 2.4.1 | Soft Tissue Augmentation and Implant Restoration

Soft tissue augmentation surgical interventions, study devices and methods have been described in detail (Hammerle et al. 2023). In brief, in areas of esthetic concern, patients with needs for a soft tissue volume augmentation prior to a single tooth implant restoration had been randomly treated with either autogenous SCTG (standard of care control) or VCMX (Geistlich Fibro-Gide, Geistlich Pharma AG, Wolhusen, Switzerland). Three months later, abutment connection was performed. A small crestal incision was placed to provide access to the head of the implant. Then, the cover screw was removed and replaced with a healing cap. The final restoration was fabricated with the proper emergence profile, avoiding buccal pressure and seated on the implant according to standard clinical procedures 180 days after soft tissue grafting (Hammerle et al. 2023).

### 2.4.2 | Baseline and Follow-Up Examination

The time point 2 weeks after final implant restoration was defined to be the baseline for the present prospective non-interventional observation. An experienced blinded examiner (SJ, LM, MS, ISM) not involved in the original surgical procedures recorded all the measurements at each study center. All procedures applied were part of the standard routine, in accordance with accepted good clinical practice.

## 2.5 | Outcome Measures

The primary outcome was the change in mucosal thickness between baseline and 36 months. Secondary outcomes were changes in peri-implant tissue contour, clinical peri-implant health, esthetic outcomes and patient satisfaction.

### 2.5.1 | Mucosal Thickness

Mucosal thickness (MT) was measured using an endodontic file (31/15, Dentsply Mailefer) and a silicon stopper. The edge of the silicon stopper was placed at the most apical part of the gingival margin in order to position the needle. The measurements were taken 1.0 mm apically of the gingival margin on the buccal aspect of the implant-supported crown.

### 2.5.2 | Profilometrics of the Peri-Implant Tissue Volume

Impressions of the implant sites were taken at the baseline examination (2 weeks after loading) and at 3 years using an A-silicone impression material (President, Coltene/Whaledent) including at least the two neighboring teeth and the respective mucosa. Dental stone casts were fabricated (Fujirock, Picodent, abc dental AG, Switzerland) and optically scanned with a desktop 3D scanner (Imetric 3D, Courgenay, Switzerland). Subsequently, the obtained stereolithography (STL) files from baseline and 3 years were imported into a digital imaging software program (SMOP, Swissmeda, Zurich, Switzerland), superimposed and divided in defined linear planes 1, 3, and 5 mm below the gingival margin (Sapata et al. 2018). All the 3D analyses were performed by an experienced and calibrated examiner (Dr. Leonardo Mancini) not involved in any surgical or prosthetic procedure. The mean profilometric change between the outer surface data at baseline and 3 years was calculated by specifically designed software (SMOP, Swissmeda, Zurich, Switzerland) in millimeters (mm) at the three pre-defined linear planes 1, 3, and 5 mm below the gingival margin.

### 2.5.3 | Clinical Peri-Implant Health

In order to evaluate the health of the peri-implant soft tissue, the following parameters were measured at the implant sites:

- Basic Periodontal Examination (BPE)
- Plaque Index (PCR), in %
- Keratinized Tissue Width (KT), in mm
- Bleeding on Probing (BOP), 0/1
- Probing Depth (PD), in mm
- Mucosal margin level measured by Crown Height (CH), in mm

The position of the gingival margin was measured to the nearest mm with a UNC15 periodontal probe (PCP-UNC 15, Hu-Friedy, Chicago, USA) using both the incisal edge of the restoration and the most apical location of the mucosal margin. Outcomes were assessed using changes in recession from the incisal edge as the reference. Probing depth (PD) and width of the keratinized tissue (KT) were assessed clinically with a UNC15 probe. Oral hygiene levels were assessed with the plaque control record according to Sillness and Löe (Loe 1967), while gingival inflammation was assessed as percentage of sites with bleeding on probing. All assessments

except the KT width were assessed on 6 sites and the respective two neighboring teeth: Mesio-buccal, mid-buccal, disto-buccal, mesio-oral, mid-oral, disto-oral at baseline and 3-year follow-up visits.

#### 2.5.4 | Esthetic Evaluation

Esthetics of the peri-implant soft tissues was evaluated by recording:

- Papilla Index Score (PE), (Jemt 1997), with 5 grades (0–4) for the mesial and distal papilla.
- Pink Esthetic Score (PES), (Furhauser et al. 2005) including 7 parameters and three categories 0-1-2 (best) with the highest achievable score of 14.
- Clinician-reported satisfaction with respect to soft tissue appearance using an adapted Visual Analogue Scale (VAS) questionnaire at 3 years. Included were four categories: (1) Color, (2) texture, (3) volume of the soft tissue, as well as (4) overall esthetics.

#### 2.5.5 | Patient-Reported Outcomes

Patient-reported outcomes were evaluated by recording:

- Oral Health Impact Profile (OHIP-14), a questionnaire filled out by the patients at baseline and 3 years
- Patient-reported satisfaction in respect to soft tissue appearance and pain during patient administered cleaning using an adapted Visual Analogue Scale (VAS) questionnaire at 3 years. Included were four aspects: (1) color, (2) texture, (3) esthetics overall and (4) pain during cleaning.

### 2.6 | Statistical Analysis

#### 2.6.1 | Descriptive Statistics

Quantitative data are summarized as mean, median, standard deviations and upper (Q3) and lower (Q1), quartiles for each treatment. Categorical data are expressed as frequencies and percentages. Percentages are based on the total number of patients in the respective analysis set.

#### 2.6.2 | Exploratory Statistics

A mixed-effects model was used to compare both treatment groups. Fixed factors included treatment group, time, and their interaction, while random factors accounted for study center and patient effects. Between-group differences were estimated using a linear contrast command and two-sided 95% confidence intervals (CIs) were calculated. All *p*-values and CIs were interpreted in an exploratory manner. For continuous variables not normally distributed, such as esthetic questionnaire scores and OHIP scores, non-parametric tests were applied. Between-group comparisons were performed using the Wilcoxon–Mann–Whitney test, and within-group comparisons using the Wilcoxon signed-rank test. All statistical analyses were conducted using SAS software, version 9.4 (SAS Institute Inc., Cary, NC, USA).

## 3 | Results

The present multicenter 36-month observational study enrolled 64 patients available for follow-up at 4 centers (Center 1: Clinic of Reconstructive Dentistry, University of Zurich; Center 2: Department of Periodontology, Operative, and Preventive Dentistry, University Hospital Bonn; Center 3: Facultad de Odontologia, Universidad Complutense de Madrid; Center 4: Division of Fixed Prosthodontics and Biomaterials, University of Geneva). A total of 56 patients (28 males/28 females; mean age 48.0 ± 15.5 years) were available for the 36-months follow-up examination. Over the 3 years, one patient in the SCTG group and 6 in the VCMX group were lost to follow-up due to inability to contact them. One patient in the SCTG group was excluded due to reconstructive surgery after detection of peri-implantitis. No subject was lost due to known study-related reasons. The corresponding flow chart is displayed in Figure 1. Twenty-eight patients per group (VCMX: 15 males, 13 females; SCTG: 13 males, 15 females) were analyzed; Center 1 (28 patients, VCMX: 15; SCTG: 13), Center 2 (11 patients, VCMX: 5; SCTG: 6), Center 3 (10 patients, VCMX: 4; SCTG: 6), Center 4 (7 patients, VCMX: 4; SCTG: 3), respectively. Representative cases for each treatment group are shown in Figure 2.

An overview of baseline demographics of the study subjects including the location of the treated implant sites is presented in Table 1. Overall, at 3 years patients in general showed healthy periodontal conditions as documented by basic periodontal examination with a mean sum-BPE of 5.2 ± 3.4 (VCMX-group) and 5.0 ± 2.5 (SCTC-Group).

Clinical outcomes at baseline and after 36 months are presented in Table 2. Adjusted intra- and inter-group comparisons of clinical outcomes and their changes over time (BL to 3 years) resulting from a multilevel analysis (Multilevel model: Center, patient, implant) and from linear model analyses for profilometrics are displayed in Table 3.

### 3.1 | Changes in Mucosal Thickness

At baseline (2 weeks after insertion of the final restoration) the buccal mucosal thickness (MT) was comparable between the groups, 3.9 ± 1.4 mm in group VCMX and 3.8 ± 1.3 mm in group. After 3 years, a statistically significant decrease in MT was observed in both groups, decreasing to 2.6 ± 1.1 mm in VCMX ($p = 0.014$) and to 2.9 ± 1.2 mm in SCTG ($p < 0.001$) (Tables 2a and 3a). The estimated mean intergroup difference in change was 0.2 mm (CI: −0.70, 1.23) with no statistically significant difference between groups ($p = 0.587$) (Table 3b).

### 3.2 | Profilometric Changes of Peri-Implant Tissue Volume

For the VCMX group, the profilometric changes revealed a loss of 0.4 mm (SD: ±0.5 mm) at the 1 mm level, 0.5 mm (SD: ±0.4 mm) at the 3 mm level, and 0.4 mm (SD: ±0.6 mm) at the 5 mm level,

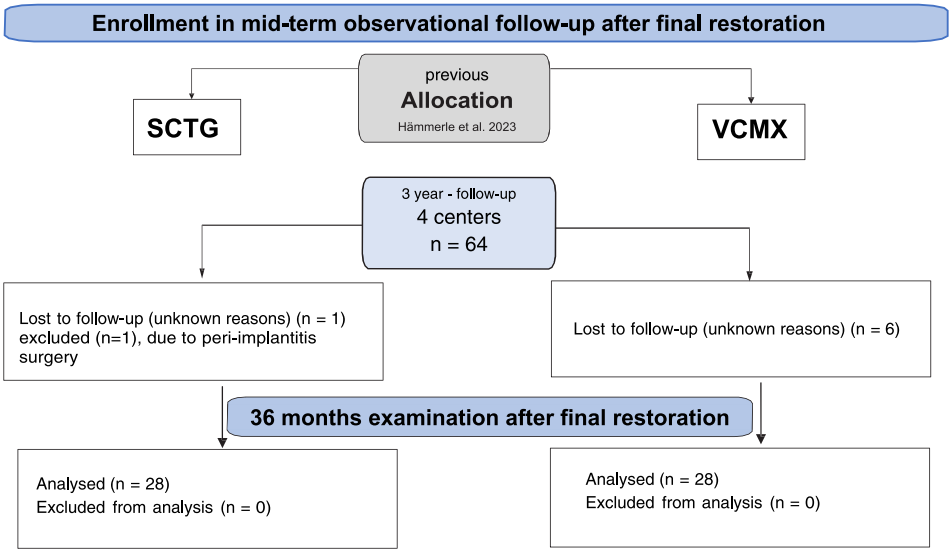


**FIGURE 1** | CONSORT patient accountability diagram. In the original multicenter study (9 centers) 88 patients/defects were randomized and allocated for test (VCMX) or control (SCTG) treatment. 79 patients were examined 1 year after final restoration. Out of 4 centers 56 patients could be analyzed 3 years after implant site restauration; 1 patient was excluded (exclusion criteria) due to peri-implantitis surgery, and 7 patients were lost to follow-up. In these 4 centers 64 patients' implant site restauration was performed (baseline).

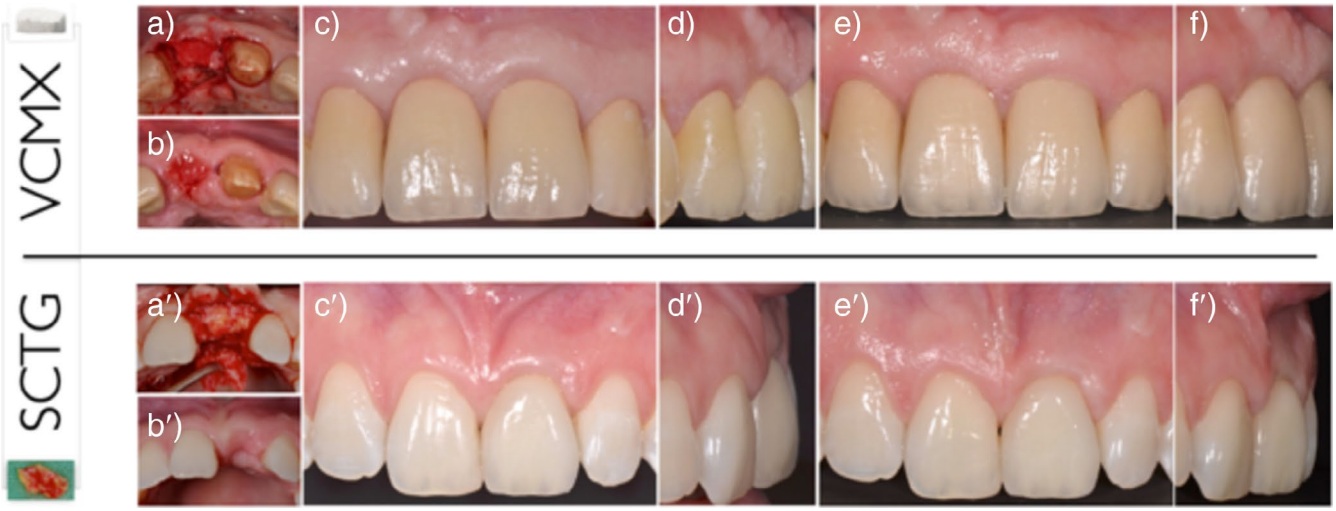


**FIGURE 2** | Representative cases of each treatment group. VCMX: (a) VCMX was placed crestally and buccally. (b) after suture removal. (c) Baseline—buccal view after final crown delivery. (d) Baseline—contour view after final crown delivery. (e) 3-year follow-up—buccal view. (f) 3-year follow-up—contour. (g) SCTG: (a') intra-operative view: SCTG placement after harvesting from the palate. (b') after suture removal. (c') Baseline view—buccal after final crown delivery. (d') Baseline—contour view after final restoration. (e') 3 year follow-up. (f') 3 year follow-up—lateral contour view (Cases provided by Karin Jepsen).

respectively. Changes in the STCG group amounted to a loss of 0.3 mm (SD: ±0.5 mm) at the 1 mm level, 0.1 mm (SD: ±0.4 mm) at the 3 mm level, and 0.2 mm (SD: ±0.6 mm) at the 5 mm level, respectively. A statistically significant intergroup difference in favor of SCTG was only found for measurements at the 3 mm level with −0.4 mm (CI: −0.659, −0.152; $p = 0.002$).

### 3.3 | Peri-Implant Conditions

Mucosal margin levels/Crown height (CH) were rather stable with changes (BL—3 Years) of −0.2 ± 1.0 mm (VCMX) and −0.2 ± 0.6 mm (SCTG) between baseline and 3 years, indicating only minimal increase in marginal recession. At 3 years, the initially shallow mean peri-implant PD had increased to 3.2 mm (VCMX) and 3.5 mm (SCTG), and mean percentage values for BOP at peri-implant sites amounted to 24% (VCMX) and 30% (SCTG). Peri-implant mean PI increased from 9.5% ± 13.9% to 11.3% ± 23.6% (VCMX) and from 14.2% ± 19.4% to 27.9% ± 42.5% (SCTG). No statistically significant intergroup differences in changes over time was found for PD, BOP, and PI. The width of keratinized tissue (KT) remained stable between baseline and 3 years, for both VCMX- and SCTG-groups (Tables 2 and 3).

**TABLE 1** | Study population.

| | Total mean (SD) $N=56$ | SCTG mean (SD) $N=28$ | VCMX mean (SD) $N=28$ |
|---|---|---|---|
| *Patient level* | | | |
| Age at crown insertion (years) | 48.0 ± 15.5 | 47.5 ± 16.33 | 49.5 ± 14.75 |
| Gender | | | |
| Male | 28 (50%) | 13 (46.4) | 15 (53.6) |
| Female | 28 (50%) | 15 (53.6) | 13 (46.4) |
| Smokers (< 10 cigarettes per day) | 12 | 6 | 6 |
| Approximate cigarettes per day (0–10) | 1.7 (1.4) | 1.5 (3.4) | 0.7 (2.0) |
| *Implant level* | | | |
| Maxillary central incisor | 16 (28.5) | 8 (28.5) | 8 (28.5) |
| Maxillary lateral incisor | 6 (10.7) | 3 (10.7) | 3 (10.7) |
| Maxillary canine | 5 (9) | 3 (10.7) | 2 (7.1) |
| Maxillary premolar | 18 (32.1) | 8 (28.5) | 10 (35.7) |
| Mandibular central incisor | 1 (1.7) | 1 (3.6) | 0 |
| Mandibular lateral incisor | 1 (1.7) | 1 (3.6) | 0 |
| Mandibular premolar | 9 (16.1) | 4 (14.2) | 5 (17.8) |

*Note:* Baseline demographics of the study subjects including the location of the treated implant sites. Patient and implant site characteristics 2 weeks after crown insertion (baseline).

### 3.4 | Esthetic Evaluation

Clinician-reported esthetic outcomes included PE and PES.

Mean Papilla Index Scores (PE) of 1.6 (VCMX) and 1.8 (SCTG) were found to be significantly improved to 2.3 at 3 years only in the VCMX group (Tables 2b and 3b).

The relatively high mean Pink Esthetic Scores (PES) of 9.9 (VCMX) and 10.2 (SCTG) at baseline showed a slight, non-significant improvement after 3 years (Tables 2b and 3b).

Clinician-reported outcomes regarding overall esthetics (Table 4b) revealed a statistical difference in favor of SCTG (8.5 vs. 7.4, $p=0.04$). Nevertheless, no statistical differences were detected between the groups with respect to soft tissue color, texture or volume.

### 3.5 | Patient-Reported Outcomes

OHIP-14 scores as measured on a scale from 0 to 70 (with higher scores indicating poorer oral health-related quality of life) and overall patient- and/or clinician-reported satisfaction by VAS scores from 0 to 10 (0 being poorest, 10 being best) are depicted in Table 4.

OHIP-14 scores started out at baseline with low values of 2.2 ± 3.3 (VCMX) and 4.1 ± 5.9 (SCTG). At 3 years, the mean OHIP scores improved even further to 1.7 ± 2.88 (VCMX) and 2.4 ± 4.8 (SCTG). Intra- and inter-group comparisons for OHIP-14 and patient-reported esthetic satisfaction (Table 4b) assessed by VAS questionnaires did not show any statistically significant differences between VCMX and SCTG.

### 3.6 | Safety Evaluation/Adverse Events

Investigators recorded no study related adverse events during the follow-up period of the study indicating that both treatments were safe and well tolerated.

The following events were reported: bleeding when brushing teeth (1 case), periimplantitis (1 case), crown loosening (1 case).

### 3.7 | Center Effect

Across nearly all parameters, there were no meaningful treatment × center interactions, indicating that treatment effects were consistent across study sites. Only mucosal thickness at 3 years showed a borderline interaction ($p=0.05$), which is likely attributable to random variation given the number of tests performed. Overall, the treatment demonstrated comparable performance across centers and the minor differences observed most likely reflect normal site-to-site variability rather than true differences in treatment response. In other words, the outcomes were not influenced by where patients were treated, underscoring the reproducibility and generalizability of the observed effects.

**TABLE 2** | Characteristics of augmented gap sites after insertion of reconstructions of clinical parameters (a), PE and PES esthetic SUM-Scores (b) at the different timepoints in both treatment groups over time. Quantitative data of 28 patients are presented as mean, median, standard deviations and upper and lower quartiles for each variable.

| | VCMX | | | | | | | SCTG | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **Mean** | **±SD** | **Min** | **Q1** | **Median** | **Q3** | **Max** | **Mean** | **±SD** | **Min** | **Q1** | **Median** | **Q3** | **Max** |
| (a) Clinical parameters | | | | | | | | | | | | | | |
| Mucosal Thickness (MT) buccal | | | | | | | | | | | | | | |
| Baseline | 3.9 | 1.4 | 2 | 3 | 4 | 5 | 7 | 3.8 | 1.3 | 2 | 2.5 | 4 | 4.5 | 7 |
| 3 years | 2.6 | 1.1 | 0.1 | 2 | 3 | 3 | 6 | 2.9 | 1.2 | 1 | 2.1 | 3 | 3 | 7 |
| Mucosal Margin/Crown Height (CH) | | | | | | | | | | | | | | |
| Baseline | 9.6 | 1.2 | 7 | 9 | 9.5 | 11 | 12 | 9.6 | 1.7 | 6 | 8.5 | 10 | 11 | 13 |
| 3 years | 9.9 | 1.7 | 7.5 | 9 | 10 | 11 | 14 | 9.7 | 1.8 | 6 | 9 | 10 | 11 | 13 |
| Keratinized tissue (KT) | | | | | | | | | | | | | | |
| Baseline | 3.2 | 1.4 | 1 | 2 | 3 | 4 | 6 | 3.5 | 1.3 | 1.5 | 2.0 | 3.0 | 4.0 | 6 |
| 3 years | 3.3 | 1.5 | 0 | 2 | 3 | 4 | 6 | 3.8 | 2.8 | 1.5 | 2.7 | 3.0 | 4.5 | 6 |
| Pocket depth (PD) (6 sites/implant- mean) (mm) | | | | | | | | | | | | | | |
| Baseline | 2.1 | 0.2 | 1.6 | 2 | 2.1 | 2.3 | 2.6 | 2.2 | 0.4 | 1.33 | 2 | 2.17 | 2.5 | 3 |
| 3 years | 3.2 | 0.8 | 1.5 | 2.6 | 3.1 | 3.6 | 5 | 3.5 | 1.4 | 1.5 | 2.7 | 3.3 | 4.1 | 8 |
| Bleeding on Probing (BOP) (6 sites/implant) (%) | | | | | | | | | | | | | | |
| Baseline | 5.9 | 11.3 | 0 | 0 | 0 | 8.3 | 33.3 | 7.4 | 10.6 | 0 | 0 | 0 | 16.6 | 33.3 |
| 3 years | 24.4 | 25.4 | 0 | 0 | 16.6 | 50 | 66.6 | 30.36 | 27.6 | 0 | 0 | 25.0 | 50.0 | 83.3 |
| Plaque Index (PI) (6 sites/implant) (%) | | | | | | | | | | | | | | |
| Baseline | 9.5 | 13.9 | 0 | 0 | 0 | 16.6 | 50 | 14.2 | 19.4 | 0 | 0 | 0 | 16.6 | 66.6 |
| 3 years | 11.3 | 23.6 | 0 | 0 | 0 | 16.6 | 100 | 27.9 | 42.5 | 0 | 0 | 8.3 | 41.6 | 66.6 |
| (b) Esthetic assessments | | | | | | | | | | | | | | |
| Papilla Evaluation (PE) | | | | | | | | | | | | | | |
| Baseline | | | | | | | | | | | | | | |
| Mesial | 1.6 | 1.0 | 0 | 1 | 1.5 | 2.5 | 3 | 1.8 | 0.9 | 0 | 1 | 2 | 2 | 3 |
| Distal | 1.6 | 1.0 | 0 | 1 | 1.5 | 2.5 | 3 | 1.8 | 0.7 | 1 | 1 | 2 | 2 | 3 |
| 3 years | | | | | | | | | | | | | | |
| Mesial | 2.3 | 0.8 | 0 | 2 | 2 | 3 | 4 | 1.9 | 0.8 | 0 | 1 | 2 | 3 | 3 |
| Distal | 2.2 | 0.6 | 1 | 2 | 2 | 3 | 3 | 1.8 | 0.8 | 1 | 1 | 2 | 2 | 3 |
| Pink Esthetic Score (PES) | | | | | | | | | | | | | | |
| Baseline | 9.9 | 2.7 | 3 | 8 | 10 | 12 | 14 | 10.2 | 3.2 | 0 | 8.5 | 10.5 | 12.5 | 14 |
| 3 years | 10.8 | 2.4 | 5 | 9.5 | 10.5 | 13 | 14 | 10.9 | 1.9 | 7 | 10 | 11 | 12 | 14 |

## 4 | Discussion

The present non-interventional follow-up observation of patients who had previously participated in a multi-center, multinational, randomized clinical trial comparing a collagen-based soft tissue substitute (VCMX) with an autogenous connective tissue graft (SCTG) for mucosal thickness augmentation was followed from crown insertion to 36 months to evaluate changes in soft tissue dimensions as well as patient- and clinician-reported esthetic satisfaction.

VMCX or SCTC showed a comparable slight reduction in buccal mucosal thickness, a buccal contour with minimal loss of volume over time, stable peri-implant mid-mucosal margin levels, for both treatment groups from crown insertion (baseline) to 36 months. Similar favorable PES scores were found in both

**TABLE 3** | Adjusted comparisons of clinical outcomes—changes over time (BL to 3 Years) – between test and control at 36 months derived from mixed model analysis (Multilevel model: Center, patient, implant). Effect sizes are presented as adjusted mean differences with 95% confidence intervals. Clinical parameters (a), esthetic parameters (b).

| Changes over time (BL to 36 months) | SCTG | | VCMX | | SCTG | SCTG | VCMX | VCMX | VCMX-SCTG | VCMX-SCTG | VCMX-SCTG |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Intra-group changes over time | | Intra-group changes over time | | Intra-group | Intra-group | Intra-group | Intra-group | Inter-group | | Inter-group |
| Intragroup and intergroup differences | Mean | SD | Mean | SD | Over time 95% CI | *p* | Over time 95% CI | *p* | Estimated difference | 95% CI | *p* |
| (a) Clinical parameters | | | | | | | | | | | |
| Primary outcome | | | | | | | | | | | |
| Mucosal thickness (MT) buccal (mm) BL-3Y | 0.9 | 1.9 | 1.2 | 1.5 | (0.285, 1.641) | 0.014 | (0.536, 1.918) | < 0.001 | 0.2 | (−0.704, 1.232) | 0.587 |
| Profile (mm) | | | | | | | | | | | |
| 1 mm | −0.3 | 0.5 | −0.4 | 0.5 | (−0.451, −0.054) | < 0.001 | (−0.588, −0.218) | 0.019 | −0.1 | (−0.422, 0.123) | 0.276 |
| 3 mm | −0.1 | 0.4 | −0.5 | 0.4 | (−0.335, 0.042) | 0.106 | (−0.722, −0.383) | < 0.001 | −0.4 | (−0.659, −0.152) | 0.002 |
| 5 mm | −0.2 | 0.6 | −0.4 | 0.6 | (−0.437, 0.110) | 0.254 | (−0.695, −0.227) | < 0.001 | −0.3 | (−0.657, 0.063) | 0.103 |
| CH (mm) | −0.2 | 0.6 | −0.2 | 1.0 | (0.575, −0.141) | 0.116 | (0.603, −0.083) | 0.221 | −0.04 | (−0.539, 0.454) | 0.864 |
| PD (mm) (6 sites/implant- mean) (mm) | −1.3 | 1.3 | −1.0 | 0.8 | (−1.790, −0.926) | < 0.001 | (−1.478, 0.630) | < 0.001 | 0.3 | (−0.301, 0.910) | 0.318 |
| BOP (mm) (6 sites/implant) (%) | −22.8 | 27.7 | −18.4 | 24.1 | (−32.88, −12.80) | < 0.001 | (−28.31, −8.60) | < 0.001 | 4.4 | (−9.678, 8.453) | 0.534 |
| PI (Plaque Index) (6 sites/implant) (%) | −12.3 | 32.9 | −2.4 | 27.1 | (−23.96, −0.736) | 0.062 | (−13.79, 9.02) | 0.646 | 9.9 | (−6.308, 6.235) | 0.225 |
| KT (mm) | −0.3 | 1.7 | 0.0 | 1.1 | (−0.833, 0.314) | 0.457 | (−0.574, 0.574) | 1.000 | 0.2 | (−0.552, 1.070) | 0.i524 |
| (b) Esthetic SUM-Scores | | | | | | | | | | | |
| PE mesial | −0.1 | 0.6 | −0.7 | 0.8 | (−0.396, 0.173) | 0.376 | (−0.958, −0.399) | < 0.001 | −0.5 | (−0.966, −0.169) | 0.006 |
| PE distal | −0.04 | 0.7 | −0.6 | 0.9 | (−0.363, 0.289) | 0.802 | (−0.892, −0.251) | 0.003 | −0.5 | (−0.991, −0.077) | 0.023 |
| PES (Fürhauser) | −0.5 | 2.3 | −0.9 | 3.1 | (−1.538, 0.575) | 0.292 | (−1.931, 0.145) | 0.137 | −0.4 | (−1.893, 1.070) | 0.580 |

**TABLE 4** | Patient- and clinician-reported outcomes. (a) OHIP-14 scores at baseline and at 36 months. Inter- or intragroup differences were statistically not significant for OHIP-14. (b) Soft tissue esthetic judgements as reported outcome measures, pain evaluation (patient), and of the soft tissue volume (dental professional). At 3 years patient evaluations deriving from questionnaires presented not statistically significant differences between SCTG or VCMX. Corresponding ratings by clinicians also did not show any statistically significant differences between SCTG or VCMX for soft tissue color, texture and volume but notably a statistical difference was found for "Esthetics overall"-judgement in favor of the SCTG.

**(a)**

| Questionnaire/ evaluation | SCTG, mean (SD) | | VCMX, mean (SD) | | SCTG vs VCMX, **intergroup differences |
|---|---|---|---|---|---|
| **Oral health related quality of life** | **Baseline, $N=28$** | **3 years, $N=27$** | **Baseline, $N=28$** | **3 years, $N=27$** | ***p*** |
| **OHIP14** | 4.1 ± 5.9 | 2.4 ± 4.8 | 2.2 ± 2.9 | 1.7 ± 2.9 | NS |

| Randomized intervention | OHIP-14 | *N* | Mean | SD | Min | Q1 | Median | Q3 | Max |
|---|---|---|---|---|---|---|---|---|---|
| VCMX | Baseline (BL) | 28 | 2.2 | 3.3 | 0 | 0 | 0.5 | 3 | 12 |
| SCTG | | 28 | 4.1 | 5.9 | 0 | 0 | 1.5 | 5.75 | 21 |
| VCMX | 3 years | 27 | 1.7 | 2.9 | 0 | 0 | 0 | 3 | 10 |
| SCTG | | 27 | 2.4 | 4.8 | 0 | 0 | 0 | 2 | 19 |
| VCMX | Difference (3Y-BL) | 27 | −0.6 | 3.7 | −11 | −2 | 0 | 0 | 9 |
| SCTG | | 27 | −1.7 | 3.6 | −11 | −4 | 0 | 0 | 5 |
| **Intergroup differences*** | | | | | | | | | |
| BL_OHIP_total | $p=0.3886$ | | | | | | | | |
| 3Y_OHIP_total | $p=0.8266$ | | | | | | | | |
| Difference_OHIP | $p=0.6567$ | | | | | | | | |

**(b)**

| Patient satisfaction** at 3 years | SCTG | VCMX | | SCTG vs VCMX, *intergroup differences |
|---|---|---|---|---|
| **VAS** | | | **Total score** | ***p*** |
| Color of the soft tissue | 9.3 ± 0.9 | 9.5 ± 0.74 | 9.4 ± 0.8 | NS |
| Texture of the soft tissue | 9.6 ± 0.7 | 9.6 ± 0.86 | 9.6 ± 0.8 | NS |
| Esthetics overall | 9.5 ± 0.7 | 9.6 ± 0.91 | 9.5 ± 0.8 | NS |
| Pain during home cleaning | 9.6 ± 1.3 | 9.3 ± 1.58 | 9.4 ± 1.4 | NS |
| **Clinician satisfaction** at 3 years** | | | | |
| **VAS** | | | | |
| Color of the soft tissue | 9.1 ± 1.1 | 8.7 ± 1.8 | 8.9 ± 1.5 | NS |
| Texture of the soft tissue | 9.1 ± 1.0 | 8.4 ± 1.8 | 8.8 ± 1.5 | NS |
| Esthetics overall | 8.5 ± 1.5 | 7.4 ± 1.9 | 8.4 ± 1.3 | 0.04 |
| Volume of the soft tissue | 8.6 ± 1.1 | 8.1 ± 1.6 | 7.9 ± 1.8 | NS |

*Wilcoxon Mann–Whitney-Test.
**VAS scores 0–10 (0 being poorest, 10 being best).

treatment groups with a papilla index more favorable over time for SCTG. Patient- and clinician-reported esthetic satisfaction scores were high, with slightly higher ratings given by the patients. Favorable baseline scores for oral health related quality of life (OHIP-14) improved slightly over time. This is in contrast to inferior values at the beginning of the original study [7.3 ± 7.0 (VCMX) and 8.5 ± 10.5 (SCTG)] (Hammerle et al. 2023).

Short-term benefits of VCMX have been demonstrated (Chappuis et al. 2018; Hammerle et al. 2023) and it is well known that after a major initial remodelling process prior to the insertion of the final restoration, the contour gains tend to remain more stable over some time and with small changes, the latter confirmed by our findings. Although in our follow-up the contour changes were small (−0.1 to −0.4 mm) for VCMX the decrease

of the outer surface profile was statistically significant at all 3 levels. The latter has to be seen in contrast to SCTG, where statistically significant changes were found at level 1 mm only. Histologically, these differences may be attributed to variations in tissue integration and differences in the composition of elastic fibers between VCMX and SCTG (Smirani et al. 2025). However, as already mentioned, all contour changes were minimal and clinical relevance may be a matter of debate. It has to be noted that the estimated difference between VCMX-SCTG of 0.4 mm (CI: −0.659, −0.152) is below the pre-defined non-inferiority margin of 0.5 mm for treatment differences in mucosal thickening (Hammerle et al. 2023). Contour deficiencies of 0.4 mm may be statistically significant but together with a stable mid-facial mucosal margin that situation may not reflect clinical relevance and may not necessarily be important for a patient (De Bruyn et al. 2015). Clinicians have to discuss with the patients how much they are willing to give up in terms of clinical efficacy relative to a "gold standard" of care in exchange for the benefits of reduced morbidity with soft tissue substitutes (Thoma et al. 2023).

A previously published RCT using a similar experimental design (Thoma et al. 2020) investigated the same soft tissue substitute versus an autogenous connective tissue graft. Between baseline (crown insertion) and the 3-year follow-up examination a slight decrease of the buccal peri-implant tissue contour, consistent with the present findings and confirmed by our findings by transmucosal probing. Notably the earlier study was single center and the patient number per group was small (up to $n = 10$).

In another recent multi-center RCT over 3 years, Surdiacourt et al. (2024) compared the same soft tissue substitute to an autogenous connective tissue graft in terms of changes in buccal soft tissue profile when applied at single implant sites. Fifty patients were re-examined after 3 years. A mean difference of 0.35 mm (95% CI: 0.06–0.65) in favor of the SCTG group was significant ($p = 0.021$). The magnitude of changes compares well to our measures of 0.1–0.4 mm in differences over time. It should be noted, however, that here a different implant protocol, different soft tissue augmentation timing, and restoration was applied. In our study implant restorations were placed 180 days after STA procedures. So, we may speculate that the longer maturation time for VCMX may be the reason for improved stability of the peri-implant tissues in the test group with no major treatment related differences in the present study. In addition, the complete submerged healing model for VCMX may have contributed to more mucosal stability. It has to be noted also that VCMX treated sites within that different implant protocol by Surdiacourt et al. (2024) experienced significantly more marginal bone loss (0.43 mm; 95% CI: 0.77 to 0.09; $p = 0.015$) than SCTG.

In the present study, no radiographs were available to assess bone level changes, because there was no reasonable clinical justification for an additional radiographic examination due to the fact that after 3 years shallow peri-implant probing values did not indicate pathologic bone loss, with the exception of 1 patient experiencing peri-implantitis. That adverse event was treated by an augmentation procedure. Keratinized tissue width (KT) remained stable, for both SCTG and VCMX consistent with findings of a systematic review (Valles et al. 2022).

After 3 years, papilla evaluation scores (PE) were reduced for VCMX with mean 0.5 of scoring difference between the groups in favor of SCTG ($p < 0.05$) (Table 3b). Although PE appeared more favorable for SCTG, a high level of patient satisfaction was achieved by the use of a replacement graft (VCMX), an observation that is in line with two recent reviews (Thoma et al. 2023; Valles et al. 2022). For that reason, clinicians have to respect the patients'point of view that their treatment of choice may not necessarily be the one that shows the highest clinical efficacy but the one that matches his/her own values and preferences (Chow et al. 2012; Thoma and Strauss 2022).

In addition, although some soft tissue changes occurred over time also PES remained stable, for both SCTG and VCMX (Table 3b). The Pink Esthetic Score (PES) showed very good ratings at baseline examination. PES sum-scores were 9.9 for VCMX and 10.2 for SCTG (Table 2b; Table S1). The 3-year examination scored above 10 for SCTG and VCMX (10.9/10.8). Compared with the present study, Thoma and co-workers (Thoma et al. 2020) found stable esthetics in a similar designed study. Well in agreement with our study no intergroup differences were found accompanied by high PES scores.

Favorable scores for oral health related quality of life (OHIP-14) were slightly improved over time from $4.1 \pm 5.9$ to $2.4 \pm 4.8$ (SCTG) and from $2.2 \pm 2.9$ to $1.7 \pm 2.88$ (VCMX) with no intergroup differences. Evidently that is in contrast to the study by Thoma et al. (2020) where patients reported outcome measures significantly different between the treatment groups [VCMX 0.5 (0.0; 2.0) and SCTG 0.0 (0.0; 0.0) (intergroup $p = 0.023$)]. In comparison to patient ratings of the original study with values of $7.3 \pm 7.0$ (VCMX) and $8.5 \pm 10.5$ (SCTG) (Hammerle et al. 2023) oral health related quality of life measures showed to be more compromised at the beginning of the study. In general, it should be emphasized that the composite value of an OHIP-14 may not specifically capture the patient experience related to the STA procedure itself.

While current image acquisition protocols would likely rely on digital files derived from intraoral scanners today, not all participating centers had access to 3D intraoral scanners at the start of the study. To ensure proper standardization, conventional impressions of the implant sites had to be taken. Dental stone casts were fabricated and optically scanned with a desktop 3D scanner.

The outcomes of the present non-interventional follow-up are limited by a number of factors: (1) the indirect technique (hybrid workflow) to obtain the outer surface/contour (STL) 3D measurements is prone to inherent errors by adding steps for linear measurement and analyses, (2) indices used by clinicians to assess esthetic outcomes like the PES score are evaluating aspects possibly not related to soft tissue volume augmentation, (3) PE-scoring is not only determined by soft tissue volume augmentation alone but also influenced by the shape of the crown. Finally, the reduced number of patients available for re-examination at 3 years compared with the 1-year follow-up limited the statistical power of the present analysis.

Despite the limitations mentioned above, this is the first multicenter RCT that provides mid-term data with a cross-linked VCMX or SCTG in a submerged and staged approach showing

safety, stability and effectiveness in thickening the buccal mucosa without differences between the tested groups. Changes in buccal mucosal thickness, a buccal profile with minimal loss over time, a stable peri-implant mid-mucosal margin, were comparable for both treatments from crown insertion to 3 years.

A crucial aspect in the interpretation of the actual findings is the distinction between statistical significance and clinical relevance. Although certain parameters, such as contour differences at 3 mm depth, demonstrated statistical significance, the absolute magnitude of these differences ($\leq$0.4 mm) is unlikely to be of perceptible esthetic impact or to influence clinical decision-making. This discrepancy underscores the fact that highly sensitive digital measurement methods may detect minimal changes that, while statistically robust, do not translate into clinically meaningful benefits.

Statistical versus clinical significance fails in the discrete evaluation of soft tissue augmentation procedures. It is very obvious that thickness and volume changes especially using 3D scanning provide accuracy beyond the eye's ability to discriminate.

Therefore, when adequately validated, a patient-reported outcome measure should be considered to be the primary outcome, since the information it provides is likely to be more relevant to patients than many clinician-reported outcomes (Thoma and Strauss 2022).

### Author Contributions

**Karin Jepsen:** conceptualization, methodology, validation, data curation, investigation, funding acquisition, writing – original draft, writing – review and editing, supervision, visualization, project administration, resources. **Søren Jepsen:** conceptualization, methodology, investigation, validation, writing – original draft, writing – review and editing, resources, supervision. **Christoph H. F. Hämmerle:** conceptualization, methodology, validation, investigation, funding acquisition, project administration, writing – review and editing, resources. **Leonardo Mancini:** writing – review and editing, formal analysis, data curation, validation. **Franz J. Strauss:** formal analysis, writing – review and editing, data curation, validation. **Malin Strasdin:** investigation, writing – review and editing, methodology, validation. **Stefan Hicklin:** investigation, validation, writing – review and editing, methodology. **Mariano Sanz:** conceptualization, methodology, investigation, validation, supervision, funding acquisition, project administration, writing – review and editing, resources. **Ignacio Sanz-Martin:** methodology, investigation, writing – review and editing. **Daniel S. Thoma:** conceptualization, methodology, data curation, investigation, funding acquisition, project administration, writing – review and editing, resources. **Irena Sailer:** methodology, validation, investigation, writing – review and editing, project administration, supervision.


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### Conflicts of Interest

The authors declare no conflicts of interest.

### Data Availability Statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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## Supporting Information

Additional supporting information can be found online in the Supporting Information section. **Table S1:** (a) Distribution of overall PES scores for test and controls at baseline and 36 months. The Pink esthetic score evaluates soft tissue around single-tooth implants. The PES is based on seven variables with 0 being the poorest score. The highest possible score is reflecting a perfect match with the reference tooth therefore is 14 (7 × 2). A score of ≥ 8 was considered as an esthetically acceptable outcome, and a score ≥ 12 was considered as an almost perfect outcome. (b) Distribution of overall papilla scores (PE) scores (Jemt 1997) 5 grades (0–4) for the implant site, distal and mesial at baseline and 36-months.