







Clinical efficacy of two vertical soft tissue augmentation techniques for peri-implant crestal bone level stability: A randomized clinical trial

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Abstract

Objectives: This study aimed to compare the efficacy of two techniques—acellular dermal matrix (ADM) grafting and tenting technique (TT)—for soft tissue height (STH) augmentation simultaneous to implant placement to minimize peri-implant crestal bone level (CBL) changes.

Methods: Forty patients with a healed single mandibular posterior edentulous site with a thin soft tissue phenotype were enrolled. Twenty patients received simultaneously to implant placement ADM grafting, while the others received submerged healing abutment (TT). Clinical peri-implant soft tissue height and radiographic CBL changes were measured at restoration delivery and 1-year follow-up.

Results: Both techniques effectively increased soft tissue thickness, resulting in a final average STH of 3.4 ± 0.5 mm after augmentation. On average, soft tissue increased by 1.6 ± 0.5 mm in group ADM and by 1.8 ± 0.4 mm in group TT after augmentation. In Group ADM, mesial CBL decreased from 0.4 ± 0.3 mm to 0.1 ± 0.2 mm, and distal CBL decreased from 0.5 ± 0.3 mm to 0.2 ± 0.3 mm over 1 year. In Group TT, mesial CBL remained stable at 0.3 ± 0.2 mm, while distal CBL reduced slightly from 0.5 ± 0.5 mm to 0.3 ± 0.2 mm. Both groups showed minimal changes in CBL, indicating great stability ($p_{\text{mesial}} = 0.003$, $p_{\text{distal}} = 0.004$). TT was particularly effective in preventing mesial bone loss ($p_{\text{mesial}} = 0.019$). The mesial CBL changes significantly differed between groups ($p = 0.019$), and not significantly at distal sites ($p = 0.944$). Neither treatment exhibited significant bone remodeling below the implant shoulder.

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Conclusion: This study suggests that both techniques were successful in STH augmentation, and they may effectively reduce peri-implant crestal bone level changes, with TT being slightly superior. TT was more prone to post-surgical complications. This RCT was not registered before participant recruitment and randomization.

KEYWORDS

bone remodeling, bone resorption, dental implant; phenotype, mucosal tissue augmentation, mucosal tissues, vertical soft tissue height

Summary Box

What is known

- Stable peri-implant bone levels are crucial contributors to dental implant success.
- Different techniques to augment vertical peri-implant soft tissue contributing to maintaining peri-implant bone levels are available.
- These techniques include grafting with acellular dermal matrix (ADM) and tenting technique (TT). However, there is a lack of comparative studies on their efficacy.

What this study adds

- This is the first randomized clinical trial comparing the efficacy of ADM and TT in vertical peri-implant soft tissue augmentation to maintain peri-implant bone levels.
- Both techniques were effective. The TT shows a slight superiority in maintaining bone levels; however, it may pose a higher risk of post-surgical complications.

1 | INTRODUCTION

Based on its strong association with esthetic success and long-term implant survival, stable peri-implant crestal bone levels are considered pivotal in modern dental implant therapy.^{1,2} It has been identified as a critical factor in the long-term health of dental implants³ and is influenced by several elements, including patient-specific behaviors and systemic conditions.^{4,5} Other factors such as smoking, poor oral hygiene, and periodontal diseases can also contribute to peri-implant crestal bone loss.⁶⁻⁸ Additionally, the selection of prosthetic components plays an important role with the height of the prosthetic abutment⁹ and the contour of the final prosthesis¹⁰ being crucial in maintaining peri-implant crestal bone levels.

Current approaches like subcrestal implant placement using conical stable connections with non-matching connections, combined with screw-retained implant-supported restorations (ISR) have gained importance and have been recognized for their potential in maintaining crestal bone.¹¹⁻¹³ These newer advancements and more classical tissue-level designs are promising approaches to reduce peri-implant inflammatory processes, as evidenced by histological studies.^{11,14,15} Other considerations include the digital planning,¹⁶ design of the final prosthesis to facilitate oral hygiene,¹⁷ the choice of material in subgingival areas, and the management of excess cement¹⁸⁻²² emphasizing the complex, multi-factorial nature of crestal bone stability in dental implantology. It is important to consider these factors collectively rather than independently. Even with the optimal choice of components, bone loss

can still occur in some cases, like when implants are placed in thin mucosal tissues.²³

In pivotal preclinical studies, Berglund and Lindhe demonstrated that supracrestal soft tissue thickness represents another important factor associated with crestal bone loss.^{24,25} Specifically, the authors observed that supracrestal soft tissues too thin to accommodate the biological width (supracrestal tissue height) resulted in crestal bone remodeling and loss.^{24,25} These observations were later clinically validated by Linkevicius et al., who showed that patients with a thin soft-tissue phenotype of <2 mm, despite being treated with a subcrestally placed implant favoring crestal bone stability, were more prone to crestal bone loss compared to patients with a corresponding thick phenotype receiving equicrestally (on the buccal aspect) placed implants.^{26,27} Conversely, the same group also demonstrated that supra-platform soft tissue height (STH) augmentation to a thickness of ≥3 mm was effective in reducing the crestal bone remodeling to a level comparable to one in thick-phenotype patients.^{25,28-30}

Multiple strategies are described in the literature for increasing peri-implant soft tissue height. These methods include ridge flattening, subcrestal implant placement, soft tissue grafting, and employing short healing abutments for tenting and expanding the soft tissues.^{26,31-33} This study aimed to directly compare the efficacy of two peri-implant soft tissue augmentation techniques, that is soft tissue grafting with an acellular dermal matrix (ADM) and using short healing abutments to expand the soft tissue using the tenting technique (TT), to limit crestal bone changes around platform-switched implants placed equicrestally.

2 | MATERIALS AND METHODS

2.1 | Experimental design

This study was performed as a two-arm, double-blind, randomized, prospective controlled clinical trial with a follow-up of 1 year at a single center (Figure 1). All data were collected at Vilnius Implantology Center (Vilnius, Lithuania).

2.2 | Outcome variables

The study's primary outcome was assessing crestal bone level (CBL) change from loading/restoration delivery until the 1-year follow-up. Two treatment study cohorts were compared, as defined by patients receiving peri-implant STH augmentation using an acellular dermal matrix (Group ADM) or tenting the supra-platform soft tissues with a submerged healing abutment (Group TT) (Figure 2). Secondary outcomes comprised STH gain—from implant placement to implant uncover after 2 months and clinical peri-implant health and oral hygiene-related variables comprising probing pocket depth (PPD), bleeding on probing (BoP), and plaque index (PI).

2.3 | Inclusion criteria

Study participants were identified from patients undergoing routine implant therapy. All patients gave informed consent after receiving

verbal and written study and treatment-relevant information related to the interventions and associated potential risks. Informed consent and medical and dental histories were collected, oral hygiene

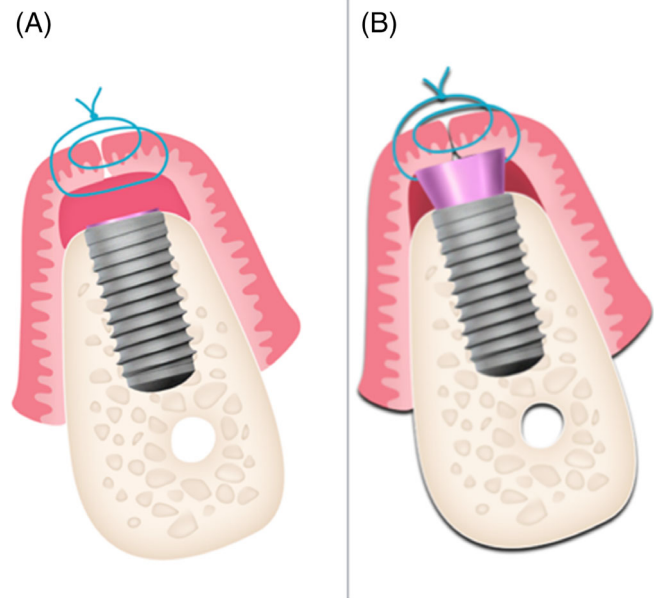


FIGURE 2 Visual representation of both interventions. A represents the usage of an ADM sutured on top of the dental implant to augment the vertical STH. B represents the group using a short healing abutment to tent and expand the vertical STH. ADM, acellular dermal matrix; STH, soft tissue height.

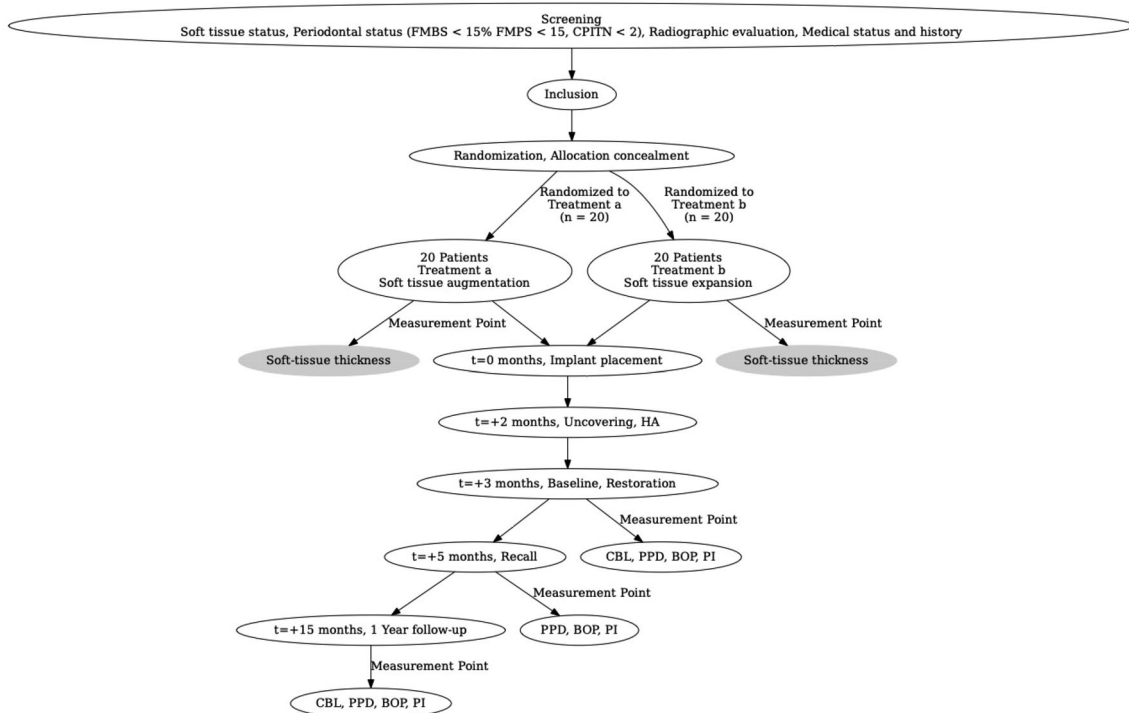


FIGURE 1 Screening, treatment intervention, and evaluation process flow-chart (Consort).

instructions were provided, and comprehensive periodontal treatment examinations were performed before study initiation.

Eligible patients were identified based on the following. Inclusion criteria: (1) Male and female patients between 18 and 75 years old; (2) physical and psychological capacity to undergo implant therapy (ASA I or II); (3) fully healed single mandibular posterior treatment sites (premolars or molars) being edentulous for at least 3 months; (4) minimal 6 mm width and 8 mm height native bone ridge; (5) No requirement nor history for concomitant regenerative treatments; (6) Minimum of 4 mm keratinized mucosa at implant site (2 mm buccal and 2 mm lingual); (7) healthy, non-inflamed keratinized soft tissues, with a maximum soft tissue height of 2 mm, measured at crestal, buccal, and lingual aspects.

Exclusion criteria: (1) Patients with untreated periodontitis; (2) poor oral hygiene as determined by the Oral Health Index (Score 3.1 or higher); (3) pregnant or lactating; (4) uncontrolled medical diseases, for example; (5) receiving or having received pharmacological treatment affecting wound healing within 3 months prior to the study-related intervention.

2.4 | Sample size calculation

The sample size was calculated using statistical software (G*Power v 3.1.9.2) using assumptions and parameters from previous similar investigations.³¹ Assuming a two-tailed significance level of $\alpha = 0.05$, a desired power of 0.80 and a potential dropout of 20%, 20 patients per group were considered to be required for the study. The expected minimal clinically relevant change used was 0.5 mm.

2.5 | Randomization and allocation concealment

Study participants were only enrolled in this study and were treated for STH augmentation if they fulfilled eligibility criteria during screening. The CBCT was used to assess whether patient have the required soft tissue dimension, although the final confirmation was made intra-surgically. Patients were not aware of which treatment group they received. Patients were randomly assigned to treatment modality ADM or TT through block randomization using a computer-generated table. The study's randomization allocation was contained in sealed envelopes and was only revealed to the surgeon by an independent investigator after flap elevation. This step ensured that patient eligibility for either treatment modality, based on the intra-surgical verification of soft-tissue dimensions, was confirmed before revealing to the surgeon which specific procedure to perform. All surgeries were performed by a single clinician. Intra-operative measurements and follow-up clinical examinations were performed by one outcome assessor who was blinded regarding the specific treatment allocation. This approach was also maintained later during the radiographic evaluation of crestal bone levels to ensure impartial assessment by the treating clinician.

2.6 | Measurement of clinical parameters and crestal bone levels

2.6.1 | Smoking habits

Self-reported smoking habits were classified in a trichotomous way into current non-smokers, smokers of <10, or of ≥ 10 cigarettes per day.

2.6.2 | Soft-tissue thickness and Implant health-related parameters

The STH augmentation was calculated by comparing soft tissue thickness at implant placement after flap elevation and 2 months after uncovering. Soft-tissue thickness as well as periodontal and peri-implant clinical parameters were assessed using a 1 mm graded periodontal probe (UNC; Hu-Friedy, Chicago, IL, USA). Pocket probing depth (PPD) was evaluated from the mucosal margin to the bottom of the pocket, rounded to the nearest millimeter at four sites (mesial, distal, lingual, and buccal) around the implant. Bleeding on probing (BoP) was calculated by gently inserting the periodontal probe into the gingival sulcus at each selected site with an approximately force of around 0.15 Ncm around implants. The probe was then withdrawn, and the site was observed for a few seconds. The presence or absence of bleeding on probing was recorded for each site. The BoP index was calculated by dividing the number of bleeding sites by the total number of sites probed, then multiplied by 100 to express it as a percentage. The Plaque Index (PI) at the implant site was scored following a procedure presented by Mombelli et al., applying a grading system ranging from 0 to 3, with scores being assigned as follows: Score 0: no detectable plaque around the implant site; Score 1: a film of plaque adhering to the free gingival margin and adjacent area of the implant; Score 2: a moderate accumulation of soft deposits within the gingival pocket, or around the implant and gingival margin visible to the naked eye and Score 3: an abundance of soft matter within the gingival pocket and/or on the implant and gingival margin.³⁴ All peri-implant parameters were reported on the cohort level as averages with standard deviations.

2.6.3 | Crestal bone levels

Crestal bone levels (CBL) at 3 months and 15 months after implant placement were measured from periapical radiographs registered using a digital film holder and individualized bite blocks to ensure reproducibly parallel orientation of the radiographic images.^{32,35} The implant platform served as a horizontal reference for the CBL. Non-distorted implant/abutment interfaces and implant threads were used to verify the correct parallel orientation of recordings (Figure 3). Crestal bone level measurements were performed using computer software (RVG Windows Trophy 7.0) at 20 \times magnification by a single blinded examiner after dimensional image calibration using the implant diameter as a reference. An increase (crestal bone level gain)

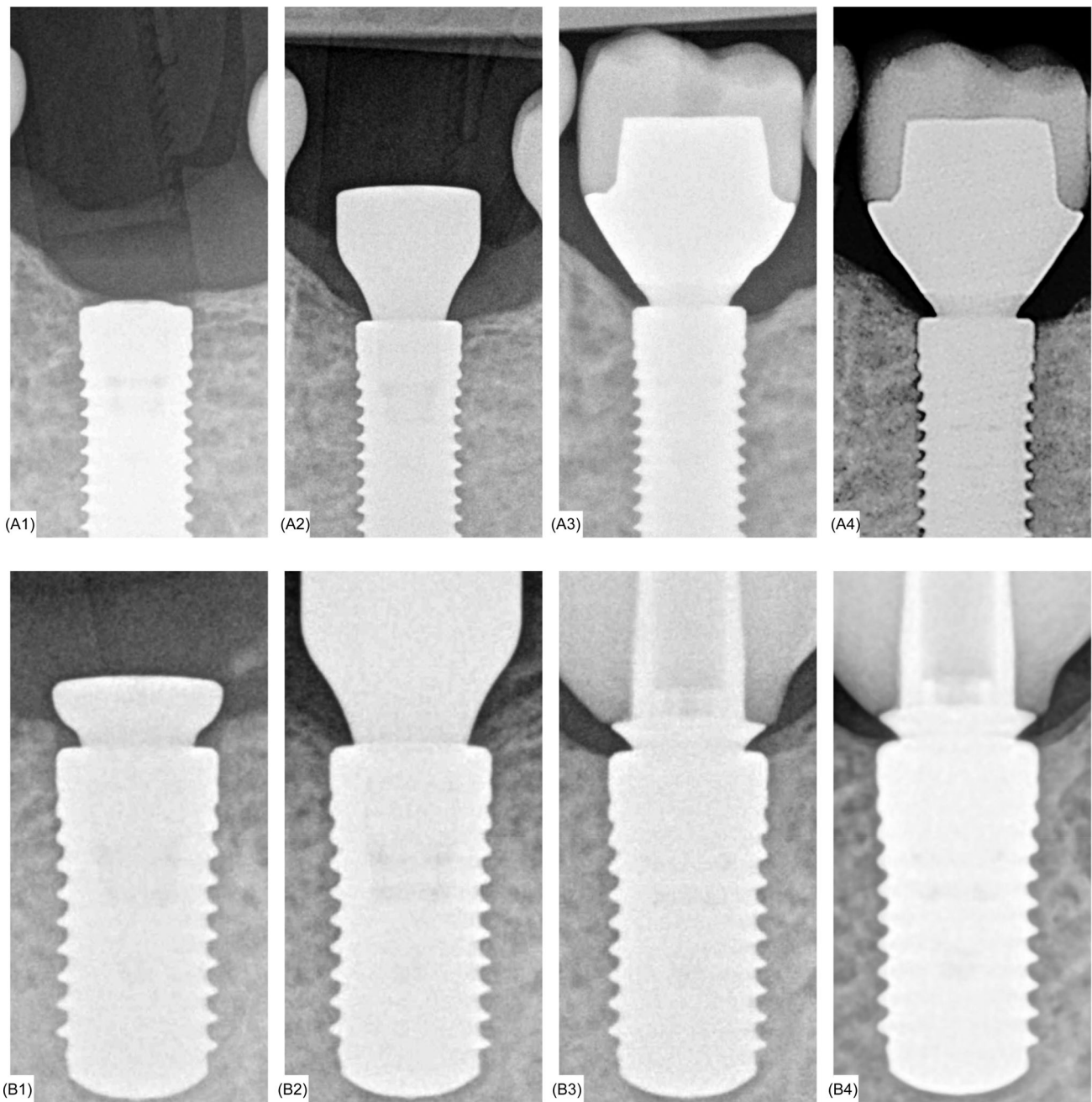


FIGURE 3 Upper Row: The sequence of four periapical radiographs illustrating the progression following implant placement and augmentation with ADM: (A1) immediately after surgery; (A2) implant uncovering at 2 months; (A3) at the delivery of the restoration (baseline; 3 months after implant placement); (A4) 1-year follow-up (15 months after implant placement). Lower Row: Sequence of periapical radiographs showing the progression after implant placement and installation of a 2 mm healing abutment: (B1) immediately after surgery; (B2) implant uncovering at two months; (B3) at the delivery of the restoration (3 months after implant placement); (B4) 1-year after loading (15 months after implant placement).

was reported as a positive value, and a corresponding decrease or loss as a negative value.

2.6.4 | Surgical procedures

An antibiotic prophylaxis regimen with amoxicillin (Ospamox; Biochemie, Kiel, Germany) was administered 1 h before surgery (1 g) and

continued for 1 week after surgery (0.5 g, three times a day). Patients were asked to rinse for 1 min with a 0.12% chlorhexidine solution (CHX) (Perio-Aid, Dentaïd, Spain) before intervention. All surgeries were performed under local infiltration anesthesia using 4% Articaine solution with epinephrine 1:100000 (Ubistesin, 3 M ESPE).

Buccal full-thickness flaps were raised after midcrestal incision expanded by intrasulcular incisions to adjacent teeth. Lingual aspects of the flap were kept in situ to assess the vertical STH using a

TABLE 1 Descriptive patient and treatment-related characteristics.

Factor	Value	All patients (N = 40)	Treatment ADM (N = 20)	Treatment TT (N = 20)	p-Value*
Gender					
	Female, N (%)	21 (52.5)	12 (60)	9 (45)	0.527
	Male, N (%)	19 (47.5)	8 (40)	11 (55)	
Age [years]					
	Average \pm SD	40.9 \pm 8.4	40.1 \pm 8.9	41.8 \pm 8	0.578
	Median (IQR)	41 (35.8–45.3)	40.5 (33.8–45.3)	41 (37.8–44.5)	
	Range	26–66	26–60	29–66	
Smoking					
	Non-smokers, N (%)	37 (92.5)	18 (90)	19 (100)	0.999
	Smokers, < 10 cigarettes p.d., N (%)	3 (7.5)	2 (10)	1 (10)	
	Smokers \geq 10 cigarettes p.d., N (%)	0 (0)	0 (0)	0 (0)	
Implant diameter [mm]					
	4.1, N (%)	33 (82.5)	17 (85)	16 (80)	0.999
	4.8, N (%)	7 (17.5)	3 (15)	4 (20)	
Implant length [mm]					
	8, N (%)	7 (17.5)	3 (15)	4 (20)	0.999
	10, N (%)	33 (82.5)	17 (85)	16 (80)	

Note: The cohort's descriptive patient- and treatment-related characteristics at the global and cohort levels.

Abbreviations: IQR: Interquartile range; N, absolute number; SD, Standard deviation; p.d., per day.

*P-values were derived from group comparisons using a Chi-square test for categorical variables or an independent t-test for continuous variables (age). % age values within brackets designate inter-category and intra-cohort ratios.

periodontal probe placed in a vertical orientation to the alveolar crest at the midcrestal position of the future implant. Next, lingual aspects of the flap were raised to expose the entire alveolar ridge and the latter was flattened using a round bur if necessary. Implant positions and sizes (Bone Level Implants, Roxolid[®], SLA[®], RC, Institute Straumann AG, Switzerland, \varnothing (4.1 and 4.8) \times (8 and 10 mm)) were planned based on peri-apical radiographs and visual assessment of the alveolar dimensions (Table 1). Osteotomies were prepared, and implants were placed equicrestal on the buccal aspect. Osteotomy dimensions and angulations were verified using corresponding alignment pins and finalized by profile drilling or additional tapping in case of hard bone.

Group ADM: Placement of a closure screw (0 mm height) and a porcine dermal collagen graft (Mucoderm[®], Institute Straumann AG, Switzerland, 15 \times 20 mm) on top. The graft was hydrated for 20 min in 0.5% Metronidazole solution (B. Braun, Germany) prior to use and trimmed to an extension of 10 by 5 mm beyond the implant margins in the buccal and lingual direction, respectively (Figure 4A2). Primary wound closure was achieved aided with double mattress sutures (6–0 Prolene, Ethicon, USA).

Group TT: After implant placement, 2 mm healing abutments (RC, Institute Straumann AG, Switzerland) were set on the implants. Flaps were adequately passively mobilized aided with vertical releasing incisions if needed. Horizontal mattress sutures and interrupted sutures were used for primary and submerged healing (Figure 4B1).

Post-operative instructions were identical for both cohorts and included instructing patients to rinse the operated site for 1 min with CHX twice a day for 1 week. Sutures were removed 2 weeks after surgery. After 2 months of healing, implants were uncovered after verifying graft integration and healing by confirming the absence of soft tissue mobility and inspecting the operated sites for tissue color and consistency. A buccal full-thickness flap was raised after infiltration anesthesia and midcrestal incision, and the soft tissue thicknesses adjacent to the implants were recorded as described above (Figure 4A3,B2). Next, flaps were advanced lingually, and closure screws (Group ADM) or 2 mm healing abutments (Group TT) were replaced by 4 mm healing abutments (RC, Institute Straumann AG, Switzerland) in both groups. Flaps were approximated, adapted around the healing abutment, and sutured tension-free with single interrupted sutures (6–0 Prolene, Ethicon, USA), avoiding excision of soft tissues for transgingival healing. Patients were instructed only to use soft brushes, avoid chewing on the operated site, and rinse twice daily for 1 week with CHX. Sutures were removed after 1 week.

2.6.5 | Restorative procedures

Single screw-retained prosthetic crowns were delivered 1 month after uncovering. Crowns consisted of Zirconium oxide (Katana Zirconia,

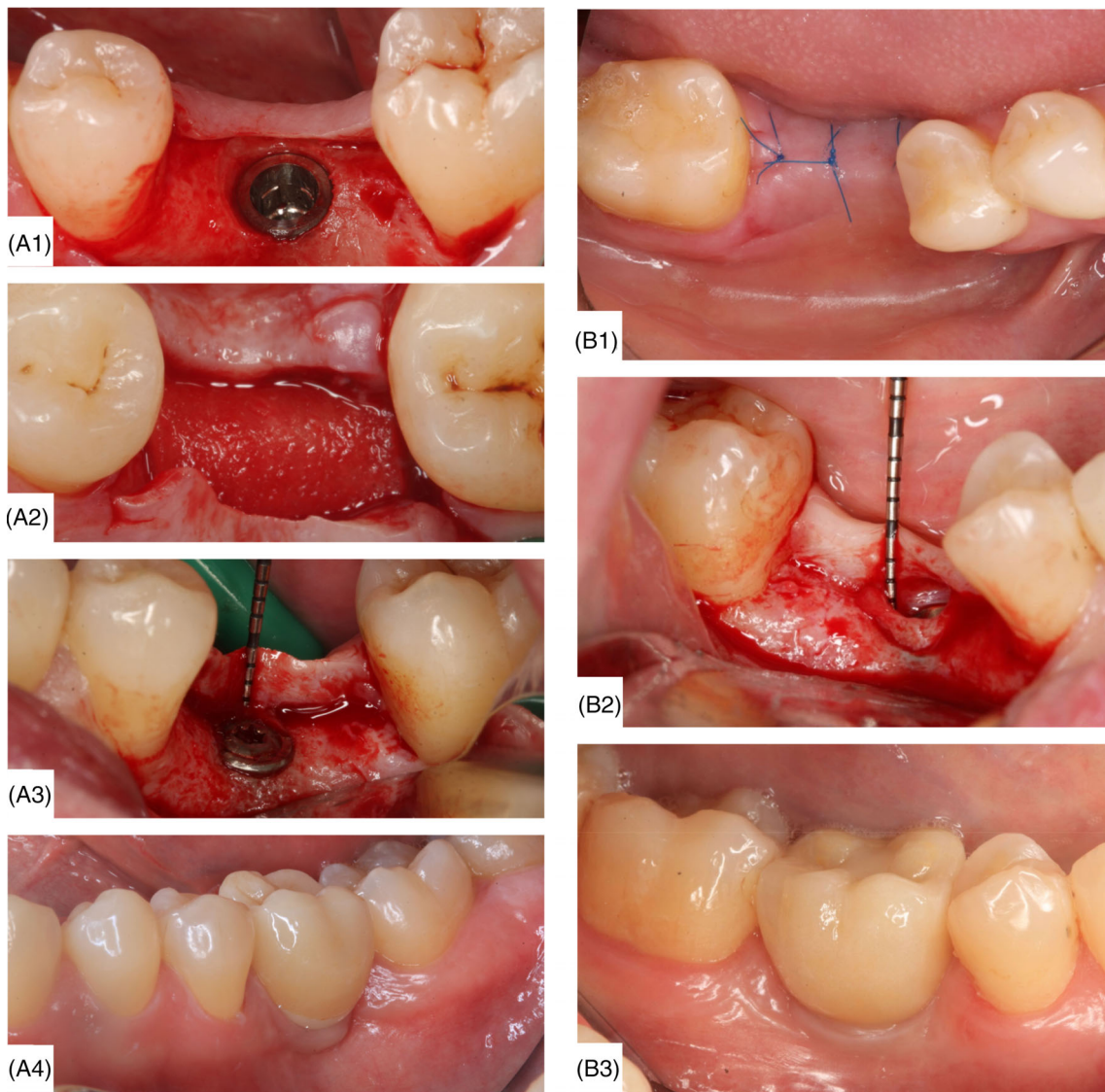


FIGURE 4 Left Side: Clinical case illustrating the treatment sequence of soft tissue augmentation modality using ADM. (A1) Implant placement in thin vertical soft tissue; (A2) Adaptation of the acellular dermal matrix before primary wound closure; (A3) augmented vertical soft tissue 2 months after implant placement. (A4) Clinical situation after final prosthesis delivery. Right Side: Clinical case illustration of tenting technique (TT) based on submerged healing of a 2 mm healing abutment providing a subepithelial healing space. (B1) Occlusal view after implant placement and the 2 mm healing abutment installation two weeks after primary wound closure. (B2) Re-entry 2 months after implant placement (B3) Clinical situation after final delivery.

Kuraray Noritake) with a highly polished surface in the corresponding subgingival area, cemented (G-CEM Link Ace; GC) on Titanium bases with a gingival height of 1 mm (RC Variobase abutment® for crowns, Institute Straumann AG, Switzerland) and were veneered with lithium disilicate (IPS e.max, Ivoclar Vivadent, Liechtenstein), using a soldering procedure with fusing material (Hotbond, Kuss Dental SL, Spain). Crowns were cleaned chair-side and mounted with a final torque of 35 Ncm. Screw access holes were filled with autoclaved PTFE tape, and the coronal 2 mm were sealed with light-cured composite (Gradia Posterior, GC, Netherlands) after hydrofluoric acid etching (9.6%, Pulpdent Corporation, USA) and silane priming (Clearfil Universal Bond Quick, Kuraray Noritake Europe, Germany).

Hygiene instructions were reinforced, and patients were enrolled in a regular 6-month recall regimen to ensure periodontal health throughout the study.

2.7 | Statistical analysis

A statistician analyzed the study data using statistical software (SPSS 15.0 for Windows, Chicago, IL, USA). Descriptive parameters and study outcomes were reported as means, standard deviations, medians, minimum, and maximum values at the study cohort level. Each implant was treated as an independent distinct statistical unit.

Time-dependent study outcomes across treatment modalities were evaluated using repeated measures ANOVA with Tukey criterion for pairwise post hoc comparisons. Differences were considered statistically significant at $p \leq 0.05$ with a confidence interval of 95%.

2.8 | Ethical approval and registration

The study was approved by the local institutional ethics committee (approval number BEC-LSMU(R)-27). Additionally, the trial was registered at [ClinicalTrials.gov](https://clinicaltrials.gov) under the ID NCT06302387. Patients who participated in the study signed informed consent and were invited to the follow-up 1 year after delivery of the final implant supported restoration. This study adhered to the Helsinki Declaration of Ethical Principles developed by the World Medical Association and followed the reporting of the study follows the CONSORT (2010) guidelines.³⁶

3 | RESULTS

3.1 | Subject eligibility and cohort baseline characteristics

Forty patients (20 per group), all completing the study are being considered in the analysis. Recruitment started in January 2018, and by April 2020, all implants were installed. Study cohorts of both groups showed statistically equivalent characteristics with regard to gender composition ($p = 0.527$), average age ($p = 0.578$), smoking ($p = 0.999$) and treatment-related characteristics, that is, implant diameter and length (both $p = 0.999$) (Table 1). The overall patient cohort was gender-equal (21 women vs. 19 men) with an average age of 40.9 ± 8.4 years and mainly composed of non-smokers (92.5%), followed by smokers consuming less than 10 cigarettes per day (7.5%).

Provided implant diameters were 4.1 mm (82.5%) and 4.8 mm (17.5%), and implant lengths were 8 mm (17.5%) and 10 mm (82.5%) (Table 1). Patients were followed up 1 year after loading, defining the study's endpoint.

3.2 | Crestal bone level changes

The mesial and distal CBL changes reported in Table 2, and Figure 5 indicated that CBL in both groups decreased over the 1-year follow-up period ($p_{\text{mesial}} = 0.003$ and $p_{\text{distal}} = 0.004$). At the mesial aspect of the implant, treatment TT yielded a higher efficacy in preventing crestal bone remodeling than treatment modality ADM ($p_{\text{mesial}} = 0.019$ and $p_{\text{distal}} = 0.944$, respectively). In Group ADM, which underwent STH augmentation with ADM, there was a notable decrease in crestal bone levels (CBL) over the 1-year follow-up period. Specifically, the mesial CBL reduced from 0.4 ± 0.3 mm to 0.1 ± 0.2 mm, and the distal CBL went from 0.5 ± 0.3 mm to 0.2 ± 0.3 mm following definitive implant-supported restoration delivery. In contrast, Group TT, which received soft TT, exhibited stability in the mesial CBL, maintaining values levels from 0.3 ± 0.4 mm to 0.3 ± 0.2 mm. before and after the 1-year follow-up. The CBL on the distal showed a minor reduction, moving from 0.5 ± 0.5 mm to 0.3 ± 0.2 mm, a change that was not statistically significant ($p = 0.944$). In terms of crestal bone level changes, in the ADM group, the mesial CBL change was -0.3 ± 0.2 mm and the distal CBL change was -0.3 ± 0.3 mm. In the TT group, the mesial CBL remained unchanged and the distal CBL change was -0.2 mm. Notably, the baseline CBL values at the time of restoration were similar for groups ADM and TT. Additionally, neither treatment modality demonstrated any significant bone remodeling below the implant shoulder, as indicated by the absolute CBL ranges reported in Table 2 and Figure 5 for the 1-year follow-up period.

TABLE 2 Crestal bone level.

Aspect	Time-point	Treatment ADM Mean \pm SD Median (min-max) [mm]	Treatment TT Mean \pm SD Median (min-max) [mm]	p -Value* time effect	p -Value* time-group effect
Mesial					
	Restoration delivery	0.4 ± 0.3 0.5 (0.0-1.0)	0.3 ± 0.4 0.15 (0.0-1.0)	0.003	0.019
	1 yr after loading	0.1 ± 0.2 0.0 (0.0-0.7)	0.3 ± 0.2 0.2 (0.0-0.7)		
Distal					
	Restoration delivery	0.5 ± 0.3 0.5 (0.0-1.1)	0.5 ± 0.5 0.5 (0.0-1.5)	0.004	0.944
	1 yr after loading	0.2 ± 0.3 0.2 (0.0-1.0)	0.3 ± 0.2 0.3 (0.0-0.5)		

Note: Repeated Measures ANOVA model comparing the temporal crestal bone level evolution using soft tissue thickening modalities ADM and TT at the mesial and distal aspects.

Abbreviation: M, months.

* p -Values for the time effect and the combined time group effect reaching statistical significance ($p < 0.05$) are marked in bold.

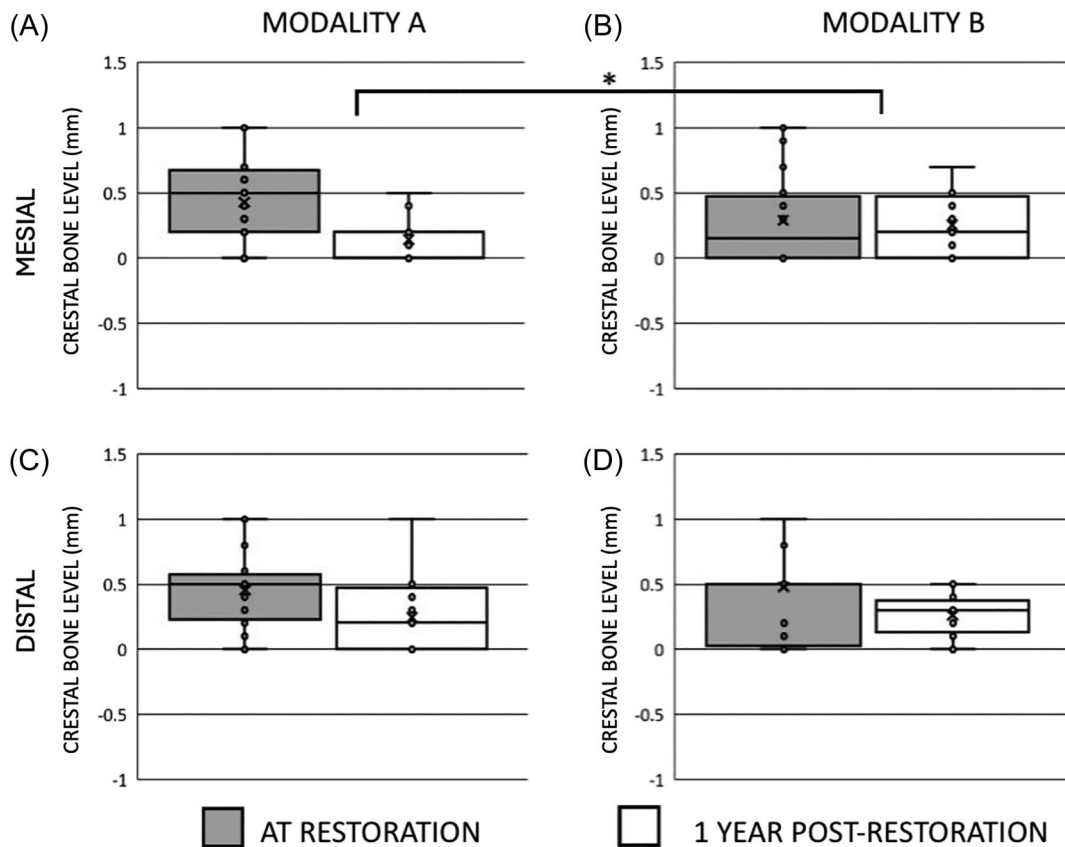


FIGURE 5 Box and Whiskers plot comparing the crestal bone levels at the time of loading (3 months) and 1-year post-loading (15 months after implant placement) for the healing modalities A (ADM) and B (TT) at the mesial and distal aspect. Boxes and horizontal lines within the boxes designate the first and third quartiles and medians, respectively. Crosses designate average values, and whiskers designate minima and maxima. Circles represent individual values. * Designate a significant time-group effect with a p -value ≤ 0.05 as determined by repeated measures ANOVA. ** Treatment A = ADM group; Treatment B = TT group. ADM, acellular dermal matrix; TT, tenting technique.

TABLE 3 Supraplatform tissue height.

Time-point	Value	Treatment ADM (N = 20)	Treatment TT (N = 20)	p-Value*
Implant placement (t = 0)				
Average ± SD		1.8 ± 0.3	1.7 ± 0.4	0.277
Median (IQR)		2.0 (1.5–2.0)	1.5 (1.5–2.0)	
Range		1–2	1–2	
Uncovering (2 months)				
Average ± SD		3.4 ± 0.5	3.4 ± 0.5	0.759
Median (IQR)		3.0 (3.0–4.0)	3.0 (3.0–4.0)	
Range		3.0–4.0	3.0–4.0	
Soft-tissue height increase				
Average ± SD		1.6 ± 0.5	1.8 ± 0.4	0.231
Median (IQR)		1.5 (1.0–2.0)	2.0 (1.5–2.0)	
Range		1.0–2.5	1.0–2.5	

Note: Supracrestal soft tissue height above the implant platform at implant placement (t = 0) and at uncovering (t = 2 M) and STH increase as difference between the corresponding values.

Abbreviations: IQR, Interquartile range; M, months; SD, Standard deviation.

*p-Values were derived from group comparisons using an independent t-test.

3.3 | Soft tissue augmentation outcomes

None of the patients displayed any signs of post-treatment infection. Two patients in cohort TT experienced premature exposure to the healing abutments. Soft tissues in all patients appeared clinically healthy and immobile 2 months after implant placement.

Both treatments showed equivalent results in terms of peri-implant STH augmentation. Corresponding values before and after treatment were comparable between both groups. Specifically, values in group ADM and TT increased from 1.8 ± 0.3 mm and 1.7 ± 0.4 mm ($p = 0.277$) prior to treatment to 3.4 ± 0.5 mm and 3.4 ± 0.5 mm ($p = 0.759$) respectively after treatment. The average soft tissue increase after STH augmentation in group ADM was 1.6 ± 0.5 mm

versus 1.8 ± 0.4 mm after soft tissue tenting in group TT. Differences were not statistically significant ($p = 0.231$; Table 3).

3.4 | Clinical parameters

Peri-implant health-related outcomes (PPD, BoP) indicated overall stable peri-implant soft tissue conditions around implants irrespective of treatment modality. Comparison of groups in terms of repeated measures ANOVA indicated a statistical temporal increase of average PPD at the distal implant aspect ($p = 0.003$) in both groups, while differences between groups for this parameter remained non-significant ($p = 0.548$) (Table 4). All other temporal or time-group effects

TABLE 4 Peri-implant parameters.

Aspect	Time-point	Treatment ADM Mean \pm SD Median (min-max)	Treatment TT Mean \pm SD Median (min-max)	<i>p</i> -Value* time effect	<i>p</i> -Value* time-group effect
Mesial					
	Restoration delivery	2.8 ± 0.8 3 (2-4)	2.8 ± 0.7 3 (2-4)	0.337	0.337
	Interim (5 months)	2.8 ± 0.7 3 (2-4)	2.9 ± 0.8 3 (2-4)		
	1 yr after loading	2.8 ± 0.8 3 (2-4)	3.4 ± 0.8 3.5 (2-4)		
Distal					
	Restoration delivery	2.6 ± 0.5 3 (2-3)	2.5 ± 0.5 2.5 (2-3)	0.003	0.548
	Interim (5 months)	2.5 ± 0.5 2.5 (2-3)	2.6 ± 0.5 3 (2-3)		
	1 yr after loading	2.9 ± 0.7 3 (2-4)	3.1 ± 0.5 3 (2-4)		
Buccal					
	Restoration delivery	2.1 ± 0.5 2 (1-3)	2.0 ± 0.6 2 (1-3)	0.392	0.811
	Interim (5 months)	2.0 ± 0.6 2 (1-3)	2.1 ± 0.6 2 (1-3)		
	1 yr after loading	2.3 ± 0.9 2 (1-4)	2.2 ± 0.7 2 (1-4)		
Lingual					
	Restoration delivery	2.0 ± 0.8 2 (1-4)	1.8 ± 0.8 2 (1-4)	0.209	0.331
	Interim (5 months)	1.7 ± 0.8 2 (1-4)	2.1 ± 0.9 2 (1-4)		
	1 yr after loading	1.5 ± 0.5 1 (1-2)	1.8 ± 0.7 2 (1-3)		

Note: Comparison of pocket probing depth (PPD) at different time points between cohorts ADM and TT at the mesial, distal, buccal, and lingual aspects. *P*-values for the time effect and the combined time group effect were calculated using repeated measures ANOVA.

Abbreviations: ADM, acellular dermal matrix; M, months.

**p*-Values reaching statistical significance ($p < 0.05$) are marked in bold.

remained below the significance threshold. In absolute values, PPDs ranged between 1 and 4 mm. Mesial and distal PPD values tended to be higher than the corresponding lingual or buccal values. For the restoration time point ($t = 3$ months), the mean PPD values were 2.8 ± 0.8 mm for the mesial aspect across both treatments and 2.6 ± 0.5 mm for the distal aspect of Treatment ADM, 2.5 ± 0.5 mm for the distal aspect of Treatment TT. By the 1-year post-loading time point ($t = 15$ months), these values slightly increased to 2.8 ± 0.8 mm and 2.9 ± 0.7 mm for the mesial and distal aspect in treatment ADM, and to 3.4 ± 0.8 and 3.1 ± 0.5 mm for treatment TT, indicating a temporal increase, particularly at the distal aspect. This data suggests that while there was a slight increase in PPD over time, the type of treatment did not significantly affect this outcome. ($p = 0.003$).

The average Bleeding on Probing (BoP) scores remained consistently low, indicating stable peri-implant health. Statistical evaluation did not indicate significant temporal or temporal-group effects. Corresponding outcomes after 1 year were identical for both groups, with an average BoP score of 0.3 ± 0.47 (Table 5).

Modified plaque indices were stable and low and ranged between 0 and 1 in all patients for all assessed time points, corresponding to no to little plaque accumulation restricted to the gingival margin of the

implants and adjacent areas (Table 6). Repeated measures ANOVA analysis did not indicate significant temporal changes ($p = 0.455$) or inter-group differences ($p = 0.918$).

4 | DISCUSSION

This randomized controlled clinical trial compared the efficacy of two peri-implant soft tissue augmentation modalities, that is, ADM grafting versus tenting technique, in preventing crestal bone loss around platform switched single implants placed at buccally crestal bone level as part of a 2-stage protocol in fully healed mandibular sites. The following main observations were obtained from comparing the different study group outcomes: (1) ADM soft tissue augmentation and TT resulted in average STH gains of 1.6 ± 0.5 mm and 1.8 ± 0.4 mm, respectively and were equally effective in vertically increasing peri-implant soft tissue thickness. (2) Following the uncovering phase, both groups exhibited crestal bone remodeling within the 1-year follow-up, leading to a reduction in crestal bone levels, yet these levels consistently remained above the implant platform. (3) Compared to ADM augmentation, soft tissue tenting (TT) resulted in slightly more stable

TABLE 5 Bleeding on probing.

Time-point	Treatment ADM Mean \pm SD Median (min-max)	Treatment TT Mean \pm SD Median (min-max)	<i>p</i> -value* time effect	<i>p</i> -Value* time-group effect
Restoration delivery	0.4 ± 0.5 0 (0-1)	0.2 ± 0.4 0 (0-1)	0.212	0.083
Interim (5 months)	0.1 ± 0.2 0 (0-1)	0.3 ± 0.4 0 (0-1)		
1 yr after loading	0.3 ± 0.5 0 (0-1)	0.3 ± 0.5 0 (0-1)		

Note: Repeated measures ANOVA model comparing the evolution of bleeding on probing (BOP) as a function of soft tissue thickening modality. *P*-values indicate the level of significance of the time and the combined time group effects.

Abbreviation: M, months.

**p*-Values reaching statistical significance ($p < 0.05$) are marked in bold.

TABLE 6 Plaque index.

Time-point	Treatment ADM Mean \pm SD Median (min-max)	Treatment TT Mean \pm SD Median (min-max)	<i>p</i> -Value* time effect	<i>p</i> -Value* time-group effect
Restoration delivery	0.3 ± 0.4 0 (0-1)	0.3 ± 0.4 0 (0-1)	0.455	0.918
Interim (5 months)	0.2 ± 0.4 0 (0-1)	0.2 ± 0.4 0 (0-1)		
1 yr after loading	0.2 ± 0.4 0 (0-1)	0.3 ± 0.4 0 (0-1)		

Note: Repeated Measures ANOVA model analyzing the evolution of plaque index (PI) over the different treatment and follow-up time points as a function of soft tissue thickening modalities a and b through *p*-values for the time effect and the combined time group effects.

Abbreviation: M, months.

**p*-Values reaching statistical significance ($p < 0.05$) are marked in bold.

crestal bone levels. At the mesial aspect, ADM resulted in a crestal bone level change from 0.4 ± 0.3 mm at restoration to 0.1 ± 0.2 mm at 1 year, whereas TT maintained levels from 0.3 ± 0.4 mm to 0.3 ± 0.2 mm. Statistical analysis indicated that changes over time were not significantly different between treatments ($p = 0.019$ mesial, $p = 0.944$ distal) 4) Both treatment modalities were characterized by a steady increase in PPD at the distal aspects while maintaining overall low and similar levels of BoP.

The trial findings suggest that both ADM and tenting technique TT were equally effective in augmenting soft tissue thickness and stabilizing crestal bone levels. However, the tenting technique showed a slight advantage in maintaining bone levels but with a higher risk of post-surgical complications. These results indicate the applicability of both methods in clinical settings, considering the slight differences in outcomes and potential complications.

The importance of a mature soft tissue seal to protect and maintain the osseointegrated implant-bone interface is well accepted.^{37–40} Peri-implant soft tissues comprise two major compartments: an epithelial and a connective tissue zone.⁴¹ These tissues have been reported to develop and mature within 8 weeks post-surgery,⁴² with overall and individualized physiological dimensions that appear to be based on biological demands rather than healing protocols, that is, one stage versus two stages healing.^{6,14,24} Histological studies in the animal model⁶ and human specimens^{43–45} have shown that the overall biological width from the mucosal margin to the first bone to implant contact measures 3 to 4 mm with 1.5–2 mm of epithelial and 1–1.5 mm of connective tissue. Studies by Berglundh et al., Vervaeke et al., Linkevicius et al., and others have repeatedly demonstrated a relation between supracrestal soft tissue thickness and crestal bone loss, indicating that crestal bone loss may result from insufficient supracrestal soft tissue dimensions (≤ 3 mm) to support a purely supracrestal tissue height—that is, biological width.^{24,46,47} In this context, both studied soft tissue thickening techniques resulted in soft tissue thicknesses considered sufficient to support a STH (biological width) with minor crestal bone remodeling under the adoption of a crestal placement regimen.

Puisys et al. and Linkevicius et al. have recently studied both soft tissue thickening modalities individually. Puisys et al. reported that STH augmentation using the same type of graft used in this study resulted in a significant increase in soft tissue thickness from 1.65 ± 0.36 mm to 3.45 ± 0.52 mm (range: 3.0 mm to 4.0 mm) 2 months after implantation, which is well in line with the results observed in this publication.⁴⁸ In the same study, histological analysis revealed favorable soft tissue integration with minimal signs of inflammation and resulting soft tissue morphology of the augmented tissues comparable to the adjacent native gingiva.

Compared to the study of Puisys et al., ADM were instilled with 0.5% metronidazole solution before implantation as part of the current protocol. Metronidazole is a first-line antibiotic against anaerobic oral infections and was applied locally to protect the graft against perioperative contamination with anaerobic pathogens.^{49,50} The comparable results presented here and in other studies confirm that the additional local application of this antimicrobial did not

negatively impact the regenerative outcome of the procedure.^{48,49} The herein-adopted soft tissue tenting was also previously individually studied by Linkevicius et al., who reported an increase from 1.85 ± 0.26 mm to 3.65 ± 0.41 mm at the 2-month follow-up.³¹ These results are also comparable with the outcomes of this study. In line with our observations, the authors also reported a certain level of premature exposure of the healing abutments. This exposure was attributed to the excessive tension exerted by the technique on the relatively thin mucosal tissues, resulting in their perforation. Such perforations may result in early exposure of the supra-platform tissue complex to the bacterial-laden oral environment, potentially negatively affecting crestal bone healing and stability. Although such observations were repeatedly reported in other studies, no negative impact of early exposure on crestal bone levels was observed as part of the current study.

Additionally, Verardi et al. recently directly compared both applied soft tissue thickening modalities as part of a protocol comprising uncovering and restoration after 6 months post-placement.⁵¹ The authors focused their study on soft tissue thickening without analyzing any crestal bone level changes and reported an increase of 1.33 ± 0.71 mm for the soft tissue augmentation compared to a significantly lower increase of 0.43 ± 0.55 mm for the tenting technique. However, a major difference to the applied protocol was related to the long follow-up period between the augmentation (graft placement or tenting) and uncovering, which, in the authors' opinion, led to a considerable amount of graft resorption. A second difference was related to the relatively high rate of premature exposure rates of healing abutments in the tenting group over the 6-month healing period. According to the authors, this complication was observed in 18 out of 23 patients, compared to 2 out of 20 patients in the current study, suggesting that a substantially longer healing period may have an apparent negative impact on thickening effectiveness. Likewise, the applied protocol resulted in stable buccolingual and increasing mesio-distal probing depths exceeding the changes in crestal bone levels. This observation indicates that augmented or expanded soft tissues may adapt around single crowns similarly to native soft tissues, as previously described.⁵²

Finally, to this extent, the present study is also the first to describe the effectiveness of the corresponding soft tissue augmentation techniques in a head-to-head comparison in conjunction with peri-implant crestal bone level changes.

Implant-abutment-related design aspects, for example, platform-switching and supracrestal connecting geometries, represent other important factors impacting crestal bone stability.^{10,11,53–55} From a recent systematic review, Valles et al. concluded that subcrestal placement of platform-switched implants reduced crestal bone resorption by increasing the dimensions of the peri-implant mucosa and, specifically, the barrier epithelium. Consequently, this crestal placement modality may be considered less favorable to support crestal bone stability and, thus, potentially more adequate to test the effect of concomitant soft tissue thickening on crestal bone stability.⁵⁶ At the same time, subcrestal placement may, from a clinical perspective, often be restricted by anatomic limitations, requiring the consideration of other

factors like soft-tissue procedures and the optimization of transmucosal contours to prevent crestal bone loss.^{10,32,55}

The crestal bone level changes between restoration and the 1-year follow-up after soft tissue augmentation were -0.29 ± 0.31 mm at the mesial and -0.21 ± 0.40 mm at the distal aspect, compared to -0.035 ± 0.334 mm and -0.22 ± 0.49 mm when the tenting technique was applied, respectively. These values aligned well with other studies, including corresponding cohorts undergoing comparable treatment protocols. Puisys and Linkevicius, for example, reported crestal bone level changes ranging from -0.16 ± 0.06 mm to -0.20 ± 0.0 mm following soft tissue augmentation with an allogenic soft tissue graft adopting an immediate transgingival healing protocol. Following soft tissue expansion, Linkevicius et al. reported a crestal bone loss around crestally (on the buccal aspect) placed implants between uncovering and a 2-year follow-up of 0.51 mm. Additional study time points allowed the authors to attribute most of the bone loss (0.43 mm) to the period between uncovering and restoration.³¹ This aspect was not considered in the current study design. However, it might have provided additional information on whether augmented and expanded soft tissues may differently influence crestal bone resorption in view that most crestal bone changes tend to occur concurrently with the development and maturation of peri-implant tissues during the initial healing period following uncovering.^{31,45,57} Differences in soft tissue quality may also be related to the fact that the acellular dermal matrix was, for practical reasons, applied underneath a full-thickness flap, that is, underneath the periosteum and not as part of a split-thickness flap as recommended by the manufacturer. As the periosteum is responsible for the blood supply to the crestal bone, a potential effect on crestal bone remodeling may not be fully excluded.^{58,59} In terms of cost-effectiveness, the tenting technique might be superior. However, the tenting method involves may involve a slightly more complex surgical procedure and potential higher risk of healing abutment exposures. A future combination of the tenting and STH augmentation techniques may help elucidate this potential effect further. Furthermore, such a combination may render the techniques more efficacious by reducing the risk of early healing abutment exposures.

A few limitations are acknowledged in this study. This randomized clinical trial provided initial insights into the efficacy of both treatment modalities. However, it is noted that the follow-up period of 1 year might not adequately capture the long-term outcomes and stability of peri-implant tissues and crestal bone.

It is also acknowledged that one of the main limitations of ADMs and soft tissue substitutes may be shrinkage over time, which becomes could be more evident in the long term, and evaluating this in 2 months may be a limitation. However, this study's early evaluation at 2 months still provides valuable insights, as initial tissue response and integration are critical for long-term outcomes. Bias related to patient selection, post-operative care practices, and the specificity of the surgeon's skill set may have been introduced due to the study being conducted at a single center. The exclusion of patients with conditions affecting soft tissue healing and bone regeneration limits the generalizability of the

findings. Despite thorough precautions to ensure precision, the reliance on periapical x-rays for crestal bone measurements faces inherent limitations due to potential variations in angulation and direction, which could result in the overlap of buccal and lingual bone structures. Additionally, the outcomes may have been influenced by variations in patient adherence to post-operative care instructions and oral hygiene practices over the observed 1-year period.

5 | CONCLUSION

The results of this study yielded that:

- The study revealed that the use of both ADM grafting and the TT are effective strategies for augmenting soft tissue thickness around dental implants, thereby contributing to maintain crestal bone levels.
- Vertical peri-implant soft tissue augmentation using ADM and a submerged 2 mm healing abutment (Tenting technique) were equally effective in peri-implant augmentation of supra- platform soft tissue.
- The tenting technique offers a slight benefit over ADM grafting in terms of maintaining stability of the crestal bone.
- Tenting technique TT may carry a higher risk of post-surgical complications, when compared to ADM.

AUTHOR CONTRIBUTIONS

Algirdas Puisys: Concept/design; data analysis/interpretation; critical revision of article; data collection; approval of article. **Egle Vindasiute-Narbutė:** Critical revision of article; data collection; approval of article. **Dainius Razukevicius:** Critical revision of article; data collection; approval of article. **Samuel Akhondi:** Data analysis/interpretation; drafting article; drafting article; visualization; critical revision of article; approval of article. **German Gallucci:** Data analysis/interpretation; drafting article; critical revision of article; approval of article. **Ignacio Pedrinaci:** Concept/design; data analysis/interpretation; drafting article; critical revision of article; approval of article.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest related to the conduct of this research. However, the materials used in this study were provided at no cost by Institut Straumann AG.

DATA AVAILABILITY STATEMENT

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

PATIENT CONSENT

All patients who participated in this study provided signed informed consent.

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