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Soft tissue stability around dental implants after soft tissue grafting from the lateral palate or the tuberosity area – A randomized controlled clinical study

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Abstract

Aim: To compare the soft tissue stability (STA) around single implants previously augmented with either subepithelial connective tissue graft (SCTG) from the lateral palate (LP) or from the tuberosity area (TA).

Material and Methods: Twenty-nine patients showing 33 implants with buccal volume deficiency randomly received SCTG from LP (control group/CG) or TA (test group/TG). At 4 months (FU-4) the definitive crown was installed and an intra-oral scan performed. At 12 months (FU-12), a new scan was registered. Between FU-4 and FU-12 STA was evaluated by STL image superimposition. Clinical parameters and the modified pink aesthetic score (PES) (Fürhauser et al. 2005) were recorded.

Results: After FU-4 both tissues demonstrated a similar STA without statistically significant differences (SSD). The mean soft tissue changes were 0.03 ± 0.22 mm for CG and 0.04 ± 0.23 mm for TG (p = .870). SSD were observed for changes in keratinized tissue (KT) with greater stability for TG (0 ± 0.32 mm) compared with CG (−0.3 ± 0.33 mm) (p = .002). PES resulted in mean values of 8.37 ± 2.46 for CG and 8.54 ± 2.43 for TG (p=.59).

Conclusions: Both groups demonstrated similar STA between the definitive crown placement and 12 months, while greater stability of the KT gained was observed in TG.

KEYWORDS
dental implants, soft tissue augmentation, soft tissue stability, volumetric analysis

1 | INTRODUCTION

The definition of success in dental implants includes the biological and the aesthetic success. To accomplish the aesthetic success, the harmony of the peri-implant soft tissues with its adjacent structures has to be achieved. (Papaspyridakos, Chen, Singh, Weber, & Gallucci, 2012). The importance of the quality and quantity of the soft tissues around dental implants has thus gained relevance, not only because of its influence on the aesthetic outcomes but also because of the emerging evidence that appears to point out a relationship between soft tissue parameters and health-related outcomes such as bleeding on probing (Roccuzzo, Grasso, & Dalmasso, 2016; Schrott, Jimenez, Hwang, Fiorellini, & Weber, 2009). Moreover, a recent systematic review has indicated that the augmentation of

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soft tissue around dental implants may produce a benefit in terms of peri-implant health stating that implants which received a soft tissue augmentation procedure may have less marginal bone loss when compared with non-augmented implants (Thoma et al., 2018).

Regarding the impact of soft tissue augmentation procedures on the aesthetic outcomes of implant supported restorations, it appears that aesthetic scores evaluated by patients and clinicians in delayed implants which received SCTG were higher when compared with the non-augmented implants (Wiesner et al., 2010). Similarly, around immediate implants, the aesthetic perception was more favourable when using a soft tissue augmentation procedure (Cosyn et al., 2011; Migliorati, Amorfini, Signori, Biavati, & Benedicenti, 2015). Increasing the peri-implant buccal soft tissue thickness by means of coronally advanced flap in combination with SCTG seemed to be able to move coronally the mucosal margin around dental implants (Zucchelli et al., 2013). An appropriate tissue thickness has also been underlined as a key factor in masking the prosthetic components and avoiding imbalances in soft tissue colour around dental implants (Ferrari, Carrabba, Vichi, Goracci, & Cagidiaco, 2017; Lops et al., 2017; Sala, Bascones-Martínez, & Carrillo-de-Albornoz, 2017).

Although the majority of the studies which reported soft tissue augmentation procedures around implants, harvested SCTG from the lateral palate (LP) (Burkhardt, Joss, & Lang, 2008; Zucchelli et al., 2013), autogenous soft tissue may be obtained from different locations in the oral cavity (Zuhr, Bäumer, & Hürzeler, 2014). The tuberosity area (TA) has been proposed due to the low content of fatty and glandular tissue and richness in dense connective tissue (Jung, Um, & Choi, 2008; Roccuzzo, Gaudioso, Bunino, & Dalmasso, 2014; Zuiderveld, Meijer, den Hartog, Vissink, & Raghoebar, 2018). A clinical and histological study compared two augmentation procedures around teeth harvesting a SCTG from LP or TA (Dellavia et al., 2014). In terms of soft tissue thickness gain, higher values were obtained when using SCTG from TA. However, in this group, aesthetic complications occurred by means of hyperplastic response. Similarly, the immunohistochemical analysis showed a decrease in metalloproteinases and an increase in parameters related to collagen cross-linking in the TA. A randomized clinical trial (RCT) was performed evaluating both donor areas in terms of soft tissue volume gain (VG) around dental implants (Rojo et al., 2018). Again, a tendency of more volume gain and keratinized tissue gain was observed for the patients who received SCTG from the TA at 3 months, although these differences were circumscribed to the most apical areas. The histological report that evaluated the structural composition of the grafts used in the previous investigation, reported that grafts obtained from the TA had more lamina propria and less submucosa with SSD when compared with the LP (Sanz-Martín et al., 2019). Nevertheless, long-term results are needed to evaluate the stability of these outcomes.

It is known that abutment connection or crown placement has an impact on soft tissue volume and contour (Benic et al., 2016; Cardaropoli, Lekholm, & Wennström, 2006). To the best of our knowledge, there is no data on the soft tissue response and stability after definitive crown placement around dental implants, which have previously received SCTG either from the LP or the TA. Therefore, the purpose of this study was to compare the response of grafted tissues from LP or TA around dental implants after definitive crown placement and followed during an eight-month period.

Clinical Relevance

Scientific rationale for study: Soft tissue augmentation is a common procedure to enhance soft tissue volume around implants. However, the STA of SCTG harvested from different sites at the palate has not been studied.

Principal finding: Volumetric changes between FU-4 and FU-12 after the augmentation procedure were evaluated by analysing linear changes after the superimposition of STL images. Similar STA was observed for LP and TA, whereas TA resulted in significantly greater stability of KT.

Practical implications: SCTG from LP or TA were equally stable after definitive crown placement; however, greater stability of the KT gained was observed in TA.

2 | MATERIAL AND METHODS

The study was designed as a randomized controlled clinical trial with a parallel design, performed at Universitat Internacional de Catalunya's dental clinic. Ethic approval was obtained from the local regional committees (PER-ECL-2011-10-NF). The present investigation reports follow-up data of a previously published RCT and was comprised of 32 patients in need of soft tissue VG around dental implants using autogenous subepithelial connective tissue grafts harvested from the LP or TA.

Power analysis was performed based on a recent study (Dellavia et al., 2014), where SCTG from LP area and TA was compared. The mean difference between both groups was 1.2 mm with a *SD* of 1.1 mm. Applying these values with a level of 95 (alpha risk 0.05), power of 80 (beta risk 0.2) and a dropout rate of 15% resulted in a sample size of 16 patients per group. Further details regarding the methodology can be found in a previous publication reporting on the 3 months outcomes after soft tissue augmentation (Rojo et al., 2018). Briefly, the inclusion criteria were:

- Patient ≥ 18years old and able to understand the nature of the proposed surgery and to sign the informed consent.
- Single-tooth implants located between two natural teeth.
- All implant locations with a need of a soft tissue volume augmentation as determined by a concavity that was present in the edentulous area or tissues that were thinner than 2 mm.
- LP tissue ≥2 mm of thickness measured in the surgical appointment with a periodontal probe (UNC 15) in the premolar area and a minimum of 12 mm in the mesio-distal dimensions of the TA.
- Full mouth plaque and bleeding scores <20%.

Exclusion criteria

- Previous soft tissue augmentation in the area.
- Heavy Smokers (>10 cigarettes per day).
- Local or systemic conditions that would interfere with routine periodontal therapy.
- Allergy to Non-Steroidal Anti-Inflammatory Drugs.
- Patients taking medications that cause gingival enlargement or the presence of gingival idiopathic overgrowth.
- Untreated periodontal disease or caries

A total of 32 patients participated in the clinical trial. Sixteen patients with a mean age of 50.47 ± 13.61 years in the CG (nine females, seven males) and 16 patients with a mean age of 55.44 ± 8.00 years in the TG (six females, 10 males). Four patients contributed with 2 implants; therefore, a total of 36 implants were treated. Five drop outs were registered. Four patients (2 CG, 2 TG) were excluded from the study on the basis of refusal to attend follow-up appointments. In one patient (CG), the superimposition was not possible due to a non-assessable scan image. Finally, 27 patients with 31 implants were evaluated. Implants were mainly located in the maxilla (73% of the cases in CG and 72% in TG) and in the anterior region (67% of implants in CG and 78% in TG). Submerged healing represented 58% of the sample, whereas transmucosal healing represented 42% (Table 1). Early healing was uneventful in all patients.

2.1 | Clinical procedure

After patient inclusion, a prophylaxis (oral hygiene instructions, ultrasonic instrumentation and supragingival polishing) was performed one week before the surgery. Soft tissue grafting was performed 6 weeks after transmucosal implant placement or at the time of abutment connection, 12 weeks after, in those implants that were placed in a submerged healing. Briefly, intra-sulcular incisions at the buccal side of the implant and adjacent teeth were performed followed by partial-thickness elevation of the buccal mucosal flap. A double-bladed scalpel handle (SKU 10-130-05D; Hu-Friedy) was used in both areas to obtain the same thickness (1.5 mm) in each graft. In the control group CG, the SCTG was harvested from the LP by means of a double incision made 2–3 mm apical to the gingival margins of the first and second premolars. In the test group (TG), the tissue was harvested from the TA where a double incision was made in this zone followed by a second perpendicular incision.

The epithelium was removed from the graft. After that, the graft dimensions were standardized (10 mm height, 12 mm length and 1.5 mm thick) and secured in the recipient site. Finally, single interrupted sutures were used to approximate the mesial and distal flap margins.

More details of the surgical procedure can be found at the previous article (Rojo et al., 2018).

TABLE 1 Patient demographics, implant and prosthetic information

	CG	TG	TOTAL
N	16	16	32
Gender (Male/Female)	7/9	10/6	32
Implants (*N*/%)	18/50%	18/50%	36
Drop out (Patient/Implant)	3	2	5
Age (mean ± *SD*)	50.47 ± 13.61	55.44 ± 8	
Location			
Maxilla	11	13	24
Mandible	7	5	12
Anterior implant (15–25)	12	14	26
Posterior implant	6	4	10
Healing Modus			
One stage	9	7	16
Two stage	9	11	20
Type of implants			
One piece	1	5	6
Two piece	17	13	30
Bone augmentation			
Yes	5	7	12
No	13	11	24
Crown material			
Metal ceramic	15	16	31
Zirconia/Lithium disilicate	0	1	1
Screw retained or cemented			
Screw retained	15	15	30
Cemented	0	2	2

Abbreviations: CG, Control group; TG, Test group.

2.2 | Outcomes measurements

2.2.1 | Soft tissue volume stability (primary outcome)

An intra-oral optical scanner (Lava Chairside Oral Scanner C.O.S., 3M ESPE) was used to obtain stereolithographic (STL) images 2 weeks after definitive crown placement (4 months post-surgery ([FU-4]) and 1 year post-surgery (FU-12). The STL image included the implant and at least two adjacent teeth (mesial and distal). An example of the scanning time points has been explained in Figures 1 and 2.

2.2.2 | STL image matching

The intra-oral optical scan created STL files, which were uploaded to an image analysis software (Geomagic Qualify 12; 3D Systems). Superimpositions of FU-4 STL data and FU-12 STL data were performed for each patient by a single blinded examiner (O.GM) to evaluate horizontal contour changes. To achieve an adequate

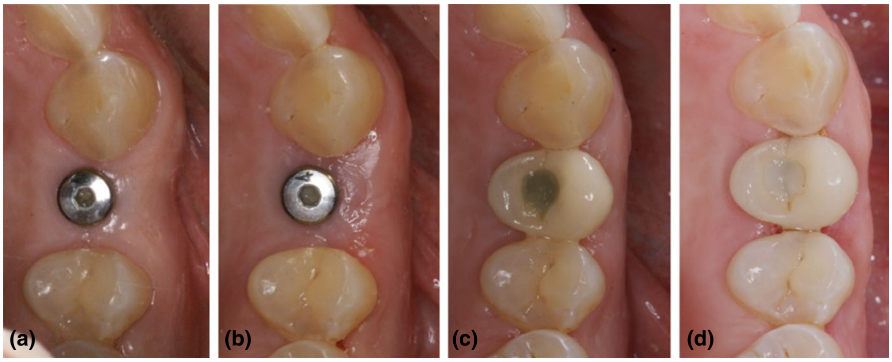

FIGURE 1 Example of CG case. In each time point, an intra-oral optical scan was registered. (a) Baseline clinical situation. (b) 3 months after SCTG from palate area. (c) 2 weeks after the final restoration delivery. (d) 1 year after the soft tissue volume augmentation

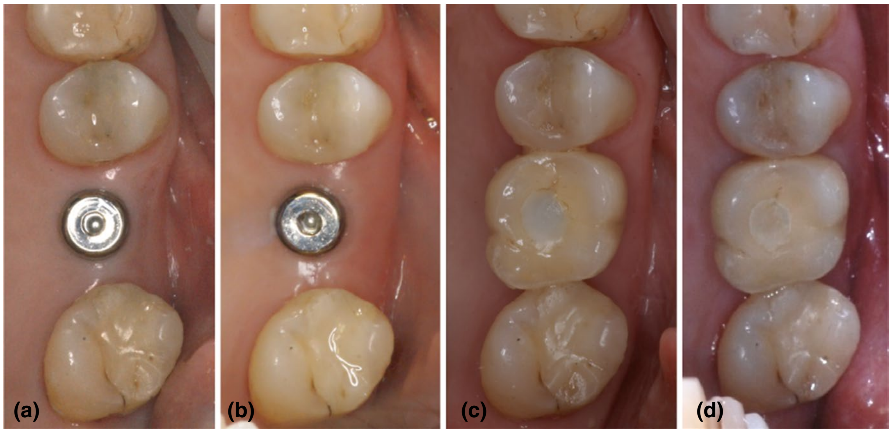

FIGURE 2 Example of TG case. In each time point, an intra-oral optical scan was registered. (a) Baseline clinical situation. (b) 3 months after SCTG from palate area. (c) 2 weeks after the final restoration delivery. (d) 1 year after the soft tissue volume augmentation

superimposition, the implant crown and adjacent teeth were used as common reference points to allow proper matching of the two STL files. The superimposition was achieved based on the best match of common points selected in FU-4 and FU-12 models, a total of 300 randomly selected points were used to get an initial orientation. A final fine adjustment based in 1,500 points selected automatically by the software was carried out to achieve the final alignment.

2.2.3 | Image analysis

Linear measurements: The vestibular area used to evaluate the volume changes was bordered by the mucosal margin at the implant restoration, by 2 mm to the mesial and distal line angles and extended 7 mm apically. For each set of scans, labio palatal sections were obtained perpendicular to the mesio-distal centre of the crown. In these sections, the distance between the FU-4 and FU-12 soft tissue profile was measured from 1 to 7 mm, in an apical direction from the crown margin (Figure 3). The exact proceeding is described in detail in a previous publication (González-Martín, Veltri, Moráguez, Belser, & Dent, 2014).

2.2.4 | Clinical parameters

At FU-4 and FU-12 the plaque index (PI) and marginal bleeding on probing (BI) parameters were evaluated. Probing depth (PD) was measured in six locations around the implant and the neighbouring teeth. The width of keratinized tissue (KT) was assessed in the buccal aspect of the implant and at two adjacent teeth using the roll technique with a UNC-15 periodontal probe (Hu-Friedy). These clinical parameters were assessed by three experienced, calibrated and blinded examiners (ER, GS, BP). The calibration session resulted in an intra-class correlation coefficient of 0.81 (CI 95% = 0.75–0.88).

2.2.5 | Aesthetic evaluation

The modified pink aesthetic score (PES) (Fürhauser et al., 2005) was assessed in two different time points using clinical photographs, at 2 weeks (Rojo et al., 2018) and 8 months after delivery of the final restoration.

2.3 | Statistical analysis

Continuous variables were shown as mean ± SD. To understand the sample distribution, a Shapiro–Wilk test was used. Differences between groups and changes between both time points were calculated by subtracting the values FU-12 from the FU-4 values. Differences were evaluated using the Mann–Whitney U test. A Bonferroni correction was applied for the mean values. Two-sided p-values <.05 were considered to indicate statistical significance. Statistical analysis was performed with SPSS v-22 (IBM corp.).

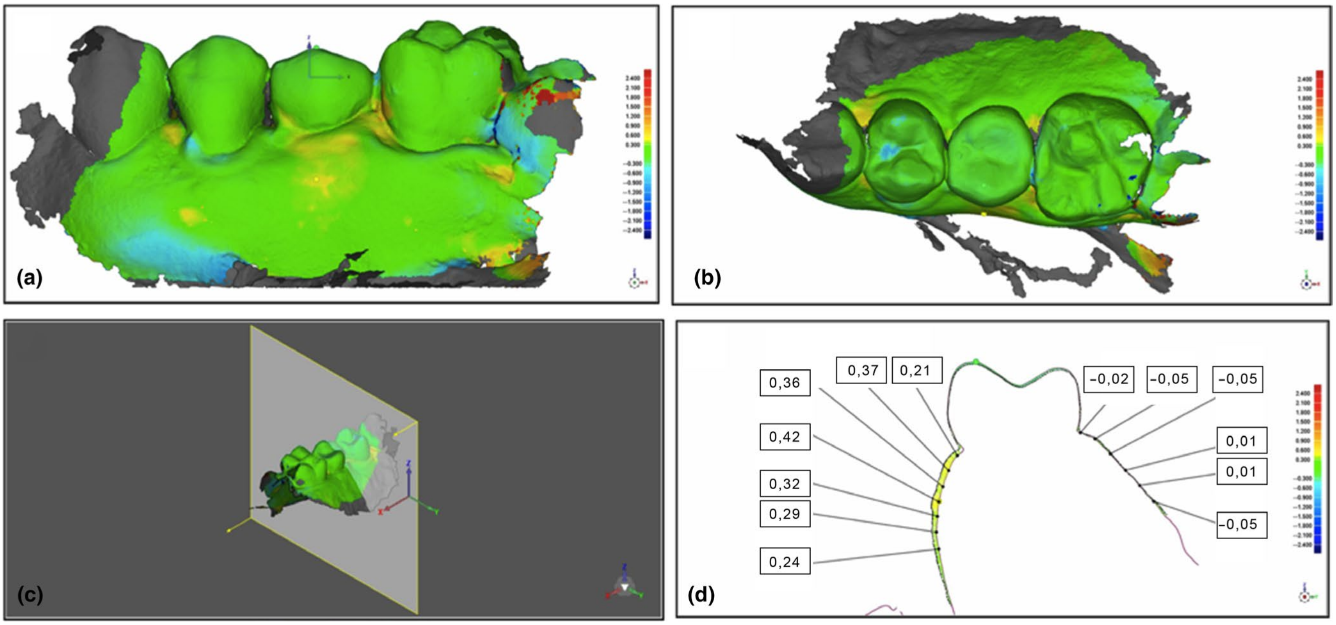

FIGURE 3 Example of a superimposition of the two STL images obtained with the intra-oral optical scan. (a) Buccal view of a superimposition of STL FU-4 and FU-12. (b) Occusal view. (c) Labio palatal sections were obtained perpendicular to the definitive crown. (d) Linear measurement between FU-4 and FU-12 soft tissue profiles was measured

TABLE 2 Soft tissue thickness analysis 4 and 12 months post-operatively. Variables in mm Mean ± *SD*/Median (Q_1 = 25th percentile – Q_3 = 75th percentile)

	CG (mm)	TG (mm)	
	Mean ± *SD*	Mean ± *SD*	*p*-value
1 mm	0.09 ± 0.1	0.17 ± 0.16	.73
2 mm	0.11 ± 0.23	0.01 ± 0.21	.8
3 mm	0.09 ± 0.23	−0.01 ± 0.21	.85
4 mm	0.08 ± 0.29	−0.01 ± 0.2	.37
5 mm	0.03 ± 0.26	0 ± 0.19	.64
6 mm	0.02 ± 0.26	0.01 ± 0.21	.17
7 mm	0 ± 0.22	0.09 ± 0.22	.51
Mean value	0.03 ± 0.22	0.04 ± 0.23	.87

Abbreviations: CG, Control group; TG, Test group.

3 | RESULTS

3.1 | Linear changes in tissue contours

Results in linear changes from FU-4 to FU-12 were calculated by measuring the distance from FU-4 to FU-12 at 1 to 7 mm apically to the implant crown. For this analysis the mean values of the four patients that had more than one implant were used. No statistical significant differences were found in the mean horizontal contour changes between FU-4 and FU-12. Changes were 0.03 ± 0.22 mm for CG, and 0.04 ± 0.23 mm for TG (*p* = .64). Results at each mm are shown in Table 2.

3.2 | Clinical parameters

No statistical significant differences between groups regarding PI, BI and PD values were observed at FU-4 and FU-12 (*p* = .31) (*p* = .63)(*p* = .60). Changes in clinical parameters between FU-4 and FU-12 were similar for both groups without statistical significant differences. A statistically significant difference (*p* = .02) in KT changes at FU-12 was observed for the TG, with a median change of 0 ± 0.32 mm, while the CG lost =-0.3 ± 0.33 mm of KT. Further analysis evaluating only the KT changes around the implant, excluding the adjacent teeth was performed. Again a statistically significant difference with higher values in terms of KT stability was obtained for TG being 0.18 ± 0.53, while the implants in the CG lost −0.42 ± 0.9 mm of KT (*p* = .03) (Table 3).

3.3 | Aesthetic outcomes

Evaluation of PES scores after 1 year resulted in mean values of 8.37 ± 2.46 for the CG, while TG obtained a mean PES score of 8.54 ± 2.43. No statistical significant differences were observed between both groups (*p*=.59) (Table 3). A minor hyperplasic response was observed in 5 cases (2 CG – 3 TG).

4 | DISCUSSION

The aim of this RCT was to evaluate the response of connective tissue grafts around dental implants harvested from different locations after the definitive crown placement. No SSD were found between

TABLE 3 Clinical parameters. PI, BI and PD expressed in % (Mean ± *SD*). KT expressed in mm (Mean ± *SD*)

	FU −4 Mean	FU−12 Mean	Difference
PI. Mean ± *SD* (%)			
CG	18.25 ± 4.4	18 ± 3.6	−0.25 ± 3.2
TG	15.71 ± 3.6	14.29 ± 4.4	−1.41 ± 3
p-value	.33	.11	.31
BI. Mean ± *SD* (%)			
CG	10.33 ± 4	10.58 ± 3.4	0.25 ± 2.7
TG	7.53 ± 3.4	7.76 ± 4.33	0.24 ± 1.7
p-value	.69	.33	.63
PD. Mean ± *SD* (mm)			
CG	2.65 ± 0.7	2.7 ± 0.6	−0.04 ± 0.34
TG	2.48 ± 0.5	2.48 ± 0.5	0 ± 0.33
p-value	.66	.39	.6
KT. Mean ± *SD* (mm)			
CG	4.13 ± 1.6	3.84 ± 1.37	−0.3 ± 0.33
TG	4.25 ± 1.27	4.25 ± 1.25	0 ± 0.32
p-value	.64	.26	.02[a]
KT implant. Mean ± *SD* (mm)			
CG	4.25 ± 1.7	3.83 ± 1.64	−0.42 ± 0.9
TG	4.59 ± 0.94	4.76 ± 1.03	0.18 ± 0.53
p-value	.31	.07	.03[a]
PES evaluation			
CG	10.07 ± 2.19	8.37 ± 2.46	−0.33 ± 1.63
TG	9.15 ± 2.34	8.54 ± 2.43	−0.62 ± 1.26
p-value	.67	.59	.74

Abbreviations: BI, Marginal bleeding on probing; CG, Control group; KT, Width of keratinized tissue; PD, Probing depth; PI, Plaque index; TG, Test group.

[a]Significantly different.

patients who received SCTG from LP or TA in terms of STA. Both tissues were equally stable after crown placement. However, the TG showed more KT gain at 3 months (Rojo et al., 2018) and more stability after 12 months.

Results at 3 months evaluating volume gain showed a tendency of greater gain for the TG in terms of mean values. At 6 and 7mm apically to the healing abutment, SSD were found favouring the TG (Rojo et al., 2018). Histological studies have revealed that grafts from TA had a greater amount of lamina propria and less quantity of submucosa when compared with LP (Sanz-Martín et al., 2019). These histological differences were particularly noticeable in the most apical areas of the grafts. These areas were the only ones that had SSD in the clinical outcome of volume gain. These findings are in agreement with a histological investigation that has reported that LP area seems to contain more lamina propria in the closest area to the gingival margin, while in the more apical areas a greater amount of submucosa is found (Bertl et al., 2015). In addition, it must be taken into consideration that the harvesting procedure using a double-bladed knife may have had an impact on the quality of the harvested tissue compared to other harvesting techniques, as the more superficial layers of LP which contain a higher concentration of lamina propria were harvested. Therefore, given the outcomes of the present investigation it might be affirmed that it is rather the harvesting technique, not the donor site itself that plays a crucial role on the clinical outcomes.

In terms of STA, no SSD were found between groups showing stable outcomes. This is in agreement with previous studies that concluded that the highest soft tissue shrinkage after augmentation occurs during the first 3 months of healing (De Bruyckere, Eghbali, Younes, De Bruyn, & Cosyn, 2015). Moreover, it has been reported that between 1 and 3.5 months a 15% of volume loss may be expected when using SCTG from LP (Studer, Lehner, Bucher, & Schärer, 2000). In a more recent RCT (Thoma et al., 2016) which compared a collagen matrix and SCTG from LP to improve volume deficiencies around single-tooth implants a reduction of 0.4 ± 2.0 mm in buccal soft tissue thickness was observed between 1 and 3 months in the SCTG group. The follow-up studies from the same investigation concluded that a −0.25 ± 0.26 mm of volume was lost during this period of time (Zeltner, Jung, & Thoma, 2017) and that this volume remained stable between the definitive crown insertion and the one year evaluation (Huber, Zeltner, Hämmerle, Jung, & Thoma, 2018).. In a prospective case series (De Bruyckere et al., 2015) soft tissue augmentation was performed around dental implants. The greatest VG was observed two weeks after the surgical procedure, due to post-surgical oedema. After this, a decrease was observed at the 3-month evaluation, with a mean loss of −0.38 mm. At 3 months, the definitive crown was placed, and between the 3- and 12-month follow-up, tissue thickness had a minimal change from 1.10 mm to 0.97 mm.

In terms of KT gain, the TG obtained a more stable outcome between FU-4 and FU-12 with 0 ± 0.32 mm, while the CG lost −0.3 ± 0.33 mm of KT. To the best of our knowledge, this is the first study that has shown more KT gain at 12 months when using a bilaminar technique with SCTG from TA around dental implants. In a classical study (Ouhayoun, Sawaf, Gofflaux, Etienne, & Forest, 1988), a thick FGG was split in a superficial epithelium-connective tissue graft and a deep connective-submucosal graft. Then, grafts were fixed and left exposed into a mucosal bed. While the superficial grafts were able to show KT composition, deep connective tissue graft did not show these properties when transplanted. Having in mind that superficial grafts may have more lamina propria, it could be speculated that grafts with more lamina propria may obtain more KT and therefore may be a better option when augmentation of KM is needed.

Even though in the present RCT no statistical significant differences were observed between groups in terms of PES, other investigations (Dellavia et al., 2014) described a generalized unaesthetic hyperplasic response when using SCTG from tuberosity area. These differences might be due to the fact that a thicker graft was used in this study (3.5 mm thickness). However, in the present study, a hyperplasic response was found in 2 cases of CG and 3 cases of TG.

The immunohistochemical analysis of the grafts used in the present investigation evaluated among other parameters the levels of different cytokeratines (cytokeratine 10 and cytokeratine 13). The results showed a tendency for higher cytokeratine expression in the epithelium and rete pegs of TA samples (Sanz-Martín et al., 2019). This might explain to some extent the gain in KT and the increased stability of KT for the sites grafted with TA. However, the true role of cytokeratines on the epithelialization of the peri-implant mucosa remains unclear and further research is needed to understand the factors that govern the healing of these grafts and their impact on the peri-implant mucosa.

The assessment of the patient-related outcomes measurements (PROMs) would have added valuable information to the present study, Recent data (Amin, Bissada, Ricchetti, Silva, & Demko, 2018) which compared PROMs after harvesting soft tissue grafts from LP and TA concluded that pain level in TA was significantly lower when compared with LP.

Finally, there are some limitations that must be taken into consideration when evaluating the outcomes of the present study. Changes in hard tissue during these time periods were not evaluated and this may have had an impact on the tissue contours. Furthermore, due to the methodology used, the initial soft tissue defect could not be assessed and therefore possible baseline differences between the two groups were not measured.

5 | CONCLUSIONS

This RCT demonstrated that soft tissues previously augmented randomly with SCTG from the lateral palate or the tuberosity area had a comparable stability 12 months after the augmentation procedure. No significant differences were observed for the stability of the tissues between the two groups although a greater gain and stability of KT was observed for the tuberosity group.

CONFLICT OF INTEREST

The authors report no conflict of interests related to the study.

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