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Single immediate implant placement in the maxillary aesthetic zone with and without connective tissue grafting: Results of a 5-year randomized controlled trial

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Abstract

Aim: To assess the 5-year effects of grafting connective tissue while undertaking single immediate implant placement and provisionalization at the mid-buccal mucosa level (MBML). Secondary outcomes were buccal bone wall thickness (BBT), marginal bone level (MBL) and patient satisfaction.

Materials and Methods: Sixty patients with a single failing tooth in the maxillary anterior region were provided with an immediately placed and provisionalized implant. At implant placement, the patients randomly received either a connective tissue graft from the maxillary tuberosity ($n = 30$, test group) or no graft ($n = 30$, control group). The alveolar socket classification was mainly Type 2A. Data were collected before removing the failing tooth (T_0), and at 1 (T_1), 12 (T_{12}) and 60 (T_{60}) months after final crown placement. The primary outcome was the change in MBML compared with the pre-operative situation. Additionally, the change in BBT, MBL, aesthetics (using the Pink Aesthetic Score–White Aesthetic Score), soft-tissue peri-implant parameters and patient satisfaction were assessed.

Results: At the 5-year follow-up, 27 patients could be analysed from each group. In each group, one implant was lost during the osseointegration period, within 3 months of placement, resulting in an implant survival rate of 96.7% in both groups. MBML change at T_{60} was −0.6 (−1.1 to −0.1) mm in the control group and 0.1 (−0.4 to 0.5) mm in the test group ($p = .008$). BBT and MBL, aesthetics, soft-tissue peri-implant parameters and patient satisfaction showed stable results and satisfied patients, without clinically relevant differences between the groups.

Conclusions: This 5-year follow-up study shows that grafting connective tissue when replacing a single failing tooth with immediately placed and provisionalized implant results in favourable peri-implant tissues and fewer MBML changes.

KEYWORDS
connective tissue grafting, immediate implant treatment, implant aesthetics, single implant, soft-tissue recession

Clinical Relevance

Scientific rationale for study: There is a paucity of medium-term and long-term randomized controlled clinical trials assessing the effect of connective tissue grafting on the aesthetics of the peri-implant mucosa around immediately placed and restored implants in the aesthetic zone.

Principal findings: The medium-term results after connective tissue grafting in immediate implant placement and immediate provisionalization cases are stable, including peri-implant mucosa levels, with less recession of the mid-buccal mucosa level.

Practical implications: Undertaking immediate implant placement and provisionalization in the aesthetic zone with connective tissue grafting appears to benefit the soft-tissue levels and aesthetics compared with no tissue grafting.

1 | INTRODUCTION

Replacing a single failing tooth in the maxillary aesthetic zone with immediate single implant placement and provisionalization (IIPP) has benefits in terms of reduced treatment time, avoidance of additional surgical interventions and a high level of patient satisfaction (Huynh-Ba et al., 2018; Slagter et al., 2014). Some systematic reviews have shown comparable implant survival rates for implant placement after alveolar ridge preservation, while others have reported slightly lower IIPP survival rates (Cosyn et al., 2019; Mareque et al., 2021; Pommer et al., 2021; Yu et al., 2022). However, all reviews mention that longer follow-up periods are needed for arriving at a definite conclusion (Donos et al., 2021).

Recession of the mid-buccal mucosa is a potential risk when applying immediate implant placement because this procedure can result in impaired pink aesthetics (Chen & Buser, 2014; Tonetti et al., 2017), even though one study failed to demonstrate this (Yan et al., 2016). The most important factor underlying recession of the marginal buccal mucosa is probably resorption of the buccal bone layer (Wu et al., 2023). Possible factors jeopardizing the buccal bone wall are a thin or defective buccal bone wall and implant placement too far to the buccal (Chen & Buser, 2014; Del Fabbro et al., 2015; Morton & Pollini, 2017). Therefore, careful implant planning and bone augmentation procedures are needed for a sufficiently thick buccal bone wall at the implant site (Jung et al., 2017; Zuiderveld et al., 2014).

IIPP may contribute to stable mid-buccal peri-implant soft tissues (Pitman et al., 2022). It was proposed that, when using immediate provisionalization, the buccal peri-implant soft tissue can be thickened with a connective tissue graft (CTG) during implant placement to reduce pre-existing buccal mucosa recession and to enhance the marginal mucosa level (Atieh & Alsabeeha, 2020; Raghoebar et al., 2021; Seyssens et al., 2021). Randomized controlled trials (RCTs) have shown that applying CTGs in immediate implant sites results in fewer mid-buccal mucosa level changes (Frizzera et al., 2019; Migliorati et al., 2015; Yoshino et al., 2014; Zuiderveld et al., 2018). However, it must be mentioned that all these studies had a short evaluation period, up to 2 years of follow-up (Frizzera et al., 2019; Migliorati et al., 2015; Yoshino et al., 2014; Zuiderveld et al., 2018). However, a retrospective study showed that, despite the initial good results following soft-tissue grafting in immediate implant placement cases, the buccal mucosa continued to recess and was not stable in a considerable number of patients (Kolerman et al., 2016). The 5-year prospective study by Cosyn et al. (2016) also showed increased recession of the buccal mucosa despite applying CTG. Hence, to conclude whether a CTG is favourable for IIPP, well-designed medium-term and long-term RCTs are needed. Therefore, the aim of the present 5-year RCT was to assess whether additional CTG with single IIPP influences mid-buccal mucosa levels compared to IIPP with no CTG. The secondary outcomes were buccal bone wall thickness (BBT), marginal bone level (MBL) and patient satisfaction.

2 | MATERIALS AND METHODS

2.1 | Study design

The initial study was set up as a 1-year RCT. The Medical Ethical Committee (METc) of the University Medical Center Groningen (UMCG), the Netherlands, gave their consent for the 1-year RCT (NL43085.042.13). As the 5-year follow-up visit was part of a regular control appointment, and not for the collection of additional data except for a questionnaire to be filled in by the participants, the METc concluded that it was not a new clinical research with test subjects as meant in the Medical Research Involving Human Subjects Act (METc communication M21.285739, dated 3 November 2021). The 1-year and 5-year studies were registered in the Netherlands Trial Register, with the respective numbers NTR_NL-3627 (publication date 23 January 2013) and NTR_NL-9860 (publication date 5 November 2021; https://onderzoekmetmensen.nl/en). All the patients gave written informed consent before enrolment and verbally approved the use of the research data obtained during the follow-ups.

Patient enrolment, implant placement and follow-up visits were done at the Department of Oral and Maxillofacial Surgery of the UMCG. Patients (aged ≥18 years) with a single failing tooth (incisor, canine, first premolar) in the maxillary aesthetic zone were included if they (i) practiced adequate oral hygiene, (ii) had a mesial–distal width of ≥6 mm, (iii) had a vertical buccal distance between the coronal bone level and marginal mucosa of <5 mm, measured after extraction with a periodontal probe, (iv) had no medical and general contraindications for implant surgery, (v) were suffering from no periodontal disease, (vi) were non-smokers, (vii) had no head/neck radiation history and (viii) were not pregnant. Randomization sequence generation was performed by shuffling concealed envelopes. These sealed envelopes

were then used to randomly allocate the patients. After extracting the patients' failing tooth, a tapered implant was placed immediately (NobelActive, Nobel Biocare AB, Gothenburg, Sweden). The implant was immediately restored with a provisional crown. The implants were either placed without a soft-tissue graft (control group) or with a CTG from the tuberosity region (test group).

The control group consisted of 30 patients (male/female: 15/15) with a mean age of 47 ± 16.5 years, who received a single implant located in the central incisor ($n = 12$), lateral incisor ($n = 10$), cuspid ($n = 7$) or first premolar ($n = 1$) region. The 30 patients (male/female: 13/17), with a mean age of 45 ± 15.5 years, who were allocated to the test group received a single implant in the central incisor ($n = 16$), lateral incisor ($n = 9$), cuspid ($n = 3$) or first premolar ($n = 2$) region. After removing the single failing tooth, patients in the control group and test group had a mean vertical buccal distance between the coronal bone level and marginal mucosa of 4.3 ± 0.9 mm and 4.7 ± 0.7 mm, respectively. In the control group, the division in alveolar socket classification was 6 and 24 patients with Type 1 and Type 2A, respectively. The division in alveolar socket classification for the test group was 3 and 27 patients with Type 1 and Type 2A, respectively (Chu et al., 2015). The implant sizes varied, with the control group receiving implants with 4.3 mm diameter with a regular platform (16/19) and the test group receiving a 3.5-mm-diameter implant with a narrow platform (14/11).

Details of the study design, sample size calculation and 1-year follow-up results have been described previously (Zuiderveld et al., 2018).

2.2 | Intervention procedure

Antibiotics were prescribed 1 day before operation as a prophylaxis (amoxicillin 500 mg, three times daily for 7 days, or clindamycin 300 mg, four times daily for 7 days in case of amoxicillin allergy). Post-operatively, 0.2% chlorhexidine mouthwash (two times daily for 7 days) was prescribed for oral disinfection. The non-restorable tooth was removed as atraumatically as possible, under local anaesthesia, without raising a flap. Next, according to the implant manufacturer's manual, the implant site was prepared on the palatal side of the alveolus using a surgical template representing the ideal position of the future implant crown. The last-used implant drill was kept in place to fill the space buccally with augmentation material (1:1 mixture of autogenous bone and anorganic bovine bone [Geistlich Bio-Oss, Geistlich Pharma AG, Wolhusen, Switzerland]) (Slagter et al., 2015). Autogenous bone was collected from the implant drills and was harvested from the maxillary tuberosity region. After careful removal of the last implant drill, the implant was inserted, with a minimum torque of 45 N cm for primary stability, 3 mm apical to the most cervical aspect of the future clinical crown for the best possible emergence profile. To enable fabrication of a screw-retained provisional crown, an implant-level impression was taken right after implant placement, whereafter a corresponding healing abutment was connected to the implant. Next, in the test group, a CTG was harvested from the same maxillary tuberosity region where the bone graft had been taken. The CTG was then inserted in the supraperiosteal prepared envelope flap at the labial site and secured. In both groups, wound closure was done with Ethilon 5-0 nylon sutures (Johnson & Johnson Gateway, Piscatatway, USA), which were removed 2 weeks after the surgery.

Both groups received a provisional crown at the end of the same day, screwed with 20 N cm torque using a manual torque wrench (Manual Torque Wrench Prosthetic; Nobel Biocare AB) and adjusted to function free from centric contacts with the antagonist teeth.

After a provisional phase of 3 months, a final implant crown was designed with an individualized zirconia abutment (NobelProcera, Nobel Biocare AB). Depending on the location of the screw access hole, the final crown was either screw-retained by fusing porcelain directly to the abutment or cement-retained by means of a zirconia Procera coping (Nobel Biocare AB). The abutment screws were fixed with 32 N cm torque. Glass ionomer cement (Fuji Plus cement, GC Europe, Leuven, Belgium) was used to fix the cement-retained crowns.

2.3 | Outcome measures

The change in mid-buccal mucosa level from removing the failing tooth to the evaluation time points was assessed on photographs (primary outcome). The secondary outcome measures were the change in interproximal mucosa level, radiographic MBL proximal to the implant, buccal bone thickness, peri-implant mucosa health, probing pocket depth, amount of plaque, bleeding upon probing, keratinized gingiva width, implant and restoration survival, aesthetics and patient satisfaction.

2.4 | Photographic assessment

Standardized pictures were taken of the failing single tooth (baseline, T_0) and of the final implant crown 1 (T_1), 12 (T_{12}) and 60 (T_{60}) months after implant placement (camera: Canon EOS 650D with ring flash; Meijndert et al., 2004), calibrated with a periodontal probe (Williams Colour-Coded probe, Hu-Friedy Chicago, IL, USA; Slagter et al., 2015).

Full-screen analysis of the pictures was done using Adobe Photoshop (Adobe Photoshop, Adobe Systems Inc., San Jose, USA). To measure the mid-buccal and interproximal mucosa level at all time points, a horizontal line was drawn through the incisal edges of the natural neighbouring teeth in order to get a reproducible reference line. Then the distance between the reference line and the mucosal margin of the failing tooth was measured. The intra-class correlation coefficient of the method was rated as high, being 0.88 (95% confidence interval [CI]: 0.72–0.95); it was 0.83 (95% CI: 0.60–0.93) for the photographic intra- and inter-observer agreement (Zuiderveld et al., 2018).

The aesthetics of the peri-implant mucosa and the implant crown were evaluated at T_{12} and T_{60} according to the Pink Aesthetic Score–White Aesthetic Score (PES/WES; Belser et al., 2009).

2.5 | Radiographic assessment

MBL was measured on standardized digital intra-oral radiographs taken with an individualized lab-made acrylic splint (Meijndert

et al., 2004) 1 (T_1), 12 (T_{12}) and 60 (T_{60}) months after the final implant crown placement. MBL change was calculated with a specially designed dedicated software (DicomWorks, Biomedical Engineering, UMCG, the Netherlands). First, the radiographs were calibrated according to the known diameter of the implant. Next, the distance from the implant shoulder to the first-bone-to-implant contact along the axis of the implant was measured at the distal and mesial side of the implant. Bone exceeding the implant platform was analysed as no bone loss. Regarding the radiographic assessment, the respective intra-class correlation coefficients for intra- and inter-observer agreement were 0.71 (95% CI: 0.32–0.87) and 0.91 (95% CI: 0.75–0.96), respectively (Zuiderveld et al., 2018).

BBT was assessed on cone beam computed tomography (CBCT) scans (iCAT 3D exam scanner, KaVo Dental GmbH, Biberach, Germany) taken before the tooth extraction and 1 (T_1), 12 (T_{12}) and 60 (T_{60}) months after the final implant crown placement using Nobel-Clinician (version 2.1, Nobel Biocare-Guided Surgery Center, Mechelen, Belgium). The exact coordinates of each implant were noted from the CBCT image taken after the treatment. The coordinates obtained after aligning the CBCT image before implant placement and that after surgery could be used to place a planned implant in the pre-surgical record. This enabled buccal bone measurements of the prospective implant position on the pre-surgical CBCT image. It must be noted that the BBT measurement on a pre-surgical CBCT image is actually the distance between a virtual implant and the outer contour of the buccal bone plate. This distance may cross the tooth root. Details of the buccal bone thickness measurements and the results of the 1-year follow-up have been described by Slagter et al. (2015, 2017), Meijer et al. (2019) and Zuiderveld et al. (2021).

2.6 | Clinical assessments

The following clinical parameters were collected at T_0, T_1, T_{12} and T_{60}:

- probing pocket depth at four sites (mesio-buccal, buccal, disto-buccal and mid-palatal), using a manual periodontal probe;
- amount of plaque (modified plaque index; Mombelli et al., 1987): 0 = no plaque, 1 = plaque, detected by running a probe across the surface of the tooth; 2 = plaque visible with the naked eye, 3 = abundance of plaque;
- bleeding on probing (modified sulcus bleeding index; Mombelli et al., 1987): 0 = no bleeding on probing, 1 = isolated bleeding spots visible, 2 = confluent red line of blood along the gingival margin, 3 = profuse bleeding;
- gingival condition (gingival index; Loe, 1967): 0 = normal gingiva; 1 = mild inflammation: slight change in colour, slight oedema; 2 = moderate inflammation: redness, oedema, vitreous aspect; 3 = severe inflammation: redness and oedema evident, ulcerations;
- width of the keratinized mucosa: 0 = no keratinized gingiva, 1 = up to 1 mm of keratinized gingiva, 2 = 1–2 mm of keratinized gingiva, 3 = more than 2 mm of keratinized gingiva;
- implant survival, defined as the existence of an implant in the oral cavity (Laney, 2007) at the follow-up.

2.7 | Patient satisfaction

Overall patient satisfaction with the current implant site was assessed at T_1, T_{12} and T_{60} using a self-(privately) filled-in questionnaire with a visual analogue scale (VAS) ranging from 0 ('very dissatisfied') to 10 ('very satisfied').

2.8 | Statistical analyses

All the analyses were performed per protocol strategy. In addition, the intention-to-treat strategy was applied to the primary outcome as sensitivity analyses. Here, we considered the last observation carried forward, best–worst scenario (+1 and −1SD) and worst–best scenario (−1 and +1SD) methods as appropriate (Jakobsen et al., 2017). The sensitivity analyses are presented in Table S1. The distribution of continuous data was checked visually on histograms and was supplemented by the Shapiro–Wilk test and *Q*–*Q* plots. Normally distributed data are reported as means with 95% CI and compared between groups by using the independent *t*-test. The non-normally-distributed variables are reported as medians and interquartile ranges (first quartile to third quartile) and compared between groups with the Mann–Whitney *U* test. Categorical data are reported as absolute numbers with their respective percentages, and compared using the Fisher's exact test.

Because some of the outcomes (i.e., mid-buccal mucosa level [MBML] change, interproximal mucosa level change and MBL change) consisted of repeated measurements, linear mixed-effect models (LMMs) were fitted using restricted maximum likelihood estimations to assess the between-group differences of these repeated measurements (Bender & Lange, 2001; Li et al., 2017; Parker & Weir, 2022). The multivariable models included the fixed effects of the type of intervention, baseline outcome measurement, follow-up in months and the interaction between the intervention and follow-up (intervention × follow-up). The latter fixed-effect term was included in all the models because the interaction term significantly improved the model. The included random effects were the patients (i.e., random intercepts). In addition, the association between the gingival biotype and mid-buccal mucosa level change (i.e., the primary outcome) was assessed by introducing the fixed effect into the model. The random effect of the follow-up (i.e., random slopes) was also tested but did not significantly improve the model fit in any of the estimated models, and was therefore excluded from the models. Model improvement was tested using likelihood-ratio tests. The assumptions underlying the final linear mixed-effect models were tested and met. Effect estimates of each group at specific time points, including corresponding *p*-values, were derived by centring the follow-up variable for each specific time point. Statistical comparison was performed using the type III analysis of variance (ANOVA) test, with Satterthwaite's method to estimate the degrees of freedom. The statistical analyses

were performed in R, version 4.0.5 (R Core team), using the *lme4*- and *lmertest*-packages. In all the analyses, a *p*-value <.05 was considered statistically significant.

3 | RESULTS

3.1 | Patients

At the 5-year follow-up, one patient had died, one patient had moved too far to participate and two patients had moved without leaving an address. One patient in each group had lost their implant during osseointegration within 3 months of the placement, resulting in an implant survival rate of 96.7% in both groups. Consequently, the control and test groups consisted of 27 patients each at the 5-year follow-up (Figure 1).

3.2 | Change in mid-buccal and interproximal mucosa level

At the 5-year follow-up, the mean change in MBML from the pre-operative situation was −0.6 (−1.1 to −0.1) mm in the control group and 0.1 (−0.4 to 0.5) mm in the test group ($p = .008$) and significantly different between the groups (Table 1; $p = .008$; Figure 2). Adjusting for gingival biotype in the LMM showed that gingival biotype was not associated with a change in MBML ($B = -0.23$ [−0.54 to 0.07], $p = .128$). Comparing the per-protocol and intention-to-treat results did not reveal significant differences.

Compared with the pre-operative status, mean mucosa level changes in the control group at the mesial side was −0.5 (−0.8 to −0.2) and at the distal side −0.7 (−1.0 to −0.4). The mean mucosa level changes in the test group at the mesial side was −0.3 (−0.7 to 0.1) and at the distal side −0.4 (−0.9 to 0.0). No significant differences could be found in mucosa level changes at the mesial and distal sides of the implant at all time points (Table 1).

3.3 | Changes in MBL and buccal bone thickness

Mean MBL changes in the control group at the mesial side was 0.01 (−0.4 to 0.4) and at the distal side −0.02 (−0.3 to 0.3). Mean MBL changes in the test group at the mesial side was −0.49 (−0.8 to −0.2) and at the distal side −0.1 (−0.3 to 0.1). These changes at the mesial and distal sides of the implant were small in both groups throughout the 5-year evaluation period. However, there was a significant gain in the control group's MBL on the mesial side between T_1 and T_{60} (Table 1; $p = .014$).

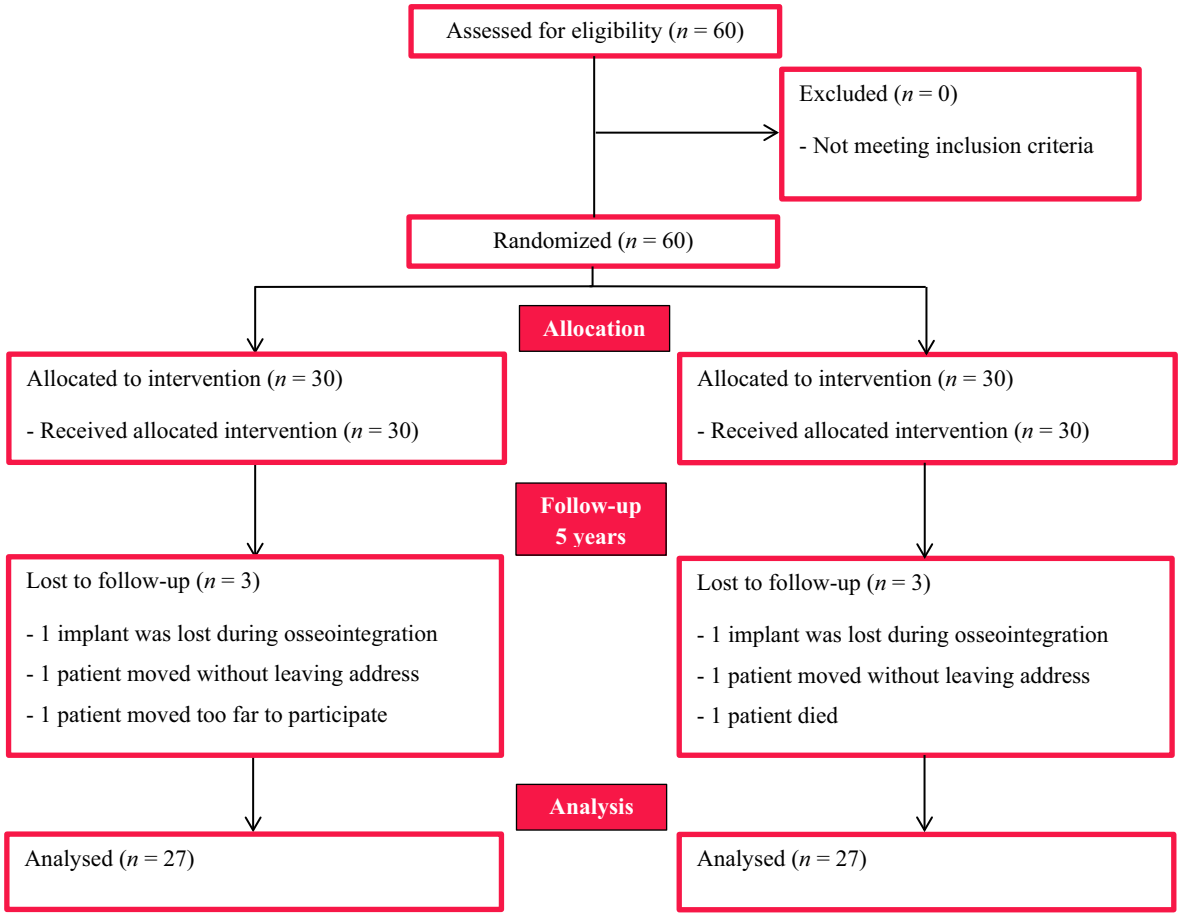

FIGURE 1 Cohort flow diagram.

TABLE 1 Changes in mid-buccal and interproximal mucosa levels at T_1, T_{12} and T_{60} after implant crown placement.

Variable	T_0–T_1 Mean (95% CI) Control group ($n = 29$)	T_0–T_1 Mean (95% CI) Test group ($n = 29$)	T_1–T_{12} Mean (95% CI) Control group ($n = 29$)	T_1–T_{12} Mean (95% CI) Test group ($n = 29$)	T_{12}–T_{60} Mean (95% CI) Control group ($n = 27$)	T_{12}–T_{60} Mean (95% CI) Test group ($n = 27$)	T_0–T_{60} Mean (95% CI) Control group ($n = 27$)	T_0–T_{60} Mean (95% CI) Test group ($n = 27$)	Estimated difference at T_{60} minus baseline Mean (95% CI)*	*p*-Value
Mid-buccal mucosa level change (MBML; mm)	−0.5 (−0.9 to −0.1)	0.1 (−0.3 to 0.4)	0.0 (−0.1 to 0.1)	0.0 (−0.1 to 0.1)	−0.2 (−0.4 to −0.1)	−0.2 (−0.3 to 0.0)	−0.6 (−1.1 to −0.1)	0.1 (−0.4 to 0.5)	0.8 (0.3 to 1.3)	.008*

	T_0–T_1 Mean (95% CI)		T_1–T_{12} Mean (95% CI)		T_{12}–T_{60} Mean (95% CI)		T_0–T_{60} Mean (95% CI)		Estimated difference at T_{60} minus baseline	*p*-Value
Interproximal mucosa level change (IML)										
Mesial of implant (mm)	−0.3 (−0.6 to −0.3)	−0.4 (−0.6 to −0.1)	−0.1 (−0.3 to 0.1)	0.1 (−0.1 to 0.2)	−0.2 (−0.4;0.0)	−0.2 (−0.5 to 0.1)	−0.5 (−0.8 to −0.2)	−0.3 (−0.7 to 0.1)	0.4 (−0.1 to 0.8)	.111*
Distal of implant (mm)	−0.6 (−0.9 to −0.3)	−0.4 (−0.6 to −0.2)	0.0 (−0.2 to −0.1)	−0.1 (−0.3 to 0.2)	0.0 (−0.3 to 0.3)	−0.4 (−1.1 to 0.3)	−0.7 (−1.0 to −0.4)	−0.4 (−0.9 to 0.0)	1.33 (−1.3 to 4.0)	.319*

	T_1–T_{12} Mean (95% CI)		T_{12}–T_{60} Mean (95% CI)		T_1–T_{60} Mean (95% CI)		Estimated difference at T_{60} minus baseline	*p*-Value
Marginal bone level change								
Mesial of implant (mm)	−0.06 (−0.2 to 0.1)	−0.04 (−0.2 to 0.1)	0.05 (−0.3 to 0.4)	−0.5 (−0.7 to −0.2)	0.01 (−0.4 to 0.4)	−0.49 (−0.8 to −0.2)	−0.4 (−0.7 to −0.1)	.014*
Distal of implant (mm)	0.03 (−0.1 to 0.2)	0.02 (−0.1 to 0.2)	0.03 (−0.3 to 0.3)	−0.1 (−0.3 to 0.1)	−0.02 (−0.3 to 0.3)	−0.1 (−0.3 to 0.1)	−0.1 (−0.4 to 0.1)	.257*

	T_{12} Mean (95% CI)		*p*-Value	T_{60} Mean (95% CI)		*p*-Value
PES	6.8 (6.3 to 7.4)	6.4 (5.8 to 6.9)	.21	6.4 (5.7 to 7.1)	6.2 (5.5;6.8)	.35
WES	7.4 (6.9 to 7.9)	6.9 (6.1 to 7.6)	.30	8.0 (7.5 to 8.5)	7.6 (6.9 to 8.2)	.56
PES/WES	14.2 (13.3 to 15.1)	13.2 (12.1 to 14.4)	.18	14.4 (13.4 to 15.5)	13.7 (12.6 to 14.8)	.71

	T_0 Mean (95% CI) Control group ($n = 30$)	T_0 Mean (95% CI) Test group ($n = 30$)	*p*-Value	T_1 Mean (95% CI) Control group ($n = 29$)	T_1 Mean (95% CI) Test group ($n = 29$)	*p*-Value	T_{12} Mean (95% CI) Control group ($n = 29$)	T_{12} Mean (95% CI) Test group ($n = 29$)	*p*-Value	T_{60} Mean (95% CI) Control group ($n = 27$)	T_{60} Mean (95% CI) Test group ($n = 27$)	*p*-Value
Probing pocket depth (mm)												
Mesial of tooth/implant	2.6 (2.3–2.9)	2.8 (2.5–3.1)	.52	3.0 (2.6–3.4)2.2	3.1 (2.6–3.6)	.90	3.0 (2.7–3.3)	2.8 (2.4–3.2)	.23	2.1 (1.8–2.4)	2.2 (1.9–2.5)	.49
Mid-buccal of tooth/implant	2.6 (2.1–3.1)	2.2 (1.9–2.5)	.37	(1.8;2.6)	2.6 (2.2–3.0)	.22	2.5 (2.0–2.9)	2.3 (2.0–2.6)	.81	1.7 (1.4–2.0)	1.8 (1.6–2.0)	.42
Distal of tooth/implant	2.5 (2.1–2.9)	2.9 (2.5;3.3)	.07	2.9 (2.4–3.4)2.3	3.0 (2.6–3.4)	.50	2.9 (2.4–3.4)	2.9 (2.6–3.3)	.39	2.2 (1.8–2.6)	1.9 (1.6–2.2)	.33

TABLE 1 (Continued)

	T_0			T_1			T_{12}			T_{60}		
	Mean (95% CI)			Mean (95% CI)			Mean (95% CI)			Mean (95% CI)		
	Control group (n = 30)	Test group (n = 30)	p-Value	Control group (n = 29)	Test group (n = 29)	p-Value	Control group (n = 29)	Test group (n = 29)	p-Value	Control group (n = 27)	Test group (n = 27)	p-Value
Palatal of tooth/implant	2.2 (1.8–2.6)	2.6 (2.0–3.2)	.34	(2.0–2.6)	2.4 (2.1–2.7)	.64	2.3 (2.0–2.6)	2.2 (1.9–2.5)	.68	2.0 (1.7–2.3)	1.9 (1.7–2.1)	.46

	T_1			T_{12}			T_{60}		
	Median (IQR)		p-Value	Median (IQR)		p-Value	Median (IQR)		p-Value
Overall patient satisfaction (Scale 0–10)	9.2 (8.1–9.8)	9.1 (7.9–9.6)	.70	9.2 (8.2–9.8)	9.3 (7.9–9.9)	.87	8.7 (8.0–9.8)	9.4 (8.6–9.9)	.12

Note: Marginal bone level changes at T_{12} and T_{60}, aesthetic evaluation at T_{12} and T_{60}, clinical outcome parameters at T_0, T_1, T_{12} and T_{60} and overall patient satisfaction at T_1, T_{12} and T_{60} are given. The negative values, on subtracting the baseline value (T_0) from the T1 value from the T12, and the T0 value from the T60, denote recession, and positive values denote tissue gain. T_0, pre-operative; T_1, 1 month after final crown placement; T_{12}, 12 months after final crown placement; T_{60}, 60 months after final crown placement. Normally distributed data, reported as means with 95% confidence intervals, were compared between groups by using the independent sample *t*-test.

Abbreviations: CI, confidence interval; IQR, interquartile ranges; PES, Pink Aesthetic Score; WES, White Aesthetic Score.

*p-Values were derived from the linear mixed effect models that incorporated all the repeated measurements into a single model for each outcome.

Table 2 shows the medians and interquartile ranges of each group's buccal bone thickness in the upper 5-mm section of the implant, starting at the implant neck towards the apical point (location M0–M5, Table 2), at T_0, T_1 and T_{60}. CBCT images of only 27 of the control group patients could be analysed at T_1 because of one lost implant and two non-readable scans. At T_{60}, only 24 CBCT images could be measured because of one lost implant, two patients not being able to participate and three non-readable CBCTs. In the test group, 28 CBCT images were available at T_1 for measurement as a result of one lost implant and one non-readable scan. At T_{60}, only 27 CBCT images could be analysed because of one lost implant, one patient passing away and one patient unable to participate in the follow-up. There were no significant differences between the groups in the distance between the implant and the outer buccal bone wall at all levels.

3.4 | Clinical outcomes

At the 5-year follow-up, no plaque was detected around the implant crown in any of the patients. Bleeding on probing was also not seen in any of the patients. One patient (3.7%) from the control group and three patients (11.1%) from the test group showed point bleeding. None of the patients in the control group and two patients in the test group (7.4%) showed a confluent bleeding line.

Almost no sign of gingival inflammation was detected. Only one patient in the test group showed mild inflammation.

3.5 | Aesthetic assessment

At the 5-year follow-up, the mean PES score in the control group was 6.4 (5.7–7.1) and the mean WES score was 8.0 (7.5–8.5). The mean PES score in the test group was 6.2 (5.5–6.8) and the mean WES score was 7.6 (6.9–8.2). Both groups showed acceptable levels of peri-implant mucosal and implant crown aesthetics (PES/WES score ≥6), without significant differences between the groups (p = .35 for PES and p = .56 for WES; Table 1).

3.6 | Patient satisfaction

At all the follow-up appointments, the patients gave high VAS scores for the implant and the implant crown, meaning they were satisfied. The VAS-scores in the groups were comparable, with 8.7 (8.0–9.8) for the control group and 9.4 (8.6–9.9) for the test group, p = .12 (Table 1).

4 | DISCUSSION

The long-term results of our study suggest that the insertion of a CTG with IIPP leads to more favourable MBMLs in the short term, which remained stable 5 years after final implant crown placement.

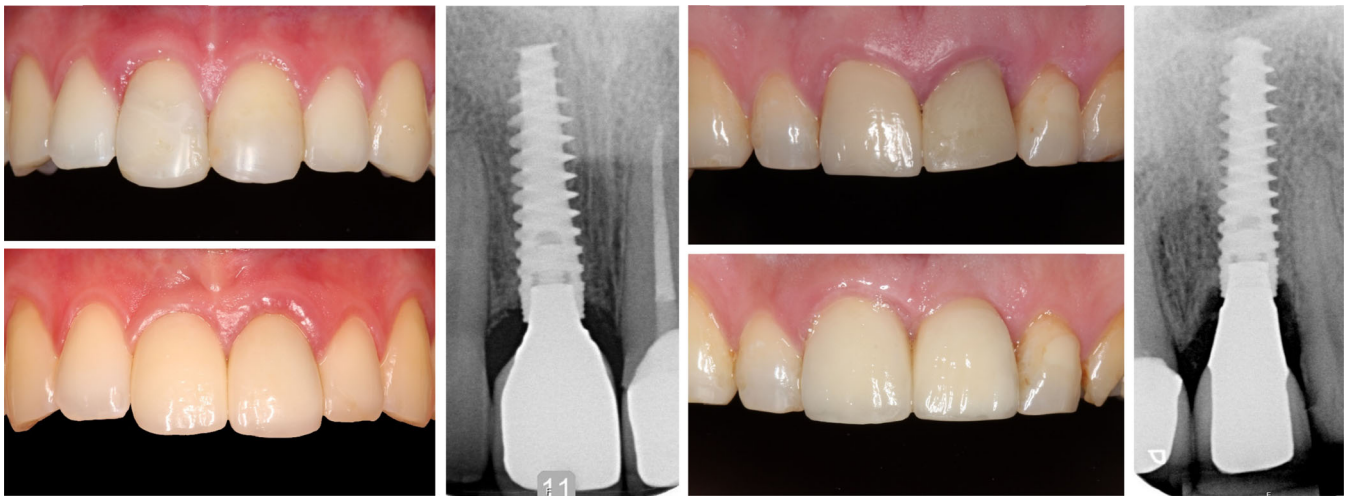

FIGURE 2 (a) Test group: pre-operative clinical situation of the failing right central incisor. (b) Test group: clinical situation 60 months after placing the right central final implant crown. (c) Test group: dental radiograph 60 months after placing the final implant crown. (d) Control group: pre-operative clinical situation of the left central incisor. (e) Control group: clinical situation 60 months after placing the left central final implant crown. (f) Control group: dental radiograph 60 months after placing the final implant crown.

TABLE 2 Median buccal bone thickness at T_0 (pre-extraction), and T_1 and T_{60} after restoration placement in the control group (no soft-tissue graft) and in the test group (connective tissue graft harvested from the maxillary tuberosity).

	Control group	Test group	
Buccal bone thickness pre-extraction	**Median (interquartile range) in mm ($n = 27$)**	**Median (interquartile range) in mm ($n = 28$)**	**Significance**
M0 (at neck)	2.14 (1.55–2.69)	2.14 (1.84–2.74)	$p = .56$
M1	2.43 (1.59–2.74)	2.26 (1.76–2.86)	$p = .87$
M2	2.33 (1.65–2.78)	2.68 (1.68–3.13)	$p = .42$
M3	2.23 (1.63–2.75)	2.55 (1.85–2.94)	$p = .49$
M4	2.05 (1.49–2.69)	2.43 (1.73–2.95)	$p = .39$
M5	1.84 (1.25–2.56)	2.35 (1.35–2.95)	$p = .33$
Buccal bone thickness T_1	**($n = 27$)**	**($n = 28$)**	
M0 (at neck)	1.49 (0.49–1.91)	1.03 (0.54–1.63)	$p = .40$
M1	1.93 (1.49–2.44)	1.43 (0.66–2.26)	$p = .07$
M2	2.03 (1.80–2.55)	1.43 (1.03–2.33)	$p = .07$
M3	2.13 (1.64–2.45)	1.95 (1.19–2.59)	$p = .30$
M4	1.75 (1.53–2.45)	1.75 (1.25–2.33)	$p = .45$
M5	1.85 (1.00–2.36)	1.56 (1.14–2.35)	$p = .66$
Buccal bone thickness T_{60}	**($n = 24$)**	**($n = 27$)**	
M0 (at neck)	1.29 (0.64–1.73)	0.64 (0.34–1.64)	$p = .24$
M1	2.03 (1.33–2.33)	1.63 (0.56–2.26)	$p = .26$
M2	2.13 (1.45–2.57)	1.57 (1.17–2.47)	$p = .20$
M3	2.05 (1.18–2.50)	2.05 (1.19–2.54)	$p > .99$
M4	1.95 (1.13–2.55)	2.03 (1.15–2.43)	$p = .60$
M5	1.65 (0.99–2.35)	1.85 (0.95–2.44)	$p = .74$

Note: All the data were non-normally distributed and are therefore reported as medians and interquartile ranges (first quartile; third quartile); between-group comparisons were done with the Mann–Whitney *U* test.

Only RCTs with a short follow-up period are available regarding this topic (Wu et al., 2023). Clinical studies with a longer follow-up include those by Noelken et al. (2018) and Kan et al. (2023). Noelken et al. (2018) investigated the effect of CTG insertion compared with no CTG in cases with extensive recessions before operation (1–3 mm recession; mean follow-up of 45 months). The application of a CTG significantly improved the recession from 2.3 to 0.5 mm compared with an improvement from 1.8 to 0.9 mm without a CTG (Noelken et al., 2018). Noelken et al.'s (2018) study results support our findings of a better MBML on applying a CTG during IIPP in the short term and stable tissue levels in the long term. However, it must be mentioned that their results must be interpreted carefully because of the small study population at the beginning (13 patients per group) as well as the fact that only 10 of the control group and 5 of the test group patients remained at the final follow-up. Additionally, comparison of our and Noelken et al.'s (2018) results might be impaired because we did not consider pre-existing recessions. Future studies should take this into account when interpreting their results.

Kan et al. (2023) reported a slight change in MBML with a mean recession of −0.19 mm in both groups together after a mean follow-up of 8.2 years compared with the pre-operative situation. These favourable results cannot be compared with ours because their CTG group results were not reported separately. Furthermore, the CTG was applied in the facial tissue zone without flap reflection (Kan et al., 2023). In our study, gingival biotype did not appear to be a predisposing factor for a change in MBML, irrespective of whether a CTG was used. Hence, contrary to Kan et al. (2011) and Levine et al. (2014), but in line with Kan et al.'s (2009) study, the risk of advanced recession in patients with a thin biotype might not be high.

Our study shows that the buccal bone thickness was not significantly different between the groups at all levels of measurement (location M0-M5) and all follow-up points. The control group's buccal bone thickness is in line with that reported by Slagter et al. (2021) for the immediate placement and restoration group. However, we noted a tendency of a slightly more bone loss in the test group's implant neck region (M_0–M_2), although it was not statistically significant. The change in BBT between T_0 and T_{12} reported in one of our earlier publications was significantly different in the M_2 and M_3 regions ($p = .02$; Zuiderveld et al., 2021). Possibly, when preparing the supraperiosteal envelope flap to insert the CTG, the vascularization between the periosteum and mucosa was disrupted, and hence the higher bone loss in this area (Cosyn et al., 2013; Mazzocco et al., 2017; Vignoletti et al., 2012). Jiang et al.'s (2020) study with a 6-month follow-up appears to be the only RCT that investigated both a change in MBML and a change in BBT in IIPP, with or without CTG. They found that the buccal bone plate resorption was slightly more pronounced in the test group than in the control group (Jiang et al., 2020). Their results are comparable with ours only to a limited extent, but certainly support our 1-year results. Contrarily, the retrospective Noelken et al. (2018) study found a comparable thickening of the buccal bone lamella in both groups. It must be pointed out that a CBCT at a regular control appointment must be justified. To date, there is limited evidence of the outcome of having a thin buccal bone layer and augmented bone. To analyse the BBT in patients with immediate implant placement, the general protocol is to first perform a CBCT when placing the definitive restoration (as a reference), and then after 1, 5 and 10 years. However, endorsing the principle of limiting the radiation doses as much as possible by future research projects and by general practices must be considered if the acquired information justifies the radiation load.

The MBLs were stable throughout the follow-up period and were not different between the groups, which is in line with Naiem et al.'s (2023) results. Our reported significant gain in mesial MBL in the control group compared with the test group from T_{12} to T_{60} could also be explained by the fact that the supraperiosteal vascularization had not been disturbed when inserting a CTG and thereby, possibly, bone resorption was prevented (Cosyn et al., 2013; Mazzocco et al., 2017; Vignoletti et al., 2012). The systematic review by Slagter et al. (2014) already pointed out a significant association between CTG insertion and MBL loss.

High PES scores were recorded at the 5-year follow-up, and were not different for both groups. The same was found by Naiem et al. (2023), although they used the Fürhauser et al. (2005) PES scoring system and we used Belser et al.'s (2009) scoring system. Noelken et al. (2018) also reported high PES scores in their retrospective study while using Fürhauser et al.'s (2005) scoring system, without differences between the groups.

At the 5-year follow-up, the peri-implant tissues were in a good and healthy condition. There was no plaque, and only a few patients showed bleeding on probing. The probing pocket depths remained stable and healthy, and the CTG did not influence the health of the peri-implant tissues, which is in line with Noelken et al.'s (2018) study. The positive peri-implant tissue results are comparable with the good outcomes reported in other IIPP studies with a long follow-up (Cosyn et al., 2016; Slagter et al., 2021).

Both Noelken et al.'s (2018) and Kan et al.'s (2023) retrospective studies reported a 100% implant survival rate in a population of 26 and 22 implants, respectively. Two IIPP studies with a follow-up of 8 years (Raes, Cosyn, et al., 2018; Raes, Eghbali, et al., 2018) reported survival rates between 93.8% and 100%. These survival rates are comparable with those of our study and show that the chance of implant loss is low in the long term.

Both patient groups reported high satisfaction rates, without a significant difference between the groups. This is in line with Naiem et al.'s (2023) findings. The overall patient satisfaction score is comparable with that described by Slagter et al. (2021).

Some limitations exist, which should be addressed by future studies. It is still unclear from this study what the risk factors are for soft-tissue loss to justify the need for soft-tissue augmentation; what is the ideal time point for soft tissue augmentation in the treatment trajectory; and what is the optimal grafting material. Also, profilometric changes are missing from the present study.

5 | CONCLUSIONS

This 5-year RCT shows that replacing a single failing tooth with IIPP results in favourable peri-implant tissues. CTG with immediate implant

placement appears to limit recession. Soft-tissue augmentation may be recommended for high aesthetic priority cases, carried out simultaneously with immediate implant placement, to reduce soft-tissue recession.

AUTHOR CONTRIBUTIONS

Elise G. Zuiderveld: Concept/design; data analysis/interpretation; surgery; drafting the article. **Henny J. A. Meijer**: Data collection; concept/design; statistics; data analysis/interpretation; drafting the article. **Barzi Gareb**: Statistics; data analysis/interpretation; critical revision of article. **Arjan Vissink**: Concept/design; statistics; data analysis/interpretation; critical revision of article. **Gerry M. Raghoebar**: Concept/design; data analysis/interpretation; surgery; critical revision of article. All authors gave final approval and are accountable for all aspects of the work.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

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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SUPPORTING INFORMATION

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

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