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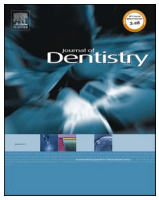

Influence of mucosal tissue height on implant crestal bone: A 10-year follow-up of a controlled clinical trial

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ABSTRACT

Objective: To evaluate the 10-year influence of soft tissue height (STH) on crestal bone level changes (CBC) in bone-level implants with non-matching internal conical connections.

Material & Methods: From the initial 97 patients, 59 (19 men, 40 women, age 55.86 ± 9.5 years) returned for the recall visit. Based on baseline STH, they were categorized into T1 (thin STH ≤2 mm, $n = 33$), T2 (thin STH augmented with allogenic tissue matrix (ATM), $n = 32$), and C (thick STH >2 mm, $n = 32$). Implants were placed in the posterior mandible using a one-stage approach and received single screw-retained restorations. Clinical (PPD, BOP, PI) and radiographic examinations were conducted after 10 years, with CBC calculated mesial and distal to each implant.

Results: After 10 years, implants in surgically thickened (T2) or naturally thick STH (C) showed bone gains of 0.57 ± 0.55 mm and 0.56 ± 0.40 mm, respectively ($p < 0.0001$) shifting from an initial CBC of -0.21 ± 0.33 mm to 0.36 ± 0.29 mm in the thick STH group and -0.2 ± 0.35 mm to 0.37 ± 0.29 mm in the surgically thickened STH group. Implants in naturally thin STH yielded a non-significant trend of bone loss (-0.12 ± 0.41 mm; $p > 0.05$).

Conclusions: Implants in thin STH (≤2 mm) exhibited greater CBC over the study period. Significant bone gains were observed in thick STH cases, indicating that naturally thick STH or STH augmentation with ATM may contribute to maintain CBC in long-term around implants.

Clinical significance: This is the first long-term follow-up study suggesting that adequate soft tissue height around implants helps maintain stable peri-implant bone levels. While tissue thickness plays a key role, other factors also interact with peri-implant tissue height to sustain crestal bone stability over time.

1. Introduction

Crestal bone stability constitutes one of the fundamental determinants of long-term implant health [1], particularly in the context of short implants survival and prevention of peri-implant soft tissue deficiency (PSTD) [2-4]. The role of the peri-implant phenotype [5] and particularly its vertical mucosal height, has been described in animal studies as early as 1996 [6], and offered early indications of the pivotal role played by tissue height in maintaining crestal bone stability. Recently, the significance of understanding and respecting the peri-implant phenotype in order to obtain predictable long-term successful implant-supported restorations (ISR) has been emphasized [7,8]. Clinically, a minimum (≥ 3 mm) of vertical soft tissue height has been demonstrated to maintain crestal bone stability [9]. Thus, implants placed into thin tissues sites yielded greater crestal bone loss compared to implants placed in thicker tissues. Moreover, implant designed to

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preserve crestal bone (i.e. implants with non-matching connection) cannot prevent bone loss in thin tissues [10]. Other factors have been demonstrated to influence crestal bone stability as the height of the prosthetic abutment [11] and the contour of the final prosthesis [12]. However, any of these factors alone cannot be exclusive determinants and they must be considered as a whole. Accordingly, it was shown that implants in thin mucosa could still experience significant bone loss even when a tall abutment was chosen [13].

This indicates that crestal bone stability relies on multiple factors, extending beyond implant type. Other factors has been demonstrated to have an impact on crestal bone level stability such as: (1) patient's oral hygiene [14], the final prosthesis design to promote access to oral hygiene [15], the contour angle of the final prosthesis [16], the effect of one-pedrtime abutment placement [17], the correct choice of prosthetic abutments, which should preferably be original abutments [18,19], the choice of material in subgingival areas, managing excess cement [20–24], the patient's systemic conditions [25]. Furthermore, iatrogenic factors can also influence the crestal bone, clinicians should respect the manufacturer's recommendation when it comes to the positioning of adjacent implants. Early exposure of submerged implants can also lead to crestal bone loss [26].

Therefore, this study aims to investigate crestal bone level changes of bone level implants placed in naturally thin vertical soft tissues compared to implants placed in naturally thick or surgically thickened vertical soft tissues over 10 years follow-up period. The H0-hypothesis suggests that the height of the soft tissue around bone-level implants does not play a role in determining the long-term stability of the crestal bone.

2. Material & methods

2.1. Experimental design

The current study constitutes an observational 10-year follow-up evaluation of a previously published prospective controlled trial [27]. This non-interventional cohort evaluation commenced with an initial group of 102 patients from the XX, who received 105 implants. However, three of these patients, each with one implant, were later excluded due to their refusal to attend follow-up checkups. A randomization process was conducted to ensure a patient-based study design, where only one implant per patient was included in the analysis. This involved envelope drawing to select one implant from patients who received multiple implants. As a result of this selection process, the study's final sample size was narrowed down to 97 patients, comprising 28 men and 69 women. The average age of these participants was 47.3 ± 1.2 years. Each of them received one bone-level implant, with each implant measuring 4.1 mm in diameter (Institute Straumann AG, Switzerland). Implants were equicrestally placed in the posterior mandible using a one-stage approach. Patients were categorized based on vertical gingival height into three groups: test T1 (thin, ≤2 mm, $n = 33$), test T2 (thin tissues thickened with allogenic matrix, $n = 32$), and control C (thick, > 2 mm, $n = 32$). Single screw-retained metal-ceramic restorations were delivered after successful osseointegration of the implants. Inclusion criteria and further details of the original study are described elsewhere [27]. 10 years after placement of the implants, 59 patients returned for examination. (Fig. 1.) From the original cohort, 59 patients (20 from group T1, 19 from group T2, and 20 from the control group C) returned for the follow-up examination (Average Age 55.86 ± 9.75 years). This continuation of the study provides a comprehensive long-term analysis of the peri-implant tissue changes and the success rates of the implants placed a decade ago (Table 1).

2.2. Outcome variables

For crestal bone level assessment, a radiographic examination was conducted using a paralleling technique, employing a Rinn-like film holder to ensure precise imaging. The radiograph acquisition was carefully executed to ensure optimal visibility of the implant/abutment interface and threads. This approach was adopted to facilitate the

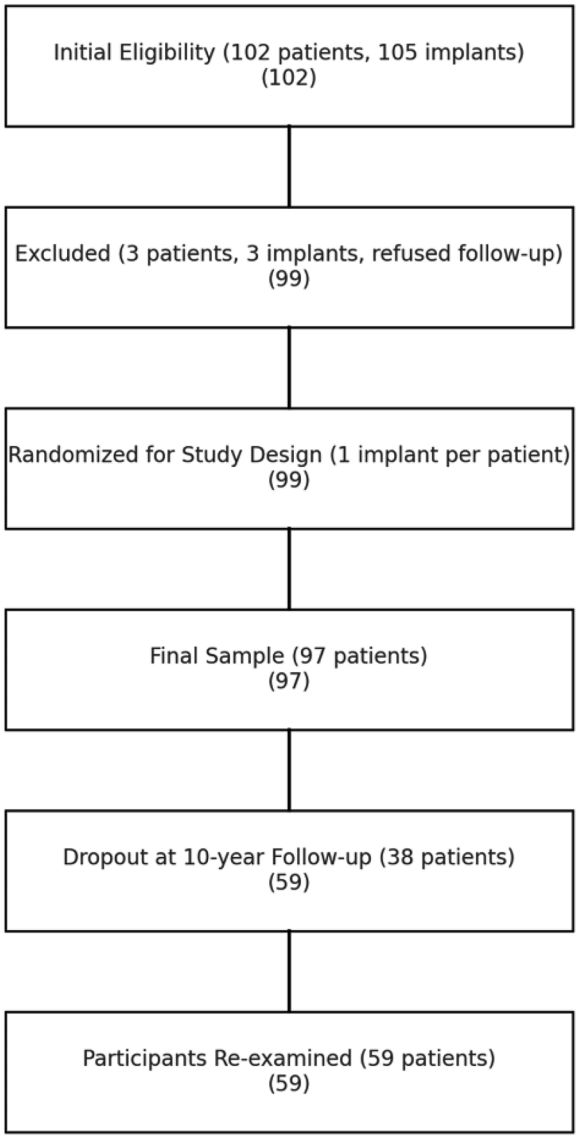

Fig. 1. Flowchart illustrating patient selection and follow-up. Initially, 102 patients with 105 implants were assessed for eligibility. After excluding 3 patients (and 3 implants) who refused follow-up, 99 patients were randomized for the study design. The final sample included 97 patients. At the 10-year follow-up, 38 patients had dropped out, leaving 59 patients who were re-examined.

Table 1
Sample Demographic Data of Patients after Ten-Year Follow-Up.

Parameter		T1 $N = 20$	T2 $N = 19$	C $N = 20$	P-value
Age	Mean (SD)	54.3 (8.78)	58.9 (8.30)	54.5 (11.60)	0.261 *
	Median (Q1-Q3; Min-Max)	56.5 (51–59; 38–70)	59 (56–65; 35–70)	56.5 (45.5–63.5; 35–70)	
Sex	Male	4 (20.0)	7 (36.8)	8 (40.0)	0.416 **
	Female	16 (80.0)	12 (63.2)	12 (60.0)	

* Kruskal-Walis test.
** Fisher exact test.

subsequent radiological evaluation and measurements which were carried out using RVG Windows Trophy 7.0 software (Trophy Radiologie Inc., Paris, France). Before assessing crestal bone changes, a calibration step was performed using the Trophy RVG software. The implant diameter served as the reference point for this calibration process. To maintain consistency, bone loss measurements and comparisons were reported separately for distal and mesial sites. Intra-examiner agreement was determined through second and third measurements, conducted with a one-month interval. Remarkably, the mean difference between these measurements was less than 0.1 mm, and the average of the three measurements was used for analysis.

Additionally, the following clinical parameters were assessed for each patient: Plaque Index, Bleeding on Probing (BOP), and Probing Pocket Depth (PPD). Plaque Index was recorded to assess oral hygiene and plaque accumulation. The presence or absence of BOP was noted as an indicator of gingival health. PPD was measured at four sites (mesial, buccal, distal, oral) using a periodontal probe, with a probing force of approximately 0.25 N for teeth and 0.15 N for implant sites.

2.3. Statistical analysis

Statistical analysis was carried out using SPSS 15.0 for Windows (SPSS; Chicago, IL, USA) software. Each implant was treated as a distinct statistical unit. Mean bone loss was computed for each group, accompanied by standard error values. As the data did not exhibit a normal distribution pattern, the Mann–Whitney *U test* was employed to identify differences between the groups. Significance was established at a level of $P \leq 0.05$, with a confidence interval of 95 %.

2.2. Ethical approval and registration

The current follow-up study received approval from the XX regional ethical committee for biomedical trial (No.158200–07–512–149). Patients who had participated in the original study were invited to participate in this follow-up and provided signed informed consent.

This study was conducted in compliance with the “Strengthening the Reporting of Observational Studies in Epidemiology“ (STROBE) guidelines [28,29] and fully complies with the Declaration of Helsinki of 1965 [30]. This study was registered in ClinicalTrials.gov (NCT06302322 “long-term follow up of Mucosal Tissue Height Influence on peri-implant bone levels”).

3. Results

3.1. Sample characteristics

In the initial study, all ninety-seven non-matching connection bone-level implants (Institute Straumann AG, Switzerland) successfully integrated into the patients, resulting in a 100 % implant survival rate after 1 year of function for T1, T2 and the control group. Crestal bone level changes across all groups between the 2-month and 1-year follow-up periods were previously reported (Table 5) including the mean bone loss around implants mesially and distally as well as the statistical difference between groups. [27]. 38 patients out of the initial 97 patients were not available for the 10-year follow-up which results in a dropout rate of 39.18 %. 59 patients (19 males, 40 females) were available for the follow up and were re-examined. Participant characteristics at baseline are summarized in Table 1. The mean average age of the remaining participants was 55.86 ± 9.75 years. Out of these 59 patients, 20 had implants placed in thin vertical soft tissues (Group T1), 19 had implants placed in surgically thickened vertical soft tissues (Group T2) and 20 patients had implants placed in naturally thick vertical soft tissues (Control Group).

3.2. Radiographic outcomes

In this ten-year study follow-up, different patterns in crestal bone level changes (CBC) were observed among the three groups. In the group with thick soft tissue height (STH), improvements were observed, with bone levels shifting from an initial mean of −0.21 ± 0.33 mm to 0.36 ± 0.29 mm after 10 years. Similarly, in the surgically thickened STH group, the change was from −0.2 ± 0.35 mm initially to 0.37 ± 0.29 mm. These results suggest a significant bone gain in implants placed in both surgically thickened (T2) and naturally thick vertical mucosa (C), with increases of 0.57 ± 0.55 mm and 0.56 ± 0.40 mm respectively ($p < 0.0001$) compared to bone levels after one year. Conversely, crestal bone levels around implants in the thin mucosal tissue group (T1) without augmentation displayed a trend of bone loss over the 10-year period (−0.12 ± 0.41 mm), although this trend did not reach statistical significance ($p > 0.05$). These findings highlight the significant improvements in crestal bone levels around the implants in the surgically thickened and naturally thick groups compared to the thin tissue group (Fig. 2).

3.3. Clinical parameters

Regarding clinical parameters, Bleeding on Probing (BOP), Plaque Index, and Probing Pocket Depth (PPD) among the 3 groups were assessed at the 10-year follow-up. Probing depths around implants placed in thin vertical soft tissues (T1) had a mean value of 3.62 ± 0.71 mm whereas the mean probing pocket depth in surgically thickened vertical soft tissues (T2) had a mean value of 3.47 ± 0.82 mm. In the control group (C) the mean depth of the probed pockets was 3.61 ± 0.75 mm. There was no statistically significant difference between the PPD of the three different groups (Table 2).

Among the implants in group T1, 6 out of 20 showed signs of bleeding on probing. Similarly, in group T2, 6 out of 19 implants exhibited bleeding during probing. In the control group, 6 out of 20 implants displayed bleeding upon probing. No statistically significant differences were found in bleeding on probing among the three group (Table 3).

In terms of the Plaque-Index in group T1, plaque was detected around 5 out of 20 implants, while in group T2, it was observed around 4 out of 19 implants. Similarly, in the control group (group C), plaque was found around 5 out of 20 implants. No statistically significant difference was found for the Plaque-Index (PI) among the three groups (Table 4).

4. Discussion

At the 10-year follow-up recall, 38 out of the initial 97 patients were unavailable, leading to a dropout rate of 39.18 %. The composition of this follow-up group remained well-distributed across the three study groups: 20 patients in Group T1 (thin vertical soft tissues), 19 in Group T2 (surgically thickened vertical soft tissues), and 20 in the Control Group (naturally thick vertical soft tissues).

Despite this significant loss, the distribution of dropouts was evenly spread across the three study groups and maintained a consistent gender ratio. This suggests that the dropouts occurred arbitrarily and did not favor any particular group or gender. As a result, the follow-up cohort can be considered representative of the original group’s demographic and clinical profile. Nevertheless, the high dropout rate introduces a degree of uncertainty, which has to be acknowledged and factored into interpretations.

The findings of this article highlight the potential long-term stability and success of implant osseointegration while stressing the impact of mucosal tissue height on peri-implant bone maintenance over the course of a decade. This 10-year follow-up provides insights into the long-term impact of peri-implant tissue height on crestal bone stability around dental implants and confirms the initial findings from Puisys et al. 2015, ultimately affirming that both naturally thick and surgically thickened

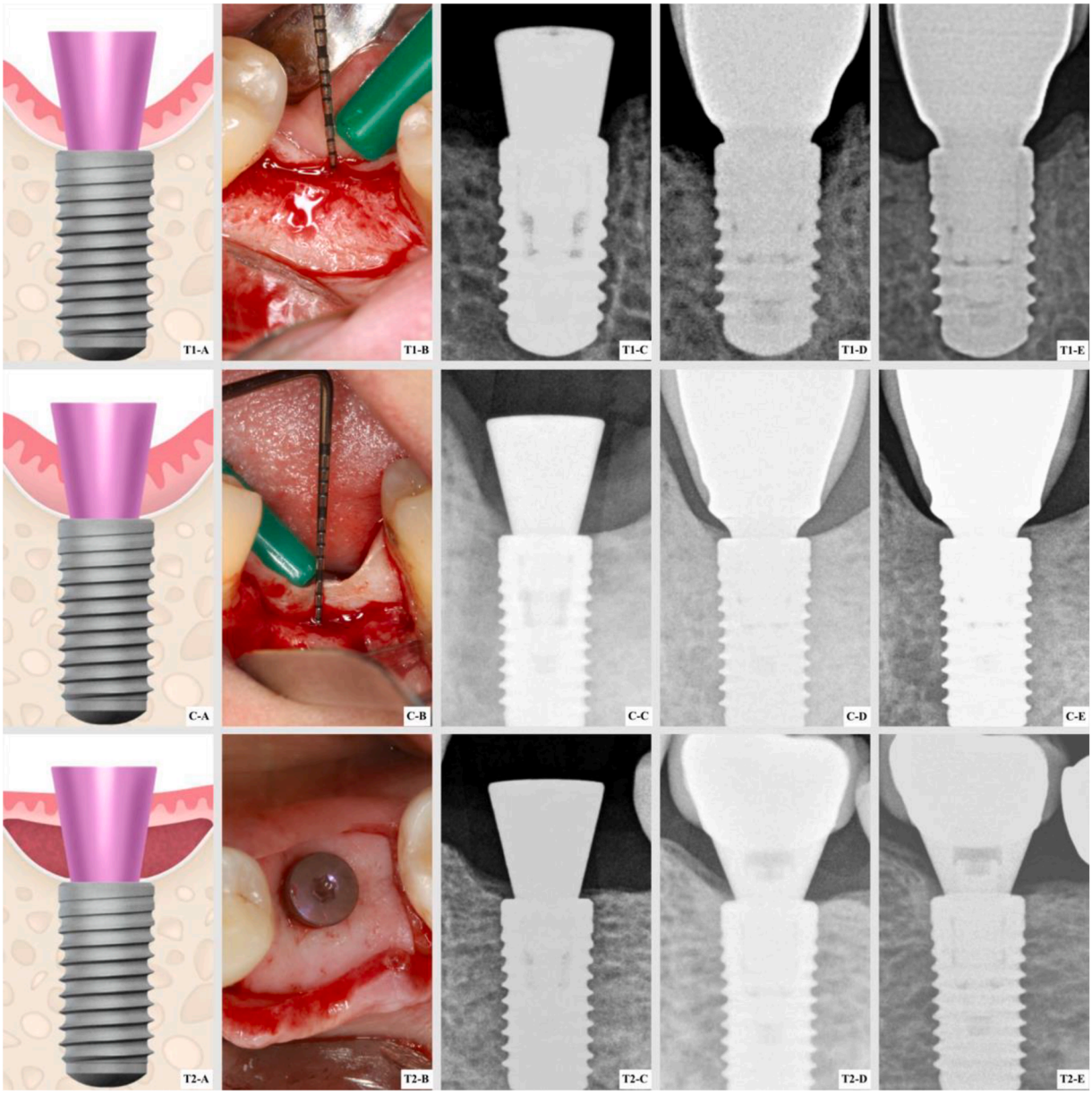

Fig. 2. Crestal Bone Level Evaluation at Implant Sites Across Study Groups. Top row ('Thin STH' T1) displays T1-A, a schematic of the clinical condition; T1-B, baseline clinical situation; T1-C, crestal bone level immediately after implant placement; T1-D, crestal bone level 1-year post-placement; T1-E, crestal bone level 10 years post-placement. Middle row ('Thick STH' Control) shows C-A, clinical setup drawing; C-B, intraoperative image; C—C, crestal bone level immediately after implant placement; C-D, crestal bone level at 1-year; C-E, crestal bone level at 10 years. Bottom row ('Thin Thickened' T2) presents T2-A, clinical scenario illustration; T2-B, surgical site photograph; T2-C, crestal bone level immediately post-placement; T2-D, crestal bone level 1-year later; T2-E, crestal bone level 10 years later.

mucosal tissues can preserve and maintain crestal bone over an entire decade [27]. At the same time this study did not identify statistically significant alterations in gingival health and plaque accumulation parameters. With crestal bone significantly improving in thick tissues over the period of 10 years, this raises the question if early crestal bone remodeling can consistently be described as permanent bone loss. Rather it would seem like implants that have a favorable peri-implant tissue height can remineralize [31] over time, further underlining the importance of the peri-implant phenotype.

It has been previously described that the peri-implant tissues around implant are typically longer when compared to the supracrestal tissue attachment (i.e.: biologic width) around natural teeth, measuring approximately 3–4 mm. [5,32,33]. The findings of this study are in agreement with animal studies [6] and clinical studies [34] suggesting that the development of the supracrestal tissue height (i.e.: biological width) around implants could potentially lead to bone remodeling when the mucosal tissues available are insufficient in height. It was revealed that implants in group T2, where thin mucosal tissues were thickened with an allogenic tissue matrix, continued to exhibit significantly less crestal bone loss throughout the 10-year period and even gained bone (0.57 ± 0.55 mm), compared to thin peri-implant tissue height in group T1 (which lost bone (-0.12 ± 0.41 mm). Interestingly, these findings highlight the protective effect of mucosal tissues surgically thickened with allogenic matrix persisted over the long term, which make this a reliable technique to modify thin peri-implant tissues.

Similarly, implants in control group C, characterized by naturally thick soft tissues, continued to yield no bone loss, and even exhibited bone gain which was not statistically different from the implants in

Table 2
Probing Pocket Depth (PPD) Measurements after 10-Year Follow-Up and statistical difference between groups (Kruskal-Wallis test, significant when $P \leq 0.05$).

Parameter		T1 $N = 20$	T2 $N = 19$	C $N = 20$	P-value
Mesial	Mean (SD)	3.7 (0.67)	4.1 (0.62)	4.1 (0.60)	0.101 *
	Median (Q1-Q3; Min-Max)	4 (3–4; 2–5)	4 (4–4; 3–5)	4 (4–4; 3–5)	
Distal	Mean (SD)	3.8 (0.70)	3.9 (0.74)	3.9 (0.79)	0.904 *
	Median (Q1-Q3; Min-Max)	4 (3–4; 3–5)	4 (3–4; 3–5)	4 (3–4.5; 3–5)	
Buccal	Mean (SD)	3.4 (0.93)	3.1 (0.52)	3.3 (0.73)	0.174 *
	Median (Q1-Q3; Min-Max)	4 (3–4; 1–4)	3 (3–3; 2–4)	3 (3–4; 2–4)	
Lingual	Mean (SD)	3.7 (0.47)	2.9 (0.74)	3.2 (0.52)	0.001 *
	Median (Q1-Q3; Min-Max)	4 (3–4; 3–4)	3 (2–3; 2–4)	3 (3–3.5; 2–4)	

* Kruskal-Walis test.

Table 3
Bleeding on Probing (BOP) after 10-Year Follow-Up and statistical difference between groups (Fisher's Exact Test, significant when $P \leq 0.05$).

Parameter		T1 $N = 20$	T2 $N = 19$	C $N = 20$	P-value
BOP	0	14 (70.0)	13 (68.4)	14 (70.0)	1.000*
	1	6 (30.0)	6 (31.6)	6 (30.0)	

* Fisher exact test.

Table 4
Plaque Index Scores after 10-Year Follow-Up and statistical difference between groups (Fisher's Exact Test, significant when $P \leq 0.05$).

Parameter		T1 $N = 20$	T2 $N = 19$	C $N = 20$	P-value
Plaque Index	0	15 (75.0)	15 (79.0)	15 (75.0)	1.000*
	1	5 (25.0)	4 (21.1)	5 (25.0)	

* Fisher exact test.

Table 5
Crestal bone loss around implants after 1-year follow-up and statistical difference between groups (Mann–Whitney *U test*, significant when $P \leq 0.05$). Table corresponding to previous study (Puisys & Linkevicius, 2015).

Group	Mean ± SE	Median	Maximum	Minimum
T1 (n = 33)	Mesially: −1.22 ± 0.08 Distally: −1.14 ± 0.07	Mesially: −1.20 Distally: −1.20	Mesially: −0.10 Distally: −0.10	Mesially: −2.10 Distally: −1.90
T2 (n = 32)	Mesially: −0.24 ± 0.06 Distally: −0.19 ± 0.06	Mesially: 0.00 Distally: 0.00	Mesially: 0.00 Distally: 0.00	Mesially: −1.10 Distally: −1.30
C (n = 32)	Mesially: −0.22 ± 0.06 Distally: −0.20 ± 0.06	Mesially: 0.00 Distally: −0.05	Mesially: 0.00 Distally: 0.00	Mesially: −1.10 Distally: −1.00

Group	Mesially	Distally
T1 and T2	$P = 0.000$	$P = 0.000$
T2 and C	$P = 0.909$	$P = 0.312$
T1 and C	$P = 0.000$	$P = 0.000$

group T2 with surgically thickened tissues (0.56 ± 0.40 mm). This suggests that both naturally thick and surgically thickened mucosal tissues remain equally effective in maintaining crestal bone stability around implants over a 10-year horizon. In contrast, the implants in group T1, where thin tissues were not augmented, continued to exhibit more bone loss over the course of 10 years, underscoring the critical importance of adequate initial mucosal tissue height [10]. This reconfirms the hypothesis that supracrestal tissue height around implants formed in thin mucosal tissues is somehow less stable than the peri-implant seal which was initially formed in thick or thickened mucosa.

The outcomes of the present study challenge previously established success criteria for dental implants. The criteria set forth by Albrektsson et al. in 1986, which suggested that dental implants that lose less than 0.2 mm annually are deemed successful, may warrant reconsideration. [35] This research indicates that when vertical soft tissues and peri-implant phenotype are adequately addressed and respected, continuous bone less might not necessarily be expected. The long-term findings suggest that implants with favorable peri-implant tissue height might even remineralize over time, emphasizing the importance of the peri-implant phenotype in determining the success of osseointegrated implants.

Recent studies have suggest the significant impact of prosthesis contour, specifically contour angle and emergence profile, on crestal bone maintenance which highlights the link between peri-implant tissue height and prosthesis contour, both essential for implant supracrestal complex health [12]. While implant design and surface characteristics do play a role, studies reveal that mucosal tissue height is the key factor for long-term success [10]. This underscores the importance of assessing tissue height when digitally planning implant procedures [36]. Thin tissues may require techniques like soft tissue grafting or subcrestal implant placement in order to obtain crestal bone stability. These findings stress the need for comprehensive virtual treatment planning in implantology, considering the intended restoration, assessment of peri-implant tissues, implant selection, supra-platform components and surgical plan as they are all interconnected and crucial for long-term success [37].

While this study provides valuable long-term insights, certain limitations should be taken into consideration. First, the study design was not randomized. Secondly, the radiologic assessment could potentially be a source of distortion over the extended period of a decade as they were not standardized, however a number of precautions were taken in order to ensure the capturing of the radiographic images from the same angle. Despite the abovementioned limitations, this study with broad inclusion criteria provides results that closely resemble real-life patient regarding long-term crestal bone level changes. Nevertheless, prospective long-term controlled clinical studies are needed in order to accurately evaluate the extent of causality in the sample and further enhance understanding on this subject.

The study's participants, who were selected based on specific eligibility criteria and represented a specific demographic profile, underwent dental implant procedures in a controlled clinical setting. While the results indicate a significant influence of soft tissue height on the long-term stability of crestal bone around implants, extrapolating these findings to a broader population should be approached with caution. The specific conditions employed in this study, such as the type of implants used and the surgical techniques applied, may limit the applicability of the findings in different clinical scenarios or populations. Therefore, while the study provides valuable insights for similar clinical contexts, further research in varied settings is necessary to enhance the external validity of these findings.

5. Conclusion

This long-term study suggests the effectiveness of thick or surgically thickened soft tissue height around implants maintaining crestal bone levels. A significant improvement in bone levels around implants was

observed in the group with soft tissue height (> 2 mm) during the 10 years follow-up period. However, a non-significant trend towards bone loss was identified in the thin tissue height group (≤ 2 mm). This highlights the importance of maintaining a minimum soft tissue height to ensure long-term crestal bone stability. Nevertheless, it is necessary to acknowledge that while tissue thickness plays a main role, other contributing factors are interconnected with peri-implant tissue height in sustaining crestal bone stability over time.

Data availability

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

Ethics statement

The current follow-up study received approval from the XXX reginal ethical committee for biomedical trial (No.158200–07–512–149).

Patient consent

All patients signed the informed consent form before coming to this follow-up.

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CRediT authorship contribution statement

Algirdas Puisys: Writing – review & editing, Writing – original draft, Visualization, Validation, Resources, Investigation, Formal analysis, Data curation, Conceptualization. **Egle Vindasiute-Narbute:** Writing – review & editing, Validation, Resources, Investigation. **Danius Razukevicius:** Writing – review & editing, Validation, Resources, Investigation. **Samuel Akhondi:** Writing – review & editing, Writing – original draft, Visualization, Validation, Methodology, Formal analysis, Data curation. **German O. Gallucci:** Writing – review & editing, Validation, Supervision, Project administration. **Ignacio Pedrinaci:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Formal analysis, Data curation, Conceptualization.

Declaration of competing interest

The corresponding author declares that none of the co-authors of this article have financial or personal conflicts of interest to report pertaining to the conduction of this study

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