

Retrospective Cohort Study of 4,591 Straumann Implants Placed in 2,060 Patients in Private Practice with up to 10-Year Follow-up: The Relationship Between Crestal Bone Level and Soft Tissue Condition

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Purpose: The purpose of this report is to describe the crestal bone level (CBL) around implants of various designs, describe the peri-implant soft tissue condition, and evaluate the relationship between the two over time. **Materials and Methods:** This retrospective cohort study reports on 2,060 patients with 4,591 implants evaluated after 3 months; 1, 3, 5, and 7 years; and up to 10 years. Periapical radiographs were used to evaluate changes in CBL. The peri-implant soft tissue was evaluated using a modified Bleeding Index termed the Implant Mucosal Index (IMI) where: 0 = no bleeding; 1 = minimal, single-point bleeding; 2 = moderate, multipoint bleeding; 3 = profuse, multipoint bleeding; and 4 = suppuration. **Results:** At 3 months, the mean CBL was 0.06 ± 0.22 mm; by 8 to 10 years, it had increased to 0.44 ± 0.81 mm. The median CBL remained stable throughout the study at < 0.1 mm. At 8 to 10 years, 15% of implants exhibited a CBL > 1.02 mm, and 5% exhibited a CBL > 2.28 mm. More than 50% of patients experienced some bleeding, as seen by an IMI ≥ 1 during follow-up. A positive correlation was found between IMI and CBL, as shown by a mean CBL after 4 years of 0.33 mm, 0.71 mm, and 1.52 mm for IMI = 2, 3, and 4, respectively. One exception was between IMI = 0 and IMI = 1, where no significant difference was found and bone loss was minimal. **Conclusion:** Bone loss, as measured by changes in CBL during the first 10 years of implant life spans, was minimal for most implants. Nevertheless, it is not unusual to observe implants with advanced bone loss. The soft tissue condition is a good indicator of bone loss. Time alone and minimal bleeding did not correlate with bone loss, but care should be taken for implants with profuse bleeding or suppuration. *INT J ORAL MAXILLOFAC IMPLANTS* 2016;31:e168–e178. doi: 10.11607/jomi.4932

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Numerous studies and systematic reviews report good implant survival rates with follow-up times of 5 to 10 years or longer.^{1,2} A recent meta-analysis of dental implants reported high survival rates of 95.7% at 5 years and 92.8% at 10 years.³ However, despite high survival rates and a trend toward improved results when comparing new versus older implant designs,

significant complication rates are still possible, including but not limited to progressive marginal bone loss (MBL).^{3,4} Although the early literature tended to under-report biological complications,⁵ some subsequent reports show progressive MBL as high as 22% at the implant level,⁶ other studies report an MBL of 16% at the implant level,⁷ and one review of long-term studies reported that “significant bone loss” was only 2.7% on average.⁸

There may be several reasons for the variation in reported MBL rates, including various definitions and baselines used to describe bone loss, but other considerations are described below. One reason relates to whether the patient or the implant is being evaluated, with bone loss from patient-level data being higher than that from implant-level data.⁹ Another reason for the variation relates to the selected observation time, with MBL increasing over time. According to Pikner et al,¹⁰ the percentage of implants with MBL > 3 mm at 10, 15, and 20 years was 15.2%, 17.2%, and 23.5%, respectively. In addition, variations in the implant design

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abutment connection affects what is termed normal crestal bone remodeling and can lead to variations in MBL. The two-stage Brånemark standard platform (SP) typically presented with 1.5 mm of “normal” crestal bone remodeling from the implant-abutment junction (IAJ), and this was reported as successful by Albrektsson et al,¹¹ whereas later studies of SP designs used 3 mm or a third thread to compare normal remodeling with progressive bone loss.^{9,12} One study of Brånemark implants that used a threshold of 3 mm beyond the IAJ reported a MBL of 20.4% and progressive bone loss after 9 to 14 years.¹³ One-stage designs such as the Straumann tissue-level (TL) implants, with a 2.8-mm machined collar, lose no bone to microgap so typically have < 0.5-mm remodeling past the smooth-rough interface.^{14,15} In addition, the more recent designs of two-stage platform-switch implants also exhibit less MBL in the first year related to remodeling from the IAJ than do standard platform-switch implants, as shown in a recent series of systematic reviews in which a smaller amount of bone loss (in the order of 0.5 mm) was typically noted around non-SP design implants.^{16–18} Other implant factors also may affect progressive MBL, including the type of prosthesis and implant length,¹⁹ location in the jaw, and prosthetic design.²⁰

The peri-implant soft tissue condition may be associated with MBL; however, there are few established indices for evaluation of tissue inflammation with dental implants. In evaluating teeth, bleeding on probing (BOP) as a percentage of whole-mouth probing is often used to evaluate periodontal status, but it does not apply easily to implant therapy because implants typically are limited to only a few sites.²¹ Another commonly used index for gingival assessment on teeth is the Gingival Index (GI),²² with examination by probing based on tissue-tone appearance and bleeding. The GI is not as well suited to implants, in part because implants have been shown to have higher false-positive BOP rates (13.7% on implants compared with 8% on teeth).²³ Furthermore, material-related gingival discoloration limits application of the visual coloration used in the GI.^{24,25} For example, mild inflammation, as represented by GI = 1, is based solely on color changes and not on bleeding. To date, most studies reporting the peri-implant tissue condition have used binary analysis by evaluating the presence or absence of BOP.^{26–28} In the absence of other clinical symptoms, however, BOP around implants has been reported as a weak indicator of ongoing or future loss of crestal bone.²⁶ Some studies evaluating peri-implant soft tissue have used modifications of the Mombelli index, including gradations of sulcus bleeding on gingival stimulation; however, they do not use a standardized probe force and do not incorporate the presence of suppuration.^{27,29,30}

To overcome the limitations of gingival discoloration and the limitations of binary bleeding analysis, as well as to incorporate suppuration, the present study used a modification of the Mombelli Bleeding Index in which gradations of bleeding up to and including suppuration on probing were used to reference the soft tissue condition, as described in the Materials and Methods section.

Crestal bone level (CBL) and soft tissue conditions are essential parameters for the diagnosis of mucositis and peri-implantitis. How the two parameters are related is an important question, and some reports describe the bleeding score in longer-term outcomes,^{8,31} yet a limited number of studies have evaluated the relationship. There are, however, numerous studies relating various factors of the peri-implant condition to bone loss, including the relationship of pocket depth,³² periodontal pathogens,^{33,34} and quality of plaque control,³⁵ but only a few studies have systematically examined the relationship of BOP and progressive MBL over time.^{27,30,36,37} Indeed, mucositis and peri-implantitis may represent a continuous spectrum, as shown by two studies^{38,39} that reported a lack of microbiological differences between mucositis and peri-implantitis, or between moderate and severe peri-implantitis, suggesting that the disease evolves gradually from mucositis to peri-implantitis.³³ Suppuration, however, has been shown to be related to bone loss,⁴⁰ but whether it is suppuration or the conditions leading up to infection as part of a continuum of mucositis that lead to bone loss remains unclear.

The objectives of the current study are to estimate CBL and soft tissue condition around dental implants and to assess the relationship between the two based on a cohort study of up to 10 years.

MATERIALS AND METHODS

A description of the study cohort, as well as explanatory variables and univariate and multivariate implant survival analysis, has been published elsewhere.⁴¹

This retrospective observational study consisted of 2,060 patients with a total of 4,591 implants. The cohort includes 922 (44.8%) males and 1,138 (55.2%) females with a mean age at surgery of 50.58 ± 12.96 years and a range of 15 to 85 years. All implants were placed between 1999 and 2012 in Calgary, Alberta, Canada. One periodontist (DF) performed all implant surgeries as open-flap procedures, with surgical principles and protocol as described in the survival analysis.⁴¹ Restorations were placed by a variety of general dentists and specialists in the Calgary region. All measurements were taken by the examiner (DF) who placed the implants, and no intraexaminer calibration was performed.

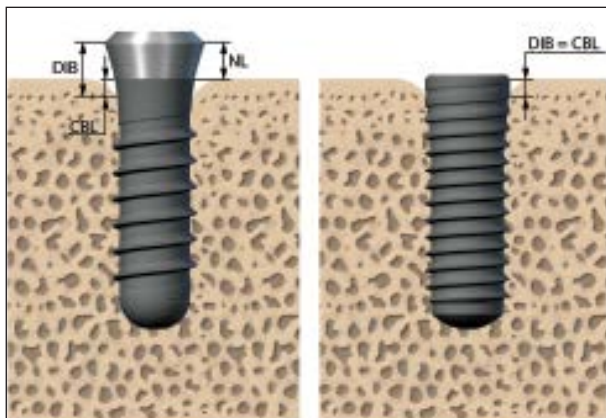


Fig 1 Crestal bone level (CBL) in relation to the micro-rough surface. NL = neck length (standard = 2.8 mm or standard plus = 1.8 mm and CBL is from the implant neck on the bone-level design. DIB = first bone-to-implant contact.

The inclusion criterion was the presentation of edentulous or partially edentulous sites, and the only exclusion criterion was an ASA Class III score or higher.⁴² Implants were placed according to the manufacturer's guidelines and used for approved indications. All potential implant locations were used, and the location and type of implants were determined on the basis of the patient's and prosthetic requirements; no set location or group of locations was planned or declined. Patient education was provided and consent to implant surgery was obtained. The study is part of an ongoing long-term evaluation of dental implants associated with a University of British Columbia retrospective clinical study on dental implants. The study was approved by the Clinical Research Ethics Board at the University of British Columbia, Vancouver, Canada. Data analysis was designed to preserve patients' anonymity.

Of importance to this report is that all implants were inserted in suitable prosthetic position such that there were no nonrestorable implants. The implants were placed with primary stability, and the border between the machined and micro-rough SLA surface was positioned fully in bone for the circumference of the implant, with only two exceptions. In the case of a narrow residual alveolar ridge, implant placement was done with simultaneous guided bone regeneration to cover exposed rough surface using particulate bone, barrier membrane (ePTFE or collagen), and closed-wound healing, such that the rough surface of the implant was expected to be fully in bone before restoration. In the case of immediate socket placement, the rough interface of the implant was placed at least 1 mm subcrestally in a fully intact socket, and if the bone-to-implant gap was less than 1.5 mm, the gap was not grafted. The impact of guided bone regeneration and/

or immediate socket placement on the CBL of implants in this cohort is the subject of further review.

Follow-up after implant treatment was scheduled at 1-, 3-, and 5-year intervals. After 5 years, follow-up was less structured, with patients returning for routine follow-up in larger cases (such as > 4 to 5 implants), when additional implant surgery was indicated, or if a concern was noted by the patient or referring dentist. In this study, follow-up after implant treatment was up to 133 months. Radiographs were obtained and clinical evaluation was performed at stage 2 (3 months), 1, 2 to 3, 4 to 5, 6 to 7, and 8 to 10 years after implant placement. Radiographs were obtained and interpreted by the same examiner (DF) who placed the implants using a proprietary parallel film holder and software calibrated to sensor dimensions (Dexis). In each radiographic image, the location of the implant-crown margin (implant shoulder), the first crestal bone-to-implant contact, and the apical border of the implant were identified as reference points. For each patient, the actual implant length served as the calibration value *r* to derive the distance from implant shoulder to the first bone-to-implant contact (DIB).^{30,43}

In this study, CBL was defined as DIB minus the neck length (machined surface) of an implant. Therefore, the following standard values were used to account for the different implant neck designs (Straumann Dental Implant System, Institut Straumann AG): 2.8 mm for standard tissue level, 1.8 mm for standard plus tissue level and tapered effect, and 0 mm for bone-level implants. For each implant, CBL was recorded as the greatest value from the mesial or distal measurements because it effectively describes the worst-case scenario. Because the border between the smooth and the micro-rough SLA surfaces was positioned at the crestal level or slightly subcrestally during surgery, CBL was a good approximation for MBL occurring after implant placement. Bone loss occurring during implant follow-up (eg, stage 2 to 1 year, 1 year to 2 or 3 years) was defined as the difference between two successive CBL measurements of each implant (Fig 1).

The peri-implant soft tissue was evaluated by probing with a light vertical probe force of 17 g using a calibrated-force automated probe (Florida Probe Corporation) or a manual probe (CP-12 Qulix, 3-6-9-12, Hu-Friedy) with the same examiner calibrated to about 17 g at six locations around the implant (mesiobuccal, buccal, distobuccal, mesiolingual, lingual, distolingual) or fewer locations if dictated by limited access resulting from prosthetic contour.⁴⁴ The modified Mombelli Index—termed the Implant Mucosal Index (IMI)—which is based on probing, was applied using the criteria shown in Table 1. Each implant was given a single IMI score only and the score was evaluated at each visit. The score assigned to an implant was

always the highest IMI score recorded during the entire follow-up period, thereby effectively representing the worst-case scenario for each implant. For example, if an implant had suppuration at any time, the IMI score remained at 4 even if it was corrected surgically and no bleeding occurred at a later date.

Statistical Analysis

CBL and bone loss are, by nature, scale variables and have been summarized by calculating the mean and median as central tendency statistics, and the standard deviation, range, and percentiles as dispersion statistics. Because the distribution of bone loss is skewed with a right tail, for descriptive purposes, the bone-loss measurement level was reduced from scale to categorical, with steps of 0.5 mm. The frequency distribution of bone loss as a categorical variable was calculated for each time interval.

The IMI is an ordinal variable with five categories. IMI scores at the patient level are determined as the most severe IMI score among all implants in the patient. IMI was stratified according to follow-up, and the frequency distributions were calculated both at implant and patient level and are illustrated by bar charts. To illustrate the relationship between CBL and IMI, the mean CBL over time (profiles) by IMI scores are graphically presented.

Linear mixed models were used to test the hypothesis regarding CBL and bone loss acting as the dependent variables of the models. These models account for an intraclass correlation as a result of several implants having been placed in a patient. Furthermore, these models also capture the correlation structure between repeated measurements on the same implant. To explore the relationship between IMI and CBL, IMI scores and times were entered as the fixed component of the model, and the following random components were included: random patient specific effects associated with both the intercept and slope (ie, the effect of time) and random effects associated with the intercept for each implant nested within a patient. A diagonal covariance structure for the residuals was added to account for repeated measurements on the same implant. The assumption of normality for the residuals was investigated by drawing normal Q-Q plots (not shown) for the residuals. The statistical analysis was performed with SPSS software (IBM Corp, Version 19.0) and with R software (R Foundation for Statistical Computing). The significance level was set at .01.

RESULTS

The study cohort included 2,060 patients (55.2% female) with a mean age at surgery of 50.58 ± 12.96

Table 1 Summary of Implant Mucosal Index (IMI)

IMI	Bleeding on probing ^a
0	No bleeding
1	Minimal, single-point bleeding
2	Moderate, multipoint bleeding
3	Profuse, multipoint bleeding
4	Suppuration

^aProbing six sites with 17-g probe.

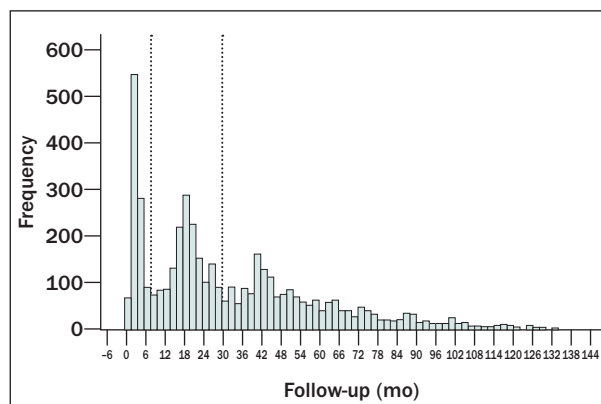


Fig 2 Frequency distribution of follow-up time. N = 4,591 implants; mean = 32.2; SD = 26.8.

years. The study was carried out from March 1999 to March 2012. Study participants received a total of 4,591 implants (51% in the maxilla), with a mean number of implants per patient equal to 2.23, a range of 1 to 14, and a mode equal to 1 implant per patient. The most common (mode) implant location was the mandibular molar area (32.2%) followed by the maxillary premolar (19.3%) and maxillary molar (18.1%). Standard tissue-level implants with an SLA surface were the dominant implant design (82.7%) and were used throughout the study period. This is in contrast to the tapered-effect implants that had limited use between 2005 and 2012 and the bone-level implants whose use began in 2007. The most frequently used implants by diameter/length were 4.8 mm/10 mm (19.8%), 4.1 mm/12 mm (16.3%), and 4.1 mm/10 mm (16.1%).

The cohort was followed up for as long as 133 months, with a mean follow-up of 32.2 ± 26.8 months. Implant follow-up was as follows: 2 to 3 years, n = 2,372; 4 to 5 years, n = 1,178; and 6 to 10 years, n = 560. Figure 2 shows the follow-up distribution.

During the study period, the authors observed 32 implant failures that resulted in cumulative survival rates of 99.3%, 99.0%, and 98.4% at 3, 5, and 7 years,

Table 2 Summary Statistics for Crestal Bone Level Over Time

Statistic	Crestal bone level (mm)					
	Stage 2 (n = 4,524)	1 year (n = 3,532)	2–3 years (n = 2,372)	4–5 years (n = 1,178)	6–7 years (n = 389)	8–10 years (n = 171)
Mean ± SD	0.06 ± 0.22	0.13 ± 0.31	0.16 ± 0.37	0.21 ± 0.45	0.34 ± 0.62	0.44 ± 0.81
95% confidence Interval ^a	0.05, 0.07	0.11, 0.14	0.14, 0.18	0.16, 0.23	0.26, 0.42	0.25, 0.57
Median	0	0	0	0	0	0.1
85th percentile	0	0.3	0.4	0.5	0.85	1.02
95th percentile	0.4	0.7	0.9	1.1	1.8	2.28
Range	0–3.90	0–4.00	0–4.00	0–3.50	0–3.50	0–5.60

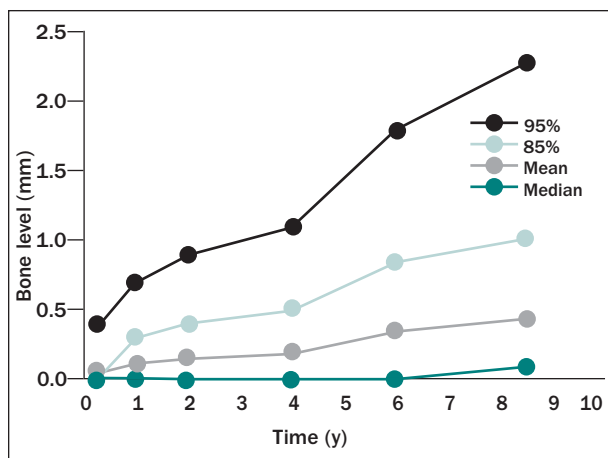


Fig 3 Central tendency and dispersion for crestal bone level over time.

respectively. More information regarding the effect of explanatory variables on survival using a multivariate analysis is included in a detailed survival analysis publication.⁴¹

CBL and Bone Loss

For the current analysis, 32 failing implants were excluded, leaving 4,559 implants for analysis. Bone measurements had been performed at stage 2 (3 months), 1, 2 to 3, 4 to 5, 6 to 7, and up to 8 to 10 years after placement. Table 2 presents the summary statistics for CBL over the study period. The median, mean, and 85th and 95th percentiles are shown in Fig 3. During the study period, the mean CBL increased from 0.06 mm at stage 2 to 0.44 mm at 8 to 10 years. The increase in standard deviation over time indicates that, at later stages of follow-up, CBL exhibited a greater variability, with a higher chance of showing extreme values. As shown in Table 2, CBL among 50% of implants (median) was stable at 0 mm throughout the study period. At 8 to 10 years, 15% of implants (85th percentile) exhibited a bone level above 1.02 mm, and only 5%

Table 3 Bone Loss Over the Study Period

Period	No. of pairs	Mean	95% CI ^a	P value ^b
Stage 2, 1 year	3,528	0.06	0.05, 0.08	< .01
1 year, 2–3 years	2,372	0.04	0.03, 0.06	< .01
2–3 years, 4–5 years	1,178	0.03	0.02, 0.05	< .01
4–5 years, 6–7 years	389	0.04	0.00, 0.09	.06
6–7 years, 8–10 years	170	0.06	0.00, 0.12	.06

^aBased on linear mixed model with patient identification as a random intercept effect.

^bTesting the null hypothesis that bone loss is equal to zero.

of implants (95th percentile) exhibited a bone level greater than 2.28 mm. Table 3 presents the mean and 95% confidence interval for bone loss, as opposed to CBL; bone loss was calculated between two successive time points. As shown in Table 3, greater bone loss occurred between stage 2 surgery and the first-year follow-up (mean = 0.06 mm, *P* < .01) and goes on with 0.03 to 0.04 mm (*P* < .01) between the next two time points until year 4. Afterward, bone loss was not significant (*P* = .06), which means that bone loss continued for only the first 4 to 5 years and then stabilized. Table 4 presents the frequency distribution of bone loss between two successive time points. With 1 mm as a threshold (green line), only 0.7%, 1.3%, 2.8%, and 1.2% of implants (above the green line in Table 4) exhibited bone loss greater than 1 mm during the first, second, third, and last interval, respectively.

Soft Tissue Scores at Implant and Patient Levels

Table 5 presents the incidence of BOP using IMI scores after the second year of follow-up. Figure 4 illustrates

Table 4 Bone Loss Frequency Distributions Over Time

Bone loss (mm)	Interval 1 1 to 2–3 years		Interval 2 2–3 to 4–5 years		Interval 3 4–5 to 6–7 years		Interval 4 6–7 to 8–10 years	
	Frequency	%	Frequency	%	Frequency	%	Frequency	%
≥ 2	4	0.2	6	0.5	2	0.5	2	1.2
1.5–1.99	3	0.1	3	0.3	3	0.8	—	—
1–1.49	10	0.4	6	0.5	6	1.5	—	—
0.5–0.99	67	2.8	31	2.6	10	2.66	4	2.4
0–0.49	2,148	90.6	1,025	87.2	310	79.9	157	92.4
–0.5–0.01	129	5.4	90	7.7	49	12.66	7	4.1
< –0.5	10	0.4	14	1.2	8	2.1	—	—
Total	2,371	100	1,175	100	388	100	170	100

Green line = 1-mm threshold.

Table 5 Implant Mucosal Index (IMI) Score by Follow-up Time at Implant and Patient Levels

Follow-up	IMI					Total
	No bleeding	Minimal, single point	Moderate, multipoint	Profuse, multipoint	Infection with suppuration	
2–3 years						
Implants	1,485 (64.1%)	571 (24.6%)	183 (7.9%)	52 (2.2%)	27 (1.2%)	n = 2,318
Patients	554 (53.55%)	319 (30.8%)	113 (10.9%)	32 (3.1%)	18 (1.7%)	k = 1,036
4–5 years						
Implants	714 (61.5%)	287 (24.7%)	102 (8.8%)	37 (3.2%)	21 (1.8%)	n = 1,161
Patients	257 (49.0%)	163 (31.0%)	66 (12.6%)	25 (4.8%)	14 (2.7%)	k = 525
6–7 years						
Implants	219 (56.7%)	98 (25.4%)	42 (10.9%)	14 (3.6%)	13 (3.4%)	n = 386
Patients	80 (43.0%)	56 (30.1%)	31 (16.7%)	10 (5.4%)	9 (4.8%)	k = 186
≥ 8 years						
Implants	96 (56.8%)	48 (28.4%)	14 (8.3%)	2 (1.2%)	9 (5.3%)	n = 169
Patients	33 (42.9%)	26 (33.8%)	12 (15.6%)	1 (1.3%)	5 (6.5%)	k = 77

n = number of implants; k = number of patients.

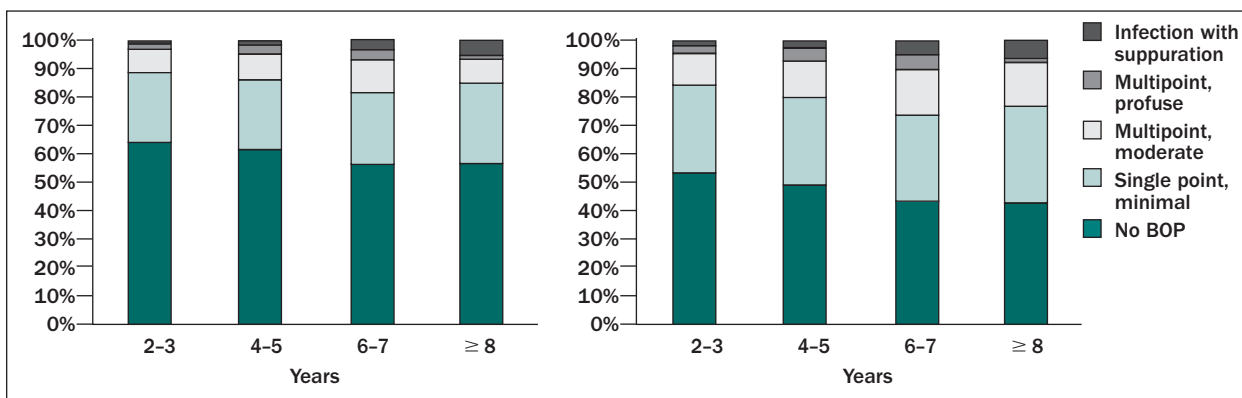


Fig 4 Implant Mucosal Index by follow-up time at implant (left) and patient (right) levels.

the same results at the implant level and patient levels. Table 5 shows that after 8 years, 56.8% of implants had no sign of bleeding (IMI = 0). At the patient level, only 42.9% of patients exhibited an optimal result, with no sign of bleeding among all implants. The incidence of infection with suppuration after 8 years was 5.3%

and 6.5% at the implant and patient levels, respectively. The incidence of IMI = 0 and IMI = 1 tended to decrease, while the top three IMI scores tended to become more prominent (Fig 4). For example, at the implant level, the prevalence of healthy implants with no sign of bleeding (IMI = 0) decreased from 64.1% at

Table 6 Mean Crestal Bone Level (mm) According to Implant Mucosal Index (IMI) Score and Time

IMI Score	Time (y)					
	0.25 (n = 3,406)	1 (n = 3,349)	2 (n = 2,318)	4 (n = 1,161)	6 (n = 386)	8.5 (n = 169)
No bleeding	0.05	0.10	0.12	0.14	0.21	0.27
Minimal, single point	0.07	0.14	0.16	0.19	0.31	0.26
Moderate, multipoint	0.11	0.26	0.27	0.33	0.55	0.85
Profuse, multipoint	0.13	0.37	0.48	0.71	0.69	0.50 ^a
Infection with suppuration	0.26	0.44	0.93	1.52	1.87	2.62

^aBased on two implants.

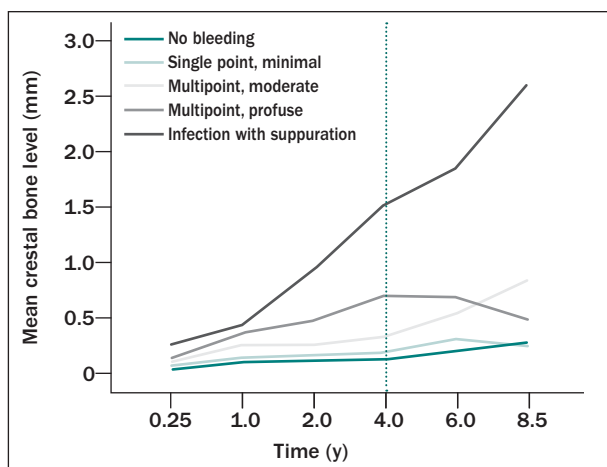


Fig 5 Bone-level profiles according to Implant Mucosal Index (IMI) score.

2 to 3 years to 56.8% after 8 years, while the incidence of infection with suppuration (IMI = 4) increased from 1.2% to 5.3%.

This comparison between implant- and patient-level data shows that the implant-level analysis underestimates the incidence of soft tissue inflammation around implants. During the study period, the incidence of the top three IMI scores was higher at the patient level, and no sign of bleeding (IMI = 0) was always lower at the patient level.

Relationship Between CBL and Soft Tissue Scores

Table 6 presents the mean CBL for each IMI score at each time point. The corresponding graph (Fig 5) illustrates the difference between mean CBLs over time around implants with different IMI scores. The mean CBL was very low—and overlapping—for IMI = 0 and IMI = 1 throughout the study period (Fig 5). CBL profiles for IMI = 2, 3, and 4 differ from each other, with a higher mean CBL and increasing slope over time. The highest mean bone levels were found around implants with infection and suppuration (IMI = 4) (1.52 mm, 1.87

Table 7 Relationship Between Implant Mucosal Index (IMI) Score and Crestal Bone Level Over Time

Parameter	Estimate	SE	P value
Time ^a	0.03	0.004	< .01
Single point ^b	0.06	0.02	.01
Multipoint, moderate ^b	0.27	0.03	< .01
Multipoint, profuse ^b	0.54	0.06	< .01
Infection with suppuration ^b	1.26	0.07	< .01
Single point × time	0.007	0.005	.17
Multipoint, moderate × time	0.05	0.008	< .01
Multipoint, profuse × time	0.10	0.01	< .01
Suppuration × time	0.30	0.02	< .01

^aTime centered to 4 years.

^bCompared with no bleeding on probing (IMI = 0).

mm, and 2.62 mm at 4, 6, and 8.5 years, respectively). Table 7 presents estimates for the relationship between IMI and CBL. At 4 years (vertical line in Fig 5), the difference between no bleeding and minimal, single-point bleeding (IMI = 1) is 0.06 mm, with borderline significance ($P = .01$). The difference increases to 0.27 mm, 0.54 mm, and 1.26 mm when no bleeding is compared with moderate, multipoint bleeding (IMI = 2); profuse, multipoint bleeding (IMI = 3); and infection with suppuration (IMI = 4), respectively. These differences are highly significant ($P < .01$). The interaction terms with time (Table 7) estimate the slope differences between profiles in Fig 5. According to this model, there is no significant difference between IMI = 0 and IMI = 1 ($P = .17$) with regard to bone-level slope, indicating that the bone loss rate does not differ between the first two IMI scores. However, the interaction is significant ($P < .01$) for the other IMI scores, indicating that bone loss occurs more rapidly in implants with moderate, multipoint bleeding; profuse, multipoint bleeding; and infection with suppuration compared with no bleeding.

DISCUSSION

In this study, the relationship between CBL and soft tissue inflammation scores was evaluated using a modified Mombelli Bleeding Index that included sup-puration (and utilized controlled force probing). This was a single-center, private practice study, so unlike university-based studies using pooled data with more stringent patient selection and follow-up, this study may better reflect the expected outcomes associated with the dental implant care in a real-world scenario.^{3,26} Though the study had a mean follow-up of about 3 years, the overall size of the cohort allowed for a relatively large sample of sites to be followed up for as long as 7 years ($n = 389$, which is similar to another retrospective study of implants with a similar SLA surface that reported survival rates of $> 98\%$).⁴³

Many factors can affect MBL, and in this cohort, the authors recorded various patient and implant factors that may have influenced MBL. For the purpose of this study of the relationship between the soft tissue condition (IMI) and CBL, the authors evaluated the entire cohort. Further analysis of the effects of various implant and patient factors on CBL is the subject of a future report.

Periapical radiographs are commonly used to evaluate bone level on implants in clinical practice. In this study, periapical radiographs with a proprietary parallel film holder were used because they allowed for a reasonable measurement of reliability within the limitations of daily practice. Sanz and Chapple⁴⁵ established that when using nonstandardized periapical radiographs, MBL greater than 1 mm is required to account for measurement error. Consequently, the authors used a 1-mm threshold for frequency analysis. This is comparable to the threshold level of 1.2 mm loss beyond the margin of the micro-rough surface (Straumann standard tissue-level implants) used in a study with a similar design.⁴³

Radiographic CBL was low, with a mean of < 0.2 mm over a 1- to 3-year period and remained low (< 0.5 mm) over the 5- to 10-year period for both tissue-level and bone-level designs. These findings are in agreement with those for similar micro-rough implants of either monotype transgingival design as well as the more recent platform-switch designs.^{14,15} There was a trend toward increased bone remodeling in the first year and toward more stable bone levels over time. These results confirm those of earlier reports of MBL around one- and two-stage dental implants.^{11,15}

Historically, mean values for bone loss have been presented, but a range of bone levels has been advocated to present the proportion of implants exhibiting continuous crestal bone loss.²⁶ For this reason, the authors included the 5% and 15% strata of implants

that lost the most bone and the median bone score. Despite the trend toward MBL over the first year, the median bone score remained at 0 mm for up to 7 years, indicating that a large number of implants did not lose any bone. In addition, the difference from the median to mean measure indicated a significant impact on average bone loss from a small group of outliers in this cohort. This effect was evaluated by looking at the 85th and 95th percentiles. Five percent of implants had more than 2 mm of bone loss by the latter half of the study (6 to 10 years). Despite this, the majority of implants did not continue to lose bone, with less than 3% of implants exhibiting more than 1 mm of bone loss. This finding suggests that bone loss was sporadic and did not progress over time. This pattern of sporadic loss is not unlike the reported pathogenesis for chronic periodontitis.⁴⁶ Furthermore, less than 3% of implants exhibited bone loss of more than 1 mm overall, which may reflect the recall and intervention strategies used in this study.

It has been shown that in the absence of other clinical symptoms, BOP around implants may be a weak indicator of ongoing or future loss of crestal bone,²⁶ and this may relate to the use of a binary analysis of bleeding versus no bleeding and the reported high false-positive bleeding score.²³ In this study, BOP was a common finding at the implant level, and it was never below 35% of sites over all time points. At the patient level, more than 45% of patients had some bleeding at one or more implants over all time points. That so many sites exhibited some BOP, albeit only light bleeding, is important with regard to studies that use bleeding as a reference to bone loss risk.^{27,28} A trend toward higher IMI scores over time was noted, suggesting that over the long term, peri-implant mucositis becomes more prominent.

Most studies associating bleeding with bone loss on implants have used a binary scale of bleeding and this may explain why both individual studies and reviews have found only weak or no correlation between bleeding and MBL.^{23,25–28,37} Recent studies have used a modified sulcus bleeding index with four categories,^{25,47} but other studies pooled results into a two-category scale, which may lose some of the benefit of a multiple ordinal scale.²⁹ The use of an ordinal scale with five categories may differentiate light, single-point bleeding from moderate and profuse bleeding, thus distinguishing false-positive bleeding from inflammatory-related bleeding. Over time, bone loss occurred more rapidly in implants with moderate BOP or profuse BOP, as well as in suppuration sites, than in implants with light or no BOP. In this study, MBL increased with higher IMI scores. Moreover, each increase in the IMI score was accompanied by an increase in expected bone loss when evaluated over time. However, time alone did not lead

to bone loss; the study findings suggest that bone loss may be related to inflammatory events.

Suppuration at dental implants warrants inclusion in an index. It is reported to be associated with progressive CBL and occurs with a prevalence of about 5% up to 10 years.^{26,40} Although the literature to date has treated suppuration as a separate entity rather than as a continuum of bleeding score,^{9,13,26,27,40} this study included suppuration in the IMI because inflamed pockets exhibiting heavy bleeding are potentially contaminated with similar periopathogens.^{30,33,34,38,39} Indeed, a recorded suppuration score was related to more bone loss, with a doubling of average bone loss at 4 years (IMI = 4) compared with profuse bleeding (IMI = 3).

The relatively high percentage of suppuration (IMI = 4), particularly in the latter part of this study, may be due in part to the sample. The recall schedule was set at 1, 3, and 5 years; after 5 years, recall appointments were less structured and included cases of large reconstruction, patients referred for treatment of new implant sites, or cases of complications with an existing implant.

Suppuration rates at 4 to 5 years—when patients were still on a regular recall schedule and the sample was large ($n = 1,178$)—remained relatively low at 1.8% at the implant level and 2.7% at the patient level. In contrast, suppuration rates at 6 to 8 years reached 3.4% at the implant level and 6.5% at the patient level. A suppuration rate of 5% to 6% at 8 to 10 years may not reflect the true infection rate because of the study design; nonetheless, a 10-year suppuration rate of 5% has been reported elsewhere.^{26,40} Although the difference in sample size from 1 to 5 years compared with 6 to 10 years represents a major limitation with respect to evaluating the interaction of bone loss and bleeding, the scenario is, nonetheless, typical of private practices in which patients who have not experienced complications may tend to drop out, whereas those with problems return, thus increasing the relative percentage of problematic cases. To the authors' knowledge, such findings have not been reported in the literature, but they could be instructive for large practices with regard to resource management.

Study Limitations

One limitation of this study is that the examiner and clinician who placed the implants is the same person (DF), so a potential bias is present. Furthermore, the examiner was not calibrated with respect to intra-examiner variability, so some range of error is present. Another limitation is that although IMI was evaluated at each recall appointment, only the highest score over all time points was recorded, whereas CBL was recorded at each recall. This was a limitation in the

design of the data recording system, but it was chosen at the outset of the study to reflect the possibility that inflammation at any of the follow-up recalls may relate to bone loss. Nonetheless, because bone loss tends to happen in one direction whereas the tissue condition can worsen or improve the relationship, evaluating the worst tissue condition with respect to CBL remains feasible. Future studies of similar design may benefit by having a separate score for CBL and bleeding at each interval.

Another limitation of this study is that probing pocket depth was not included. Although previous studies have used pocket depth as an indication of bone loss risk, it is subject to factors that may not be related to bone loss, including—but not limited to—soft tissue thickness, abutment height, and prosthetic design.³⁵ Consequently, probing depths are not easily compared between patients and are difficult to compare between studies. Nonetheless, probing depths > 5 mm have been reported as a potential risk factor for bone loss, and probing depth values are clinically useful as a means to evaluate progressive changes in a patient.^{27,35,39}

Finally, this was a clinical study that did not include histologic examination, which limits the ability to validate inclusion of suppuration in a modified index. Furthermore, the lack of histologic analysis restricts the ability to evaluate alternative explanations, such as implants as foreign bodies,⁴⁸ whereby a gradually developing immune reaction to a foreign body may have a similar relationship to inflammatory status and bone loss over time.

CONCLUSIONS

This retrospective cohort study with up to a 10-year follow-up evaluates CBL, soft tissue bleeding around implant sites, and the relationship between the two in a sample of 4,559 implants. The IMI, a modification of the sulcus bleeding index, was used to classify the peri-implant soft tissue condition.

Overall, there was a low mean CBL of 0.44 mm up to 10 years, and the median CBL was stable at 0 mm over the study's duration. However, at 8 to 10 years, 15% of patients exhibited a CBL > 1.02 mm and 5% exhibited a CBL > 2.28 mm; these changes had an impact on overall mean CBL. Bone loss, measured between two successive time points, was typically greatest between stage 2 surgery (3 months) and the first-year recall appointment (mean CBL = 0.06 mm, $P < .01$). Bone loss continued minimally and generally stabilized by 4 to 5 years.

Bleeding on probing was a common finding, with more than 40% of implants exhibiting some bleeding

during the study. Despite the high prevalence of bleeding, less than 3% of implants exhibited more than 1 mm of CBL over time, indicating that minor bleeding and time alone do not account for bone loss. The incidence of $IMI \geq 2$ tended to become more prominent, indicating that, over time, an increase in inflammatory events was found. A statistically significant relationship was found between inflammation and CBL; as IMI scores became higher, bone loss tended to be high and occur more rapidly. When comparing no bleeding ($IMI = 0$) with light, single-point bleeding ($IMI = 1$), no significant difference was observed with regard to CBL. On the other hand, a doubling of the mean CBL at 4 years was noted with each IMI score of 2 or greater, with a mean CBL of 0.33 mm, 0.71 mm, and 1.52 mm for $IMI = 2$, $IMI = 3$, and $IMI = 4$, respectively.

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