Soft tissue grafting and single implant treatment in the aesthetic region

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CHAPTER 6

The influence of different soft-tissue grafting procedures at single implant placement on aesthetics: a randomized controlled trial

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Abstract

Aim:

To assess whether grafting the buccal peri-implant mucosa using either a connective tissue graft (CTG) or xenogeneic collagen matrix (XCM) at implant placement in preserved alveolar ridges results in less mid-buccal mucosa recession compared to no grafting.

Materials & Methods:

Sixty patients randomly received either no graft (n=20, NG group), a CTG (n=20, CTG group) or XCM (Mucograft®, Geistlich Pharma AG, Wolhusen, Switzerland; n=20, XCM group) when placing an implant in a preserved alveolar ridge. Changes in mid-buccal mucosal level (MBML) at one (T_1) and twelve (T_{12}) months after final implant crown placement was compared to the pre-extraction situation. Additionally, aesthetics, marginal bone level, clinical peri-implant parameters and patient satisfaction were assessed.

Results:

At T_{12}, mean changes in MBML were -0.48±1.5 mm, -0.04±1.1 mm and -0.17±1.3 mm in the NG, CTG and XCM groups (p=0.56), respectively. Regarding the other outcome variables, no significant inter-group differences were observed.

Conclusion:

Soft tissue grafting at single implant placement in preserved alveolar ridges does not result in a better aesthetic outcome or in better peri-implant health and should not be considered as a standard procedure.

Introduction

Single implant treatment in the maxillofacial aesthetic zone to replace a single failing tooth is a valuable treatment modality (den Hartog et al. 2008, Jung et al. 2012). However, long term data demonstrated stable aesthetics in just 37% of the cases (Rokn et al. 2016).

It is presumed that to achieve stable aesthetics, the implant should be inserted in an optimal three-dimensional position in the available bone dimensions with preservation of sufficient buccal bone volume for a proper soft tissue support (Merheb et al. 2014, Chappuis et al. 2017). Since the buccal bone wall in most sites of the maxillary aesthetic zone is very thin (≤1 mm; Januario et al. 2011) and is associated with significant buccal bone resorption following tooth removal (Avila-Ortiz et al. 2014, Lee & Poon 2017), correct three-dimensional implant placement might be impaired. Therefore, to reduce bone dimensional changes, augmentation of the extraction socket prior to implant placement was proposed to preserve both the alveolar ridge (Araújo et al. 2015, MacBeth et al. 2017) and buccal soft tissue (Barone et al. 2013). However, bone loss in width and height is still expected despite alveolar ridge preservation, as well as soft tissue changes (Ten Heggeler et al. 2011, Barone et al. 2013).

To compensate for soft tissue changes, the application of a connective tissue graft (CTG) was proposed to increase soft tissue volume (Thoma et al. 2009, Buser et al. 2017) and to establish a better soft tissue profile. According to the literature, grafting the buccal peri-implant soft tissue with a CTG effectively increases the soft tissue contour (Wiesner et al. 2010, Schneider et al. 2011, De Bruyckere et al. 2015, Hanser & Khoury 2016, Stefanini et al. 2016). Additionally, connective tissue grafting (CT grafting) was demonstrated to be effective in preserving the mid-buccal mucosal level (Schneider et al. 2011, Stefanini et al. 2016, Zuiderveld et al. 2018). In contrast to this, a retrospective study (Bienz et al. 2017) showed that CT grafting resulted in minimal changes of soft tissue volume and level without a significant difference compared to no soft tissue grafting over 5 years follow-up.

As an alternative to CTG as golden standard for soft tissue augmentation (Thoma et al. 2014a, b), the use of a xenogeneic collagen matrix (XCM) was introduced to decrease patient morbidity caused by the harvesting procedure of the CTG (Sanz et al. 2009, Herford et al. 2010). In several studies, applying a XCM to increase soft tissue thickness was found to be as effective as a CTG (Lorenzo et al. 2012, Thoma et al. 2016, Zeltner et al. 2017). XCM was also demonstrated to be effective on the long term with stable aesthetics (Maiorana et al. 2018). In contrast to this, Cairo et al. (2017) observed a more effective increase in soft tissue thickness with the application of CTG than with XCM. In terms of recession reduction using a coronally advanced flap (CAF) with either a CTG or XCM, both achieved comparable and stable results (Cardaropoli et al. 2012, Jepsen et al. 2013).

As far as we know, Froum et al. (2015) is the only study comparing the effect of applying a XCM with no soft tissue graft during implant placement. They found no differences between the groups, but intra-group comparisons revealed that, compared to baseline levels, patients receiving the XCM showed a significant thickening of the buccal keratinized tissue. There is a paucity of papers evaluating the effect of applying a CTG or XCM on mid-buccal mucosa recession, although CT grafting has demonstrated to be effective and XCM was judged to be comparable to CTG. Therefore, we assessed whether grafting the buccal peri-implant mucosa using either a CTG or XCM at implant placement in preserved alveolar ridges results in less mid-buccal mucosa recession compared to no grafting.

Materials & Methods

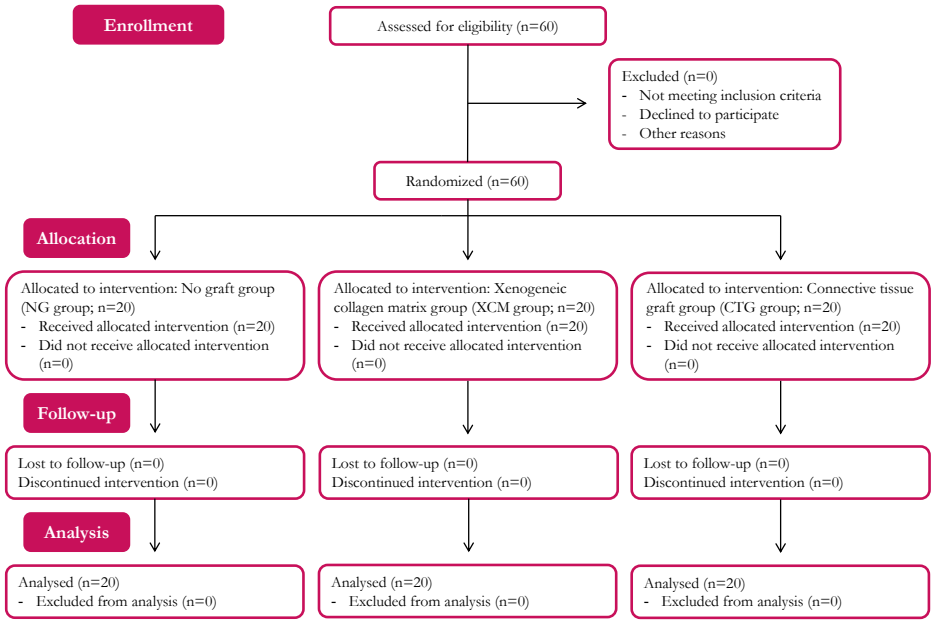
Study design

Between December 2012 and July 2015, all consecutive patients (≥18 years) referred for implant treatment due to a maxillary single failing tooth (incisor, canine, first premolar) were invited to participate in this randomized controlled clinical study. The study was approved by our Medical Ethical Committee (NL43085.042.13) and registered in the Dutch trial register (www.trialregister.nl: NTR3815; 01-23-2013). The following in- and exclusion criteria had to be fulfilled: adequate oral hygiene (i.e., modified plaque and sulcus bleeding index ≤1; Mombelli et al. 1987), diastema width of ≥6 mm and sufficient interocclusal space for a non-occluding temporary crown, no medical and general contraindications for the surgical procedure (i.e., ASA score ≥III; Smeets et al. 1998), no active and uncontrolled periodontal disease (probing pocket depths ≥4 mm and bleeding on probing (index score >1)), non-smoker, no head and neck radiation, not pregnant (Fig. 1). Patients provided written informed consent before enrollment.

According to a pre-operative cone beam computed tomography scan, insufficient bone volume on the palatal side was present to place an implant with primary stability. Additionally, all patients presented with a vertical buccal bone wall defect of >5 mm of the extraction socket, assessed post-extraction by a bone sounding technique. Therefore, all extraction sockets were augmented prior to implant insertion and closed with a mucosa graft. Four months thereafter, patients were treated with an implant (NobelReplace CC, Nobel Biocare AB, Gothenburg, Sweden) and then randomly distributed, via sealed envelopes opened by an uninvolved research-nurse, to receive either:

- no soft tissue graft (No graft group; NG group, n=20);
- a connective tissue graft harvested from the palate (Connective tissue graft group; CTG group, n=20);
- a xenogeneic collagen matrix (Mucograft®, Geistlich Pharma AG, Wolhusen, Switzerland) (Xenogeneic collagen matrix group; XCM group, n=20).

Fig. 1 – Cohort flow diagram



Intervention procedure

One day prior to implant surgery, patients started taking antibiotics (amoxicillin 500mg, t.i.d. for 7 days or clindamycin 300mg, q.i.d. for 7 days in case of amoxicillin allergy) and used a 0.2% chlorhexidine mouthwash (twice daily for 7 days) for oral disinfection.

All surgical procedures were performed under local anaesthesia by the same oral and maxillo-facial surgeon (G.M.R.). In all groups, the extraction socket was augmented with the tuberosity bone graft shaped to match the buccal bone defect and inserted with the cortical side facing the periosteum (Fig. 2a). A mixture of autologous bone and Bio-Oss® (Geistlich Pharma AG) spongious bone substitute (0.25-1.0 mm) was tightly packed into the extraction socket (Fig. 2b). Then, the extraction socket was closed with a full-thickness mucosa graft (Fig. 2c), which was also harvested from the maxillary tuberosity region.

Fig. 2a – Clinical view of the tuberosity bone graft in the extraction socket grafting the buccal bone defect.

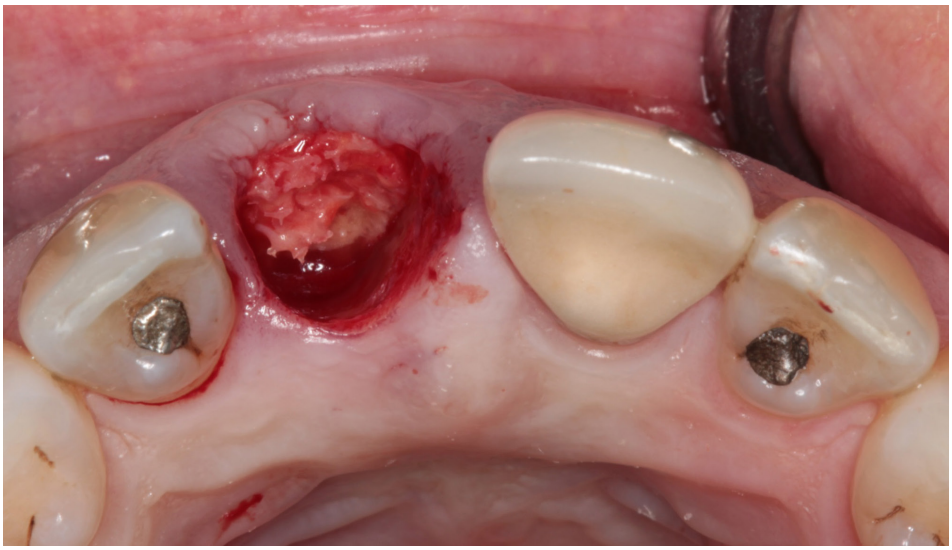


Fig. 2b – Clinical view of a mixture of autologous bone and Bio-Oss® spongious bone substitutes tightly packed into the extraction socket.

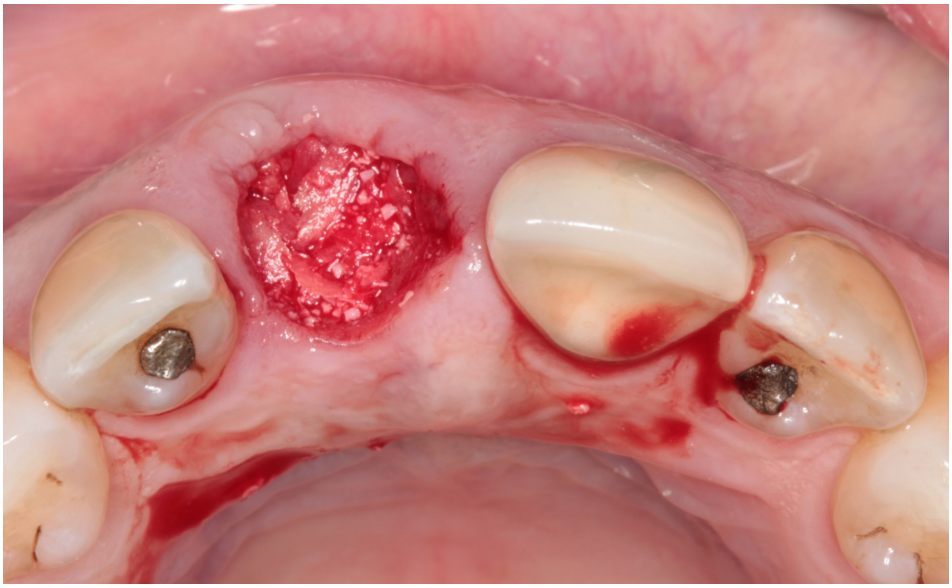
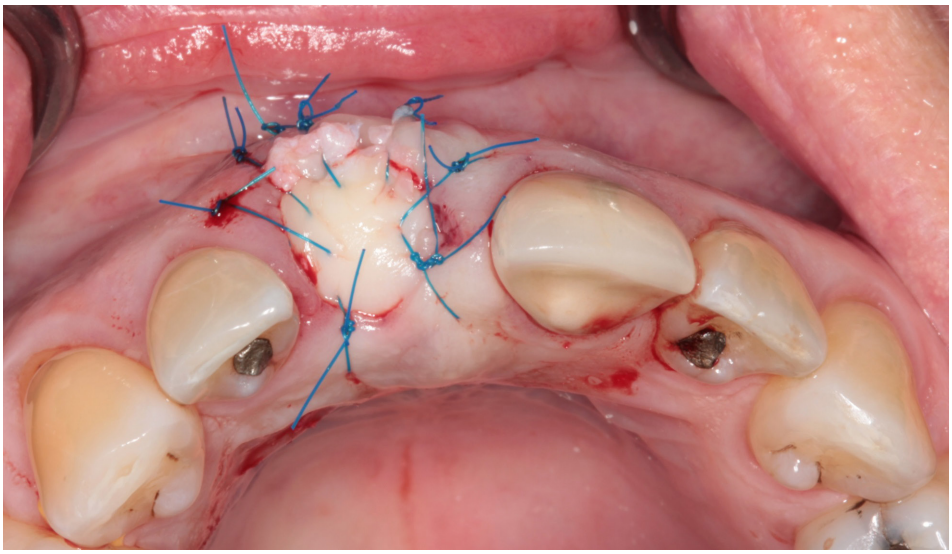


Fig. 2c – Clinical view of the extraction socket closed with a full-thickness mucosa graft.



The implant was inserted four months after the augmentation procedure (Fig. 3). A small palatal crest-incision was made to expose the alveolar ridge, followed by extensions through the buccal and palatal sulcus of the adjacent teeth and a divergent relieving incision at the distal tooth to elevate the minimal mucoperiosteal flap. The implant site was prepared according to the manufacturer's manual and with a surgical template representing the ideal position of the prospective implant crown. All implants were installed with a torque controller (OsseoCare, Nobel Biocare AB) with 45Ncm and provided with a cover screw. The implant shoulder was placed 3 mm apical to the most facial and cervical aspect of the prospective clinical crown to ensure a proper emergence profile, including being levelled with the alveolar bone.

The randomization procedure was done immediately after implant installation. Regarding the CTG group, the CTG was harvested from the palate (Fig. 4).
Both the CTG and the XCM were placed in the prepared mucoperiosteal flap at the facial site and secured with vertical and horizontal mattresses (4-0 vicryl, Johnson & Johnson Gateway, Piscatatway, USA; Figs. 5a-d). The control group did not have a graft placed in the prepared mucoperiosteal flap. In all groups, the wound at the implant site was closed with Ethilon 5-0 nylon sutures (Johnson & Johnson). All sutures were removed two weeks after surgery. During the healing phase, patients wore a removable partial denture that did not interfere with the wound.

Fig. 3 – Clinical view of the implant placed in the pre-augmented alveolar ridge.

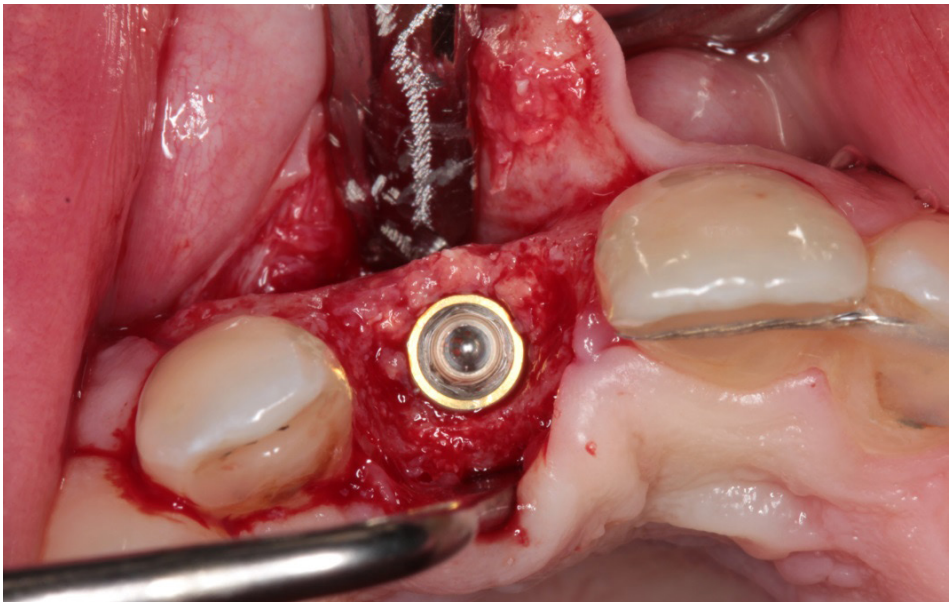
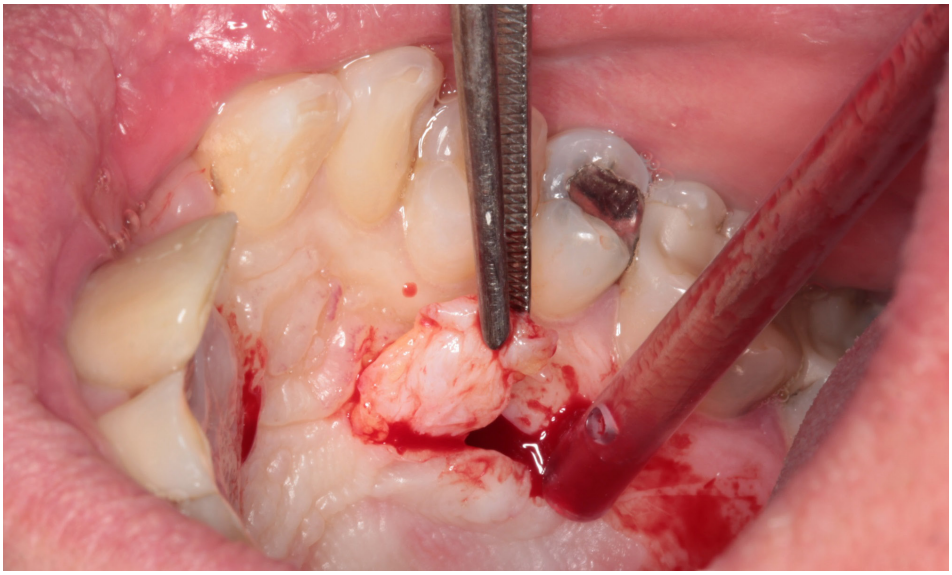
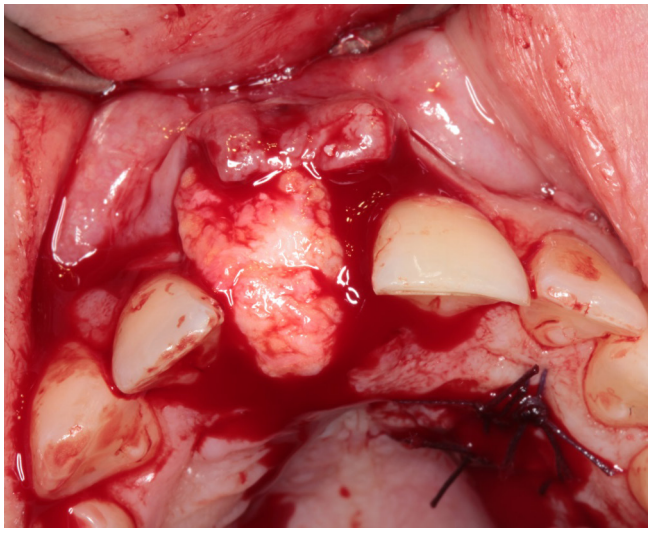


Fig. 4 – Harvesting procedure of the connective tissue graft from the palate.



Figs. 5a, b – Placement of the connective tissue graft in the prepared mucoperiosteal envelope flap, which was secured with horizontal and vertical mattresses.

a



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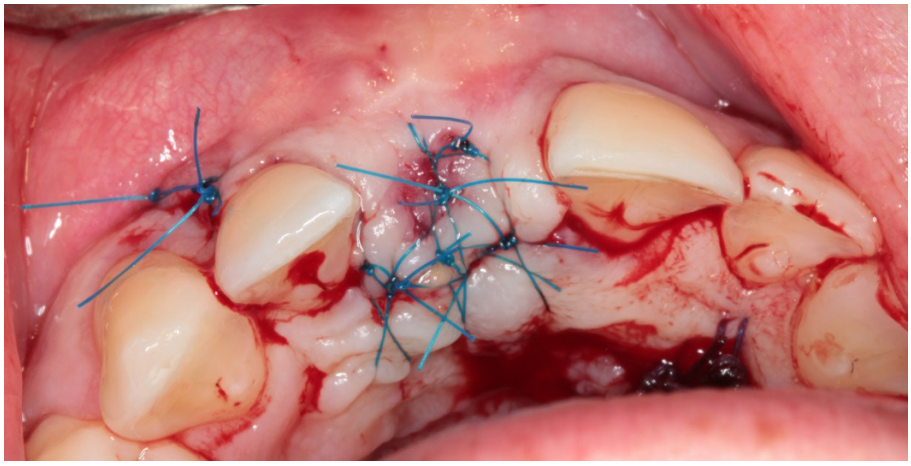
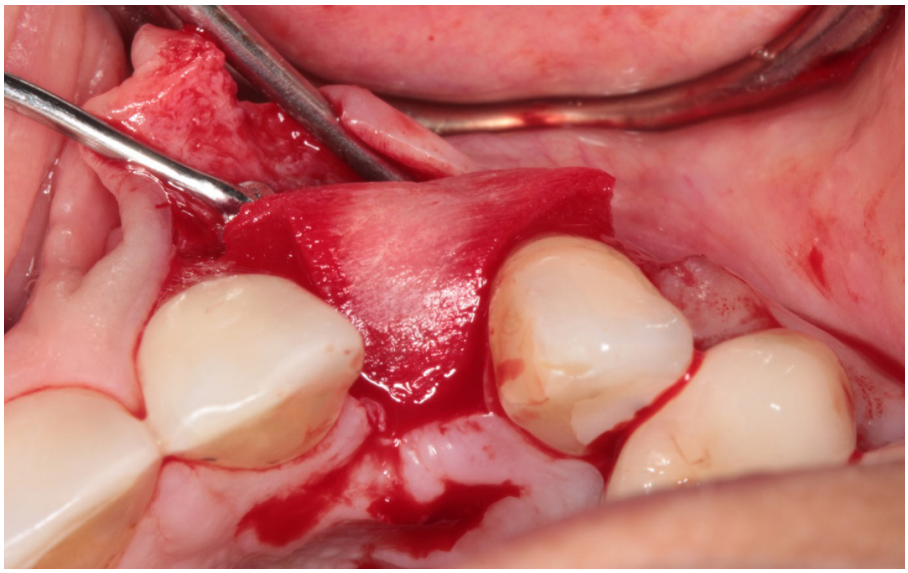


Figs. 5c, d – Placement of the xenogeneic collagen matrix in the prepared mucoperiosteal envelope flap, which was secured with horizontal and vertical mattresses.

c



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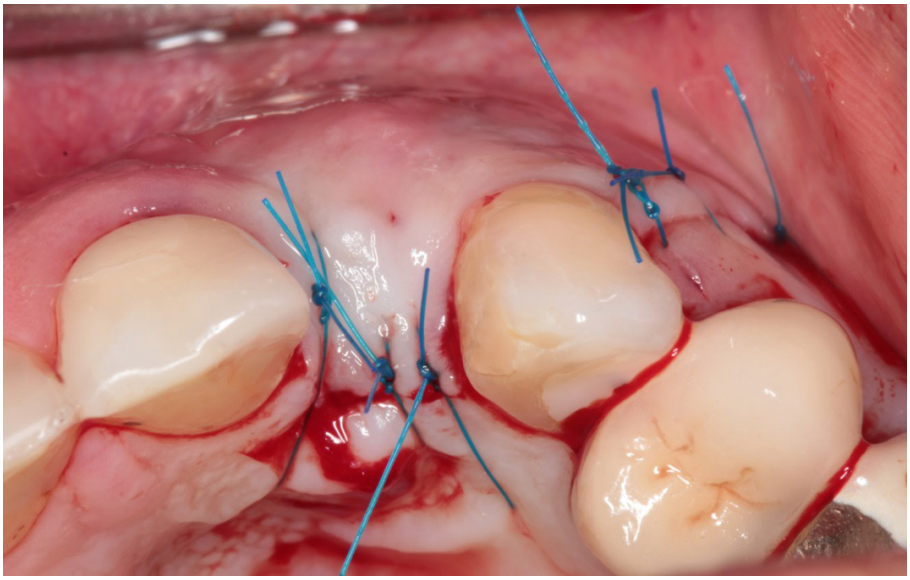


After three months, the implants were uncovered and an implant-level impression was made for the fabrication of a screw-retained provisional crown in the dental laboratory. All implants had been installed with a healing abutment (Nobel Biocare AB). The provisional crown was fitted that same day onto the implant with 20Ncm by a manual torque wrench (Nobel Biocare AB) and adjusted to function free from centric and eccentric contacts with the antagonist teeth. Patients were instructed to follow a soft diet and to avoid exerting force on the provisional restoration.

Three months later, a final open-tray implant-level impression was taken using polyether impression material (Impregum Penta, 3M ESPE, Seefeld, Germany). An individualized zirconia abutment (NobelProcera, Nobel Biocare AB) was made from the digitally designed final implant crown. Depending on the location of the screw access hole, the final crown was screw-retained or cement-retained. Abutment screws were torqued with 35Ncm.

All prosthetic procedures were accomplished by two prosthodontists (H.J.A.M. and C.S.).

Photographic assessment

The primary outcome measure was the change in mid-buccal mucosal level (MBML), assessed from standardized intra-oral photographs (Canon EOS 650D with ring flash) taken before tooth extraction (T_{pre}), one (T_1) and 12 months (T_{12}) after final implant crown placement. Changes in inter-proximal mucosal levels (IML) were measured the same way. The photographs were calibrated by a periodontal probe (Williams Color-Coded probe; Hu-Friedy, Chicago, IL, USA) held close to and parallel to the long axis of the tooth next to the implant. Full-screen analysis was done using Adobe Photoshop CS5.1 (Adobe Systems Inc., San Jose, USA). MBML changes were measured at T_{pre} and T_1 by drawing a horizontal line through the incisal edges of the adjacent teeth and the distance between this line and the mucosal margin was calculated (Fig. 6a). The T_1-T_{12} MBML changes were assessed from the length of the implant crown (Fig. 6b). MBML changes between T_{pre} and T_{12} were calculated by adding both measurements (Zuiderveld et al. 2018).

Peri-implant mucosa and implant crown aesthetics were assessed from photographs taken at T_{12} using the Pink Esthetic Score-White Esthetic Score (PES/WES; Belser et al. 2009).

Fig. 6a – Measurement of change in MBML between T_{pre} and T_1.

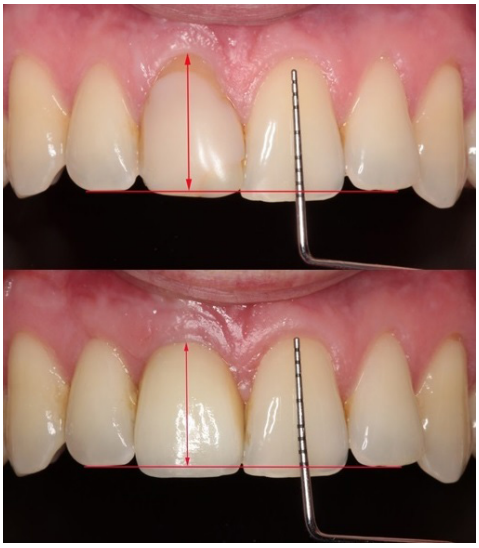
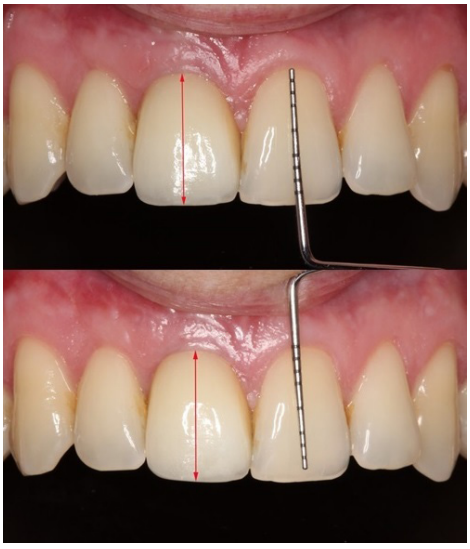


Fig. 6b – Measurement of change in MBML between T_1 and T_{12}.



Radiographic assessment

At T_1 and T_{12}, the marginal bone level was measured on standardized digital intra-oral radiographs taken with an individualized device (Meijndert et al. 2004). The distance between the implant platform and first bone-to-implant contact along the implant was measured using specifically designed software. Bone above the implant platform was scored as no bone loss.

Clinical assessments

Clinical data of any implant was collected by a single examiner (E.G.Z.), who was blinded regarding group allocation, at T_1 and T_{12}. The following parameters were assessed: (1) gingival biotype, as measured by means of transparency of a periodontal probe through the gingival margin of the failing tooth (only at T_{pre}; Kan et al. 2010); (2) probing pocket depth using a periodontal probe at the mesio-buccal, mid-buccal, and disto-buccal and mid-palatal aspect; (3) amount of plaque (modified plaque index; Mombelli et al. 1987); (4) bleeding after probing (modified sulcus bleeding index; Mombelli et al. 1987); (5) gingival condition (gingival-index; Loe 1967); (6) width of the keratinized mucosa: no keratinized mucosa, <1 mm of keratinized mucosa, 1-2 mm of keratinized mucosa, ≥2 mm of keratinized mucosa; (7) volume of the interproximal papilla, using the papilla index (Jemt 1997); (8) implant survival; (9) implant success, defined as ≤1 mm marginal bone loss one-year post-loading and ≤0.2 mm thereafter and the absence of pain, infection, mobility, peri-implant radiolucency and alteration in sensitivity (Albrektsson et al. 1986).

Patient satisfaction

OHIP-14 questionnaires (van der Meulen et al. 2012), including questions about overall satisfaction with the current dentition and compared to the pre-operative situation to be answered on a 10 cm Visual Analogue Scale (VAS), were completed at T_{pre}, T_1 and T_{12}. Additionally, questions regarding aesthetics and satisfaction with the treatment procedure to be answered on a 10 cm VAS were provided. All questionnaires were handed out and filled in privately before collecting the clinical data.

Statistical analysis

G*power 3.1 was used to calculate the sample size (Faul et al. 2009). A recession of the mid-buccal mucosa of 0.5 mm from implant placement to 12 months after placement of the final implant crown was considered to be a clinically relevant difference between the groups. With an expected standard deviation of 0.6 mm, as derived from the literature (Slagter et al. 2016), and a power of 80%, a minimum of 18 patients per group would be needed. We decided to include 20 patients per group in case of any withdrawals from the study.

The Shapiro-Wilk test was used to assess the normal distribution of the continuous variables and Normal Q-Q-plots were depicted. Normal distributed data were analysed using ANOVA. Non-normal distributed data were evaluated with Kruskal-Wallis tests. Within-group comparisons were done using Wilcoxon tests. Analysis of categorical data was performed with Chi-square or Fisher's exact tests.

The Pearson's correlation coefficient was calculated to explore the influence of gingival biotype on the mid-buccal mucosal level.
All analyses were done using a p-value of 0.05 to indicate statistical significance and were performed using SPSS (SPSS Statistics 23.0, SPSS Inc.; IBM Corporation, Chicago, IL, USA).

Results

Baseline characteristics of the 60 included patients are depicted in Table 1. No significant differences between the groups were noticed for sex, age, gingival biotype, implant site location, implant length and implant diameter. All patients received their assigned treatment (Fig. 1). Figures 7a-c are showing the pre-operative clinical situation and the clinical situation one year after placement of the final implant crown in the NG, CTG and XCM groups, respectively. No signs of soft tissue complications, nor extensive bleedings or perforation through the maxillary sinuses were noted at the donor site. During follow-up, no objective signs of infections were observed. No implants had been lost at T_{12} (implant survival rate of 100%) and none of them displayed marginal bone loss in excess of 1 mm; they also fulfilled all the other success criteria (success rate of 100%).

Table 1 – Patient characteristics per study group.

Variable	NG group (n=20)	CTG group (n=20)	XCM group (n=20)
Male/female ratio	7/13	11/9	7/13
Age (years) mean±SD (range)	42.0±15.7 (18-71)	38.2±16.7 (18-69)	45.4±17.0 (18-73)
Gingival biotype thin/thick	15/5	13/7	10/10
Implant site location $I_1/I_2/C/P_1$	9/8/0/0	16/3/1/0	11/4/3/2
Implant length (mm) 13/16	10/10	11/9	12/8
Implant diameter (mm) 3.5/4.3	9/11	4/16	5/15

Abbreviations: NG group, No graft group; CTG group, Connective tissue graft group; XCM group, Xenogeneic collagen matrix group.

Reliability of photographic and radiographic measurements

Interclass correlations (ICCs) for the photographic measurements were high: 0.88 (95% CI 0.72-0.95) and 0.83 (95% CI 0.60-0.93) for the intra- and inter-observer agreements, respectively. The same applied for radiographic measurements: 0.71 (95% CI 0.32-0.87) and 0.9 (95% CI 0.75-0.96) for the intra- and interobserver agreements. The ICCs for aesthetic assessments were 0.86 (95% CI 0.68-0.94) and 0.90 (95% CI 0.77-0.96) for the intra- and interobserver agreements, respectively (Zuiderveld et al. 2018).

Change in mid-buccal and interproximal mucosal level

No significant differences in MBML changes between the groups were observed (Table 2). At T_{12}, the MBML showed an average loss, compared to baseline levels, of 0.48±1.5 mm in the NG group, 0.04±1.1 mm in the CTG group and 0.17±1.3 mm in the XCM group (p=0.56). The changes in MBML between T_{pre} and T_1 and between T_1 and T_{12} were negligible in all groups (p=0.67 and p=0.15, respectively). Pre-treatment gingival biotype had no influence. IML changes at T_{12} of both implant sides were comparable for the control and both test groups (mesial: p=0.63; distal: p=0.85; Table 2).

Change in radiographic marginal bone level

Between T_1 and T_{12} median (IQR) marginal bone level changes were 0.00 (-0.18-0.00) for the mesial side and 0.00 (-0.02-0.39) for the distal side in the NG group, respectively. For the CTG group changes were 0.00 (-0.13-0.01) and 0.00 (-0.29-0.06) and for the XCM group changes were 0.00 (-0.21-0.27) and 0.00 (-0.08-0.15), respectively. Changes were comparable between the groups (mesial side: p=0.67, distal side: p=0.24; Table 2).

Clinical outcome

Outcomes concerning probing pocket depths and papilla volume around the implant crown at T_1 and T_{12} are depicted in Table 2. None of the implant crowns displayed plaque at T_{12}. Upon probing, 55% of the patients in the NG and CTG groups and 45% in the XCM group demonstrated no bleeding (score 0). 30% of the NG and CTG patients and 40% of XCM patients had an isolated bleeding spot (score 1). A score 2 (confluent red line) was encountered in 15% of the patients of all the groups.

At T_{12}, the peri-implant mucosa was healthy in almost all patients; the exceptions were one patient in the NG group and one in the CTG group who showed signs of mild inflammation. 90%, 75% and 70% of the patients in the NG, CTG and XCM respective groups displayed more than 2 mm of keratinized mucosa (score 3). A 1-2 mm wide zone of keratinized mucosa (score 2) was seen respectively in 5%, 15% and 10% of the NG, CTG and XCM groups. 5% of the patients in the XCM group had a keratinized mucosa of up to 1 mm (score 1). 5%, 10% and 15%, respectively, of the patients in the NG, CTG and XCM groups showed no keratinized mucosa (score 0).

Aesthetic assessment

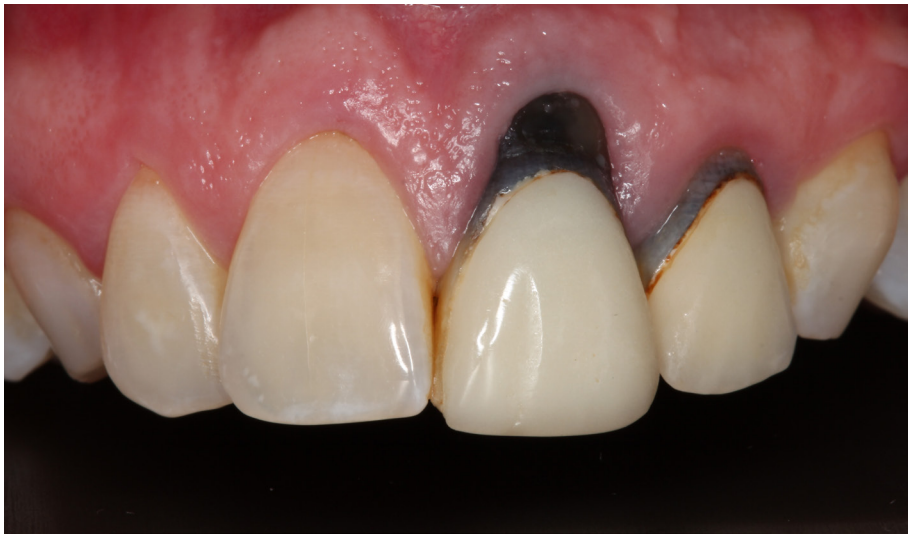
No significant inter-group differences were found with respect to PES and WES total scores as well as all the separate scoring items (Table 2). Acceptable levels of aesthetics (PES/WES ≥6) were reached in 75% of the NG group, 80% of the CTG group and 65% of the XCM group regarding the peri-implant mucosa. With respect to the implant crown, acceptable levels were reached in 100% of the NG group, 100% of the CTG group and 95% of the XCM group.

Patient satisfaction

At T_{12}, the results of the VAS-scores showed no difference in patient satisfaction, except for satisfaction with the implant and implant crown (Table 3). Satisfaction with the current dental situation improved significantly between baseline and T_1 ($p=0.00$), where after no further improvement was observed up to one year after placement of the final crown (T_{12}; $p=0.94$). No inter-group differences were found for the total OHIP-questionnaire scores. Within-group comparisons showed a favourable improvement between T_{pre} and T_1 ($p=0.00$), which continued between T_1 and T_{12} ($p=0.00$).

Fig. 7a – NG group:

a



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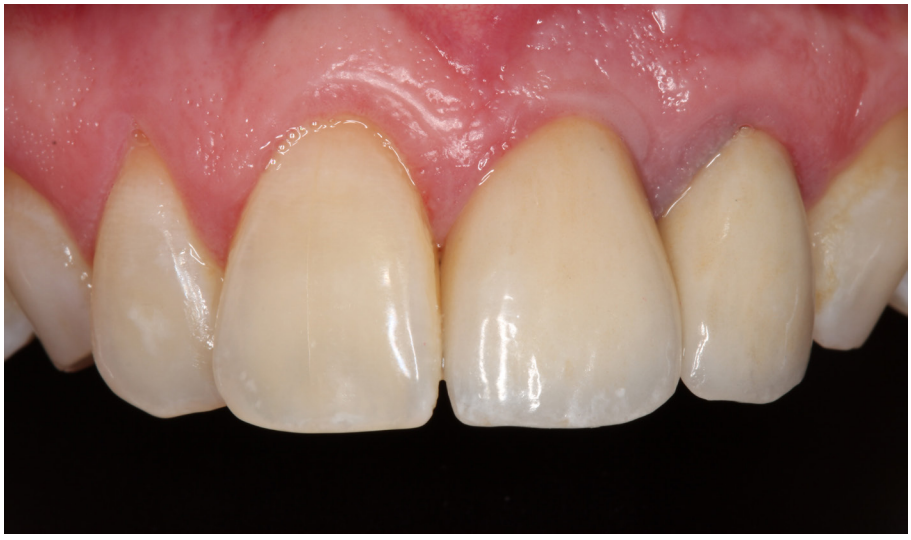
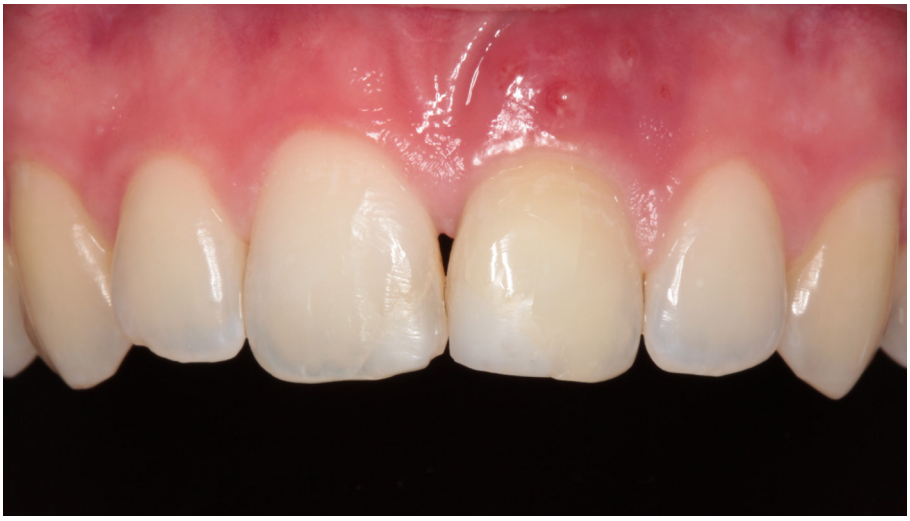


a Pre-operative clinical situation of the failing left central incisor.
b Clinical situation one year after placement of the left central final implant crown.

Fig. 7b – CTG group:

a



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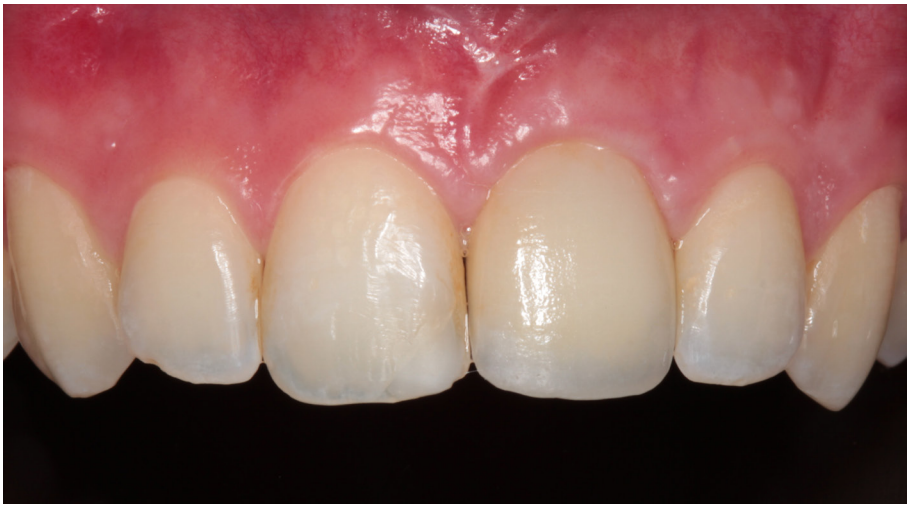
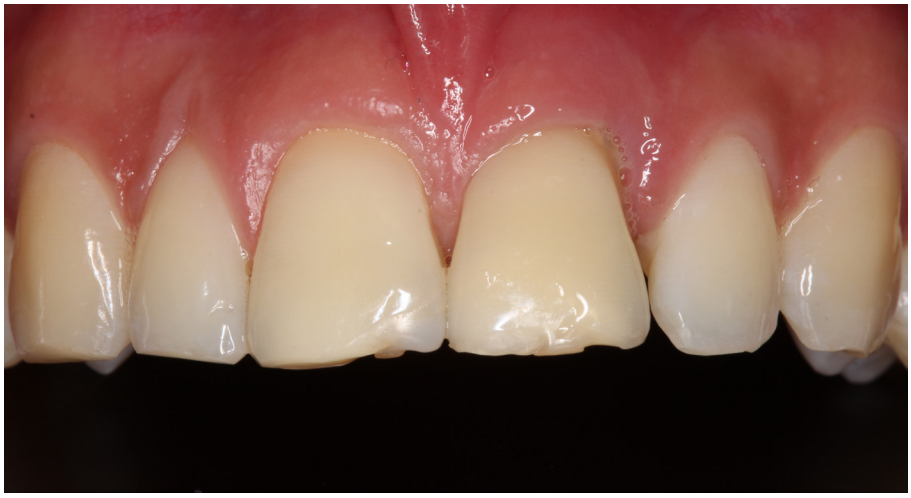


a Pre-operative clinical situation of the failing left central incisor.
b Clinical situation one year after placement of the left central final implant crown.

Fig. 7c – XCM group:

a



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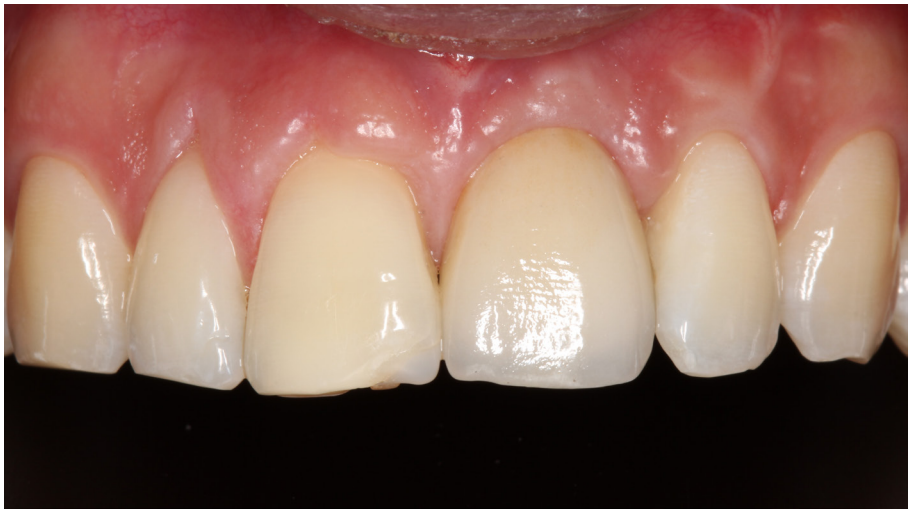

a Pre-operative clinical situation of the failing left central incisor.
b Clinical situation one year after placement of the left central final implant crown.

Table 2 – Changes in marginal soft tissue level from baseline to twelve months after final outcome measures.

	NG group (n=20)	CTG group (n=20)	XCM group (n=20)		NG group (n=20)
Variable	**$T_{pre} - T_1$ (mean±SD)**			**p-value**	
MBML (mm)	-0.34±1.5	-0.01±1.1	-0.001±1.3	0.67	-0.15±0.2
IML (mm)					
Mesial of implant	-0.9±1.2	-0.9±0.8	-0.4±0.9	0.14	0.2±0.4
Distal of implant	-0.9±1.1	-0.9±0.8	-0.9±1.0	0.95	0.1±0.6
	T_{pre} (median (IQR))				
MBL (mm)	NA	NA	NA		
Mesial of implant					0.5 (0.0-0.9)
Distal of implant					0.4 (0.0-1.1)
	T_{pre} (mean±SD)				
PES total (0-10)	--	--	--	--	--
Mesial papilla					
Distal papilla					
Curvature of facial mucosa					
Level of facial mucosa					
Root convexity/soft tissue colour and texture					
WES total (0-10)	--	--	--	--	--
Tooth form					
Outline/volume					
Colour (hue/value)					
Surface texture					
Translucency/characterization					
PES/WES total (0-20)					
Probing pocket depth (mm)	--	--	--	--	
Mesial of implant					2.5±1.1
Mid-buccal of implant					2.7±1.2
Distal of implant					2.3±0.6
Palatal of implant					2.0±0.8

crown placement and evaluation of marginal bone level, aesthetics and clinical

CTG group (n=20)	XCM group (n=20)		NG group (n=20)	CTG group (n=20)	XCM group (n=20)	
$T_1 - T_{12}$ (mean±SD)		p-value	$T_{pre} - T_{12}$ (mean±SD)			p-value
-0.03±0.2	-0.16±0.2	0.15	-0.48±1.5	-0.04±1.1	-0.17±1.3	0.56
0.1±0.4	-0.1±0.6	0.08	-0.7±1.2	-0.8±0.9	-0.5±1.0	0.63
0.3±0.5	0.02±0.4	0.29	-0.9±1.1	-0.7±0.9	-0.8±0.9	0.85
T_1 (median (IQR))			T_{12} (median (IQR))			
0.3 (0.0-0.9)	0.7 (0.3-1.6)	0.07	0.3 (0.0-0.9)	0.3 (0.0-1.1)	0.9 (0.3-1.3)	0.16
0.5 (0.0-1.0)	0.6 (0.0-1.1)	0.96	0.3 (0.0-0.8)	0.5 (0.0-1.1)	0.7 (0.1-1.0)	0.63
T_1 (mean±SD)			T_{12} (mean±SD)			
--	--	--	6.6±1.5	7.0±2.4	6.1±1.7	0.71
			1.5±0.5	1.7±0.5	1.4±0.6	0.38
			1.4±0.5	1.4±0.6	1.3±0.4	0.36
			1.4±0.6	1.6±0.5	1.5±0.5	0.85
			1.3±0.8	1.4±0.6	1.1±0.8	0.34
			1.1±0.8	1.0±0.7	1.0±0.6	0.61
--	--	--	8.7±0.9	8.9±1.2	8.3±1.6	0.39
			1.8±0.4	1.8±0.4	1.6±0.5	0.26
			1.9±0.2	1.9±0.4	1.8±0.4	0.51
			1.7±0.5	1.8±0.5	1.7±0.6	0.49
			1.7±0.5	1.8±0.4	1.8±0.4	0.80
			1.6±0.5	1.7±0.5	1.5±0.7	0.57
			15.3±1.9	15.9±2.2	14.4±2.8	0.30
2.4±1.3	2.8±1.2	0.43	2.9±1.3	3.0±1.3	3.0±1.9	0.87
3.3±1.2	2.8±1.6	0.24	2.9±0.9	3.1±1.2	2.3±1.0	0.03
2.7±1.1	2.9±0.9	0.03	3.3±1.1	3.0±1.2	3.2±1.2	0.57
2.5±0.7	2.6±0.8	0.10	1.9±0.8	2.4±0.5	2.4±0.7	0.04

Table 2 – Continued.

	NG group (n=20)	CTG group (n=20)	XCM group (n=20)		NG group (n=20)
Papilla volume (0/1/2/3/4)	--	--	--	--	
Mesial/ distal of implant					
No papilla (score 0)					0%/0%
Less than half papilla (score 1)					5%/5%
At least half papilla (score 2)					65%/35%
Entire papilla (score 3)					30%/40%
Hyperplastic papilla (score 4)					0%/0%

Resulting negative values of subtracting the baseline value (T_{pre}) from T_1 and T_1 from T_{12} means recession, positive values mean tissue gain.
Abbreviations: NG group, No graft group; CTG group, Connective tissue graft group; XCM group, Xenogeneic collagen matrix group; T_{pre}, pre-operative; T_1, one month after final crown placement;

Table 3 – Patient satisfaction regarding general satisfaction, aesthetics and treatment procedure.

	NG group (n=20)	CTG group (n=20)	XCM group (n=20)		NG group (n=20)
	T_{pre} (median (IQR))			p-value	
VAS-questions (0-10)					
How satisfied are you with your current dental situation?	5.8 (3.6-6.3)	5.5 (3.9-6.4)	4.9 (2.7-6.4)	0.65	8.1 (7.4-8.9)
How satisfied are you with your current dental situation compared to the situation before treatment?	--	--	--		8.6 (8.0-9.7)
How satisfied are you with the implant and the implant crown?	--	--	--		8.9 (7.9-9.6)
Aesthetics (0-10)					
Colour of the crown	--	--	--		9.4 (8.6-9.9)
Form of the crown	--	--	--		9.5 (8.5-9.9)
Colour of the peri-implant mucosa	--	--	--		9.0 (7.9-9.8)
Form of the peri-implant mucosa	--	--	--		7.6 (6.8-9.3)
Treatment procedure (0-10)					
I regret that I chose this treatment	--	--	--		0.1 (0.0-0.3)
I would recommend the treatment to other patients	--	--	--		9.6 (8.2-10.0)
Total OHIP-score (0-70)	24.5 (21.3-41.0)	31.0 (25.0-37.8)	25.5 (22.3-40.0)	0.39	18.0 (14.3-22.0)

Abbreviations: NG group, No graft group; CTG group, Connective tissue graft group; XCM group, Xenogeneic collagen matrix group; T_{pre}, pre-operative; T_1, one month after final

CTG group (n=20)	XCM group (n=20)		NG group (n=20)	CTG group (n=20)	XCM group (n=20)	
0%/0%	0%/0%		0%/0%	0%/0%	0%/0%	
0%/5%	15%/20%		0%/0%	0%/0%	10%/10%	
15%/35%	25%/35%		45%/55%	15%/25%	35%/50%	
85%/60%	60%/45%		55%/45%	85%/75%	55%/40%	
0%/0%	0%/0%		0%/0%	0%/0%	0%/0%	

T_{12}, twelve months after final crown placement; MBML, mid-buccal mucosal level; IML, interproximal mucosal level; MBL, marginal bone level.
NA=Not assessed; PES/WES not assessed at T_{pre} and T_1, since T_{12} was most meaningful.

CTG group (n=20)	XCM group (n=20)		NG group (n=20)	CTG group (n=20)	XCM group (n=20)	
T_1 (median (IQR))		p-value	T_{12} (median (IQR))			p-value
7.5 (7.2-8.2)	8.8 (7.9-9.7)	0.01	8.2 (7.4-8.8)	7.9 (6.8-9.0)	8.8 (7.6-9.6)	0.27
8.4 (7.5-9.3)	9.2 (7.8-9.9)	0.37	8.5 (7.8-9.1)	8.5 (8.2-9.7)	9.3 (8.7-9.6)	0.15
8.6 (8.0-9.2)	9.7 (8.9-10.0)	0.02	8.7 (8.3-9.5)	8.4 (6.9-9.2)	9.3 (8.8-10.0)	0.04
8.8 (7.4-9.8)	9.8 (9.4-9.9)	0.02	9.3 (7.2-9.9)	8.8 (6.8-9.9)	9.6 (8.9-10.0)	0.30
8.9 (7.3-9.8)	9.8 (9.0-9.9)	0.10	9.0 (7.7-9.7)	9.3 (7.1-9.9)	9.8 (9.2-10.0)	0.15
7.9 (7.0-9.1)	9.2 (7.4-9.8)	0.15	8.0 (6.9-9.7)	8.6 (7.2-9.6)	9.5 (8.6-10.0)	0.11
6.1 (4.6-8.5)	8.9 (7.0-9.8)	0.04	7.6 (5.3-9.5)	8.3 (5.6-9.7)	9.0 (7.0-10.0)	0.23
0.3 (0.1-0.6)	0.0 (0.0-0.4)	0.06	0.1 (0.0-0.8)	0.1 (0.0-0.3)	0.0 (0.0-0.3)	0.59
9.4 (8.7-10.0)	9.9 (9.3-10.0)	0.14	9.8 (9.0-10.0)	9.6 (7.9-9.9)	9.9 (9.5-10.0)	0.18
19.5 (15.3-29.8)	17.5 (14.0-26.0)	0.41	15.0 (14.0-21.3)	16.0 (15.0-22.3)	15.0 (14.0-19.8)	0.34

crown placement; T_{12}, twelve months after final crown placement. NA=Not assessed.

Discussion

This randomized controlled trial suggests that neither the application of a CTG nor the application of a XCM at implant placement in healed and preserved extraction sites results in a better retention of the level of the mid-buccal mucosa and to a better aesthetic outcome compared to the application of no soft tissue graft at implant placement.

The observed recession of the mid-buccal mucosa in all groups in this study was minor and within clinically acceptable levels (Bienz et al. 2017). Changes in MBML in the NG group and CTG group were in line with recent literature (Stefanini et al. 2016, Slagter et al. 2016, Tonetti et al. 2017). Comparing the application of a CTG to no soft tissue graft, we observed no difference for change in MBML, which is in line with a recent study (Bienz et al. 2017). The interpretation of their results, however, is limited by the retrospective study design with a small sample size. Froum et al. (2015) evaluated the effect of a XCM in a randomized controlled clinical trial compared to no soft tissue graft and reported a comparable outcome regarding the change in height and thickness of the peri-implant soft tissues. However, the study of Froum et al. (2015) has limitations. Only patients with a thin and deficient keratinized mucosa needing an implant in the posterior region were included and were followed for just three months after surgery. This is in contrast to our study which evaluated single implant placement in the anterior maxilla up to one-year post-loading without selecting patients according to volume and width of the keratinized mucosa.

The fact that we observed no significant difference between the groups for change in MBML might be explained by the augmentation surgery of fresh extraction sockets with slowly resorbing grafting material and sealing the socket with a mucosa graft, which has been demonstrated to be beneficial in preserving the buccal bone and soft tissue contour (Raghoebar et al. 2009, Jung et al. 2013). We like to hypothesize that this augmentation technique already may have contributed to the preservation of sufficient peri-implant soft tissue, which in turn may have led to no further effect when applying a soft tissue graft at implant placement.

The majority of studies on the effect of soft tissue grafting evaluate the change in mid-buccal mucosal volume (MBMV). Measurement of the change in MBMV would have been desirable, but was beyond the scope of this study. CT grafting could have resulted in an increase in the peri-implant soft tissue volume, which possibly compensated for the bone resorption inducing effect of flap elevation (Natto et al. 2017) in all study groups. Solely the last item in the PES judging root convexity, soft tissue texture and colour focuses on changes in soft tissue volume. However, this is a combined scoring item and only states whether all aspects (score 2), two aspects (score 1) or only one/no aspect (score 0) are comparable to the contralateral tooth, limiting the sensitivity of the PES to pick up small changes. The fact we could not

find any differences between the groups for this item can be explained by this limitation of scoring this item of the PES.

Changes in marginal bone level in this study are in line with the changes observed in previous studies conducted by our group, in relation to the alveolar ridge preservation procedure (Raghoebar et al. 2009, Slagter et al. 2016). This is in contrast to Wiesner et al. (2010), who observed a higher loss of marginal bone level in the test and control group. The limited change in bone level in this study may be explained by the reduced bone loss in a vertical direction as a result of the ridge preservation procedure after removal of the failing tooth (Araújo et al. 2015, MacBeth et al. 2017).

With respect to aesthetics, no differences were found in the objective rating according to PES and WES. The rates were in line with recent literature (Slagter et al. 2016). Overall, patients were highly satisfied with the form and colour of the peri-implant mucosa and the implant crown. The exception was the form of the peri-implant mucosa in the CTG group at T_1 (Table 3), possibly because the CT grafted sites appeared immature and had not yet merged with the surrounding peri-implant mucosa, as observed by Nevins et al. (2011) This dissatisfaction was not observed anymore one year after the final implant crown was placed. Conversely, the patients were generally less satisfied with the CT grafted implant sites at T_{12}. This might be explained by the higher patient morbidity when harvesting the CTG from the patient's palate compared to those who had not received a graft or a XCM and thus did not have a second surgical site (Sanz et al. 2009, Cairo et al. 2017). Nevertheless, this could not be seen on comparing the question outcomes about whether they regretted choosing this treatment and whether they would recommend the treatment to others.

Conclusion

The application of a soft tissue graft combined with placement of a single implant in a preserved alveolar ridge in the aesthetic zone does not result in a more favourable aesthetic outcome than when no soft tissue graft was applied during implant placement. Thus, soft tissue grafting should not be considered as a standard procedure.

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