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ORIGINAL ARTICLE

Factors associated with the presence of peri-implant buccal soft tissue dehiscences: A case-control study

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Abstract

Background: To identify factors associated with the presence of buccal soft tissue dehiscences (BSTD).

Methods: This cross-sectional observational study assessed 52 cases (CAS) with a minimum of 24 months of loading, with the presence of a BSTD, defined as an exposure of the prosthetic abutment, the implant neck or the implant surface in the anterior maxillae or mandible (premolar-premolar) and 52 carefully selected controls (CON) matched for age and years in function, being the only difference between groups the BSTD. Clinical parameters and radiographic findings from periapical radiographs and Cone Beam Computed Tomographies (CBCT) were analyzed to assess their association with the occurrence of BSTD using a multivariate regression model.

Results: The CAS had a mean keratinzed mucosa (KM) of 1.65 ± 1.31 mm, whereas in the CON KM was 3.27 ± 1.28 mm ($P = 0.001$). Probing depths were similar in both groups, whereas bleeding on probing and plaque scores were higher in the CAS ($P = 0.001$). Mean bone level scores in the CAS were 1.71 ± 1.04 mm, and 1.27 ± 1.01 mm in CON ($P = 0.143$). The first bone to implant contact at the buccal aspect was 4.85 ± 3.12 mm in CAS and 2.15 ± 3.44 mm in CON ($P = 0.001$). CAS were 1.48 ± 0.93 mm outside the alveolar envelope, whereas the CON were 0.46 ± 0.77 mm. Implants buccally positioned in the CBCT's were 34 times more likely to belong to the case group. The presence of >2 mm of KM at the time of evaluation, presence of adjacent natural teeth, cemented restorations and two-piece implants were protective factors.

Conclusion: The bucco-palatal implant position was the most relevant factor related to the presence of BSTD.

KEYWORDS

buccal mucosa, case-control studies, dental implants, esthetics

1 | INTRODUCTION

Localized gingival recessions around teeth have been defined as the apical migration of the gingival margin beyond the cemento-enamel junction (CEJ) exposing the root surface.[1,2] The diagnosis of these gingival recessions is, therefore, based on the exposure of the root surface occurring more frequently in adults, having a tendency to increase with age

and affecting populations with both low and high standards of oral hygiene.[3] Although the etiology of gingival recession is multifactorial, buccal gingival recessions around teeth have mostly a traumatic etiologic component in susceptible anatomic conditions. [4,5]

Localized mucosal lesions around dental implants can also occur, in spite of the high predictability and long-term survival of this medical device used to restore the lost natural dentition.[6-8] This condition around dental implants is termed buccal soft tissue dehiscence (BSTD) and it is characterized by the presence of a mucosal cleft that exposes the implant shoulder, prosthetic abutment or implant surface jeopardizing the maintenance and appearance of the peri-implant tissues. [9] The diagnosis of BSTD around implants is certainly more challenging because of the absence of a fixed landmark, as the CEJ around teeth. Similarly, BSTD refer to healthy or mucositis implants and are considered different from clinical scenarios where the migration of the gingival margin occurs secondary to peri-implantitis.

Prospective studies have shown that the apical displacement of the peri-implant soft tissue margin may occur after the delivery of the prosthetic reconstruction, particularly in the lingual and palatal aspects of both mandibular and maxillary reconstructions, respectively.[10,11] When this finding occurs in the buccal aspect, the aesthetic implications may be more significant. In a prospective study evaluating implants in the aesthetic zone,[12] mid-facial recession has been reported to average from 0.28 and 0.53 mm at 1 and 5 years, respectively. At 5 years, three out of 17 implants (17.64%) demonstrated advanced mid-facial recession (>1 mm).

Several factors have been reported to influence the position of the facial mucosal margin, among them the peri-implant soft tissue thickness, the facial bone crest, the implant position and angle, the interproximal bone crest level, the depth of implant platform or the level of the first bone to implant contact.[13] Also, the height of the keratinized mucosa has been associated with the development of soft tissue deficiencies, particularly in the lingual aspect of the mandible.[14]

Nevertheless, the relative importance of each of these factors associated with the presence of BSTD is not well understood and therefore, there are no clear guidelines on their prevention and treatment of this condition. Further, some of the key factors that may influence the development of BSTD cannot be evaluated prospectively in clinical trials because of ethical reasons, and hence, indirect information retrieved from lower levels of evidence such as case-control studies can be useful. It was, therefore, the objective of the present investigation to analyze, in patients with presence of BSTD, compared with a matched control group, the factors that may be potentially associated with this condition.

2 | MATERIAL AND METHODS

The present investigation was designed as an observational cross-sectional case-control study evaluating clinical and radiographical variables that could be associated with the presence of BSTD. Patients were included in the study once they were informed about the investigation procedures and gave their written informed consent. The procedures in this study were in accordance with the Declaration of Helsinki, as revised in 2013 and the study protocol was approved by the local ethics committee (CEICE1909).

2.1 | Sample selection

Patients who had undergone implant therapy and restorative treatment in a single specialist private clinic in Bilbao (Spain) and were currently attending a periodontal/implant maintenance care program were recruited for the present investigation. Patient recruitment was conducted from April 2015 to May 2019. Each patient contributed with one implant to the study. All implants were placed by two experienced surgeons and belonged to one implant brand, either with a one-piece* or a two-piece implant design.†

Implants with a two-piece design were restored with an intermediate prosthetic abutment. Inclusion criteria were male or female patients with ≥20 years of age with one implant with healthy or mucositis peri-implant tissue that had been restored with fixed prosthetic restorations and in function for a minimum of 24 months. Implants were only included if they were placed in the anterior and premolar areas of both maxilla and mandible. In patients who had more than one implant meeting the inclusion criteria, one of the implants was randomly selected and included in the study.

The exclusion criteria were the following:

1. implants diagnosed or treated for peri-implantitis[15];
2. BSTD caused by surgical or post-surgical complications as documented in the clinical chart or by over contoured prosthetic designs;
3. implants placed supracrestally (radiographically documented);
4. previous mucogingival surgery attempting to cover the BSTD;
5. patients who did not have periapical radiographs and a CBCT taken (for reasons other than the present study) within the last 12 months prior to the study visit;

* Tissue Level Standard or Standard Plus, Institute Straumann, Basel, Switzerland.

† Bone Level, Institute Straumann, Basel, Switzerland.

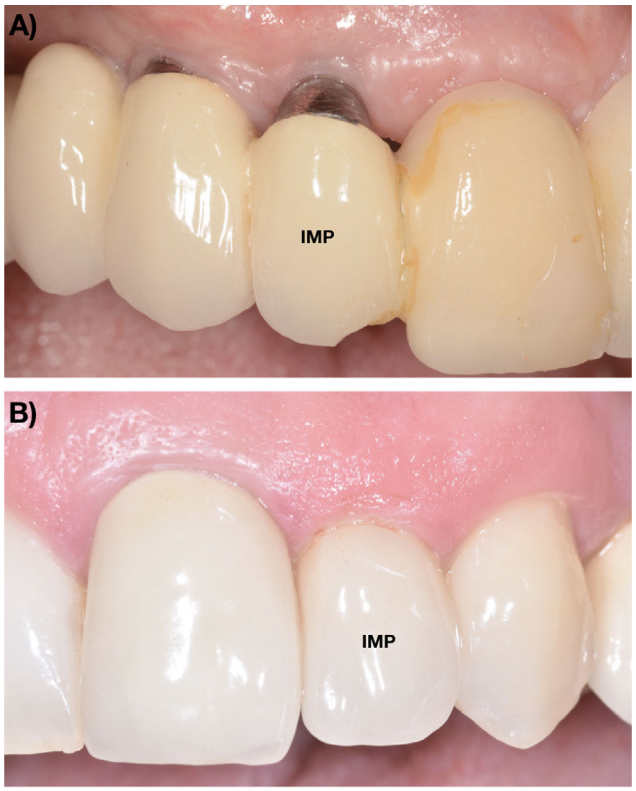

FIGURE 1 Clinical images of the case group (**A**) and control group (**B**)

6. patients with implants presenting elongated crowns when compared to the adjacent natural teeth or prosthetic restorations, which may have indicated an apical migration of the buccal soft tissue;
7. patients with untreated oral conditions such as active periodontitis or caries;
8. patients with untreated endocrine disorders, neoplastic diseases, history of radiation therapy, immunodeficiency syndromes, alcoholism, or drug abuse or any particular conditions that may influence the development of BSTD.

2.2 | Case definition

In the case group (CAS), BSTD were defined as implants that presented an exposure of the prosthetic abutment or the implant neck with or without exposure of the implant treated surface because of a deficient buccal peri-implant soft tissue (Figure 1A).

2.3 | Controls

The control group (CON) consisted of implants with the prosthetic abutments and implant neck covered with peri-implant soft tissues. These implants had been placed by the same specialists in the same center and under the same restorative conditions. All patients in the CON were selected and matched with the CAS for age (±3 years) and for follow-up (±1 year) (Figure 1B).

2.4 | Clinical measurements

All clinical and radiographic measurements were taken in a single visit by one single evaluator (ER). The following parameters were registered using a manual periodontal probe[‡]: keratinized mucosa height at the mid-buccal site (KM), peri-implant probing depth (PD), plaque index (PI) (presence/absence), bleeding on probing (BOP) (presence/absence) all registered in six sites per implant. Finally, the exposure of the prosthetic abutment, implant neck or implant surface was also measured and registered dichotomously.

2.5 | Radiographic measurements

The interproximal bone levels were recorded on periapical radiographs by measuring the distance from the implant shoulder to the first visible bone to implant contact (DIB) at the mesial and distal aspect of each implant. The mean DIB values were calculated by averaging the mesial and distal values. All measurements were performed by means of a computer image analysis software[§] once the radiograph was calibrated using the known distance between implant threads or the implant diameter.

Cone-beam computed tomographies (CBCT)[**] were also analyzed (Figure 2). The mesio-distal center of the studied implants in the cross-sectional views (bucco-lingual) was selected. Then, the images were exported to an image analysis software and were calibrated with a reference in mm (Image J). Linear measurements were performed to assess the distance from the implant shoulder to the first bone to implant contact at the buccal aspect (fBIC). For the one-piece implants the height of the polished collar was subtracted to the value obtained to calculate the dimensions of the exposed implant surface. Moreover, utilizing the same software in the selected cross-sectional view of the CBCT, the angulation of the implants in the maxillae and mandible (Mx angle, Md angle) were also assessed by drawing a line perpendicular to the occlusal plane and another line that followed the inclination of the body of the implant.

Lastly, the millimeters of implant outside the alveolar envelope were also analyzed. For this purpose the most buccal and coronal point of the buccal bone was identified, from this point a line was drawn perpendicular to the occlusal plane that crossed the horizontal line formed by the shoulder of the

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[§] Image J. National Institutes of Health [NIH], Bethesda, MD.

[**] i-CAT Classic, Imaging Sciences International, Hatfield, PA.

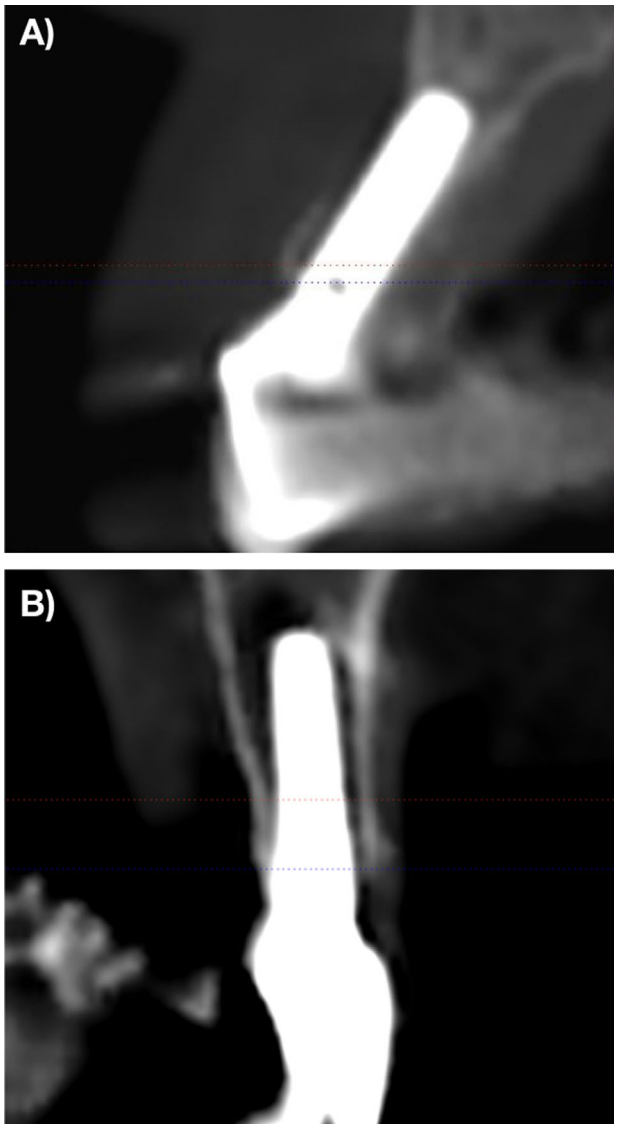

FIGURE 2 Three-dimensional images from the patients presented in Figure 1. (**A**) Corresponds to the case group and (**B**) to the control group

implant. From the point of intersection of these two lines, the distance to the most buccal aspect of the implant shoulder or implant abutment was calculated. This distance in mm was considered the amount of implant outside the alveolar envelope (Figure 3).

2.6 | Method validation and examine calibration

Radiographs and CBCT images were analyzed independently by two calibrated examiners (ISM and ER). Intra-examiner and inter-examiner reproducibility were assessed by evaluating 10 random radiographic and CBCT images. The examiners were masked and did not know whether the implants analyzed belonged to either the control or case group.

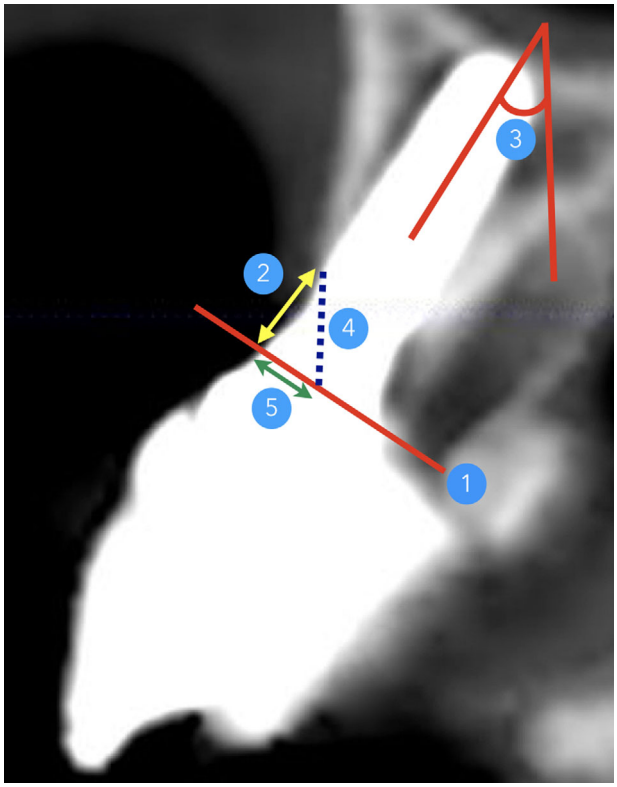

FIGURE 3 Schematic representation of the measurements taken in the CBCT images. 1; horizontal line joining the buccal and palatal aspects of the implant shoulder, 2; distance from the previous horizontal line to the fBIC (yellow arrow), 3; angulation of the implant, 4; line taken from the most coronal and buccal point of the buccal bone to number 1, 5; mm outside the alveolar envelope calculated by the distance from the intersection of 1 and 4 to the most buccal aspect of the implant platform or abutment (green arrow)

2.7 | Sample size calculation

Utilizing a statistical software,[††] 62 cases and 62 controls were necessary to detect a standardized difference in the keratinized mucosa (primary outcome) of 0.5 mm with a standard deviation of 0.5 mm based on the longitudinal assessment made by Bengazi et al.[11] The power was set at 80% and an alpha error at 5%.

2.8 | Statistical analysis

Descriptive statistics (means, standard deviations) of the continuous and categorical variables were analyzed using a statistical software program[‡‡] (SPSS Version 25.0, IBM Corporation, Chicago, IL). The patient was considered the statistical unit. The data were tested for normality by means of a Shapiro–Walk test. Demographic, clinical, and radiographic variables were analyzed and compared between both groups.

[††] Sample Power 2.0. SPSS Inc., Chicago, IL.

[‡‡] SPSS Version 25.0, IBM Corporation, Chicago, IL.

A Mann–Whitney *U* test was used for the continuous variables whereas the Chi-square test was used for the categorical variables.

A multivariate logistic regression model was constructed to determine the effect of the KM, the position of the implant (mm out of bone), the type of implant (one-piece, two-piece), the influence of the presence of neighboring teeth, the fBIC and the type of restoration (cemented versus screw retained). Additionally, a multiple linear regression model was constructed to determine the effect of the previously mentioned variables on the dimensions of the BSTD. To assess inter-examiner and intra-examiner agreement, the intra-class correlation coefficient (ICC) was calculated. Statistical significance was set at the alpha level of 0.05.

3 | RESULTS

One hundred and twenty-four patients were initially included. A total of 10 patients were excluded in each group and finally a total of 104 patients were included; 52 patients belonging to CAS and 52 patients belonging to CON. The reasons for exclusion were (1) position of the implant platform considered too coronal in the periapical radiographs ($n = 8$), (2) implant crown appearing elongated in spite of no exposure of prosthetic components in clinical photographs ($n = 8$), (3) unable to perform linear measurements in the periapical radiographs ($n = 4$).

The patients in the control group had a mean age of 68.25 ± 9.1 years, whereas the CAS had a mean age of 66.19 ± 9.09 years. The years of loading of the implants were 11.04 ± 5.35 years for the CON and 11.15 ± 4.81 years for the CAS. No significant differences were observed between the CAS and CON in terms of age and years of loading ($P = 0.253$ and 0.914, respectively). The sample in the control group consisted of 34 women and 17 men whereas in the CAS the sample consisted of 41 women and 11 men ($P = 0.189$). Patients were systemically healthy. In the control group, three patients were mild smokers (<10 cigarettes/day) whereas in the CAS there were nine mild smokers ($P = 0.061$).

No significant differences were observed in terms of the type of restoration between both groups; 30 patients presented cemented restorations in the control group whereas, 31 patients had cemented restorations in the case group ($P = 0.500$). Similarly no differences were observed with regard to the diameter of the implants ($P = 0.160$). In the CON group 29 implants were located in the maxillae whereas 36 were placed in the CAS group. These differences, however, were no statistically significant ($P = 0.105$). Nevertheless, differences were found with regard to the type of implant because the control group had 34 one-piece implants, whereas the case group had 45 one-piece implants ($P = 0.010$).

TABLE 1 Clinical parameters in the case and control groups

Variables	Control ($n = 52$)	Case ($n = 52$)	*P*
Keratinized mucosa	3.27 ± 1.28	1.65 ± 1.31	<0.001
Peri-implant probing depth	2.65 ± 0.73	2.88 ± 0.94	0.258
Plaque index	0.08 ± 0.73	0.48 ± 0.50	<0.001
Bleeding on probing	0.12 ± 0.32	0.47 ± 0.45	<0.001

TABLE 2 Radiographic parameters in the case and control groups

Variables	Control ($n = 52$)	Case ($n = 52$)	*P*
DIB mean	1.27 ± 1.01	1.71 ± 1.04	0.143
fBIC	2.15 ± 3.44	4.85 ± 3.12	<0.001
mm out of bone	0.46 ± 0.77	1.48 ± 0.93	<0.001
Mx angle	7.54 ± 7.87	14.04 ± 12.96	0.042
Md angle	3.93 ± 5.54	5.17 ± 7.03	0.589

DIB, distance from implant shoulder to first bone to implant contact in periapical radiographs; fBIC, buccal first bone to implant contact in CBCT images; Mx, maxillar; Md, mandible.

3.1 | Clinical measurements

The mean dimension of the BSTD in the case group was 2.09 ± 0.79 mm. The CAS had a mean KM of 1.65 ± 1.31 mm, whereas CON had a mean of 3.27 ± 1.28 mm ($P < 0.001$). PD was similar in both groups; 2.88 ± 0.94 in the CAS and 2.65 ± 0.73 mm in the CON ($P = 0.258$). The PI values were 0.48 ± 0.50 in the CAS and 0.08 ± 0.73 in the CON ($P < 0.001$), whereas the BOP values were 0.47 ± 0.45 in the CAS and 0.12 ± 0.32 in the CON ($P < 0.001$) (Table 1).

3.2 | Radiographic measurements

The inter-examiner and intra-examiner comparisons showed generally high ICC values for DIB values, fBIC and mm outside of the alveolar envelope (DIB ≥ 0.82 and > 0.87, inter and intra, respectively, fBIC ≥ 0.88 and >0.90, and mm outside the alveolar envelope ≥ 0.85 and >0.84). The mean DIB values were 1.71 ± 1.04 mm and 1.27 ± 1.01 mm for CAS and CON, respectively, without statistically significant differences ($P = 0.143$).

The fBIC was located significantly more apically in the case group (4.85 ± 3.12 mm versus 2.15 ± 3.44 mm). With regard to bucco-palatal position of the fixtures, the implants in the test group were significantly further outside the alveolar envelope and more buccally tilted (only in the maxilla) (Table 2).

Table 3 depicts the results from the multivariate logistic regression analysis showing that the implant position (i.e., mm out of bone) was an independent risk indicator for BSTD. Patients with implants that were >1 mm outside the alveolar enveloped were more likely to belong to the case group (odds

TABLE 3 Effect of the variables on the presence or absence of buccal soft tissue dehiscence

Variables	B(SE)	OR (CI 95%)	*P*
KM			
≤2	Ref.		
>2	−2.89 (0.87)	0.06 (0.01 – 0.30)	0.001
mm OUT bone			
<1	Ref.		
>1	3.55 (0.87)	34.65 (6.31 – 90.31)	< 0.001
One-piece IMP			
No	Ref.		
Yes	2.48 (1.08)	11.89 (1.43 – 39.00)	0.022
Single IMP			
No	Ref.		
Yes	−1.52 (1.06)	0.22 (0.03 – 1.74)	0.150
fBIC	0.20 (0.12)	1.23 (0.98 – 1.54)	0.075
Cemented			
No	Ref.		
Yes	−1.45 (0.87)	0.23 (0.04 – 1.29)	0.095

Ref., Reference; B, regression coefficient; SE, standard error; OR, odds ratio; CI, confidence intervals; KM, keratinized mucosa; IMP, implants; fBIC, buccal first bone to implant contact in CBCT images.

TABLE 4 Influence of the variables on the dimensions of the buccal dehiscence

Variables	*B (SE)*	P
KM	−0.36 (0.06)	<0.001
mm OUT bone	0.29 (0.11)	0.009
One-piece IMP (Yes vs. No)	0.32 (0.23)	0.169
Single IMP (Yes vs. No)	−0.31 (0.23)	0.187
Cemented (Yes vs. No)	0.05 (0.2)	0.796
fBIC	0.07 (0.03)	0.024

B, regression coefficient; SE, standard error; KM, keratinized mucosa; IMP, implants; fBIC, buccal first bone to implant contact in CBCT images.

ratio [OR] = 34.65, $P \leq 0.001$), after adjusting for other risk factors. Similarly, patients with one-piece implants were more likely to belong to the case group (OR = 11.89, $P = 0.022$). On the contrary, the apico-coronal height of KM appeared to be a protective factor against the presence of BSTD (OR = 0.06, $P = 0.001$). The position of the buccal bone (fBIC) did not significantly influence the presence of BSTD (OR = 1.23, $P = 0.075$), whereas implants with adjacent natural teeth and with cemented restorations did not have a significant influence (OR = 0.22, $P = 0.15$ and OR = 0.23, $P = 0.095$, respectively). The accuracy of this regression model, determined by the area under the ROC curve of the model, was 81.67%.

Table 4 depicts the results of the multiple linear regression analysis showing that the height of the KM had a significant negative influence on the magnitude of the BSTD. For every increase in one millimeter of the KM height, the dimension of the BSTD was reduced 0.36 mm. On the contrary, every mm that the implants were found to be located outside the alveolar envelope, the dimensions of the BSTD increased 0.29 mm. Also the fBIC had a statistically significant impact; for every increase of 1 mm in the distance between the implant shoulder to the first bone to implant contact, the dimensions of the BSTD increased 0.07 mm. This multiple linear regression model could explain 57% of the severity of the BSTD by the variables analyzed (adjusted $R^2 = 0.51$, $P < 0.001$).

4 | DISCUSSION

The results of the present observational study have shown a significant association between the implant position and the presence of BSTD. Implants located outside the alveolar envelope were 34 times more likely to be present in the case group as opposed to the control group and this association was independent from other studied variables. On the other hand, the presence of at least 2 mm of keratinized mucosa at the time of the evaluation appeared to be a protective factor (OR = 0.06).

The importance of the bucco-lingual position of the implant has been previously reported by other authors.[16-19] Cosyn et al. described an association between midfacial recession and a buccal implant shoulder position with an odds ratio of 17.2.[20] The buccal positioning of the implant will also imply a buccal positioning of the transmucosal components leaving limited space for the soft tissue, which is forced to migrate apically.

The protective nature of the KM noted in the present investigation does not allow us to suggest minimal KM dimensions to avoid the occurrence of BSTD, taking the cross-sectional nature of the study. In fact, the values of KM in the CAS recorded at the study visit are likely different from those at crown delivery because buccal soft tissue dehiscences around implants have been reported to occur through a reduction of KM and a reduction of PD in a prospective study[11] and therefore it is feasible that the KM had greater dimensions in the case group at loading.

With regard to the other clinical parameters, our results showed no differences between groups in PPD and DIB, although patients with BSTD had higher BOP and plaque scores indicating that the exposure of the implant surface or implant neck may have negative consequences for the maintenance of peri-implant health.

Concerning the importance of buccal bone, its influence on the development of BSTD is currently not well understood. The present investigation found that the position of the fBIC was significantly different between groups (CAS = 4.85 mm versus CON = 2.15 mm), although the measurement of association did not reach statistically significance. In fact, CON presented a relatively high fBIC and large standard deviations, thus confirming that some of the implants in this group presented bone dehiscences without the presence of BSTD. This

finding is in agreement with those reported by Veltri et al.[21] who evaluated 12 single implants placed in the maxillary incisor region where no bone augmentation was performed in spite of the presence of a bone dehiscences at implant placement. Nine-year post-operatively, the CBCT results showed all the implants had bone dehiscences (mean 3.8 mm), without BSTD and with presence of acceptable and stable pink aesthetic scores. Moreover, in a recently published randomized clinical trial,[22] single implants were placed prosthetically driven in deficient ridges and bone dehiscences (<5 mm) occurred at placement. Patients were randomized to guided bone regeneration (GBR) or spontaneous healing. At the reentry procedure the augmentation group showed bone regeneration with an improved defect height whereas in the spontaneous group the bone dehiscence remained. Interestingly, at the 18-month follow-up, no significant differences were observed between both groups with regard to the position of the mucosal margin.

These findings indicate that when implants are located within the alveolar process the presence of buccal bone dehiscence may have a lesser impact in the development of BSTD. Conversely, when implants were located outside the alveolar envelope in the present study, the position of the buccal bone was displaced even more apically, together with the concomitant displacement of the soft tissues. These factors have been similarly associated with the development of localized gingival recessions around teeth.[23] The combination of buccally placed implants and buccal bone dehiscences was shown to affect the positioning of the peri-implant soft tissues in a recently published experimental investigation where titanium and zirconia implants were placed outside the alveolar envelope and buccal bone dehiscence defects were created. Six months after loading, implants presented significant loss of peri-implant mucosal height and dimensions.[24]

Among the other factors that were associated with BSTD, one-piece implants were more likely to have BSTD. Clinical studies have shown greater apical soft tissue displacement for one-piece implants when compared to two-piece implants because of the lack of control on the dimensions of the transgingival component at one-piece implants.[25] The findings of the present investigation, however, may be influenced by the greater number of one-piece implants in the case group and by the fact that elongated crowns in two-piece implants, which may have in fact been BSTD, were not included to avoid the inclusion of false positives.

The presence of adjacent natural teeth and cemented restorations appeared to have a protective effect against BSTD as indicated by their low ORs, although the measurement of association did not statistical significance. This may be explained by the fact that cemented restorations allow the utilization of angled abutments, which may compensate buccally angled or positioned implants, therefore exerting less pressure over the buccal soft tissues with the prosthetic restorations.

The results of the present study must be interpreted with caution because this is not a prospective study and hence, some of the factors evaluated may have developed after implant placement. Furthermore, the initial number of patients planned to achieve the foreseen potency was not fulfilled. Finally, it must be taken into account that the assessment of the integrity and thickness of the buccal bone plate by means of CBCT has shown to underestimate its dimensions and there is a minimum threshold for detection beyond which, the absence of buccal bone plate does not mean that it does not exist.[26,27]

Nonetheless, this investigation has demonstrated a direct association between the orofacial implant position and the presence of BSTD underlying the clinical relevance of adequate implant position for the stability of the buccal mucosal margin. Clinicians should therefore be aware of the benefits of utilizing surgical guides to facilitate adequate placement. Finally, future studies evaluating the changes in the position of the gingival margin around implants may benefit from assessing the bucco-palatal position of the implants.

5 | CONCLUSIONS

Taking into consideration the limitations addressed, this case-control investigation has showed that implants located outside the alveolar envelope of bone and one-piece implants were more likely to present buccal soft tissue deficiencies, whereas implants with >2 mm of keratinized mucosa at the time of evaluation were less likely to present buccal soft tissue deficiencies. Lastly, implants with buccal soft tissue deficiencies had greater bleeding on probing and plaque scores.

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CONFLICTS OF INTEREST

This study was self-founded and the authors report no conflict of interest.

AUTHORSHIP

Ignacio Sanz-Martín: Conception or design of the work; drafting manuscript. Erik Regidor: acquisition of data. Jordi Navarro: analysis of data. Ignacio Sanz-Sánchez: Conception or design of the work; drafting manuscript. Mariano Sanz: data interpretation, revision manuscript. Alberto Ortiz-Vigón: Conception or design of the work; drafting manuscript.

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