



Clinical and Radiological Retrospective Multicenter Analysis on 864 Implants with more than 10 Years Follow-up

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DOI: 10.31080/ASDS.2020.04.0884

Received: June 11, 2020

Published: July 22, 2020

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Abstract

Introduction: The use of dental implants is a widely accepted treatment modality for fully and partially edentulous patients. The beginning of the year 2000 brought the development of moderately rough implant surfaces and macro-designs that are nowadays considered to represent the gold standard for implant treatment. The purpose of this retrospective cohort study was to present long-term data more than 10 years, on survival rate, marginal bone level changes and peri-implant soft tissue healthy status of 709 patients with 864 dental implants in fully and partially edentulous cases.

Material and Methods: The aim of this retrospective open cohort study was to show long-term survival data, and evaluation of several covariates such as marginal bone level changes, peri-implant soft tissue status monitored on 864 dental implants.

Patients who underwent dental implant surgery between January 2003 and September 2008, were investigated. A total of 709 patients treated in 3 different private practices. All the implants were loaded with fixed metal-ceramic or zirconium-ceramic crowns. No removable prostheses were included. X rays and clinical examinations were performed at baseline and yearly for each follow-up visit. Marginal bone level (MBL), Probing Pocket Depth (PPD), Bleeding on Probing (BOP) were assessed.

Results: During the study period there were 9 implant failures (0,9%) and 3 patients (with 7 implants) were drop-outs. The final implant survival rate was of 98% after more than 10 years of follow-up. Considering BOP at the last control visit, 210 implants were positive (24%), 635 (74,5%) negative and 10 (1,5%) was diagnosed with peri-implantitis. The median PPD for implants with negative BOP was of 3.04 mm while for the implants with positive BOP, with presence of mucositis, the median PPD was 3,75mm. For the implants with peri-implantitis the mean value was 5.1mm.

Conclusion: Within the limitation of this study, a low rate of failures and incidence of peri-implantitis was recorded. No relation is present between the failure of the implants and the loading protocols: implants placed immediately or delayed after tooth extraction show similar survival rates and peri-implant marginal bone resorption.

Keywords: Dental Implant; Long Term Follow Up; Bleeding on Probing; Marginal Bone Level

Abbreviations

PPD: Probing Pocket Depth; MBL: Marginal Bone Level.

Introduction

The use of dental implants is a widely accepted treatment modality for fully and partially edentulous patients. The success of this approach is related to the inherent ability of some dental materials, titanium in particular, to osseointegrate, which means creating direct bone-to-implant contact [1]. Further improvements toward the successful osseointegration of dental implants have involved modifications to both surface topography and surface chemistry [2,3]. The beginning of the year 2000 brought the development of moderately rough implant surfaces and macro-designs that are nowadays considered to represent the gold standard for implant treatment. In recent years, an increasing number of papers have reported on the long-term results of these types of implants [4,5]. The survival rate of dental implants has been reported to be quite high, often more than 90%, particularly up to the 5-year mark [6]. Long-term survival data over 5 years, however, is required to better assess the safe and predictable use of dental implants.

A few studies have reported long-term results [7-9], showing more favorable survival statistics for solid screws over hollow cylinder implants, for mandibular sites over maxillary, and lower survival statistics for patients presenting with a history of periodontitis [10].

The purpose of this retrospective cohort study was to present long-term data on survival rate, marginal bone level changes and peri-implant soft tissue healthy status of 709 patients with 864 dental implants (Xive, Dentsply Sirona Implants, Hanau, Germany) in fully and partially edentulous cases placed between January 2003 to September 2008 in 3 private practice. Numerous variables were evaluated for impact on survival, including implant insertion and loading and bone quality at the site of implant insertion. Additionally the soft tissues were evaluated, considering Bleeding on Probing (BOP) and Probing Pocket Depth (PPD) and their influence on implant survival rate.

Materials and Methods

Study design

This retrospective cohort study consisted of 709 patients with 864 Xive implants (Dentsply Sirona Implants, Hanau, Germany) placed in fully and partially edentulous patients between January

2003 and September 2008. The observation included 366 males and 343 females with a mean age of 56 years (ranging from 20 to 92 years). The patients were treated in 3 different private practices in Italy by 3 oral surgeons skilled in implantology. Restorations and yearly re-evaluations year by year were performed by the same oral surgeon who placed the implants.

The study was designed and conducted in full accordance with the ethical principles for medical research involving human subjects published in the year 2000 5th revision of World Medical Association Declaration of Helsinki.

All patients signed a specific written informed consent form and the study design was approved by the Ethics Committee of The University of Insubria (Varese, Italy).

The inclusion criteria were the presence of totally or partially edentulous sites, no alcohol or drugs dependence, total absence of active periodontal disease, non-smoker or < 10 cigarettes/day, good oral hygiene, and the absence of systemic disease that could compromise osseointegration such as untreated diabetes or radiation therapy in the craniofacial region within the previous 5 years.

Implants were placed using open flap surgery except for immediate placement in extraction sockets, which were carried out flapless. In sites of an atrophic mature ridge that required bone graft, particulate grafting with membrane was performed at the time of implant placement using autogenous bone, bovine xenograft (Geistlich Pharma, Wolhusen, Switzerland) or combinations with an ePTFE (Gore Tex, Flagstaff, USA) or collagen membrane (Geistlich Pharma, Wolhusen, Switzerland).

No sinus lift procedures were used in this study.

Loading protocols varied according to individual case were separated into two categories; immediate loading (within 48h after the implants placement) or conventional loading (3-6 months after implant placement). X rays and clinical examinations were performed at baseline (delivery of prosthetic reconstruction) and yearly for each follow-up visit. X-rays were taken using parallel-ray and Rinn-centering technique (XCP Device Dentsply Rinn).

Maintenance care was performed by a dental hygienist every 6 months. The following periodontal and radiological parameters were assessed:

- Bleeding on Probing (BOP) was assessed by inserting a periodontal probe to the bottom of the gingival pocket. If bleeding was proved by this instrument, the examined site was considered inflamed. BOP positivity was defined as “mucositis”, while probing pocket depth (PPD) ≥ 4 mm with bleeding or pus was defined as “peri-implantitis”. Presence/absence of suppuration was taken by manual palpation of the buccal and palatal tissue.
- Probing Pocket Depth (PPD) was measured with a periodontal probe to the nearest millimeter at four sites around the dental implant. The highest, most unfavorable, value was registered.
- Marginal Bone Level (MBL) was measured on periapical radiographs as the distance between the implant shoulder and the first bone-to-implant contact at the 10 years control.

Statistical methods

Statistical analyses were performed with SPSS21.0 software to evaluate basic univariate statistics and graphs, and multivariate analyses. In particular, box plots and clustered bar histograms have been used for representing descriptively the distributions. Pearson Chi Square test was used to evaluate association between qualitative variables. Survival was described by means of Kaplan-Meier plots. A first type error probability at 0.05 was considered significant. The methodology was reviewed by an independent statistician.

Results

The study cohort consisted of 709 patients and 864 implants. The observation includes 366 male and 343 female with a mean age of 56 years (ranging from 20 to 92).

The patients were treated with Xive implants with a diameter 3.0mm, 3.4mm, 3.8mm, 4.5-mm or 5.5mm. Implants with lengths from 8.0 mm to 15.0 mm were used. The fixture/abutment connection of this system is an internal connection (cylinder-hexagon-cylinder) with a switch-platform design. The implants were placed according to the manufacturer guidelines and used for approved indications. The distribution of implant length and diameter is shown in figure 1.

Implants, were distributed as follows (irrespective of dimension and length): n = 143 (16,5%) in the anterior maxilla, n = 352 (40,7%) in the posterior maxilla, n = 55 (6,3%) in the anterior mandible and n = 324 (37,5%) in the posterior mandible. Position were

defined according to Buser, *et al.* [7] whereby the anterior maxilla included FDI positions 13-23, the anterior mandible included 34-44.

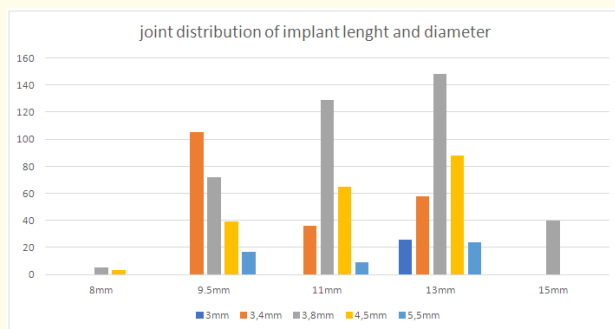


Figure 1: Implant length distribution over different implant diameters.

501 (57,9%) implants were inserted in the native bone, 147 (17%) were post-extractive implants with immediate loading (this was an immediate function without any contact in dynamic or static occlusion) and 216 (25%) required different techniques of bone graft (Figure 2).

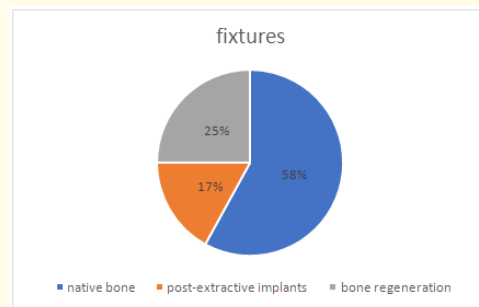


Figure 2: Implants distribution in different implant sites.

All the implants were loaded with fixed metal-ceramic, metal-resin or zirconium-ceramic crowns, from single-unit to full-arch fixed bridges. No removable prostheses were included.

The total number of implants under analysis were 855, with at least 10 years of follow-up.

During the study period there were 9 implant failures (0,9%): 3 of them occurred before the loading and 6 after loading (1 implant failure after 10 years, 1 after 11 years, 2 after 12 years and 2 after 13 years respectively). At the patient level, 4 patients who experienced at least one implant failure (1%), while 3 patients (with 7 implants) were lost to follow-up.

An implant failure was defined as an event leading to the loss of the implant or the need to remove the implant itself [11-16]. Table 1 shows the analysis of the implant under the failure risk by year.

Time	Implants	Failures	Drop out	Surv_rate
0-1 years	855	0	0	100
1-2 years	855	0	0	100
2-3 years	855	0	0	100
3-4 years	855	0	0	100
4-5 years	855	0	0	100
5-6 years	855	0	0	100
6-7 years	855	0	0	100
7-8 years	855	0	0	100
8-9 years	855	0	0	100
9-10 years	855	1	0	100
10-11 years	580	1	2	99%
11-12 years	367	2	2	99%
12-13 years	213	1	2	99%
13-14 years	75	0	1	98%

Table 1: Implant analysis with failure risk by year.

A rough graphical representation of implant survival curve are provided in table 1 by means of survival curve showing survival origin in 0.8.

Chi-square test has been used to evaluate significance of-association between implant failures and immediate loading protocol (alpha = 0.05). Joint distribution between immediate loading and failure is represented in table 2 and figure 3.

For implant with immediate loading no failure was present and only implant with conventional loading presented a failure.

However, the association is only descriptive and does not show any statistical significance (p value = 0,227) as it can be derived from Chi square below, reasonably due to zero observation cell and a low number of failure.

No	Failure		Total	
	Yes	No		
Immediate_loading Y/N	No	707	10	717
	SI	146	0	146
Total		853	10	863

Table 2: Contingency table showing joint distribution between implant failure and immediate loading.

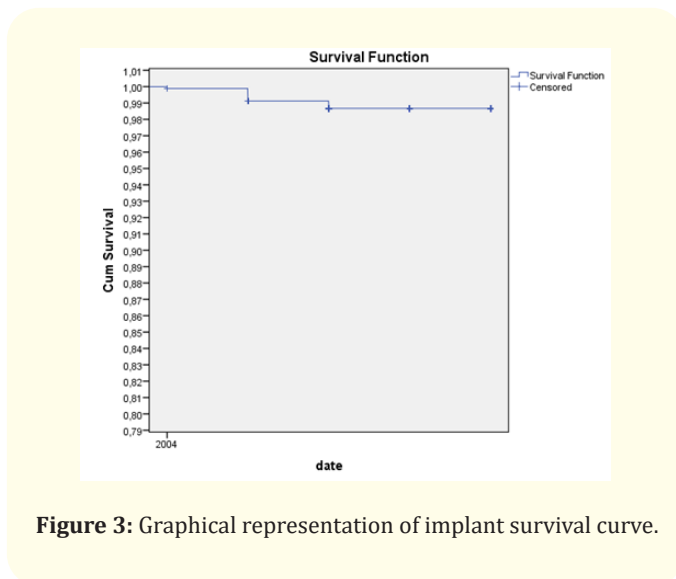


Figure 3: Graphical representation of implant survival curve.

The immediate loading protocol didn't affect the survival rate in this study population.

Distribution of bone quality over implant failure is represented in figure 4 and table 3.

Bone Quality 1 to 4 ' Failure Yes No Crosstabulation				
Count	No	Failure		Total
		Yes	No	
Bone Quality 1 to 4	1	74	0	74
	2	338	5	343
	3	276	3	279
	4	165	2	167
Total		853	10	863

Table 3: Contingency table showing joint distribution between failure and bone quality.

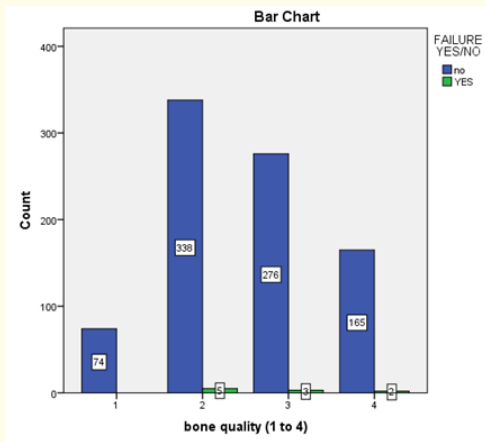


Figure 4: Clustered bar for distribution of bone quality.

In this case, the low number of implant failures in relation to total sample size must be considered.

However, failures are distributed independently on bone quality as can be derived from Chi square test; where a Chi-square= 1,154 is not significantly different from the null hypothesis of independence (p - value = 0,764).

Considering the B.I. index at the last control visit, 210 implants were positive (24%), 635 (74,5%) negative and 10 (1,5%) were positive with suppuration after the probing and the manual palpation of the buccal or palatal mucosa (Figure 5).

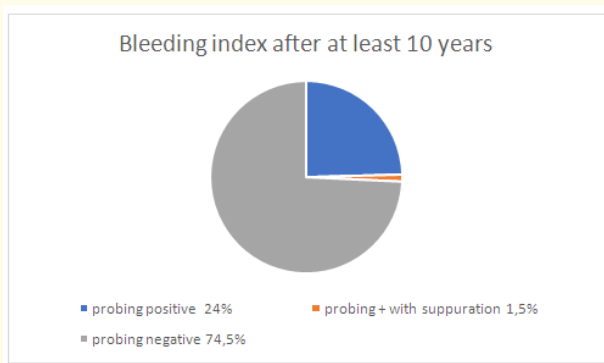


Figure 5: Pie plot to describe bleeding on probing.

For the implants with bleeding on probing a diagnosis of mucositis was formulated, while for the 10 implants positive to bleeding on probing with progressive loss of supporting bone a diagnosis of peri-implantitis was made [17]. The implants were still in function.

The median PPD after 10 years of the implants with negative B.I. was of 3.04 mm (minimum 1 mm maximum 3.9 mm) while for the implants that were positive to B.I. with presence of mucositis the median PPD was 3,75 mm (minimum 1.4 and maximum 4.5 mm).

For the 10 implants with diagnosis of peri-implantitis the mean value of PPD was 5.1 mm (minimum 2.7 and maximum 7.2), see figure 6.

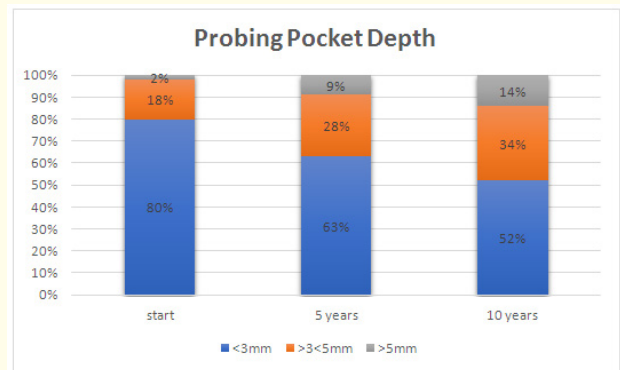


Figure 6: Distribution of probing pocket depth over time.

Associations between the BOP values and the PPD values were analyzed. Distribution of PPD over BOP is represented in figure 7-9.

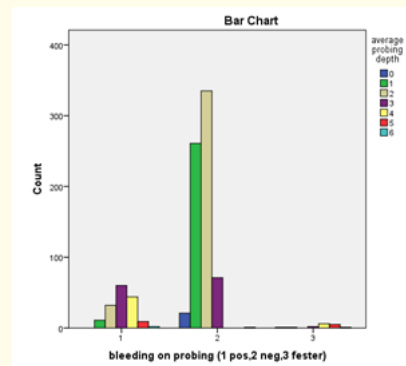


Figure 7: Clustered bars for bleeding on probing and probing depth.

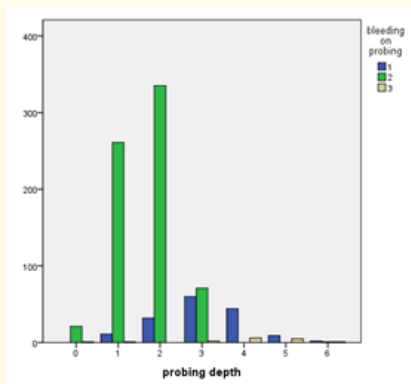


Figure 8: Clustered bars for bleeding on probing and probing depth.

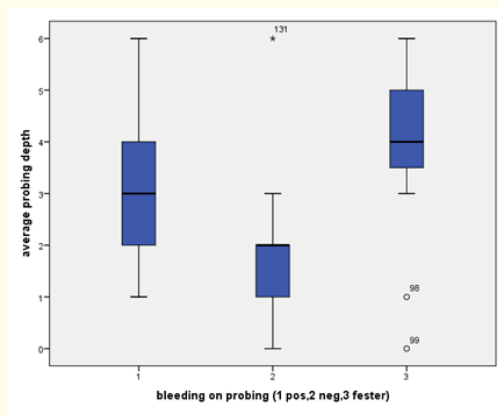


Figure 9: Box plot describing probing depth on bleeding on probing.

From boxplot above it is possible to observe that average probing depth is in median higher when bleeding is = 3. This association is statistically significant as it can be revealed by the Chi-square statistic ($p < 0.0001$) in table 4.

The bone level (B.L.) was measured on periapical radiographs as the distance between implant shoulder and first bone-to-implant contact at the 10 years control. The mean bone loss during this period was of 3.31 mm with a minimum of 2.65 and a maximum of 8.5 mm (Figure 10). The worst BL measurements were relative to the implants with a diagnosis of peri-implantitis.

Chi-Square Tests			
	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	472,419 ^a	12	,000
Likelihood Ratio	378,977	12	,000
Linear-by-Linear Association	138,635	1	,000
N of Valid Cases	863		

Table 4: Chi square test between bleeding on probing and probing depth.

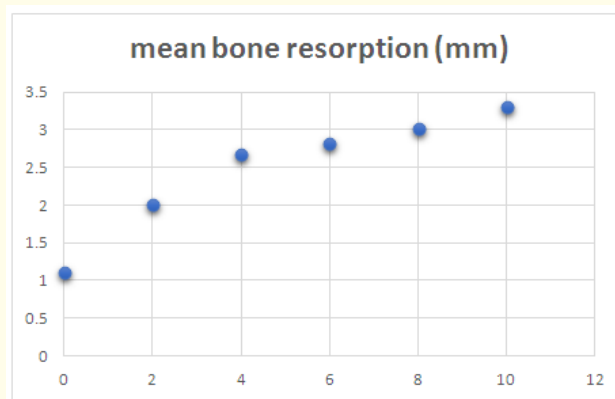


Figure 10: Mean bone resorption during the follow up period of 10 years.

Discussion

Only few studies have reported on more than 10-year survival rate of dental implants [18]. The present study showed a 10-year survival rate of 98% considering partially and fully edentulous patients and the results are comparable to recent report of Degidi and Vervaeke. Degidi assessed the 10-year performance of immediately loaded parallel design, self-tapping implants with a porous anodized surface [19] and Vervaeke, *et al.* recently concluded that both smoking and history of periodontitis affected long-term peri-implant bone stability [20]. The very high survival rate presented in this study is probably related to the oral hygiene program under which the patients were submitted after the final restoration: they were recalled for an occlusion check-up and oral hygiene appointment every 6 months (Figure 11 and 12).

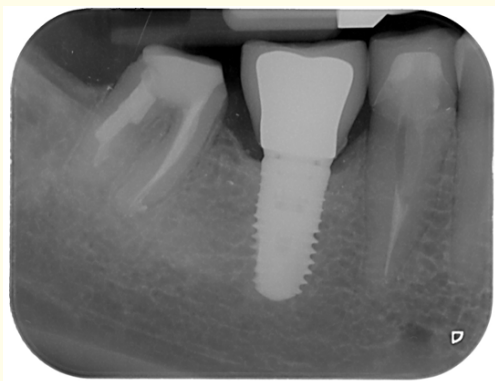


Figure 11: Periapical x ray at the delivery of the final prostheses.

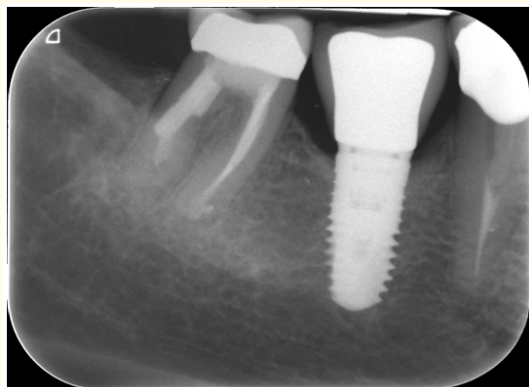


Figure 12: Periapical x ray of control after 11 years of function.

In this study two different loading protocols were compared (delayed and immediate), and the possible association between implant failures and the immediate loading protocol was analyzed. The results showed no implant failure for the immediate loading group and only implant failure for the conventional loading group.

Implant failure in relation to bone quality was analyzed, but failures were distributed independently on bone quality.

During the follow up period 10 implants showed unfavorable peri-implant signs and symptoms of peri-implantitis disease (positive bleeding index and suppuration with bone loss > than 1.5 mm) which were 1.5% of the total. This result is interesting since the percentage is slightly inferior than in the calculated meta-analysis

by Jung [21] as well to the peri-implantitis rate (<5%) suggested at a recent consensus meeting [22].

For the 10 implants with signs and symptoms of peri-implantitis disease the bone loss was very high, with values around 8 mm. This fact explained why the mean bone loss of the study sample after more than 10 years of function was around 3 mm.

There was no relation between bone loss and length and diameter of implant.

The results of the present study demonstrated that early or delayed implant installation did not compromise the implants in the long-term, despite the presence of an intra-bony defect due to the mismatch of implant and extraction socket dimensions at installation and the presence of a larger number of implants with relatively deep PD (≥ 5 mm). In contrast to clinical studies evaluating periodontitis patients over time, where PD ≥ 5 mm and the number of sites with PD ≥ 5 mm indicated a higher risk of disease progression on a tooth and patient level, respectively [23,24], no clear relationship between the peri-implant pocket depth and the implant prognosis has been established. The increase in the number of sites with PD ≥ 5 mm should be attributed to the fact that implants in this group were placed, most of the time, in the premolar/molar region, where in general thicker peri-implant mucosa is observed. Sites with thick peri-implant mucosa are expected to show less recession during peri-implant marginal bone remodeling compared with sites with thin mucosa, usually observed in the anterior region of the mouth [25,26].

In addition, the low rate of peri-implantitis in the present study seems to indicate that relatively deep pockets do not predispose to peri-implantitis. A very important role must be attributed to the strict oral hygiene program that is proposed to the patients after the prosthetic rehabilitation. These results have to be, of course, seen in the perspective of the relatively low number of implants in this study.

Conclusion

With the limitation of this study, represented by a relatively low number of implant under analysis after more than 10 years, the results are very promising, with low rate of failures and incidence of peri-implantitis. Probably they are related to the strict program of oral hygiene under which the patients are submitted after the

installation of the final prostheses. No relation is present between the failure of the implants and the loading protocols: implants placed immediately or delayed after tooth extraction show similar survival rates and peri-implant marginal bone resorption. The BOP is a very predictive index, because when it is positive it reveals that the implant is in bad healthy conditions with mucositis or peri-implantitis. On the other hand the presence of a PD > 5 mm is not always sign of suffering of the soft or hard tissues around the implant, if it is not accompanied by bleeding on probing.

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