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Randomized controlled pilot study comparing small buccal defects around dental implants treated with a subepithelial connective tissue graft or with guided bone regeneration

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Abstract

Aim: To compare subepithelial connective tissue grafts (SCTG) versus guided bone regeneration (GBR) for the treatment of small peri-implant dehiscence defects in terms of profilometric (primary outcome), clinical, and patient-reported outcome measures (PROMs).

Methods: Sixteen patients who presented with small buccal bone dehiscences (≤3 mm) following single implant placement were recruited. Following implant placement, buccal bone defect sites were randomly treated either with a SCTG or GBR. Six patients who lacked bone dehiscences after implant placement were assigned to a negative control. Transmucosal healing was applied in all patients. Patients were examined prior (T1) and after (T2) implant placement, at suture removal (T3), at implant impression (T5), at crown delivery (T6), and 12 (T7) months after crown delivery. Measurements included profilometric outcomes, marginal bone levels, buccal bone and soft tissue thickness, PROMs, and clinical parameters. All data were analyzed descriptively.

Results: The median changes in buccal contour as assessed by profilometric measures between T1 and T5 showed a decrease of 1.84 mm for the SCTG group and 1.06 mm for the GBR group. Between T2 and T7, the median change in the buccal contour amounted to 0.45 mm for SCTG and −0.94 mm (=loss) for GBR. Patients' pain perception tended to be higher in SCTG than in GBR. All peri-implant soft tissue parameters showed healthy oral tissues and no clinically relevant differences between groups.

Conclusion: Within the limitations of this pilot study, treating small peri-implant dehiscence defects with a SCTG might be a viable alternative to GBR. The use of a SCTG tended to result in more stable profilometric outcomes and comparable clinical outcomes to GBR. However, patient-reported outcome measures tended to favor GBR.

KEYWORDS
autogenous connective tissue graft, buccal bone dehiscence, dental implant, guided bone regeneration, soft tissue augmentation

1 | INTRODUCTION

The survival of dental implants with simultaneous guided bone regeneration (GBR) procedures is well-documented, showing predictable long-term outcomes (Donos et al., 2008; Hämmerle & Lang, 2001; Sanz-Sánchez et al., 2018; Thoma et al., 2019). The current shift toward backward planning in implant dentistry has led clinicians to place dental implants in a prosthetically oriented position, often resulting in small (≤3 mm) buccal peri-implant dehiscences. It has been advocated that treating small buccal peri-implant dehiscences (≤3 mm) can prevent progressive vertical bone loss in 50% of the cases (Jung et al., 2017), mucosal recessions (Monje et al., 2023), and potential biological complications such as bleeding on probing and increased probing pocket depth (Schwarz et al., 2012). Neglecting to treat these defects may affect the esthetic outcomes and the overall satisfaction of the patient (Thoma et al., 2021).

In those cases, the clinician is faced with the decision of whether to treat peri-implant buccal bone dehiscences, and traditionally guided bone regeneration (GBR) is the therapy of choice. However, even though GBR can successfully treat these dehiscences, a recent systematic review (Thoma et al., 2019) revealed that the mean dehiscence resolution after implant placement is approximately 80%, with a wide range of resolution (56.4%–97.1%). This indicates that a significant number of buccal bone dehiscences still persist despite hard tissue augmentation with GBR procedures. Implants with exposed threads have been found to be at higher risk of developing peri-implantitis (Ravida et al., 2023).

Given the rationale that rough surfaces of dental implants should not be left exposed to the oral cavity and assuming that thicker tissues may promote soft tissue seal around implants (e.g., hindering the penetration of biofilm into the sulcus), one potential alternative to GBR is soft tissue grafting.

Soft tissue grafting is a procedure that involves the harvesting of autogenous tissue, and its transplantation to the peri-implant area can enhance the mucosal seal around the implant–abutment interface. The aim of this procedure is to enhance the peri-implant volume and improve the esthetic outcome by creating a thicker and stronger soft tissue barrier (Thoma et al., 2018). Additionally, increasing the thickness of the soft tissue can limit marginal bone loss (Linkevicius et al., 2015). It is widely recognized that maintaining a healthy mucosal barrier is crucial for peri-implant health (Abrahamsson et al., 1996; Berglundh et al., 1991; Tomasi et al., 2014). Although the underlying mechanisms remain unclear, studies have indicated that soft tissue grafting procedures can lead to improved clinical (Thoma et al., 2018) and radiographic outcomes (Guglielmi et al., 2022; Thoma et al., 2018). A consensus review emphasized that soft tissue augmentation may minimize marginal bone-level changes along with improving esthetic outcomes (Thoma et al., 2021).

Moreover, the volumetric outcomes obtained by GBR may be suboptimal in the long run, as bone may account for only approximately 60% of the final volume (Schneider et al., 2011). In contrast, soft tissue grafting, particularly the use of a connective tissue graft, may achieve better and longer-lasting peri-implant volume and optimize the predictability of clinical outcomes. Therefore, it seems reasonable to find new interventions that may enhance current approaches to treat small peri-implant dehiscences and thus optimize the predictability of clinical outcomes.

Hence, the aim of the present pilot study was to investigate the feasibility of treating small peri-implant dehiscence defects (≤3 mm) with subepithelial connective tissue grafts (SCTG) and to compare SCTG to GBR for the treatment of small peri-implant dehiscence defects in terms of profilometric (primary outcome), clinical, and patient-reported outcome measures (PROMs).

2 | MATERIALS AND METHODS

2.1 | Study design and population

The present study was designed as a pilot randomized controlled clinical trial with two parallel groups in accordance with the ethical standards of the 1975 Declaration of Helsinki as revised in 2013 and was conducted according to the guidelines of the CONSORT statement. After approval by the local ethics committee (BASEC-Nr. 2018–01380), all eligible participants had to meet the following inclusion criteria:

- ≥18 years of age.
- Periodontally healthy patients (periodontal probing depths <4 mm).
- Good oral hygiene (full-mouth plaque index and bleeding on probing <25%).
- Need of implant placement in the premolar and molar region of the maxilla or mandible and a lack of alveolar ridge preservation at the corresponding site.
- A dehiscence defect (≤3 mm) after implant placement.
- At least one interproximal contact had to be present.
- Presence of antagonists.

The presence of any of the following exclusion criteria led to the exclusion of the patient:

- Self-declared pregnancy or breastfeeding at the time of inclusion.
- Active periodontal disease.
- Smoking more than 15 cigarettes per day.

A total of 28 patients were consecutively screened and 16 of the 28 patients were randomized into the treatment groups (SCTG or GBR). The remaining 6 patients were allocated to a negative control due to the lack of buccal dehiscence. The negative control group without dehiscence was included to evaluate the efficacy of the treatment interventions (SCTG or GBR) compared to no treatment at all. All the patients received a dental implant in the posterior region of the maxilla or mandible (premolars and molars).

2.2 | Clinical procedures

2.2.1 | Randomization

The randomization process was based on a computer-generated randomization list and the allocation was concealed from the surgeon until after the flap elevation by sealed envelopes. Despite the randomization process, the random assignment of two patients failed, leading to an unbalanced patient distribution (SCTG = 9 and GBR = 7; Figure 1, Flow diagram).

2.2.2 | Surgical procedure

Implant placement was performed either by applying a delayed (between 3 and 6 months after tooth extraction) or late (more than 6 months after tooth extraction) protocol. Standard protocols were followed for the placement of dental implants with a diameter of 4.2 mm and a length of 8 mm (OsseoSpeed EV®, Astra Tech Implant System, Dentsply Sirona Implants). In brief, an incision was placed at the midline of the alveolar ridge, with a releasing incision if necessary, and a full-thickness flap was elevated. Thereafter, the dental implants were placed according to the manufacturer's guidelines. Following implant insertion, the buccal bone peri-implant defect of the eligible site was measured with a periodontal probe to the nearest 0.5 mm and the patient was randomized to the corresponding treatment group (SCTG or GBR).

In the SCTG group, an autogenous graft was harvested from the patient's own palate depending on the size of the buccal bone peri-implant defect. The thickness of the SCTG was at least 1.5 mm and was placed on the buccal aspect of the exposed implant threads and then fixed with a horizontal mattress connecting it to the lingual or palatal flap.

In the GBR group, the buccal bone peri-implant defects around the dental implants were grafted with a deproteinized bovine bone mineral (DBBM) (Bio-Oss® cancellous bone granules, Geistlich Pharma AG). The defect was filled with DBBM to a horizontal buccal thickness of approximately 2.0 mm at the implant shoulder level. A collagen membrane of porcine origin (Bio-Gide® membrane, Geistlich Pharma AG) was then used to cover the graft material. The membrane was fixed on the buccal side with resorbable pins (Resor Pin®, Geistlich Pharma AG) and pulled onto the palatal or lingual side.

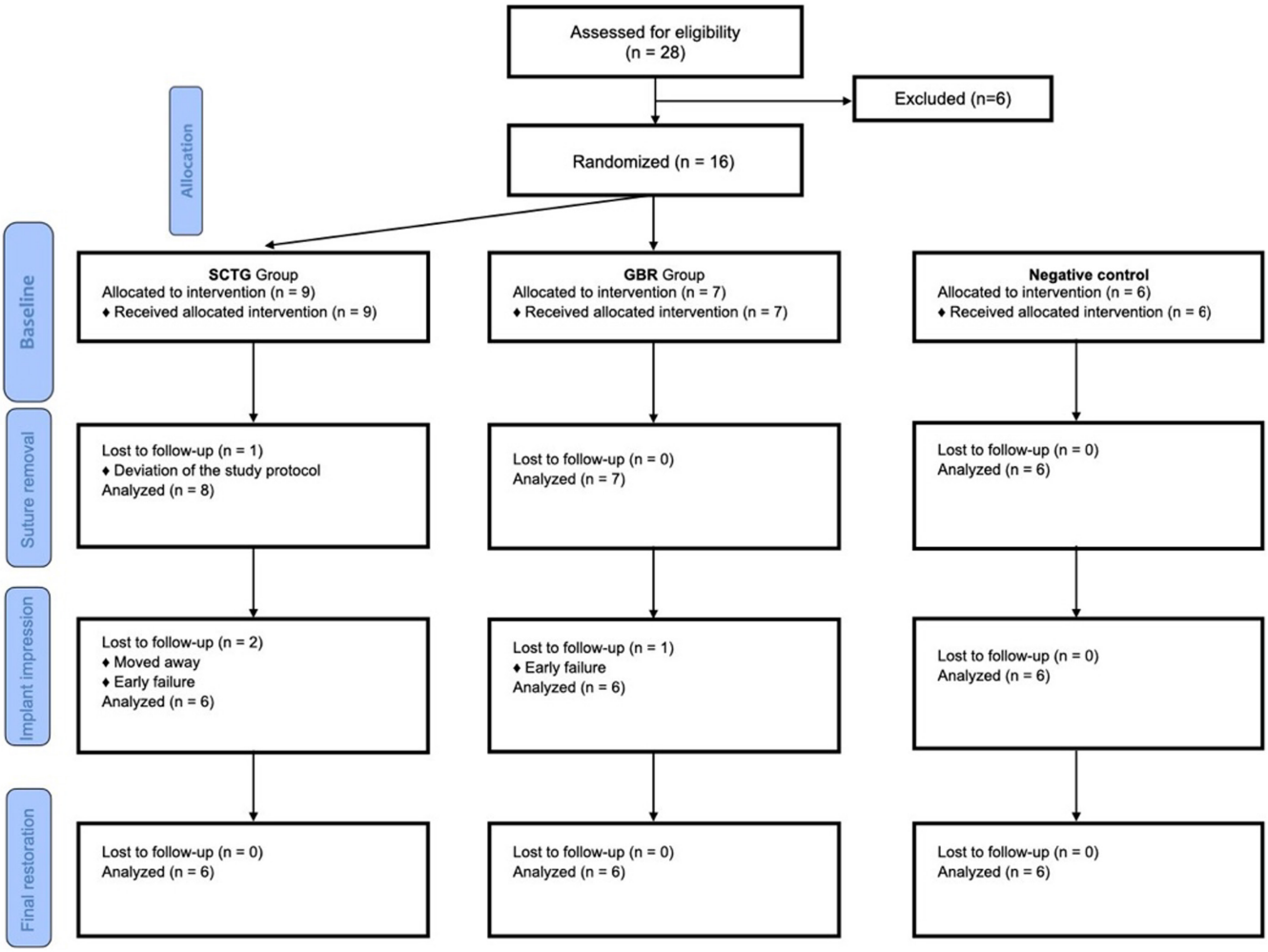

FIGURE 1 Flow diagram. GBR, guided bone regeneration; SCTG, subepithelial connective tissue graft.

After augmentation of the buccal bone defect or in cases where no defect was present, a healing abutment was used. A periosteal releasing incision was done to allow tension-free adaptation of the flap to the abutment healing and the lingual/palatal flap, allowing transmucosal healing. Suture removal was performed 1 week after surgery. Patients were instructed to rinse twice daily with a 0.2% chlorhexidine solution and to continue the antibiotic regimen for 5 days (750 mg Clamoxyl®, three times daily). In addition, analgesics (500 mg Mefenacid®) were prescribed for the next 2 days according to individuals' need. Patients were also instructed to refrain from mechanical plaque removal in the area of the procedure for 1 week.

Implant impressions were taken 3 months after implant placement and final restoration was inserted 4 months after implant placement. The patients were then followed up for 1 year.

2.3 | Outcome measures

2.3.1 | Volumetric contour changes in the peri-implant tissues (primary outcome)

Impressions of the implant sites were taken with an A-silicone impression material (President®, Coltène/Whaledent) at the following time points: pre-op (T1), post-op (T2), 3 months later at implant impression (T5), at crown delivery (T6), and after 1-year follow-up (T7). Plaster casts were fabricated (Quadro-rock®, picodent) and optically scanned with a desktop 3D scanner (Imetric 3D). The obtained digital models in STL (Standard Tessellation Language) files were imported into a digital imaging software (SMOP, Swissmeda) to analyze the profilometric and linear changes by a blinded examiner.

The study-specific STL files, pre-op (T1), post-op (T2), implant impression (T5), crown delivery (T6), and 1-year follow-up (T7), were superimposed and matched to adjacent tooth surfaces using the best-fit algorithm.

Two comparisons were made for the analysis: The pre-op model (T1) was compared to the post-op (T1–T2) and the implant impression (T1–T5). The second analysis compared the post-op model (T2) to the crown delivery (T2–T6) and the 1-year follow-up (T2–T7).

Profilometric measurements

A region of interest (ROI) was defined in the form of a trapezoid. The ROI included the following boundaries: 1 mm apical to the mid-facial mucosal margin (coronal), the mucogingival border (apical), 1 mm from the adjacent tooth (mesial, distal), and the ROI was taken at two levels below the mucosal margin: 1 mm (ROI-1), and 3 mm (ROI-3). The profilometric changes were then calculated by the software and reported in mm corresponding to the mean distance (MD) among the surfaces between different time points (T1–T2, T1–T5, T2–T6, and T2–T7). Figure 2a,b illustrate the volumetric changes among pre-op, post-op, and implant impression (T1–T2 and T1–T5) and among post-op, crown delivery, and 1-year follow-up (T2–T6 and T2–T7) in the ROI.

Linear measurements

A cross-section representing the center of the single-tooth gap (prior surgery) and the central implant axis, respectively, were selected to measure the horizontal distance, that is, the linear distance between the different time points (T1–T2, T1–T5, T2–T6, and T2–T7). The measurements for the tissue width (TW) were taken horizontally at two levels below the mid-facial mucosal margin: 1 mm (TW-1) and 3 mm (TW-3) (Figure 3). These measurements represented changes in peri-implant tissue width.

One examiner measured volumetric and horizontal changes on two separate occasions at least 1 month apart. Intra-examiner reliability was then calculated using the intraclass correlation coefficient (ICC). The intraclass correlation coefficient (ICC) for volumetric changes was 0.98 (95% CI: 0.96–0.99) and for horizontal changes 0.95 (95% CI: 0.87–0.98), indicating excellent intra-examiner reproducibility.

2.3.2 | Patient-reported outcome measures (PROMs) (secondary outcome)

A visual analogue scale (VAS) and the short form of the oral health impact profile (OHIP-14) were used to measure pain perception, patient's oral quality of life, and perception of the social impact of oral disorders on their well-being. A VAS scale was applied at suture removal (T3). The anchoring points represented the minimum and the maximum of patients' perception. The self-administered OHIP-14 was handed out to the patient's prior surgery (T1), after surgery (T2), and at crown delivery (T6). To further investigate patients' pain perception, the sub-score "physical pain" from the OHIP-14 (Question 13) at T3 was analyzed.

2.3.3 | Clinical outcome measures

Probing depth, plaque index, bleeding on probing, and keratinized tissue

The following clinical parameters were recorded with a periodontal probe at implant sites and adjacent teeth: probing depth (PD), bleeding on probing (BOP), plaque index (PCR), and keratinized tissue (KT). All measurements were taken at six sites (mesio-buccal, mid-buccal, distobuccal, disto-lingual, mid-lingual, and mesio-lingual) on each implant and adjacent teeth and recorded to the nearest millimeter. For BOP and PCR assessments, each site was recorded as 0 or 1 (absence or presence of plaque or bleeding, respectively). The mid-facial keratinized mucosa width (KTW) was measured at the implant sites and the two adjacent teeth. The clinical parameters for the adjacent teeth were recorded at T6 and T7.

Peri-implant marginal bone-level changes

Standardized digital periapical radiographs were obtained at postoperative status (T2) and at final reconstruction (T6) using a long-cone parallel technique with Rinn holders (Hawe X-ray film holders, Kerrhawe SA). X-rays were then imported into open-source software (ImageJ 1.43; National Institute of Health). Marginal bone

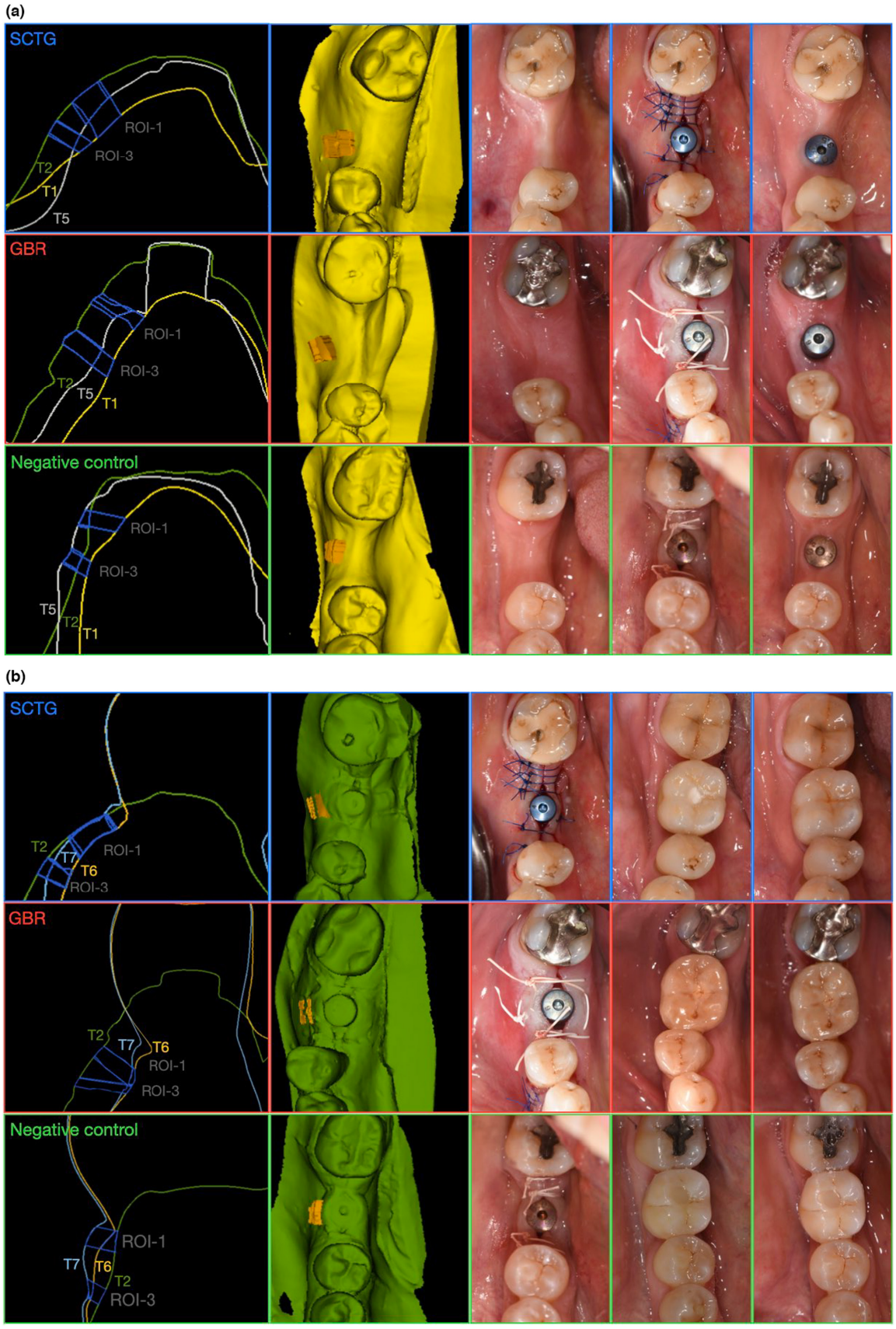

FIGURE 2 (a) Volumetric contour changes of the peri-implant tissues from T1 to T5 (pre-op to implant impression) at 1 and 3 mm below mid-facial mucosal margin. (b) Volumetric contour changes in the peri-implant tissues. GBR, guided bone regeneration; ROI, region of interest; SCTG, subepithelial connective tissue graft; T, time point.

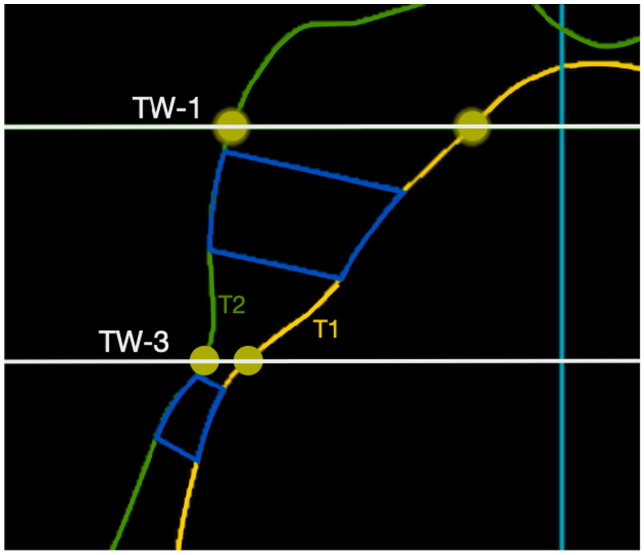

FIGURE 3 A cross-sectional view (blue line) was selected to measure the horizontal distance (grey line) between T1 and T2 in the single-tooth gap and central implant axis. Tissue width (TW) was measured horizontally at two levels below the mid-facial mucosal margin: 1 mm (TW-1) and 3 mm (TW-3).

levels (MBL) were assessed at 10–15× magnification by calculating the distance between the implant shoulder (IS) and the most apical implant–bone contact on the mesial and distal sites. The thread pitch of 0.6 mm was used to calibrate the scale.

Marginal bone-level assessments were performed by one examiner on two separate occasions at least 1 month apart. Subsequently, intra-examiner reliability was calculated using the intraclass correlation coefficient (ICC). The intraclass correlation coefficient (ICC) was for the mesial sites 0.99 (95% CI: 0.98–0.99) and for the distal sites 0.96 (95% CI: 0.88–0.99), indicating excellent intra-examiner reproducibility.

2.3.4 | Buccal-oral hard and soft tissue changes

In order to assess the contour, changes in the area of interest with respect to bone and soft tissue volume a cone-beam computed tomography scan (CBCT) was performed immediately after surgery (T2) and at crown delivery (T6). The CBCT files and the corresponding STL files from T2 and T6 were imported into a digital imaging software program (SMOP, Swissmeda AG) and superimposed. A bucco-oral cross-section perpendicular along the central axis of the dental implant was used for the analysis (Figure 4). The following parameters were assessed on each CBCT scan:

- The buccal bone thickness (BBT) and buccal soft tissue thickness (BST) were measured at the level of the implant shoulder at 0 mm (BBT-0, BST-0), 1 mm (BBT-1, BST-1), and 3 mm (BBT-3, BST-3) below in a direction perpendicular to the implant axis.

An examiner measured buccal bone and soft tissue thickness on two separate occasions at least 1 month apart. The intra-examiner

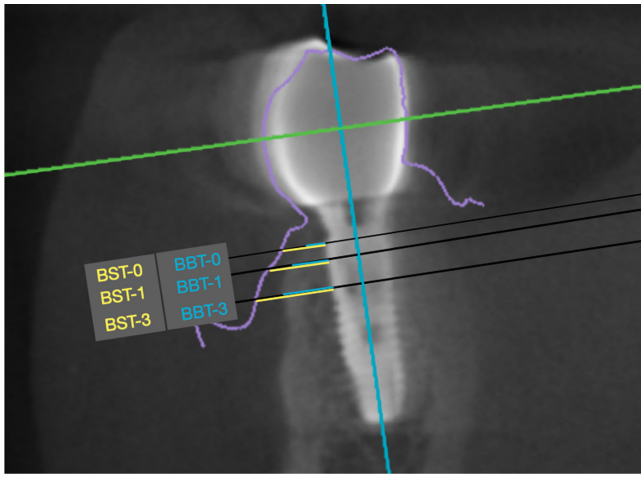

FIGURE 4 A bucco-oral cross-section perpendicular along the central axis of the dental implant was used for the analysis. The buccal bone thickness (BBT) and buccal soft tissue thickness (BST) were measured at the level of the implant shoulder at 0 mm (BBT-0, BST-0), 1 mm (BBT-1, BST-1), and 3 mm (BBT-3, BST-3) below in a direction perpendicular to the implant axis.

reliability was then calculated using the intraclass correlation coefficient (ICC). The intraclass correlation coefficient (ICC) was for BBT 0.94 (95% CI: 0.81–0.98) and for BST 0.98 (95% CI: 0.93–0.99), indicating excellent intra-examiner reproducibility.

2.4 | Statistical analysis

Due to the exploratory nature of this study and the experimental setting, a sample size calculation was not performed. The sample size was chosen pragmatically and based on clinical experience and availability with the aim of obtaining preliminary yet relevant point estimates and effect sizes to allow for an adequate sample size calculation in future confirmatory randomized controlled trials. A total number of $n = 12$ was considered sufficient to perform a preliminary comparison between the two augmentation treatments. In the event that the included patients did not have a buccal bone defect after implant placement, they were assigned to negative control. A software program (Excel, Microsoft Corporation) was used to process the data. For the metric variables, mean, standard deviations, median, and quartiles were calculated. Due to the exploratory nature of this study, descriptive statistics was performed using Prism v9 (Graphpad Software Inc.) and SPSS v.27.0, and the data were analyzed per protocol.

3 | RESULTS

3.1 | Study population

The CONSORT flow diagram is shown in Figure 1. From February 2019 to June 2020, 28 subjects were screened for the present study. A total of 28 patients were consecutively screened, and 16 of the 28

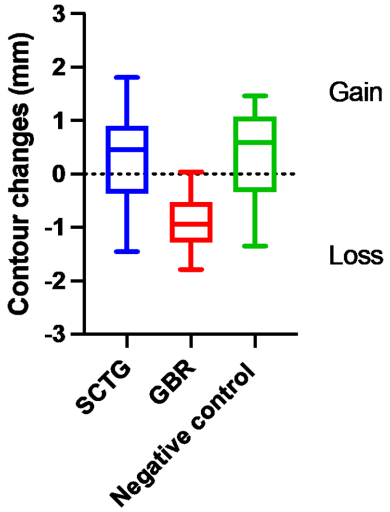

FIGURE 5 Profilometric contour changes from T2 to T7 (post-op to 1-year follow-up) at 1 mm below mid-facial mucosal margin. GBR, guided bone regeneration; NC, negative control; SCTG, subepithelial connective tissue graft.

patients were randomized into the treatment groups (STCG or GBR). The remaining 6 patients were allocated to a negative control due to the lack of buccal dehiscence. All the patients received a dental implant in the posterior region of the maxilla or mandible (premolars and molars) with at least one neighboring tooth.

One patient in the SCTG group had to be removed from the study due to a protocol deviation (submucosal healing instead of transmucosal healing after implant placement), and another one moved away. The patient who underwent submucosal healing was excluded due to compromised feasibility of the profilometric measurement. Two additional patients, one in the SCTG group and one in the GBR group, experienced early failures at implant impression and therefore dropped out of the study (Figure 1). Thus, a total of 18 patients, with dental implants located in both the upper jaw (7 premolars) and lower jaw (4 premolars and 7 molars), were included in the analysis.

3.2 | Profilometric contour changes

From T2 to T7 (post-op to 1-year follow-up) at 1 mm, the median buccal contour changes amounted to 0.45 mm (Q1: −0.37, Q3: 0.90) for SCTG, −0.94 mm (=loss) (Q1: −1.28, Q3: −0.52) for GBR, and 0.58 mm (Q1: −0.33, Q3: 1.07) for negative control (Figure 5). At 3 mm, the median contour changes were for SCTG −0.24 mm (Q1: −1.07, Q3: 0.32), GBR −1.80 mm (Q1: −2.71, Q3: −1.08), and negative control −0.05 mm (Q1: −0.47, Q3: 0.44). All data are provided in Table 1.

3.3 | Linear contour changes

Between T2 and T7 (post-op to 1-year follow-up), the median peri-implant tissue width at 1 mm below mid-facial mucosal margin amounted to 0.00 mm for SCTG (Q1: −0.57, Q3: 1.26), −1.46 mm (=loss) for GBR (Q1: −1.90, Q3: 0.81), and 0.40 mm for negative control (Q1: −0.16, Q3: 1.04). The median tissue width at 3 mm was −0.50 mm (Q1: −1.32, Q3: 0.59) for SCTG, −2.46 mm for GBR (Q1: −2.94, Q3: 1.42), and −0.13 mm (Q1: −0.90, Q3: 0.35) for negative control. All data are provided in Table 2.

3.4 | Patient-reported outcomes

The median VAS scores after implant placement at suture removal (T3) amounted to 3.6 (Q1: 0.8, Q3: 5.0) in group SCTG, 1.5 (Q1: 0.8, Q3: 3.7) in group GBR, and 0.4 (Q1: 0.0, Q3: 1.0) in the negative control (Table 3). Using the OHIP-14 questionnaire (Question 13) a similar trend was observed. At suture removal (T3), the overall OHIP scores amounted to 7.0 (Q1: 3.5, Q3: 9.0) in SCTG, 5.0 (Q1: 2.0, Q3: 11.0) in GBR, and 5.0 (Q1: 2.0, Q3: 10.7) in the negative control (Table 3).

3.5 | Clinical outcomes

3.5.1 | Probing depth, plaque index, bleeding on probing, and keratinized mucosa width

The mean probing depth was 2.8 mm in the GBR group, 2.9 mm in the SCTG group, and 3.0 mm in the negative control at 1-year follow-up. Plaque and bleeding on probing varied between 0% and 10% at 1-year follow-up. The median midfacial keratinized mucosa width (KMW) amounted to 3.5 mm in group SCTG, 2.5 mm in group GBR, and 3.1 mm in the control group. At 1 year follow-up, the median KMW amounted to 4.5 mm (Q1: 0.7, Q3: 5.0) in group SCTG, 2.5 mm (Q1: 1.7, Q3: 3.0) in group GBR, and 3.0 mm (Q1: 1.7, Q3: 3.5) in the control group. All data are shown in Table 4.

3.5.2 | Peri-implant marginal bone-level changes

The median marginal bone levels (MBL) amounted to −0.6 mm (Q1: −0.9, Q3: 0.1) for SCTG, −0.1 mm (Q1: −0.3, Q3: 2.2) for GBR, and 0.5 mm (Q1: 0.1, Q3: 1.1) for negative control at post-implant placement (T2), and to −0.35 mm (Q1: −0.6, Q3: −0.1) in SCTG, 0.1 mm (Q1: −0.3, Q3: 2.0) in GBR, and −0.0 mm (Q1: −0.3, Q3: 0.2) in negative control at final reconstruction (T6). All data are displayed in Table 5.

3.6 | Buccal hard and soft tissue changes

The median peri-implant buccal bone thickness at T6 (crown delivery) at the level of the implant shoulder (BBT-0) amounted to 0.0 mm (Q1: 0.0, Q3: 0.0) in SCTG, 2.0 mm (Q1: 0.0, Q3: 2.7) in GBR, and 1.2 mm (Q1: 0.6, Q3: 2.4) in the control group (Table 5). The median peri-implant buccal bone thickness at 1 and 3 mm below the implant shoulder is displayed in Table 5.

TABLE 1 Profilometric contour changes over time at the different regions of interest (ROI).

Variable		SCTG			GBR			Negative control	
ROI	Time point	*n*	Mean (SD)	Median (Q1, Q3)	*n*	Mean (SD)	Median (Q1, Q3)	*n*	Mean (SD)	Median (Q1, Q3)
ROI-1										
	ΔT1–T2	6	2.01 (0.65)	2.18 (1.47, 2.54)	6	2.15 (1.06)	2.41 (1.58, 3.70)	6	1.01 (0.35)	1.10 (0.70, 1.33)
	ΔT1–T5	6	1.85 (0.86)	1.84 (10.5, 2.59)	6	1.29 (0.43)	1.06 (0.99, 1.84)	6	0.91 (0.46)	0.84 (0.45, 1.37)
	ΔT2–T6	6	−0.31 (0.43)	−0.24 (−0.76; 0.02)	6	−0.78 (0.96)	−0.47 (−1.40; −0.14)	6	0.20 (0.63)	0.33 (−0.43; 0.69)
	ΔT2–T7	6	0.30 (1.05)	0.45 (−0.37; 0.90)	6	−0.91 (0.59)	−0.94 (−1.28; −0.52)	6	0.37 (0.99)	0.58 (−0.33; 1.07)
ROI-3										
	ΔT1–T2	6	2.90 (1.05)	2.65 (2.08, 3.32)	6	2.68 (1.28)	2.78 (2.02, 3.59)	6	0.56 (0.44)	0.41 (0.30, 0.81)
	ΔT1–T5	6	1.98 (1.13)	1.99 (0.55, 2.93)	6	1.21 (0.66)	1.29 (0.68, 1.67)	6	0.79 (0.72)	0.67 (0.21, 1.25)
	ΔT2–T6	6	−1.06 (0.51)	−1.13 (−1.51; −0.56)	6	−1.40 (0.77)	−1.46 (−2.12; −0.78)	6	−0.00 (0.47)	0.02 (−0.33; 0.39)
	ΔT2–T7	6	−0.48 (1.37)	−0.24 (−1.07; 0.32)	6	−1.85 (1.05)	−1.80 (−2.71; −1.08)	6	−0.05 (0.67)	−0.05 (−0.47; 0.44)

Note: Positive values indicate volume gain and negative values indicate volume loss.

Abbreviations: GBR, guided bone regeneration; Q1, Q3, quartiles 1, 3; ROI, region of interest; SCTG, subepithelial connective tissue graft; SD, standard deviation; T, time point; T1, pre-op; T2, post-op; T5, implant impression; T6, crown delivery; T7, 1-year follow-up.

TABLE 2 Peri-implant tissue width (TW) changes over time.

Variable		SCTG			GBR			Negative control	
TW	Time point	*n*	Mean (SD)	Median (Q1, Q3)	*n*	Mean (SD)	Median (Q1, Q3)	*n*	Mean (SD)	Median (Q1, Q3)
TW-1										
	ΔT1–T2	6	3.75 (1.56)	3.75 (1.56)	6	4.19 (1.83)	3.75 (3.32, 4.79)	6	2.15 (0.92)	2.14 (1.15, 3.15)
	ΔT1–T5	6	3.44 (1.94)	3.44 (1.94)	6	2.41 (0.78)	2.23 (1.71, 3.07)	6	1.60 (0.84)	1.76 (0.89, 2.30)
	ΔT2–T6	6	−0.68 (0.80)	−0.68 (0.80)	6	−1.17 (1.36)	−0.94 (−2.20; 0.03)	6	−0.15 (0.52)	−0.18 (−0.65; 0.41)
	ΔT2–T7	6	0.25 (1.69)	0.25 (1.69)	6	−1.36 (0.75)	−1.46 (−1.90; −0.81)	6	0.30 (0.89)	0.40 (−0.19; 1.04)
TW-3										
	ΔT1–T2	6	3.37 (1.12)	3.37 (1.12)	6	3.07 (1.69)	2.95 (1.83, 4.52)	6	0.86 (0.50)	0.64 (0.46, 1.39)
	ΔT1–T5	6	2.54 (1.68)	2.54 (1.68)	6	1.45 (0.93)	1.13 (0.76, 2.47)	6	0.83 (0.46)	0.81 (0.41, 1.27)
	ΔT2–T6	6	−1.28 (0.55)	−1.28 (0.55)	6	−1.57 (0.81)	−1.56 (−2.38; −0.87)	6	−0.38 (0.53)	−0.37 (−0.96; 0.09)
	ΔT2–T7	6	−0.47 (1.49)	−0.47 (1.49)	6	−2.27 (1.13)	−2.46 (−2.94; −1.42)	6	−0.32 (0.87)	−0.13 (−0.90; 0.35)

Note: Positive values indicate volume gain and negative values indicate volume loss.

Abbreviations: GBR, guided bone regeneration; Q1, Q3, quartile 1, 3; SCTG, subepithelial connective tissue graft; SD, standard deviation; T, time point; T1, pre-op; T2, post-op; T5, implant impression; T6, crown delivery; T7, 1-year follow-up; TW, tissue width.

The median peri-implant buccal soft tissue thickness at T6 (crown delivery) at the level of the implant shoulder (BST-0) decreased to 3.7 mm (2.7, 5.9) for SCTG, 3.9 mm (2.0, 5.9) for GBR, and 4.0 mm (2.5, 4.9) for negative control. All data are shown in Table 5.

4 | DISCUSSION

The current pilot RCT explored the feasibility of treating small peri-implant dehiscence defects with subepithelial connective tissue grafts (SCTG) as an alternative to standard GBR. The present study predominantly revealed that connective tissue grafts, compared to GBR, showed: (i) a trend toward greater profilometric stability (volume stability) over time; (ii) increased pain perception after surgery; and (iii) similar peri-implant clinical parameters.

Small buccal bone dehiscences are common during implant placement and can cause functional and esthetic issues. Treating these defects can prevent progressive vertical bone loss (Jung et al., 2017), mucosal recessions (Monje et al., 2023), and potential biological complications such as bleeding on probing and increased

TABLE 3 Patient-reported outcome measures (PROMs).

Variable	Time point	SCTG n	SCTG Mean (SD)	SCTG Median (Q1, Q3)	GBR n	GBR Mean (SD)	GBR Median (Q1, Q3)	Negative control n	Negative control Mean (SD)	Negative control Median (Q1, Q3)
OHIP-14										
	T1	6	4.3 (4.2)	4.0 (0.5, 7.0)	6	5.7 (6.5)	3.0 (0.0, 13.0)	6	7.1 (10.9)	2.0 (0.0, 12.0)
	T3	6	6.0 (3.0)	7.0 (3.5, 9.0)	6	6.0 (4.8)	5.0 (2.0, 11.0)	6	6.5 (5.4)	5.0 (2.0, 10.7)
	T6	6	3.3 (2.6)	3.0 (1.5, 5.0)	6	1.6 (4.0)	0.0 (0.0, 2.5)	6	4.4 (5.8)	3.0 (0.0, 8.0)
Pain (VAS)										
	T3	6	3.3 (2.5)	3.6 (0.8, 5.0)	6	2.1 (2.0)	1.5 (0.8, 3.7)	6	0.5 (0.7)	0.4 (0.0, 1.0)

Abbreviations: GBR, guided bone regeneration; OHIP-14, oral health impact profile-14; Q1, Q3, quartiles 1, 3; SCTG, subepithelial connective tissue graft; SD, standard deviation; T1, pre-op; T3, suture removal; T6, crown delivery; VAS, visual analog scale.

TABLE 4 Clinical parameters.

Variable	Time point	SCTG n	SCTG Mean (SD)	SCTG Median (Q1, Q3)	GBR n	GBR Mean (SD)	GBR Median (Q1, Q3)	Negative control n	Negative control Mean (SD)	Negative control Median (Q1, Q3)
PD										
	T6	6	3.1 (1.1)	2.7 (2.2, 3.9)	6	3.0 (0.8)	2.8 (2.4, 3.6)	6	3.0 (0.5)	3.0 (2.4, 3.3)
	T7	6	3.1 (0.7)	2.9 (2.6, 3.7)	6	2.8 (0.6)	2.8 (2.1, 3.3)	6	3.0 (0.2)	3.0 (2.9, 3.1)
BOP										
	T6	6	0.1 (0.1)	0.0 (0.0, 0.3)	6	0.1 (0.2)	0.1 (0.0, 0.3)	6	0.3 (0.3)	0.2 (0.0, 0.5)
	T7	6	0.1 (0.1)	0.0 (0.0, 0.2)	6	0.1 (0.1)	0.1 (0.1, 0.3)	6	0.3 (0.1)	0.3 (0.1, 0.3)
PCR										
	T6	6	0.0 (0.0)	0.0 (0.0, 0.0)	6	0.0 (0.0)	0.0 (0.0, 0.1)	6	0.0 (0.0)	0.0 (0.0, 0.0)
	T7	6	0.0 (0.2)	0.0 (0.0, 0.1)	6	0.1 (0.1)	0.1 (0.1, 0.3)	6	0.0 (0.1)	0.0 (0.0, 0.2)
KMW										
	T6	6	3.1 (1.4)	3.5 (1.7, 4.2)	6	2.1 (0.9)	2.5 (1.0, 3.0)	6	3.1 (1.4)	3.5 (1.7, 4.0)
	T7	6	3.3 (2.2)	4.5 (0.7, 5.0)	6	2.3 (0.8)	2.5 (1.7, 3.0)	6	2.8 (1.3)	3.0 (1.7, 3.5)

Abbreviations: BOP, bleeding on probing; GBR, guided bone regeneration; KMW, mid-facial keratinized mucosa width; PCR, plaque index; PD, probing depth; Q1, Q3, quartiles 1, 3; SCTG, subepithelial connective tissue graft; SD, standard deviation; T, time points; T6, crown delivery; T7, 1-year follow-up.

probing pocket depth (Schwarz et al., 2012). A previous RCT indicated that not treating peri-implant dehiscences can increase vertical bone loss of peri-implant defects (Jung et al., 2017). Therefore, neglecting to treat these defects may also affect the esthetic outcome of implant treatment and the overall satisfaction of the patient (Thoma et al., 2021).

Currently, GBR is the standard treatment for peri-implant dehiscences. However, the large variability in the outcomes with GBR (56.4%–97.1%) (Thoma et al., 2019) highlights the need for alternative therapies to improve the predictability of the treatment outcomes. Thus, in the present proof-of-principle study, soft tissue grafting was proposed as a potential therapeutic alternative.

This study showed that buccal peri-implant dehiscences treated with SCTG were relatively stable over time, indicated by the stable profilometric outcomes. This finding is most likely attributed to the proven stability of autogenous SCTG (Cosyn et al., 2022; Strauss et al., 2022 Thoma, Gasser, et al., 2022), which remains the gold standard for volume augmentation (Valles et al., 2022). In addition, the current report revealed a median profilometric contour change in the SCTG of about 0.5 mm at 1 year of follow-up. This value is in accordance with a recent study showing volumetric changes of ≈1 mm at 1 year of follow-up (Cosyn et al., 2022). Furthermore, in a 5-year clinical study, a similar stable trend was observed (Thoma, Gasser, et al., 2022), showing that the contour augmented with SCTG only decreased by 0.2 mm.

Conversely, GBR showed less stability over time compared to the SCTG group, as evidenced by a greater profilometric change. The loss of buccal contour in GBR cases might be attributed to a displacement of the bone graft particles during flap closure due to the lack of additional fixation of the membrane (e.g., pins) (Mir-Mari et al., 2017). Collagen membranes inherently lack inherent space maintenance, making them susceptible to collapse and displacement of bone graft particles, resulting in larger profilometric changes (An et al., 2022). The observed contour loss can also be attributed to over-augmentation of site with bone graft, which is more susceptible to greater dimensional shrinkage (Lee et al., 2022). These observations seem to be in accordance with a recent systematic review that found a large variability (56.4%–97.1%) in the resolution of

TABLE 5 Peri-implant bone-level (MBL) and the buccal bone (BBT) and soft tissue thickness (BST) of the different groups at different time points.

Variable	Time point	SCTG n	SCTG Mean (SD)	SCTG Median (Q1, Q3)	GBR n	GBR Mean (SD)	GBR Median (Q1, Q3)	Negative control n	Negative control Mean (SD)	Negative control Median (Q1, Q3)
MBL										
	T6	6	−0.5 (0.5)	−0.6 (−0.9, 0.1)	6	0.6 (1.4)	−0.1 (−0.3, 2.2)	6	0.6 (0.5)	0.5 (0.1, 1.1)
	T7	6	−0.4 (0.4)	−0.35 (−0.6, −0.1)	6	0.6 (1.4)	0.1 (−0.3, 2.0)	6	−0.0 (0.3)	−0.0 (−0.3, 0.2)
BBT										
BBT-0	T2	6	0.1 (0.2)	0.0 (0.0, 0.1)	6	3.6 (0.58)	3.6 (3.3, 4.1)	6	1.4 (0.7)	1.7 (0.6, 2.0)
	T6	6	0.0 (0.0)	0.0 (0.0, 0.0)	6	1.6 (1.4)	2.0 (0.00, 2.7)	6	1.3 (0.9)	1.2 (0.6, 2.4)
BBT-1	T2	6	0.3 (0.5)	0.0 (0.0, 0.9)	6	3.8 (0.8)	4.0 (3.4, 4.3)	6	2.6 (0.8)	2.3 (1.1, 2.8)
	T6	6	0.1 (0.4)	0.0 (0.0, 0.2)	6	1.8 (1.5)	2.02 (0.0, 3.4)	6	1.5 (1.0)	1.7 (0.4, 2.5)
BBT-3	T2	6	1.3 (1.3)	0.8 (0.0, 2.7)	6	3.8 (1.1)	4.2 (2.9, 4.5)	6	2.6 (1.3)	2.4 (1.3, 3.9)
	T6	6	1.7 (1.5)	1.8 (0.0, 3.1)	6	2.1 (2.0)	2.1 (0.0, 4.3)	6	2.1 (1.1)	2.1 (1.2, 3.2)
BST										
BST-0	T2	6	5.5 (1.5)	5.5 (4.1, 6.8)	6	5.9 (1.6)	5.3 (4.3, 8.5)	6	3.4 (1.0)	3.4 (2.3, 4.3)
	T6	6	4.1 (1.9)	3.7 (2.7, 5.9)	6	3.9 (1.8)	3.9 (2.0, 5.9)	6	3.7 (1.2)	4.0 (2.5, 4.9)
BST-1	T2	6	5.9 (1.8)	6.0 (4.3, 7.2)	6	6.4 (1.6)	6.1 (4.9, 7.9)	6	4.3 (1.3)	4.2 (3.6, 5.5)
	T6	6	4.2 (1.9)	4.0 (2.9, 6.1)	5	4.3 (1.6)	4.1 (2.8, 6.1)	6	4.2 (1.7)	4.3 (2.6, 5.5)
BST-3	T2	6	6.6 (2.2)	6.8 (4.9, 8.1)	6	7.3 (1.9)	7.2 (5.5, 9.2)	6	5.7 (1.9)	5.6 (4.1, 7.7)
	T6	6	4.5 (2.3)	4.4 (3.0, 6.9)	6	5.2 (1.7)	4.5 (4.0, 6.8)	6	4.8 (2.4)	4.7 (2.9, 6.6)

Abbreviations: BBT, buccal bone thickness; BST, buccal soft tissue thickness; GBR, guided bone regeneration; Q1, Q3, quartile 1, 3; SCTG, subepithelial connective tissue graft; SD, standard deviation; T, time points; T2, post-op; T6, crown delivery.

peri-implant dehiscences after GBR (Thoma et al., 2019). Given this large variability and assuming that bone accounts for ≈60% of the final volume (Schneider et al., 2011), relying solely on GBR might be suboptimal in certain clinical scenarios. Therefore, and despite the inherent pilot nature of the present study, it appears that treating small peri-implant dehiscence with SCTG might be a feasible alternative to GBR with presumable stable outcomes over time.

As for the post-operative pain, the present study exhibited a reduced morbidity in favor of GBR. This is most likely explained by the absence of a donor site in the GBR group. This reduced morbidity with GBR appears to be in line with a series of recent studies (Bouckaert et al., 2022; De Bruyckere et al., 2018, 2020), in which GBR and SCTG were compared for restoring buccal convexity in single-tooth gaps in the anterior region. Although pain perception was assessed descriptively in one of these studies (De Bruyckere et al., 2018), patients tended to report less pain with GBR.

Peri-implant health is an important aspect when evaluating the success of a surgical procedure. In the current study, no biological complications were observed during the follow-up. Mean PD amounted to 3.1 mm for SCTG and 3.0 mm for GBR and the mean BOP in all patients was below 20%. These healthy parameters were consistent with the low plaque levels found. These observations are consistent with other studies applying GBR (Wessels et al., 2020) and suggest that SCTG might be a viable therapeutic option.

Despite the feasibility of treating small peri-implant dehiscence defects with connective tissue grafts, the use of SCTG is inherently associated with increased morbidity and patient discomfort (Stefanini et al., 2021; Thoma, Strauss, et al., 2022). These increased pain sensations are mainly associated with a second surgical site, leading to excessive bleeding, numbness, and other complications such as tissue necrosis, which in turn leads to increased postoperative pain (Griffin et al., 2006; Thoma et al., 2016). One plausible alternative to address these drawbacks is the use of a soft tissue substitute, nevertheless, there are currently no clinical studies available that have explored this alternative.

The current clinical study has certain limitations that need to be acknowledged. First, this is a proof-of-principle study, and therefore future confirmatory RCTs with larger sample sizes are warranted to validate these observations. Second, a "true" negative control would have been patients with bone defects but without treatment. However, it would have been difficult to justify ethically, since we have previously shown that the lack of augmentation of dehiscence increases vertical bone loss (Jung et al., 2017). Third, the interventions were applied only in the posterior region, therefore it remains unclear whether the same result would be observed in the anterior region. Fourth, the accuracy of the profilometric outcomes at 3 mm below the mucosal margin could potentially been affected by the limited amount of keratinized tissue present in certain patients and a shallow vestibule. The presence of a shallow vestibule, nevertheless, is rarely reported in clinical studies (Avila-Ortiz et al., 2023). Finally, no feasibility outcomes (e.g., acceptability, time, and costs) were assessed in the present pilot study.

5 | CONCLUSION

Within the limitations of this pilot study, treating peri-implant buccal bone dehiscences with a connective tissue graft might be a viable alternative to GBR. The use of a connective tissue graft tended to result in more stable profilometric outcomes and comparable clinical outcomes to GBR. However, patient-reported outcome measures tended to favor GBR.

AUTHOR CONTRIBUTIONS

A. N. Zuercher: Software; Data curation; Investigation; Validation; Formal analysis; Supervision; Visualization; Writing—original draft; Writing—review & editing. **F. J. Strauss:** Software; Data curation; Formal analysis; Validation; Writing—original draft; Writing—review & editing; Visualization. **P. N. Paque:** Validation; Visualization; Software; Formal analysis; Data curation; Writing—review & editing. **S. P. Bienz:** Writing—review & editing; Software; Data curation; Formal analysis; Validation; Visualization. **R. E. Jung** Conceptualization; Methodology; Supervision; Funding acquisition; Writing—review & editing; Resources. **D. S. Thoma:** Conceptualization; Methodology; Supervision; Funding acquisition; Project administration; Resources; Writing—review & editing; Writing—original draft.

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CONFLICT OF INTEREST STATEMENT

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DATA AVAILABILITY STATEMENT

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

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