IMPLANTOLOGY



Effect of soft tissue thickness on crestal bone loss of early loaded implants with platform switching: 1- and 5-year data

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Objectives: The aim of this retrospective study was to evaluate the effect of vertical soft tissue thickness (STT) on crestal bone loss (CBL) of early loaded implants after 1 and 5 years. **Method and materials:** Forty-four tapered implants with platform switching and conical connection were placed in the posterior mandible and maxilla to rehabilitate edentulous sites. STT at implant sites was divided into two groups: thin (n = 21, mean STT = 2.0 ± 0.3 mm) and thick (n = 23, mean STT = 3.0 ± 0.8 mm). The implants were loaded after 6 to 8 weeks. Survival and success rates and CBL were measured after 1 and 5 years. **Results:** The survival and success rates at 1 and 5 years were 100% and 97.8%, respectively. At the 1-year follow-up, the CBL of the thin and thick gingival groups was 0.96 ± 0.49 and 0.55 ± 0.41 mm, respectively; the difference was statistically significant (P = .004). At 5 years, the CBL of the thin and thick gingiva groups increased to 1.12 ± 0.84 and 0.65 ± 0.69 mm, respectively; the difference was not statistically significant (P = .052). **Conclusion:** At 1 year, the CBL was more pronounced at sites with a thin gingiva; at 5 years the difference between the groups was not statistically significantly different. Within the limitations of this study, early loading of implants with platform switched and conical connection was safe. (*Quintessence Int 2021;52:2–9; doi: 10.3290/j.qi.b912613*)

Key words: crestal bone loss, dental implants, early loading, platform switching, soft tissue thickness

During the early years of modern dental implantology, conventional stress-free healing periods of implants with a machined surface were 3 months in the mandible and 6 months in the maxilla when inserted in type I to III bone.¹ Acid-etched surfaces were further developed on previously machined surface implants with the same design.² Removal torque experiments in tibia rabbit model³ and human histology studies^{4,5} showed that a minimally roughened acid-etched surface was able to speed up osseointegration and implant anchorage in bone as well as increase the bone-to-implant contact in soft bone. This led to shortening of the healing period in both the mandible and the maxilla from 3 and 6 months respectively to 2 months in both arches.² When airborne-particle abrasion and acid etching was implemented on implants, the osseointegration period was successfully reduced from 3 to 4 months to 6 to 8 weeks in normal bone, and to 12 weeks in soft bone.⁶ Implant treatment protocols have been classified according to implantation and loading time. Early loading in healed sites is labelled type 4B protocol, in which functional stresses are exerted 1 to 8 weeks after surgery^{7,8}; it is considered as a scientifically and clinically validated protocol with survival rates of 98% at 1 year.⁸ It has been clinically documented as a safe treatment modality on certain implant systems.^{2,6,9} Several papers noted that certain parameters of macrogeometry and implant surface directly affect implant success and time of osseointegration^{10,11}; therefore, extrapolation from one system to another is not straightforward, and careful consideration is required. Romanos et al¹² described a specific early loading protocol called "moderate early loading." After 6 weeks of healing, the authors engaged in a demanding prosthetic protocol that involved a temporary prosthesis left for 6 more weeks in infra-occlusion while the patients were instructed to remain on a soft/liquid diet, before

 Table 1
 Study population: descriptive data comparing the thin and thick soft tissue groups; the only parameter that was different between the groups was the STT

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Parameter		P [†]	Thin, n (%)	Thick, n (%)
Study variable	Sites	NA	21	23
Demographic variable	Age < 50 y	.10	16 (36%)	11 (25%)
	Age ≥ 50 y		5 (12%)	12 (27%)
	Female	.95	8 (18%)	10 (24%)
	Male		13 (29%)	13 (29%)
Site-related variable	ISQ 60-75	.19	6 (14%)	12 (27%)
	ISQ ≥ 75		15 (34%)	11 (25%)
	ITV 20–30 Ncm	.06	15 (34%)	9 (21%)
	ITV ≥ 30 Ncm		6 (14%)	14 (31%)
	STT (mm)	.0001*	21 (47%)	23 (53%)
Location	Mandible	.39	12 (27%)	17 (38%)
	Maxilla		9 (21%)	6 (14%)
Diameter	3.75 mm	.60	17 (38%)	16 (36%)
	4.2 mm		4 (10%)	7 (16%)
Length	≤ 10 mm	.70	14 (31%)	13 (29%)
	> 10 mm		7 (16%)	10 (24%)

*P < .05.

[†]Chi-square test for categorical variables. NA, not applicable.

providing final implant-supported prostheses. The complex protocol was used, after only 6 weeks of healing, because the capacity of the bone-implant interface was not relied upon to withstand a full loading protocol.

CBL around implants is a multifactorial process with multiple etiology. Several factors, like the vertical distance between the mucosal ridge and the bone crest, a parameter known as the vertical soft tissue thickness (STT) at the implant site,¹³ and height of the prosthetic abutment,¹⁴ have been identified as affecting the early amount of crestal bone loss (CBL). Studies dealing with STT have assessed implants loaded after more than 2 months following surgery. To the best of the present authors' knowledge, there is no experimental or clinical study comparing the effect of the gingiva thickness on early loaded implants. A specific bone densification response has been reported for early loaded implants compared to conventionally and immediately loaded ones.¹⁵ Thus, it remains unclear how bone reacts to early loading protocols in combination with vertical STT. Furthermore, clinical information is lacking to determine if the change in crestal bone observed at 1 year at sites harboring gingiva of distinct thickness¹³ is maintained over time, or if this is a marked early feature and the difference is abated in the longer term, eg, 5 years later.

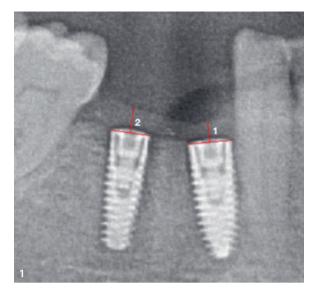
The aims of the study were therefore:

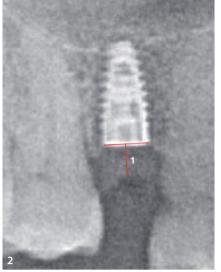
- to test the null hypothesis that STT has no effect on CBL after 1 and 5 years when early loaded implants with a platform-switching and conical connection feature were used
- to evaluate the crestal bone stability of the thin and thick gingiva groups after 1 year and 5 years.

Method and materials

Study sample and groups

This retrospective study was conducted on patients who attended the Department of Oral Implantology of the Faculty of Dentistry of Istanbul University to receive implant treatment in the posterior mandible and maxilla in accordance with the revised Helsinki Declaration of the World Medical Association of 2000. Data analysis was approved by the Ethical Committee of Istanbul University Clinical Investigations (No. 421-335).





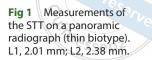


Fig 2 Measurement of the STT on a panoramic radiograph (thick biotype). L1, 3.02 mm.

Inclusion criteria

Inclusion criteria were:

- patient age above 18 years
- patient health condition corresponding to ASA 1 or 2 according to the American Society of Anesthesiologists classification
- sites healed for at least 3 months after tooth extraction
- no need for hard or soft tissue augmentation
- written informed consent
- implants that reached an insertion torque value (ITV) ≥ 20 Ncm and an implant stability quotient (ISQ) ≥ 60
- implants that were loaded within 6 to 8 weeks after implant placement.

Exclusion criteria

General exclusion criteria were:

- poor general health (uncontrolled diabetes, severe kidney disease with bone mineral disorder)
- history of radiotherapy at the head region and active chemotherapy
- untreated periodontitis
- poor oral hygiene.

Local exclusion criteria were dictated by the ITV and ISQ values obtained at implant seating; implants with ITV < 20 Ncm and

ISQ < 60 were excluded from this study; they were allotted a conventional delayed loading period.

Demographics

Forty-four consecutively inserted tapered implants (C1, MIS Implants), displaying the features of platform switching and internal conical connection, fulfilled the inclusion criteria. Implants were assigned to two groups according to their vertical STT. In accordance with Linkevicius et al,¹⁶ the threshold between the thin and thick tissue groups was set at 2.5 mm. Twenty-one implants rehabilitating nine patients entered the thin gingiva tissue group (G1); mean STT was 2.0 ± 0.3 mm, min. 1.6 to max. 2.4 mm. Twenty-three implants rehabilitating 11 patients entered the thick gingiva tissue group (G2); mean STT was 3.0 ± 0.8 mm, min. 2.5 to max. 3.8, outlier 6.3 mm; the difference between the groups was statistically significant (*P* < .001). The descriptive summary of the groups is shown in Table 1. The average age of patients was 48.2 ± 5.2 years.

Surgical and prosthetic protocol

Dental treatments including scaling and oral hygiene motivation were delivered before implant surgery. The operation was performed under local anesthesia; prior to surgery, rinsing was performed with a 0.12% chlorhexidine digluconate solution for 2 minutes. All implantation procedures were performed by a **Fig 3** Crestal bone loss at the 5-year control (thin biotype). P1, 0.40 mm; P2, 1.26 mm; P3, 1.24 mm; P4, 1.56 mm.

Fig 4 Crestal bone loss at the 5-year control (thick biotype). P1, 0.40 mm; P2, 0.37 mm.

single experienced and highly skilled surgeon with more than 20 years of clinical experience in implant surgery (CK). Midcrestal and sulcular incisions were performed and a mucoperiosteal flap was raised. Implants were placed in a crestal position to rehabilitate fixed single/splinted crowns and removable dentures, either in the mandible or the maxilla. The drilling sequence recommended by the manufacturer was implemented for all implants including the final drill. The ITV at implant seating was recorded and the ISQ was measured with the resonance frequency analysis method using a transducer specific to the implant type and diameter (Osstell Mentor, Osstell) (Table 1). A two-stage surgical protocol was implemented; at the end of the healing period, titanium abutments were selected and torgued at 30 Ncm. Final cement-retained metal-fused ceramic crowns and fixed/removable dentures were prepared and allowed a full occlusion: 12 single crowns, 8 splinted, and 6 fixed/removable dentures. The mean loading time was 7.17 ± 1.2 weeks.

Variables and endpoints

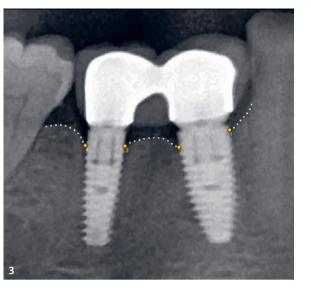
At the end of surgery, implant placement was radiographically controlled with a panoramic radiograph (Kodak 8000, Eastman Kodak) with acquisition conditions set at 75 kV and 10 mA. This voltage/current combination allows a better acquisition of the soft tissue with regards to the underlying bone. After internal calibration against the implant length, the vertical STT was assessed by measuring the vertical distance between the bone level at the crest and the top of the gray shadow corresponding to the STT.

Patients were recalled annually for a clinical and panoramic radiographic examination. The images taken at baseline and at 1 and 5 years post-loading were analyzed. Magnification, contrast adjustment, and internal calibration of the acquired radiographs against the implant length were performed using dedicated software (Image tool 3.0, UT Health San Antonio) as previously described.^{17,18} STT was measured by the same examiner (AS) after being trained on the software. STT and crestal bone levels were given by the software in millimeters at the closest tenth of millimeter.

At baseline, STT was assessed by measuring the vertical distance between the crestal bone level and the top of the gray mark corresponding to the soft tissue (Figs 1 and 2). The crestal bone levels at a given time point were assessed by measuring the vertical distance between the bone level at the crest and the first bone-implant contact on the mesial and distal sides (Figs 3 and 4).

Statistical analysis

Statistical analysis was performed with a commercially available software program (SPSS Statistics 21.0, IBM). Mean, standard deviation, standard error of mean, and minimum and maximum values were calculated. Homogeneity of the various clinical and surgical parameters of G1 and G2 was checked with





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 Table 2
 Crestal bone loss mean, standard deviation (SD), and standard error (SE) measured at implants placed in the mandible and the maxilla; the difference at 1 and 5 years was not statistically significant

Time point	Location	N	Mean ± SD	SE	Р*
1 y	Mandible	29	0.80 ± 0.55	0.10	.29
	Maxilla	15	0.63 ± 0.35	0.09	
5 y	Mandible	29	0.94 ± 0.90	0.16	.48
	Maxilla	15	0.76 ± 0.53	0.13	

*Significant at P < .05, Student t test.

Table 3Crestal bone loss mean, standard deviation (SD), standard error (SE), minimum and maximum values according to the soft tissue
groups; the difference at 1 year between the thin and thick groups was highly statistically significant; at 5 years, the difference was
close to significance

Time point	Group	Ν	Mean ± SD	SE	Min.	Max.	P *
1 у	Overall	44	0.74 ± 0.49	0.07	-0.10	1.63	NA
	Thin	21	0.96 ± 0.49	0.10	0.90	1.63	.004*
	Thick	23	0.55 ± 0.41	0.08	-0.10	1.32	
5 y	Overall	44	0.87 ± 0.79	0.12	0	2.82	NA
	Thin	21	1.12 ± 0.84	0.18	1	2.82	.052
	Thick	23	0.65 ± 0.69	0.14	0	2.51	

*Significant at *P* < .05, Student *t* test. NA, not applicable.

Table 4Crestal bone loss difference between the 1- and 5-year
controls of the STT groups; the difference between the thin
and thick groups was not statistically significant

Group	1–5 y difference (mm)	P *
Overall	0.13	.15
Thin	0.15	.31
Thick	0.10	.30

*Significant at P < .05, paired sample t test.

the chi-square test (Table 1). Implants were used as the statistical unit. Calculation with a power of 80%, a significant level of .05, and assuming a difference between groups of 0.45 mm, showed that the minimum sample size of each group was n = 16. Normality of the CBL data was checked with the Shapiro-Wilk test; the Student *t* test was used to evaluate the CBL of the groups. The paired sample *t* test was used for the timely evaluation of each group. The null hypothesis was that implant sites with thin and thick gingival tissues will display similar CBL at the 1- and 5-year follow-up.

Results

Clinical observations

Healing was uneventful during the osseointegration period; all implants completed the 1- and 5-year examination. One implant in one patient of the thick gingiva group underwent a mechanical complication, screw loosening first and then ceramic chipping after the 1-year control. No biologic complication including peri-implantitis was observed during the follow-up.

Radiographic findings

The CBLs measured at the mandible and the maxilla after 1 and 5 years were not statistically different (Table 2). At the 1-year control, the overall mean CBL for both groups was 0.74 ± 0.49 mm. CBL of G1 and G2 was 0.96 ± 0.49 and 0.55 ± 0.41 mm, respectively; the difference between the groups was statistically significant (P = .004) and the null hypothesis was rejected. After 5 years, the overall mean CBL for both groups was 0.87 ± 0.79 mm. CBL of G1 and G2 was 1.12 ± 0.84 and 0.65 ± 0.69 mm; the difference was not statistically significant (P = .052) (Table 3) and the null hypothesis could not be rejected. The pairwise

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comparison of CBL increase between the two time points was not statistically significant (Table 4).

Discussion

To the best of the present authors' knowledge, this is the first paper to address the issue of how the STT affects the CBL in the short and longer term, up to 5 years. At the 1-year control, the CBL measured at G1 was more pronounced than at G2, $0.96 \pm$ 0.49 mm vs 0.55 ± 0.41 mm, and the difference was highly statistically significant (*P* = .004); the null hypothesis was therefore rejected. This is in line with other reports dealing with conventionally loaded implants in which the STT was identified as a weighty contributing factor to the crestal bone fate, whether the implants displayed the platform-switching feature¹³ or not.¹⁹ Nevertheless, opposing views exist; Akcalı et al,²⁰ in a systematic review, found that there was insufficient evidence regarding the superiority of thick STT over thin when it comes to minimizing the marginal bone loss. It is possible that some other confounding parameters are still missed by the community.

At the 5-year control, the CBL of both groups slightly progressed compared to the 1-year data, but not in a significant way (G1, P = .31; G2, P = .30). The CBL of G1 and G2 was $1.12 \pm$ 0.84 and 0.65 \pm 0.69 mm, respectively, and the difference between groups was close to significance (P = .052); therefore, in contrast to the 1-year CBL data, the null hypothesis could not be rejected. The lack of significance is probably due to the large standard deviation of both groups; it may be that the cemented retention of the prostheses contributed to a larger dispersion of the CBL data in the longer term, especially for the thin gingiva group where cement remains are more prone to induce apical migration of the crestal bone.²¹ Another possibility is that the CBL difference between the groups abates with time; however, this hypothesis should be verified over time in other studies.

Studies that investigated the effect of vertical STT on CBL have usually set the thickness threshold between thin and thick gingiva at 2 mm.^{13,19,22} This originates from the experimental study of Berglundh et al,²³ which showed that thinning a 3-mm-thick gingiva down to 2 mm led to an increased CBL. In a first series of studies, Linkevicius et al^{13,19} divided the STT into two groups, < 2 mm and > 2 mm. In one report,¹³ the average STT of the thin group was 1.51 ± 0.09 mm and average STT of the thick group was 2.98 ± 0.08 mm; the CBL of the thin and thick gingiva sites, respectively, was 1.65 ± 0.08 and 0.44 ± 0.06 mm on the mesial side and 1.81 ± 0.06 mm and 0.47 ± 0.07 mm on the distal side. In a more recent work, the same authors¹⁶ divided the STT into three distinct groups; a thin gin-

giva group with STT \leq 2.0 mm where the average STT was 1.76 \pm 0.26 mm, a medium group of 2.5 mm, and a > 2.5 mm group where the average STT was 3.91 \pm 0.59 mm. The thick gingiva group led to the lowest CBL, 0.43 \pm 0.37 mm, and the thin one to the most pronounced CBL, 1.25 \pm 0.80 mm; the difference was statistically significant (P < .001).¹⁶ The CBL of the medium STT group was 0.98 \pm 0.06 mm; it was more pronounced than the CBL of the thick group (P = .0014) but statistically similar to the thin one (P = .31).¹⁶ The authors concluded that there was no difference between the thin and the medium STT groups.¹⁶ For this reason the threshold that discriminated between the thin and thick STT groups was set as 2.5 mm instead of 2.0 mm in the present study.

There is no gold standard method to precisely measure the STT at an implant site.²⁴ Linkevicius et al¹⁹ proposed a simple way to measure the STT before implant placement; to raise first a full-thickness buccal flap but not the lingual one, then to place a 1-mm marked periodontal probe at the bone crest in the center of the future implant position and measure the STT to the closest millimeter. In a more recent study,¹⁶ these authors used a 0.5-mm marked probe to refine their STT recording. An even more precise measuring method has been provided by determining the STT on biopsies taken with a dermal punch²²; however, this approach is time consuming and not clinically convenient. Determination of soft tissue dimension from a radiographic examination has been carried out on CBCT scans,²⁵ but to the present authors' knowledge this is the first paper reporting on STT measured on panoramic radiographs. This was made possible because the advantageous voltage/ current combination of the panoramic device allowed a better acquisition of the soft tissue with regards to the underlying bone (Fig 1). After internal calibration against the implant length, the vertical STT was assessed by measuring the vertical distance between the bone level at the crest and the top of the gray shadow corresponding to the STT. Accuracy of the measurements was at the tenth of millimeter, higher than STTs read from periodontal probes with 1-mm or 0.5-mm marks.

CBL measurements are usually gained from periapical radiographs using the long cone paralleling technique²⁰; however, panoramic radiographs have also been implemented to assess bone changes over time.^{17,18} Software is required to compensate for the measurement errors due to the heterogenous magnification of the panoramic radiographs; various authors showed that the method is reliable and does not differ between examiners.^{18,26} The advantage of the panoramic radiograph in the posterior area is that angulation of the film and the implants are kept reasonably constant if the equipment is the same, more than with the paralleling technique using periapical radiographs. Nevertheless, its accuracy is lower than for customized x-ray film holders prepared for each implant with the paralleling technique.²⁷

The current 1- and 5-year follow-up of 44 implants documents that implants with conical connection and platform switching feature can be successfully loaded after 6 to 8 weeks in both the mandible and the maxilla if the ITV is \geq 20 Ncm or the ISQ is \geq 60. This matter is relevant because it has been shown that bone response to functional stress may vary according to the loading protocol. Indeed, when an early-loaded protocol after 6 weeks was applied, Akoglan et al¹⁵ found, through CBCT examination, a denser peri-implant bone response at the 1-year follow-up compared to immediately or conventionally loaded implants. Therefore, CBL data that have been obtained for conventional loading protocols against STT might not necessary apply when implants are loaded at an earlier time point; this concern is clinically relevant for the present report.

Various consensus conferences stated that the timeframe of early loading protocols covers a span of 7 weeks from the first to the eighth week after implant placement.^{7,8} Some authors preferably load both arches after a similar time, after 3 weeks⁹ or 6 to 8 weeks^{28,29}; others discriminate between the arches, for example 6 weeks in the mandible and 8 weeks in the maxilla.³⁰ It has also been suggested that longer implants may be loaded earlier than shorter ones.³¹ The fact that consensuses suggest a 7-week interval^{7,8} shows that this categorization of early protocols is not based on a biologic response at the bone-implant interface; rather, it is the result of an empirical decision based on the academic necessity to distinguish between immediate loading protocols and longer ones, which still are inferior to conventional healing periods. In the present study, the early loading scheme was similar in the mandible and maxilla because this suited a patient-orientated shortened treatment procedure and was compatible with the internal organization of the implant rehabilitation department.

A limitation of the study is the limited numbers of implants and patients under follow-up. In addition, the panoramic radiographic examination might be less precise than periapical radiographs taken with a customized film holder for each implant.

Conclusion

After 1 year of follow-up, the CBL was more pronounced at sites with a thin gingiva, similarly to conventionally loaded implants; at 5 years the difference between the groups was not significantly significant. Between 1 and 5 years, the CBL increased slightly for both groups but did not reach significance. Early loading of implants with conical connection and a platform switching feature within 6 to 8 weeks was safe, and no implant failed over the 5 years of follow-up. Further comparative clinical studies with early loaded and conventionally loaded implants are needed to confirm the present CBL data, especially in the longer term.

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