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ORIGINAL ARTICLE

Impact of mucosal phenotype on marginal bone levels around tissue level implants: A prospective controlled trial

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Abstract

Background: The aim of this 1-year prospective clinical trial was to compare clinical parameters and marginal bone levels (MBLs) around tissue level implants with a partially smooth collar between patients with thin (≤2 mm) and thick (>2 mm) vertical mucosal phenotypes.

Methods: Thirty patients needing a single dental implant were recruited and allocated to thin (n = 14) or thick (n = 16) phenotype groups. Post-restoration, clinical (probing depth, recession, width of keratinized mucosa, bleeding on probing, suppuration, implant mobility, plaque index, and gingival index) and radiographic bone level measurements were recorded at different timepoints for 1 year.

Results: Twenty-six patients (13 per group) completed the 1-year examination. No implants were lost (100% survival rate). There were no significant differences (P >0.05) between thin and thick vertical mucosal phenotypes for any clinical parameter or for the radiographic MBL.

Conclusions: Tissue level implants at 1 year of function placed in thin vertical mucosa achieved similar clinical parameters and radiographic MBLs as those in thick tissue. The formation of the peri-implant supracrestal tissue height plays a key role in MBL than mucosal thickness in tissue level implant.

KEYWORDS
phenotype, dental implant, soft tissue therapy, peri-implant endosseous healing, alveolar bone loss

1 | INTRODUCTION

A recent literature review proposed that the peri-implant mucosal phenotype (i.e., horizontal and/or vertical mucosal thickness) may influence bone remodeling around dental implants.[1] An animal study has correlated the presence of angular bony defects with thin peri-implant supracrestal tissue height (STH).[2] Defined by Avila-Ortiz et al., the peri-implant STH is composed of the sulcular epithelium, junctional epithelium, and the supracrestal connective tissue around an implant; the authors stated that STH affects bone remodeling independently from implant level design or prosthetic features.[3] In dogs, a surgically-induced thin (≤2 mm) phenotype produced slightly more bone resorption, implying that a minimum mucosal thickness is required to allow

the formation of a stable STH.[4] In a series of prospective trials on humans, Linkevicius and coworkers have shown that implant sites in subjects with a thin (≤2 mm) vertical mucosal phenotype develop more radiographic bone loss than sites in subjects with a thick (>2 mm) phenotype.[5–8]

Several authors have suggested that marginal bone loss can be mitigated by platform switching, or the lateral positioning of the implant platform-abutment interface away from the alveolar bone and toward the center of the implant.[9–11] Vanderweghe and DeBruyn concluded that platform switching reduces marginal bone loss by up to 30% only in sites where the peri-implant mucosa is thicker than 4.22 mm.[12] Linkevicius et al. found platform switching does not prevent radiographic bone loss in sites with a thin mucosal phenotype.[6] A systematic review by Hsu et al. reported a mean marginal bone loss of 0.36 mm within the first year of function in platform-switched implants and a trend toward less bone resorption at sites with a thick horizontal mucosal phenotype.[13]

The vertical positioning of the implant platform with respect to the alveolar crest (e.g., subcrestal, equicrestal, or supracrestal) at time of placement[14] as well as prosthetic factors that create vertical distance between bone and restorative components (e.g., abutment height, crown contours)[15] can also affect post-surgical bone remodeling. Several researchers have argued that the marginal bone is preserved not by having thick mucosa but by using an abutment over 2 to 3 mm tall.[15–17] Pico et al. demonstrated that marginal bone loss is twice as severe when short (1 mm) instead of tall (3 mm) abutments were used on platform-switched implants placed equicrestally, regardless of mucosal phenotype.[18] Over-contoured crowns (emergence angle >30°) placed on bone level implants have four times more radiographic bone loss than tissue level implants due to patient's reduced ability to clean these restorations during self-perform mechanical plaque control.[19] As most studies find that thin vertical and horizontal mucosal phenotypes and a lack of keratinized mucosa increase the risk of peri-implant diseases, the current clinical dogma is to place implants in sites with thick and adequate keratinized mucosa (KM), whether these conditions are natively present or surgically enhanced.[20,21–24] Scarce material exists on the impact of mucosal phenotype on the marginal bone level (MBL) around tissue level implants.[25] The aim of this prospective clinical trial is to compare clinical parameters and MBL around implants with a 1.8-mm supracrestal smooth collar between patients with a thin (≤2 mm) vertical mucosal phenotype and those with a thick (>2 mm) presentation.

2 | MATERIALS AND METHODS

This prospective cohort study was reviewed and approved by the University of Michigan Health Science Institutional Review Board (HUM00095933), registered at ClinicalTrials.gov (ID:NCT02925078), and conducted in accordance with the Helsinki Declaration of 1964 as revised in 2013. Research subjects were recruited from new or active patients receiving dental care at the University of Michigan School of Dentistry from November 2016 through December 2019. Before enrollment, each subject received information about the study design and signed an informed consent. A summary of this study timeline is depicted in Figure 1A.

2.1 | Patient selection

Patients who were eligible for the study fulfilled all seven of the following criteria: 1) aged >18 years, 2) partially edentulous at a maxillary or mandibular premolar or first molar region, 3) adjacent teeth present mesial and distal to the edentulous site, 4) residual bone height >9 mm and bone width >5 mm, 5) >2 mm width of KM, 6) optimal oral hygiene (full-mouth plaque scores of <10%),[26] and 7) clinical gingival health on an intact or reduced periodontium. Exclusion criteria included any of the following: 1) need for bone augmentation, 2) current smoking or smoking cessation of <1 year, 3) current or planned pregnancy, 4) uncontrolled systemic disease, 5) conditions known to alter bone metabolism (e.g., diabetes, osteopenia, osteoporosis, hyperparathyroidism), 6) current or historical use of oral or intravenous bisphosphonates, 7) history of radiation therapy, 8) need for active periodontal therapy, or 9) poor oral hygiene. Figure 1B shows the experimental flowchart for this study.

2.2 | Presurgical screening

Patients were allocated to the thin (≤2 mm) or thick (>2 mm) vertical mucosal phenotype group at a presurgical screening appointment.[8] Under local anesthesia, an endodontic file with a rubber stopper was used to measure the vertical mucosal thickness of the edentulous site at the mid-crestal region. Standardized intraoral radiographs and cone-beam computerized tomography (CBCT) were taken to confirm adequate ridge dimensions that precluded advanced grafting. Customized putty bite blocks were fabricated for each patient to ensure reproducibility of standardized digital intraoral radiographs. Preliminary alginate impressions were taken to fabricate study models,

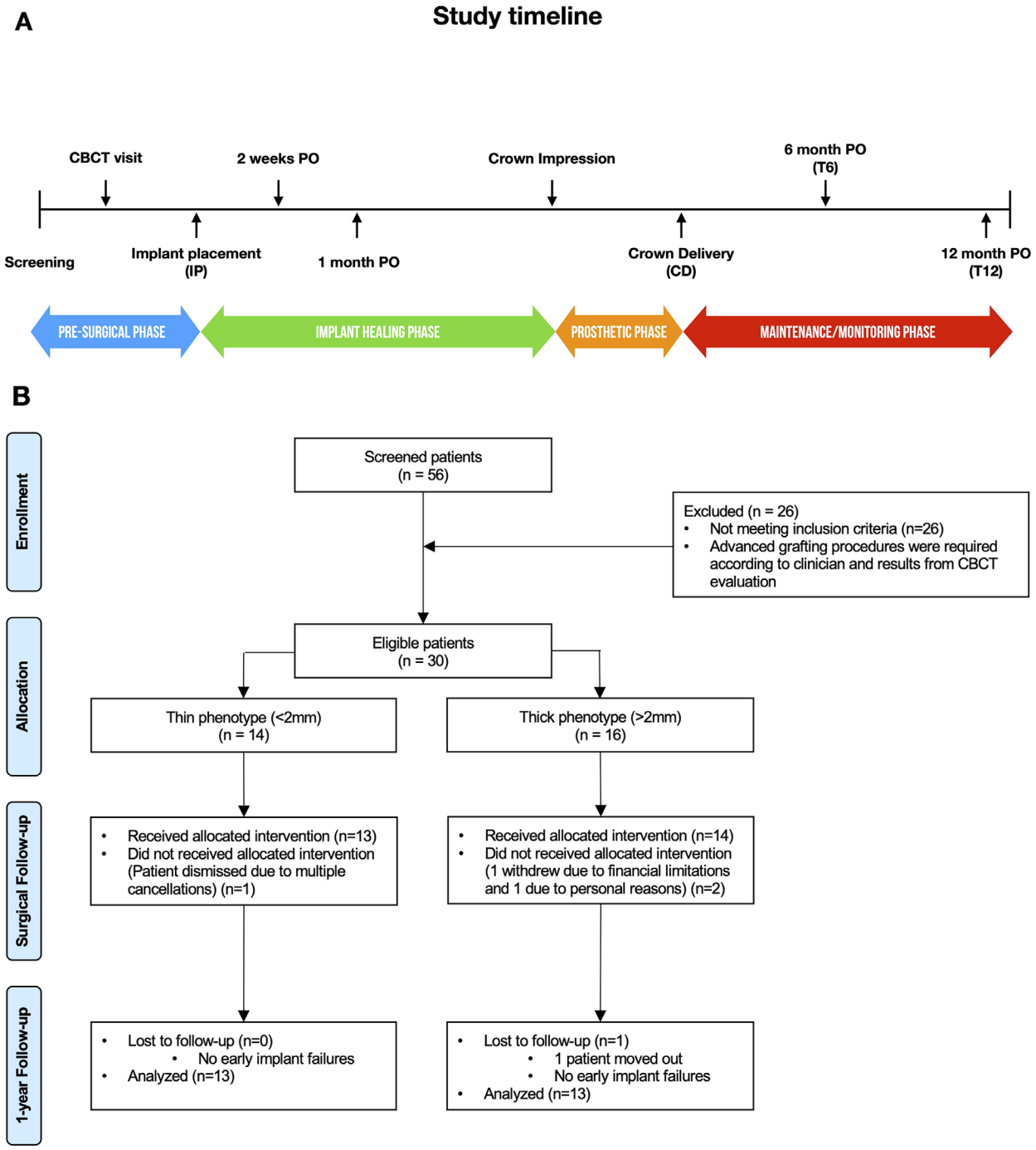

FIGURE 1 Experiment timeline and flowchart.**A)**Study timeline.**B**) Flowchart of patient allocation, intervention and postoperative follow-ups

and a surgical guide was made based on ideal prosthetic positioning, which was confirmed through CBCT analysis.

2.3 | Surgical protocol

Each implant placement (IP) was performed by an experienced periodontist (HLW) under local anesthesia with 2% lidocaine with 1:100,000 epinephrine and 2% lidocaine with 1:50,000 epinephrine for hemostasis. Intrasulcular incisions were made around the teeth adjacent to the edentulous site, and a mid-crestal incision was made bisecting the width of KM. A full-thickness flap was raised on the buccal and lingual/palatal aspects of the edentulous site to expose the alveolar ridge. A dental caliper* and a peri-

* Backhaus dental implant caliper, ProDent USA, East Brunswick, NJ.

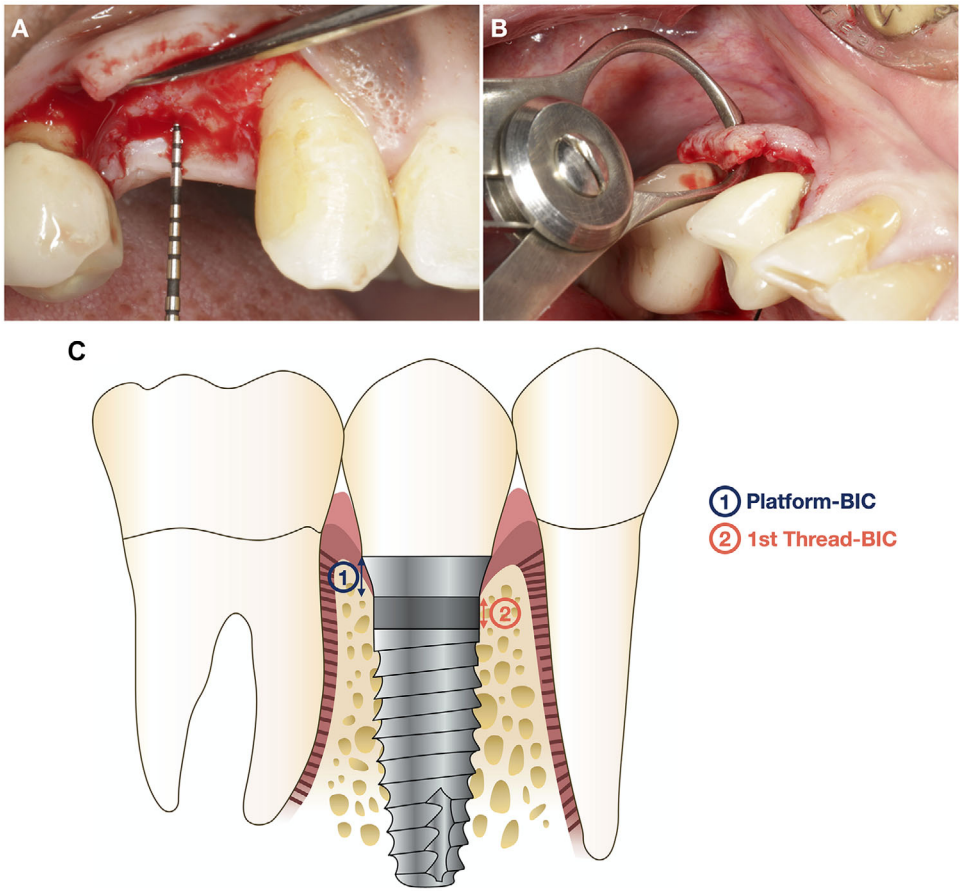

FIGURE 2 Illustration of clinical and radiographic measurements. **A)** A periodontal probe and (**B**) a dental caliper were used to measure mucosal thickness and alveolar ridge width. **C**) Diagram to illustrate radiographic measurements included distance from first implant thread to bone-implant contact (BIC) (first thread-BIC) and implant platform to BIC (platform-BIC)

odontal probe[*] were used to measure mucosal thickness at 3 mm apical to the incision line on the buccal flap (horizontal mucosal thickness) and vertical mucosa height in the center of the ridge at the time of surgery (Figure 2A).

Osteotomies were performed following the manufacturer's drilling sequence using a surgical guide. After site preparation was completed, a dental implant[†] was placed in the premolar or first molar region; the smooth-rough junction along the implant collar was surgically positioned at the crest such that only the machined portion was supracrestal. Either 3.8-mm diameter, 3.5-mm platform implants or 4.5-mm diameter, 4.6-mm platform fixtures were placed based upon available ridge width. Fixture length ranged between 9 to 12 mm based on anatomical variations. Following placement, a 4-mm tall healing abutment with a regular emergence profile (<30°) was seated, and interrupted dense polytetrafluoroethylene[‡] sutures were used to close each surgical site. A standardized periapical radiograph was taken post-surgically.

2.4 | Postoperative instructions

Subjects were instructed to rinse with warm salt water once a day for 2 weeks. All subjects were prescribed amoxicillin 500 mg three times a day for 10 days. If an allergy to amoxicillin was reported, the patient was prescribed a 5-day dose pack of azithromycin 250 mg. Additionally, ibuprofen 600 mg was prescribed for swelling and pain control. Sutures were removed 2 weeks postoperatively; checks to ensure proper healing were performed 1 and 4 months post-implantation.

2.5 | Prosthetic protocol

All restorative treatment was completed by Gustavo Mendonca. Final crown impressions were performed 3 to 5 months after implant placement. Crown delivery

[*] University of North Carolina manual probe with 1 mm markings, Hu-Friedy, Chicago, IL.
[†] Tapered Tissue Level implant, BioHorizons, Birmingham, AL.
[‡] dPTFE, Osteogenics Biomedical, Lubbock, TX.

occurred 2- to 4-weeks post-impression. Custom abutments and screw-retained implant prostheses were used. Proper occlusion, flat or slightly convex crown contours, and sealed crown margins were achieved and/or confirmed at the final restorative visit. Post-delivery adjustments were made based on patient need.

2.6 | Clinical assessment

Clinical measurements including probing depths (PD), recession (REC), bleeding on probing (BOP), suppuration, plaque index (PI), gingival index (GI) at six sites (mesio-buccal, mid-buccal, disto-buccal, mesio-lingual, mid-lingual, and disto-lingual) were recorded using a University of North Carolina manual probe,* and implant mobility. Mean values among the six sites were obtained at the time of implant crown delivery (CD) as well as 6 months (T6) and 12 months (T12) post-restoration. Additionally, width of KM was recorded post-surgically at mid-facial during IP from mid-buccal mucosal margin to the mucogingival margin. Supportive implant therapy using mechanical instrumentation was also performed at T6 and T12.

2.7 | Radiographic assessment

Standardized radiographs were taken at crown impression, CD, T6, and T12; a new CBCT scan was taken at T12. Radiographic measurements included distance from first implant thread to bone-implant contact (BIC) (first thread-BIC) – pathologic bone remodeling and implant platform to BIC (platform-BIC) – physiologic bone remodeling; these were taken at the time of implant placement (IP) through T12 (Figure 2C). Preoperative and postoperative bone width (BW) of the buccal and palatal/lingual plates were measured from CBCT images using computer software.* All measurements were collected (by CGP and JM) after intra- and inter-examiner calibration. Using the Kappa test, the inter- and intra-examiner agreements were calculated to be 0.79 and 0.85, respectively.

2.8 | Statistical analysis

A test significance level (α) of 5% was used, and the power analysis was 80%. Sample size for each group was calculated using a computer program with two-sided equivalence for difference of proportions in two group design.† According to a previous study,[8] mean bone loss around an implant placed in a thin tissue biotype (μ_1) is 1.450 mm; an implant placed in a thick tissue biotype has 0.170 mm of mean bone loss (μ_2). The difference in means between the two groups ($\mu_1 - \mu_2$) is 1.280 mm with a common standard deviation (σ) of 1.160 mm. Based on these figures, the sample (n) needed in each group in this present study was calculated to be 14 patients. A non-parametric analysis for longitudinal data (Brunner-Langer model) was performed for all clinical and radiographic measurements. ANOVA-type statistics were used to detect differences between groups at a 95% confidence interval.

TABLE 1 Baseline demographic data

Variables		Thin group (n=13)	Thick group (n=13)
Age (years)		56.54 (10.39)	56.54 (13.30)
Sex (%)	Women	5 (38.46%)	5 (38.46%)
	Men	8 (61.53%)	8 (61.53%)
Vertical mucosal thickness (mm)	Preoperative	1.77 (0.72)	2.42 (0.49)
	Intraoperative	1.9 (0.48)	2.42 (0.45)
Horizontal mucosal thickness (mm)	Intraoperative	0.65 (0.24)	0.99 (0.43)
Implant location (%)	Maxilla	2 (15.38%)	6 (46.15%)
	Mandible	11 (84.61%)	7 (53.84%)
Replaced tooth (%)	Molar	9 (69.23%)	5 (38.46%)
	Premolar	4 (30.76%)	8 (61.53%)
Preoperative CBCT Ridge width (mm)		7.45 (1.11)	6.85 (1.27)

3 | RESULTS

A total of 30 patients were identified—16 were allocated to the thick tissue group (>2 mm vertical mucosal height), and 14 were allocated to the thin tissue group (≤2 mm vertical mucosal height). Three patients in the thick tissue group dropped out of the study (one reported financial limitation, one moved away, and one was lost for unknown reasons); one patient from the thin tissue group was dismissed due to non-compliance. Twenty-six patients (13 per group) completed the 1-year study. A summary of the baseline demographic data is presented in Table 1. No statistical difference was noted between groups at baseline demographic, clinical, and radiographic parameters (P >0.05). Figure 3 documents the treatment and follow-up of a patient with a thick vertical mucosal phenotype (Figures 3A and 3B) and one with a thin vertical mucosal phenotype (Figures 3C and 3D).

* Blue Sky Bio, Libertyville, IL.

† nQuery Advisor, version 7.0; Statsols, Los Angeles, CA.

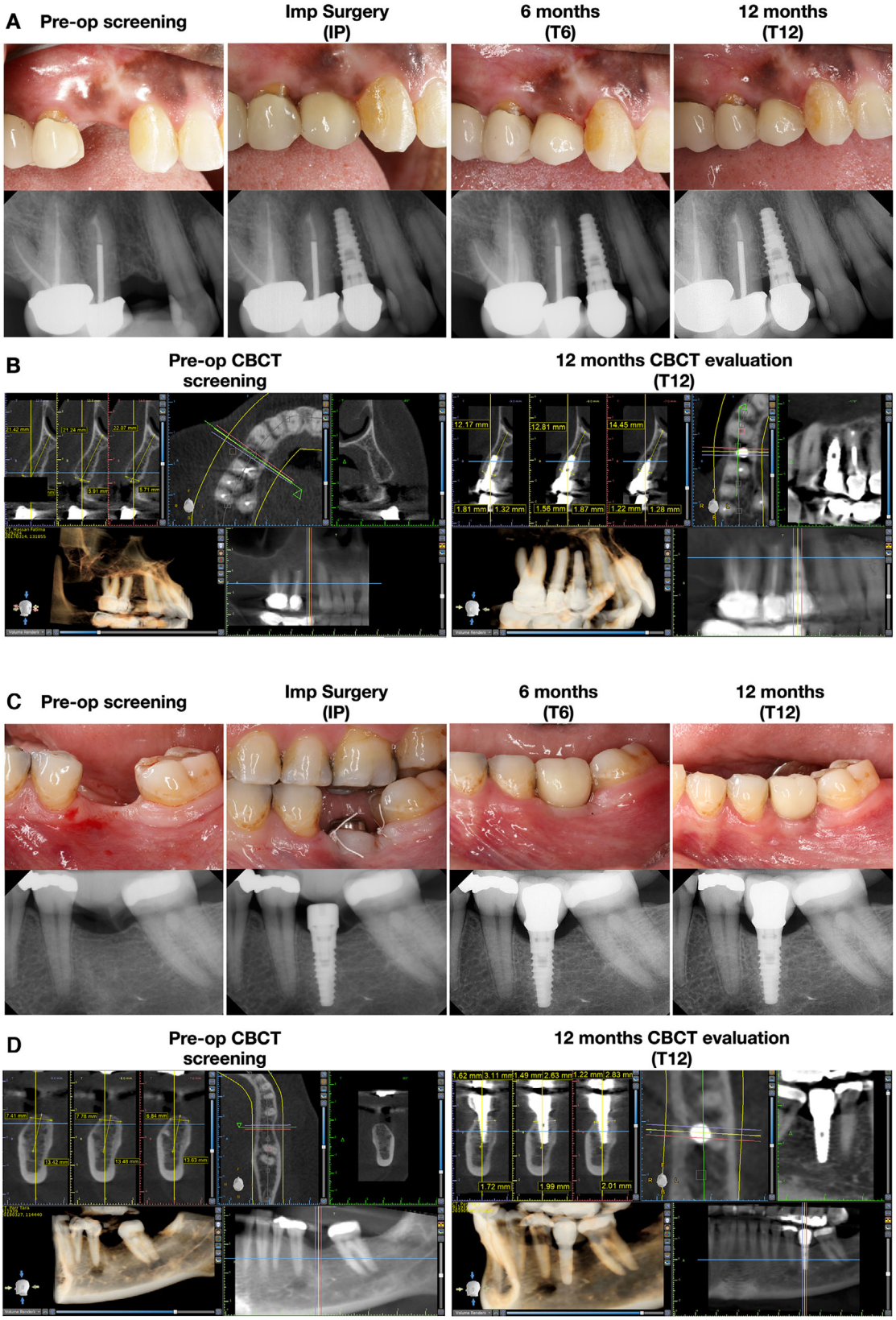

FIGURE 3 Clinical cases illustration in both treatment groups. **A**) Thick tissue phenotype group; baseline, intraoperative, 6 months, and 12 months postoperative documentation of a dental implant with thick (>2 mm) mucosal phenotype. **B)** Preoperative and 12 months postoperative CBCT evaluation of a dental implant with thick (>2 mm) mucosal phenotype. **C**) Thin tissue phenotype group; baseline, intraoperative, 6 months, and 12 months postoperative documentation of a dental implant with thin (≤2 mm) mucosal phenotype. **D**) Preoperative and 12 months postoperative CBCT evaluation of a dental implant with thin (≤2 mm) mucosal phenotype

3.1 | Clinical findings

In the thick vertical tissue group, the intraoperative mean mid-buccal and mid-lingual bone width immediately following implant placement was 1.65 ± 0.98 mm and 1.65 ± 0.82 mm, respectively. In the thin vertical tissue group, the corresponding measurements were 1.04 ± 0.64 mm and 1.69 ± 0.75 mm, respectively. There were no significant differences noted in buccal ($P = 0.072$) or lingual ($P = 0.902$) bone thickness between the two groups immediately following implant placement.

Normal healthy clinical parameters (e.g., PD <4 mm, ≥2 mm KM, and <0.5 mm REC) were observed in both thin (≤2 mm) and thick (>2 mm) vertical tissue height groups for all recorded measurements (Tables 2 through 5). Between CD and T12, the mean PD in the thin tissue group increased by 0.65 mm (CD = 2.47 mm, T12 = 3.13 mm, $P < 0.001$); mean PD deepened by 1.35 mm (CD = 2.12 mm, T12 = 3.46 mm, $P < 0.001$) in the thick phenotype group (Figure 4A). Deeper PDs were found around implants with thick mucosa compared with those with thin phenotypes from CD-T6 and CD-T12 ($P < 0.05$). Mid-facial PD and REC values, however, did not differ between groups from CD-T12 ($P = 0.195$) (see supplementary Figure 1 in online *Journal of Periodontology*). Mean REC values remained ≤0.3 mm and did not differ between groups at any timepoint ($P > 0.05$) (Table 2, Figure 4B).

There was a trend toward higher PI (thin group = 0.26 ± 0.23 mm, thick group = 0.13 ± 0.13 mm), BOP (thin group = 42.31%, thick group = 34.62%), and GI (thin group = 0.58, thick group = 0.35) in the thin phenotype compared with the thick at 1-year post-restoration, but none of these differences were statistically significant (Table 2; Figures 4C through 4E). The width of KM decreased by ≈ 1 mm in both groups from implant placement to crown delivery (IP-CD) (thin: $P < 0.05$; thick: $P < 0.05$) and remained stable from crown delivery to 1-year post-restoration (CD-T12) ($P > 0.05$) (Figure 4F). No statistically significant difference in mean KM width between the thin and thick mucosal groups were detected at all time points ($P = 0.687$). No mobility of any implant was detected at any timepoint.

A subset analysis was performed to examine the influence of horizontal mucosal thickness (thin <1 mm and thick ≥1 mm) on PD, KM, BOP, and GI (Table 3), no statistical significance difference ($P > 0.05$) was found between groups.

3.2 | Radiographic findings

At T12, the mean mid-buccal bone width obtained through a CBCT evaluation was 1.73 ± 0.74 mm in the thick tissue group and 1.37 ± 0.43 mm in the thin tissue group, and no

TABLE 2 Mean differences in clinical and radiographic measurements between vertical and horizontal mucosal phenotypes (Mean differences in clinical measurements between thin (≤2 mm) and thick (>2 mm) vertical mucosal phenotypes)

Variable	Timeline	Thin Mean (SD)	Thick Mean (SD)	Thin-thick (mm)
PD (mm)	CD	2.47 (0.46)	2.12 (0.25)	0.35
	T6	3.42 (0.37)	3.36 (0.42)	0.06
	T12	3.13 (0.45)	3.46 (0.53)	0.33
	CD-T6	0.96 (0.57)*	1.24 (0.43)*	0.28
	T6-T12	−0.29 (0.26)*	0.10.(0.51)	0.36*
	CD-T12	0.65 (0.62)*	1.35 (0.58)*	0.70*
KM (mm)	IP	3.96 (1.65)	3.92 (1.36)	0.04
	CD	2.77 (1.24)	2.92 (1.05)	0.15
	T6	3.00 (1.35)	3.00 (0.93)	0.00
	T12	2.96 (1.13)	2.96 (1.12)	0.00
	IP-CD	−1.19 (1.15)*	−1.00 (0.96)	0.11
	IP-T6	−0.96 (1.35)*	−0.92 (0.86)	0.26
	IP-T12	−1.00 (1.47)*	−0.96 (1.03)	0.26
	CD-T6	0.23 (0.73)	0.08 (0.28)	0.15
	CD-T12	0.19 (0.63)	0.04 (0.14)	0.15
	T6-T12	−0.04 (0.59)	−0.04 (0.32)	0.00
REC (mm)	CD	0.03 (0.09)	0.00 (0.00)	0.02
	T6	0.03 (0.06)	0.00 (0.00)	0.03
	T12	0.03 (0.16)	0.02 (0.05)	0.01
	CD-T6	0.00 (0.07)	0.00 (0.00)	0.00
	T6-T12	0.00 (0.00)	0.02 (0.05)	0.02
	CD-T12	−0.04 (0.59)	0.02 (0.05)	0.06
BOP (%)	CD	19.23 (24.39)	3.84 (9.99)	15.39
	T6	33.33 (24.62)	29.48 (22.72)	3.85
	T12	42.31 (24.17)	34.62 (22.01)	7.69
	CD-T6	15.28 (39.22)	25.64 (25.11)*	10.36
	T6-T12	8.33 (18.12)	5.13 (32.19)	3.20
	CD-T12	23.08 (39.40)*	30.77 (23.42)*	7.69
PI (Score)	CD	0.20 (0.29)	0.10 (0.30)	0.10
	T6	0.10 (0.24)	0.10 (0.30)	0.00
	T12	0.26 (0.23)	0.13 (0.33)	0.13
	CD-T6	−0.10 (0.29)	−0.01 (0.18)	0.09
	T6-T12	0.15 (0.36)*	0.03 (0.22)	0.12
	CD-T12	0.06 (0.35)	0.02 (0.23)	0.04
GI (Score)	CD	0.09 (0.13)	0.03 (0.06)	0.06
	T6	0.36 (0.32)	0.33 (0.25)	0.03
	T12	0.58 (0.31)	0.35 (0.25)	0.23
	CD-T6	0.29 (0.38)*	0.31 (0.26)*	0.02
	T6-T12	0.22 (0.36)*	0.31 (0.26)	0.21
	CD-T12	0.49 (0.34)*	0.31 (0.26)*	0.17

BOP, bleeding on probing; CD, crown delivery; GI, gingival index; IP, implant placement; KM, keratinized mucosa (post-surgically); PD, probing depth; PI, plaque index; REC, recession; T12, 12-month follow-up; T6, 6-month follow-up.

*$P < 0.05$.

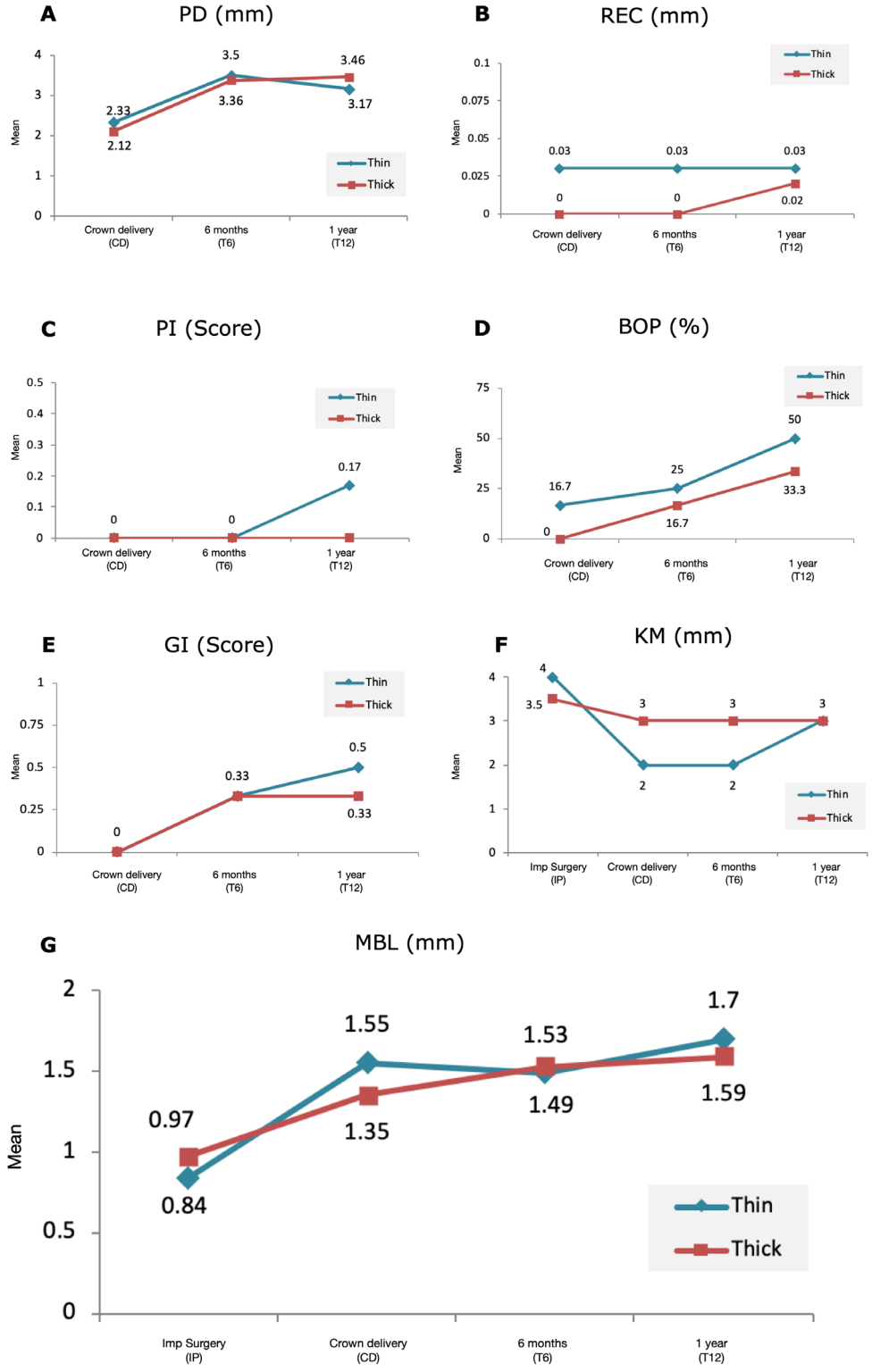

FIGURE 4 Clinical and radiographic outcomes between thin (≤2 mm) and thick (>2 mm) mucosal phenotypes. PD: Probing depths, REC: Recession, Pl: Plaque Index, BOP: Bleeding on probing, GI: Gingival Index, KM: Keratinized mucosa, MBL: Marginal bone loss

statistically significant difference presented between phenotypes ($P = 0.151$) (Table 4). From implant placement through 1 year of function (IP-T12), there was no significant change in mid-buccal bone width between groups ($P > 0.05$).

A statistically significant apical positioning of the marginal bone level from IP-CD was noted in both thin (0.52 ± 0.43 mm, $P < 0.001$) and thick (0.33 ± 0.52 mm, $P = 0.022$) phenotype groups using this implant design (Table 4). Slightly less bone remodeling occurred in the

TABLE 3 Mean differences in clinical and radiographic measurements between vertical and horizontal mucosal phenotypes (mean differences in clinical measurements between thin (<1 mm) and thick (≥1 mm) horizontal mucosal phenotypes)

Variable	Timeline	Thin Mean (SD)	Thick Mean (SD)	Thin-thick (mm)
PD (mm)	CD	2.31 (0.47)	2.27 (0.29)	0.04
	T6	3.43 (0.38)	3.31 (0.42)	0.12
	T12	3.21 (0.54)	3.43 (0.46)	0.22
	CD-T6	1.11 (0.57)*	1.09 (0.43)*	0.08
	T6-T12	−0.22 (0.27)*	0.19 (0.58)	0.30
	CD-T12	0.90 (0.71)*	1.17 (0.63)*	0.26
KM (mm)	IP	3.97 (1.61)	3.90 (1.35)	0.06
	CD	2.91 (1.24)	2.75 (0.98)	0.15
	T6	3.09 (1.32)	2.85 (0.82)	0.24
	T12	3.09 (1.13)	2.75 (0.98)	0.34
	IP-CD	−1.06 (1.41)*	−1.15 (0.97)	0.09
	IP-T6	−0.88 (1.26)*	−1.05 (0.86)*	0.18
	IP-T12	−0.88 (1.41)*	−1.15 (0.97)*	0.28
	CD-T6	0.19 (0.66)	0.10 (0.32)	0.09
	CD-T12	0.19 (0.57)	0.00 (0.00)	0.19
	T6-T12	0.00 (0.55)	−0.10 (0.32)	0.10
REC (mm)	CD	0.02 (0.08)	0.00 (0.00)	0.02
	T6	0.02 (0.06)	0.00 (0.00)	0.02
	T12	0.02 (0.06)	0.03 (0.06)	0.00
	CD-T6	0.00 (0.06)	0.00 (0.00)	0.00
	T6-T12	0.00 (0.00)	0.03 (0.06)	0.02
	CD-T12	0.00 (0.06)	0.03 (0.06)	0.02
BOP (%)	CD	15.63 (23.15)	5.00 (11.25)	0.10
	T6	34.38 (23.15)	25.93 (23.73)	0.09
	T12	40.63 (21.92)	35.00 (25.40)	0.06
	CD-T6	18.75 (36.45)*	24.07 (25.15)*	0.01
	T6-T12	6.25 (17.08)	7.41 (38.29)	0.03
	CD-T12	25.00 (36.51)*	30.00 (24.60)*	0.04
PI (Score)	CD	0.21 (0.29)	0.06 (0.10)	0.17
	T6	0.11 (0.24)	0.08 (0.21)	0.03
	T12	0.21 (0.21)	0.17 (0.28)	0.04
	CD-T6	−0.10 (0.26)	0.02 (0.19)	0.14
	T6-T12	0.09 (0.29)*	0.08 (0.33)	0.03
	CD-T12	0.00 (0.28)	0.11 (0.31)	0.13
GI (Score)	CD	0.05 (0.10)	0.07 (0.12)	0.01
	T6	0.39 (0.29)	0.28 (0.28)	0.11
	T12	0.52 (0.31)	0.37 (0.27)	0.16
	CD-T6	0.33 (0.34)*	0.24 (0.28)*	0.12
	T6-T12	0.14 (0.36)	0.07 (0.38)	0.05
	CD-T12	0.47 (0.32)*	0.30 (0.28)*	0.17

BOP, bleeding on probing; CD, crown delivery; GI, gingival index; IP, implant placement; KM, keratinized mucosa (post-surgically); PD, probing depth; PI, plaque index; REC, recession; T12, 12-month follow-up; T6, 6-month follow-up.

*P <0.05.

thick biotype group, but this tendency did not reach statistical significance under comparison ($P = 0.277$). From CD-T12, there was a non-significant ($P > 0.05$) MBL change of 0.26 ± 0.44 mm in the thin vertical tissue group and a non-significant change of 0.28 ± 0.57 mm for the thick vertical tissue group. At 1 year (T12), the radiographic MBL for the thin and thick vertical tissue phenotypes was 1.69 ± 0.54 mm and 1.59 ± 0.83 mm, respectively; this difference between groups was not significant (Table 4, Figure 4G). The mean MBL change from IP-T12 was statistically significant at 0.78 ± 0.66 mm (thin group) and 0.61 ± 0.71 mm (thick group), but there was no significant difference between the groups ($P = 0.591$).

We compared results from quartile phenotypic extremes to check for hidden trends. Four of the thinnest sites (mean vertical tissue height: 1.33 ± 0.28 mm) were evaluated against four of the thickest sites (mean vertical tissue height: 3.00 ± 0.40 mm). At T12, a slighter greater MBL was noted in the thin group (1.92 ± 0.52 mm) compared with the thick group (1.42 ± 0.97 mm), but neither this difference nor the ones for clinical parameters reached statistical significance between the group extremes ($P > 0.05$).

A subset analysis was performed to examine the influence of horizontal mucosal thickness (thin <1 mm and thick ≥1 mm) on MBL (Table 5), no statistical significance difference ($P > 0.05$) was found between groups although both groups showed significant MBL changes from IP up to T12 were noted in both groups.

4 | DISCUSSION

Although most clinical studies[27–30] have previously evaluated MBL changes occurring around tissue level implants, the present prospective study did not find significant clinical or MBL changes in tissue level implants when considering thin and thick mucosal phenotypes. These results differ from those reported by most clinical studies[5,7,8,31–33] and systematic reviews,[21,34] which have indicated that thicker mucosa moderates bone remodeling. The main differences between other studies and this clinical trial are the type of implant used and the implant platform depth relative to the alveolar crest. We used a tissue level implant placed supracrestally (smooth collar placed above the crest) whereas others followed bone level implants placed equicrestally or subcrestally (roughened collar below the crest).

Linkevicius et al. compared the effects of rough-surfaced implants when placed 1.5mm subcrestally and epicrestally.[32] The authors observed less reduction of MBL when implants were placed subcrestally compared with epicrestally placed implants.[8,31] Soft tissue tenting over 2-mm healing abutments and subcrestal implant placement

TABLE 4 Mean differences in clinical and radiographic measurements between vertical and horizontal mucosal phenotypes (mean differences in radiographic measurements between thin (≤2 mm) and thick (>2 mm) vertical mucosal phenotypes)

Variable	Timeline	Thin Mean (SD)	Thick Mean (SD)	Thin-thick (mm)
IP intraoperative bone width	Buccal	1.04 (0.64)	1.65 (0.98)	0.61
	Lingual	1.69 (0.75)	1.65 (0.82)	0.00
	Average	1.37 (0.58)	1.65 (0.71)	0.28
MBL (mm)	IP	0.90 (0.61)	0.98 (0.69)	0.08
	CD	1.43 (0.56)	1.31 (0.68)	0.12
	T6	1.50 (0.61)	1.51 (0.91)	0.01
	T12	1.69 (0.54)	1.59 (0.83)	0.10
	IP-CD	0.52 (0.43)*	0.33 (0.52)	0.2
	IP-T6	0.60 (0.67)*	0.53 (0.75)	0.07
	IP-T12	0.78 (0.66)*	0.61 (0.71)	0.18
	CD-T6	0.07 (0.37)	0.20 (0.59)	0.13
	CD-T12	0.26 (0.44)	0.28 (0.57)	0.02
	T6-T12	0.19 (0.34)	0.08 (0.38)	0.61
T12 CBCT bone width (mm)	Buccal	1.96 (0.63)	1.95 (0.74)	0.01
	Lingual	2.52 (1.00)	1.80 (0.69)	0.57
	Average	2.24 (0.79)	1.92 (0.60)	0.32

CBCT, cone-beam computerized tomography; CD, crown delivery; IP, implant placement; MBL, marginal bone level; T12, 12-month follow-up; T6, 6-month follow-up.
*P <0.05.

TABLE 5 Mean differences in clinical and radiographic measurements between vertical and horizontal mucosal phenotypes (mean differences in radiographic measurements between thin (<1 mm) and thick (≥1 mm) horizontal mucosal phenotypes)

Variable	Timeline	Thin Mean (SD)	Thick Mean (SD)	Thin-thick (mm)
IP intraoperative bone width	Buccal	1.15 (0.88)	1.65 (0.81)	0.50
	Lingual	1.75 (0.81)	1.55 (0.72)	0.20
	Average	1.45 (0.70)	1.6 (0.60)	0.15
MBL (mm)	IP	1.06 (0.67)	0.76 (0.58)	0.30
	CD	1.46 (0.60)	1.21 (0.63)	0.25
	T6	1.73 (0.74)	1.13 (0.67)	0.60
	T12	1.87 (0.61)	1.26 (0.65)	0.82
	IP-CD	0.41 (0.51)*	0.45 (0.45)*	0.05
	IP-T6	0.68 (0.75)*	0.38 (0.60)*	0.30
	IP-T12	0.82 (0.72)*	0.50 (0.58)*	0.32
	CD-T6	0.27 (0.52)	−0.08 (0.35)	0.35
	CD-T12	0.41 (0.47)	0.05 (0.48)	0.37
	T6-T12	0.14 (0.30)	0.12 (0.45)	0.02
T12 CBCT bone width (mm)	Buccal	2.03 (0.71)	1.84 (0.64)	0.19
	Lingual	2.32 (0.83)	2.01 (1.02)	0.31
	Average	2.17 (0.72)	1.92 (0.71)	0.25

CBCT, cone-beam computerized tomography; CD, crown delivery; IP, implant placement; MBL, marginal bone level; T12, 12-month follow-up; T6, 6-month follow-up.
*P <0.05.

can significantly reduce crestal bone loss, compared with vertical soft tissue thickening by tenting of epicrestally placed implants. Ercoli et al. noted that subcrestal implant positioning of a platform-switched implant generates less crestal bone loss than an equicrestally placed implant with a tenting healing abutment.[14,32]

Formation of the peri-implant STH, along with implant design (polished collar, laser-microtexturing),[35,36] fixture positioning (supracrestal), and prosthetic features (particular abutment lengths, gently contoured crowns),[15,16] has likely influenced the outcomes of this study and dwarfed any effects of the native mucosal thickness. Linkevicius et al. determined that platform switching did not maintain crestal bone loss in patients with thin tissue phenotypes.[36] Conversely, Wallner and coworkers reported that mucosal phenotype does not affect marginal bone loss.[35] In the present study, minimal but statistically significant MBL increases were noted in both groups from implant placement through timepoints up to 1 year. The statistically relevant resorption occurred before CD, signifying that formation of the peri-implant STH causes the greatest alterations in MBL (Table 4). No implant in either phenotypic group displayed radiographic bone loss beyond physiological bone remodeling after 1 year in function. These findings suggest that the peri-implant STH is re-established regardless of mucosal phenotype before the prosthetic phase and is maintained during function in tissue level implants with a 1.8-mm tall, polished collar. The biological response may differ for bone level implants, as evidenced by studies from the Linkevicius and van Eekeren groups that linked thin phenotypes to greater bone loss.[5–8,25]

This study did not find differences in clinical or radiographic measurements between thin and thick vertical tissue phenotypes; this may imply that once peri-implant STH is established with relative health, the influence of mucosal phenotype may be neutralized. Although implants in the thin tissue group trended toward greater BOP, PI, and GI score compared with those in the thick group, no statistical differences were found between groups in BOP, PI, or GI, and no peri-implant disease was diagnosed for any fixture at any time. Additionally, correlations between intraoperative and CBCT outcomes should be interpreted carefully. A slight increase in buccal bone width was noted after 1 year of implant placement in CBCT evaluation when compared with intraoperative measurements. The difference may be caused by the CBCT scattering or beam hardening. Furthermore, these differences address the limitations between the chosen non-invasive (CBCT) and invasive (surgical re-entry) techniques.

Thin peri-implant mucosa may raise the risk for peri-implant diseases. In a cross-sectional study, Mailoa et al. noted significantly greater mid-facial recession in sites with peri-implantitis (0.79 ± 2.22 mm) as well as in those with a thin vertical mucosal phenotype (0.71 ± 1.53 mm).[37] To prevent such biological complications, soft tissue augmentation is currently endorsed to correct thin phenotypes.[23,38] Mucosal autografts or allografts can thicken soft tissue[7] and improve esthetics.[38] Soft tissue augmentation around bone level implants with thin phenotypes results in significantly less radiographic bone loss compared with non-grafted sites.[7,24]

Implants lacking KM are associated with plaque accumulation, tissue inflammation, recession, and attachment loss, though not with radiographic bone loss.[39,40] In this trial, we ensured that a sufficient band of KM (≥2 mm) was present at the time of implantation. Irrespective of phenotype or adequate initial KM, we noted an ≈1 mm reduction in KM width from implantation to CD, which may be due to coronally flap repositioning around the polish collars that triggers a slight loss of KM. Nonetheless, post-crown delivery, the peri-implant tissues remained stable for up to 1 year. One study using the same implant type as in the present study determined that KM width is unchanged up to 3 years if flap was positioned in the bone level.[41]

Scarce evidence is available related to influence of horizontal mucosal thickness on the clinical and radiographic parameters. Results from this study indicated there is no difference between thin (<1 mm) and thick (≥1 mm) with regards to MBL and clinical parameters recorded. More study in this area is needed to further validate these findings. Nonetheless, it has been demonstrated that horizontal mucosal thickness is inversely correlated with the integrity and thickness of the buccal bone.[42] The present data were in line with this observation which showed buccal thickness of 0.57 mm and 1.21 mm in thin (<1 mm) and thick (≥1 mm) horizontal tissue phenotypes, respectively.

This study tracked implants for 12 months post-crown delivery; a longer follow-up may reveal soft tissue and MBL changes that do not appear until later. Although we assessed signs of inflammation, we did not directly evaluate peri-implant diseases or the influence of tissue phenotype on them. These results apply only to one type of tissue level implant; future studies should analyze various implant designs, placement depths, and prosthetic features to clarify the effect of tissue phenotype in other scenarios.

5 | CONCLUSIONS

Within the limitations of this study, tissue level implants at 1 year of function placed in thin vertical mucosa achieved similar clinical parameters and radiographic MBL as those in thick vertical tissue; the native soft tissue phenotype does not impact implant health possibly because peri-implant STH is rapidly established in the implant design we used. Longitudinal studies are required to

confirm the impact of mucosal thickness in different implant designs and surgical and prosthetic situations.

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AUTHOR CONTRIBUTIONS

Carlos Garaicoa-Pazmino, Gustavo Mendonça, Alice Ou, Hsun-Liang Chan, James Mailoa, Fernando Suárez-López Del Amo, and Hom-Lay Wang contributed to the conception and design of this work. Carlos Garaicoa-Pazmino, Gustavo Mendonça, Alice Ou, Hsun-Liang Chan, James Mailoa, Fernando Suárez-López Del Amo, and Hom-Lay Wang were involved in treatment procedures and data collection; Carlos Garaicoa-Pazmino and Hom-Lay Wang analyzed the data; Carlos Garaicoa-Pazmino and Hom-Lay Wang designed the schematic illustrations; and Carlos Garaicoa-Pazmino, Hsun-Liang Chan, James Mailoa, Fernando Suárez-López Del Amo, and Hom-Lay Wang collaborated on manuscript writing.

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SUPPORTING INFORMATION

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

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