Evaluation of Clinical Outcomes and Bone Loss around Titanium Implants with Oxidized Surface: Six-Year Follow-Up Results from a Prospective Case Series Study

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ABSTRACT

Purpose: The aim of this prospective study was to assess long-term clinical outcomes and peri-implant bone level changes around oxidized implants supporting partial fixed rehabilitations.

Materials and Methods: Twenty-two partially edentulous patients were included in the study. A total of 33 fixed rehabilitations were placed, supported by 54 titanium implants with oxidized microtextured surface. Prostheses were delivered after 3 and 6 months of implant placement in the mandible and maxilla, respectively. Patients were scheduled for follow-up at 6 and 12 months and then yearly. At each follow-up, plaque level and bleeding scores were assessed and periapical radiographs were taken. The main outcomes were prosthesis success, implant survival, implant success, and marginal bone level change.

Results: Three patients were excluded from the study because they did not attend the 1-year follow-up. Nineteen patients, accounting for 49 implants, were followed for at least 6 years after prosthesis delivery. The mean follow-up duration was 81.8 months (range 75–96 months). One mandibular single-tooth implant failed after 1 year in a smoker woman. Cumulative implant survival and success at 6 years were 98.0% and 95.9%, respectively. Prosthesis success was 96.7%. The mean peri-implant bone loss at 6 years was 0.76 ± 0.47 mm. Not significantly ($p = .75$) greater bone loss was found in the maxilla (0.78 ± 0.14 mm, $n = 19$) as compared with the mandible (0.74 ± 0.59 mm, $n = 30$). In the maxilla, bone loss was significantly greater around implants supporting partial prostheses as compared with single-tooth implants ($p = .03$). Full patient satisfaction was reported.

Conclusion: Implants with oxidized microtextured surface may achieve excellent long-term clinical outcomes in the rehabilitation of partial edentulism.

KEY WORDS: bone loss, dental implants, mandible, maxilla, oxidized surface, partial edentulism

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INTRODUCTION

The long-term success of osseointegrated implants has been documented in a number of studies and with several implant systems.[1] The early scientific reports of successful implant treatment were initially confined to the rehabilitation of fully edentulous patients, especially in the mandible. The rehabilitation of partially edentulous patients is technically more demanding because of nonmodifiable occlusal patterns that may be determined by other occluding teeth, as compared with the completely edentulous jaws. The approach to implant placement in the maxilla has also evolved cautiously, mainly due to the low bone density, especially in the posterior region, which may prevent the achievement of adequate primary stability. This has led to the development of dedicated clinical protocols for implant site preparation in low-density bone, aimed at maximizing implant fixation and allowing implant osseointegration also in such regions of the jaws. The role of implant surface characteristics has long been identified as critical for the success of treatment, which depends on a proper osseointegration.[2,3] It has long been recognized that titanium itself does not establish an intimate contact with the surrounding tissues.[4,5] Instead, the titanium oxide surface layer, which normally is self-formed with the surface exposure to the atmosphere, is biocompatible and allows the implant osseointegration.[6]

Many histological studies demonstrated that implants with rough surface develop a higher bone-to-implant contact as compared with implants with machined surface.[7–10] Furthermore, a higher torque is necessary to remove rough-surfaced implants as compared with machined ones.[11–13]

The aim of this longitudinal prospective study was to evaluate survival and success rates and peri-implant bone resorption of implants with rough surface supporting partial fixed rehabilitations up to 10 years of function. A secondary aim was to evaluate if clinical variables as implant size, site features, and type of restoration (single crowns or partial prostheses) may affect the result after the established follow-up period. Follow-up results after 6 years of function are described in the present report.

MATERIALS AND METHODS

This prospective single cohort study was conducted according to the principles of the Helsinki Declaration of 1975, as revised in 2000. Ethical approval was received from the Review Board of the Istituto Ortopedico Galeazzi. Patients were informed of the nature of the study, of the relevance of the radiographic follow-up, and of possible alternative treatments. They signed an informed consent form. A single experienced surgical team performed all the surgical procedures at a single clinical center (Dental Clinic of the Istituto Ortopedico Galeazzi, Milan, Italy).

Nobel Replace implants (Nobel Biocare, Göteborg, Sweden) with internal hexagon connection were placed. All implants had an oxidized microtextured surface (TiUnite®, Nobel Biocare) with a highly crystalline titanium oxide layer characterized by a microstructured surface with 1- to 10-μm pores.

Selection Criteria

Subjects requiring dental implants were recruited according to the following inclusion criteria: older than 18 years; physically and psychologically able to undergo conventional implant surgery and restorative procedures (American Society of Anesthesiologist class I or II); presence of partial edentulism; and presence of sufficient residual host bone width and height to allow placement of 10-mm or longer implants with 3.5 mm minimum diameter. In case of tooth extraction, at least 4 months of socket healing was allowed before implant placement.

Exclusion criteria were the following: presence of uncontrolled systemic disease, such as diabetes mellitus, and bone metabolic disease; smoking of 20 or more cigarettes a day; head or neck radiotherapy in 12 months prior to surgery; heavy parafunctions (e.g., bruxism); inadequate bone volume and quality that would require reconstruction procedures; immediate implant placement in sockets of nonsalvageable teeth scheduled for extraction; active periodontal infection or inflammation at any site; pregnancy; poor oral hygiene; and motivation and unavailability to attend regular follow-up visits.

Surgical Procedure

Each patient received 2 g of amoxicillin and clavulanic acid (Augmentin®, Roche, Milan, Italy) as prophylaxis starting from 3 days before surgery and 1 hour before the intervention. Patients rinsed with chlorexidine digluconate 0.2% mouthwash (Curasept®, Curaden Healthcare s.r.l., Saronno, Italy) for 1 minute before starting the surgery procedure.

After preparation of the patient, local anesthesia with articaine chlorhydrate 4% and adrenaline 1:100,000 (Alfacaina N, Weimer Pharma, Rastat, Germany) was administered.

A mucoperiosteal flap was raised and the implant site was prepared according to the manufacturer's instruction for both Tapered and Straight Replace implants, following the recommended sequence of drills. Bone quality at the implant site was assessed according to the Lekholm and Zarb classification.[14] The implant driver was connected to the handpiece through a standard technique following the manufacturer's instructions. All implants were placed with the neck at the same level of the bone crest or slightly above (0.5 mm above).

A cover screw cap was placed and implants were left to heal in a submerged way in order to avoid implant contamination during the healing phase. Flaps were re-approximated and sutured. Sutures were removed after 7 to 10 days.

Prosthetic Phase

The second surgical phase was performed after 6 months for implants placed in the maxilla and after 3 months for implants placed in the mandible.

After 2 weeks of soft tissue healing around healing screws, transfer copings were mounted on the fixture and an elastomeric (vinyl polisylioxane) impression was taken using pickup technique and open tray. Resin occlusal rims were used to record vertical dimension and centric relation. All final restorations included a cast framework in gold alloy with porcelain teeth as veneers and were cemented (Precision ImplaCem, Dentalica, Milan, Italy) to a titanium abutment individualized by the dental technician. The abutment screw was tightened at 35 Ncm.

Follow-Up

All patients were scheduled for control visits at 6 and 12 months after prosthesis delivery and yearly thereafter. At each control, clinical parameters (probing depth, bleeding, and plaque indexes) were evaluated and standardized digital intraoral radiographs (with memory phosphor system) were taken using the right-angle technique and, when possible, an individual x-ray holder. Reference radiographs were taken immediately after the prosthesis connection. At each follow-up visit, the stability of the implants and prosthesis, as well as proper occlusion, were also checked.

Outcome Variables

1. Prosthesis success. When the prosthesis was in function, without mobility and pain, even in face of the loss of one or more implants. Prosthesis stability was tested at each follow-up visit by means of two opposing instruments' pressure.
2. Implant survival. When the implant was in function and stable with no evidence of peri-implant radiolucency and no suppuration or pain at the implant site or ongoing pathologic processes.
3. Implant success. In addition to the criteria for implant survival, the marginal bone loss around the implant must not exceed conventionally accepted values, that is, 1.5 mm during the first year of function and 0.2 mm yearly thereafter.[15]
4. Biological and prosthetic complications, such as peri-implant mucositis, peri-implantitis, fistulas or abscess, or any mechanical or prosthetic complications such as fracture of the implant and/or of any prosthetic component.
5. Marginal bone level change. The marginal bone level was assessed on digital intraoral radiographs using an image analysis software (University of Texas Health Science Center at San Antonio [UTHSCSA] Image Tool, version 3.00, for Windows, UTHSCSA, San Antonio, TX, USA). An experienced evaluator (F.A.) performed all the measurements. The known distance between the screw threads was used to calibrate each image. The implant-abutment connection level was used as the reference for each measurement. The linear distance between implant neck and the most coronal bone-to-implant contact was measured. Mesial and distal values were averaged so as to have a single value for each implant. Bone loss around implants placed in the mandible was compared with that around implants in the maxilla.
6. Oral hygiene level. The presence of plaque and bleeding on probing was assessed at four surfaces per tooth or implant and expressed as percentage over full-mouth examination (Full Mouth Plaque Score % [FMPS%] and Full Mouth Bleeding Score % [FMBS%]).
7. Patient satisfaction. Esthetics, phonetics, and mastication function were assessed by means of an ad hoc

prepared nonstandardized questionnaire 1 year after delivery of the final restoration. Each item was rated as excellent, very good, good, sufficient, or poor.

Data Analysis

Cumulative implant survival and success rates were calculated by an actuarial life table method (Kaplan-Meier analysis). The effect of the type of restoration (partial prosthesis vs single tooth [ST]) and of implant location (maxilla vs mandible) on bone loss around implants was evaluated by means of unpaired Student's *t*-test. $p = .05$ was considered as the significance level.

RESULTS

During the period from June 2003 through February 2005, a total of 54 implants with oxidized titanium surface (Nobel Replace) were inserted in 22 patients (12 females and 10 males). Six patients were smokers at the time of recruitment (mean nine cigarettes/day). Before surgery, all patients had good oral hygiene levels with mean FMPS% and mean FMBS% equal to 12% and 10%, respectively. These implants supported 33 fixed rehabilitations, out of which 15 ST (six in the mandible and nine in the maxilla) and 18 partial prostheses (13 in the mandible and five in the maxilla). The distribution of implants in the mandible and maxilla is shown in Figures 1 and 2, respectively.

Three patients, accounting for a total of five implants, did not attend the scheduled follow-up controls and were excluded from the study after 1 year. Therefore, the present data analysis is based on outcomes of 49 implants in 19 patients that were followed for at least 6 years.

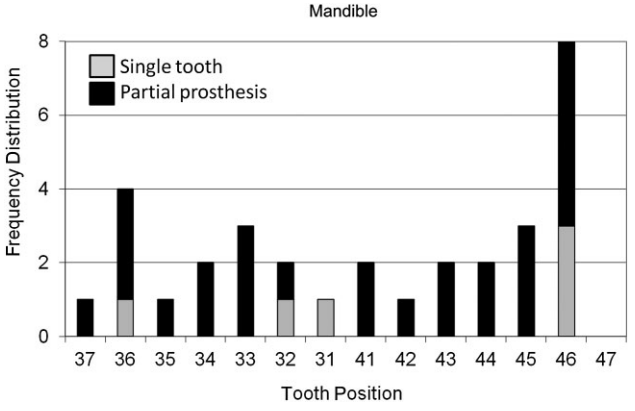

Figure 1 Distribution of the implants in the mandible, according to the type of prosthetic rehabilitation.

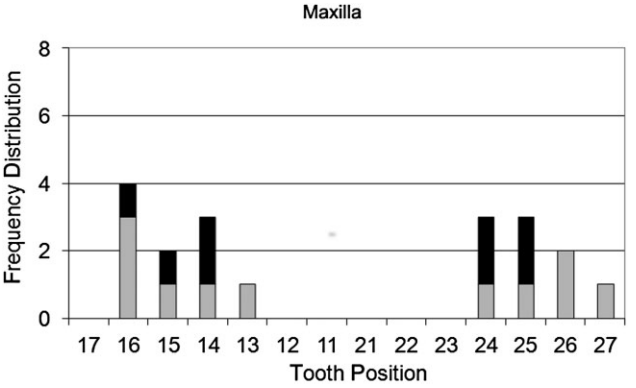

Figure 2 Distribution of the implants in the maxilla, according to the type of prosthetic rehabilitation.

Twenty-one implants were of Straight type and 28 of Tapered type. Three implants were inserted in healed postextraction sites 4 months after extraction.

One implant had to be removed 1 year after loading due to a severe bone resorption in a 46-year-old woman, who smoked 15 cigarettes per day and also maintained a poor oral hygiene level. The implant supported a single crown in the region of the first lower molar, and the prosthesis was also classified as a failure. After 3 months, a new implant of the same size was successfully inserted, a prosthesis was delivered 4 months later, and no further complication was recorded. The new implant was not considered for analysis.

After 6 years of loading, the overall cumulative implant survival was 97.96%. Kaplan-Meier (life table) analysis up to 8 years of function is shown in Table 1. Cumulative implant survival was 100% for the maxilla ($n = 19$ implants placed) and 96.67% for the mandible ($n = 30$). Overall prosthesis survival was 96.67% (100% in the maxilla and 94.74% in the mandible). No partial prosthesis failed while the survival of ST rehabilitation was 93.33% after 6 years.

One implant displayed a marginal bone resorption of 3.4 mm after 5 years, which exceeded the 99% confidence interval. This implant was 15 mm long with 3.5 mm diameter. It was inserted in the region of lateral lower incisor supporting a bridge in a male patient aged 48. Despite such advanced bone loss, the implant was not excluded from the statistical analysis.

The overall mean bone resorption around implants was 0.76 ± 0.47 mm after 6 years of loading. There was no statistically significant difference in marginal bone loss between mesial and distal sides. Peri-implant bone

TABLE 1 Overall Life Table Analysis up to 7 Years

Time of Function, Interval	N. Implants (Patients) at the Beginning of Interval	Dropout Implants (Patients)	N. Implant Failures	Interval Implant Survival	Cumulative Implant Survival
0–1 year	54 (22)	5 (3)	1	97.96%	97.96%
1–2 years	48 (19)	0	0	100%	97.96%
2–3 years	48 (19)	0	0	100%	97.96%
3–4 years	48 (19)	0	0	100%	97.96%
4–5 years	48 (19)	0	0	100%	97.96%
5–6 years	48 (19)	0	0	100%	97.96%
6–7 years	48 (19)	0	0	100%	97.96%

loss in the maxilla (0.78 ± 0.14 mm, $n = 19$) was not significantly greater (p value = .75) than in the mandible (0.74 ± 0.59 mm, $n = 30$).

A statistically significant difference in marginal bone loss ($p = .03$) was found in the maxilla between ST implants (0.71 ± 0.11 mm, $n = 9$) and implants supporting fixed partial prostheses (FPPs) (0.85 ± 0.14 mm, $n = 10$). In the mandible, such difference was not significant ($p = .38$), being 0.54 ± 0.11 mm ($n = 6$) and 0.79 ± 0.65 mm ($n = 24$) around ST and FPP implants, respectively. Peri-implant bone resorption around ST implants was greater in the maxilla than in the mandible ($p = .009$), while no significant effect of the arch was found for FPP implants ($p = .77$). A series of periapical radiographs of one case is shown in Figure 3, A–D. The periapical radiograph presented in Figure 3D shows good peri-implant bone level stability after 6 years of loading.

No significant effect of smoking habits, of the implant type, and of implant size on the extent of bone loss could be evidenced.

Full satisfaction was reported by patients after 1 year. Surgical complications occurred in two patients (10.5%), one of which reported a transient ipoaesthesia that lasted for 2 days and another suffered from postoperative swelling. During the follow-up period, prosthetic complications (including abutment screw loosening and loss of occlusal closure of the screw access) were recorded in nine patients (47%), among which four partial fractures of the final prosthesis (21%), involving one single crown and three partial bridges. All complications were successfully managed. Biological complications were observed in two patients (four implants): one peri-implantitis caused the failure of one implants, while three fixtures in one patient showed peri-implant mucositis at the 2-year follow-up, which was successfully treated.

DISCUSSION

The present prospective study, even in face of a limited sample size, demonstrated that implants with oxidized surface used to support fixed partial reconstructions may achieve and maintain an excellent clinical performance up to 6 years of function. In the present report, only data relative to 6 years are described as all patients attained such follow-up.

Several studies investigated the features of the TiUnite surface, showing that it actively participates in the process of implant integration with the human bone. In vivo studies showed that the structure of soft tissue around implants with this rough surface resembles that around the natural teeth[16] and a higher implant stability was observed as compared with machined surfaces.[2] Other studies have evaluated the outcome of these implants in both clinical and preclinical situations, using different protocols.[3–6]

The present results can be compared with those reported by other authors that evaluated the clinical outcomes of the Nobel Replace Implant System.

Bahat assessed marginal bone resorption around 290 implants, placed together with guided bone regeneration (GBR) procedures, followed for at least 3 years.[17] Implant survival after 3 years was 99.3% and the average peri-implant bone resorption was 2.74 mm. The latter value was considerably higher than in the present study probably because of the better average score for bone quality. In fact, no implant has been placed in bone type 4 quality, 45% in bone type 3, and the remaining implants mostly in bone type 2 (53%). We cannot exclude that a possible different clinicians' perception of

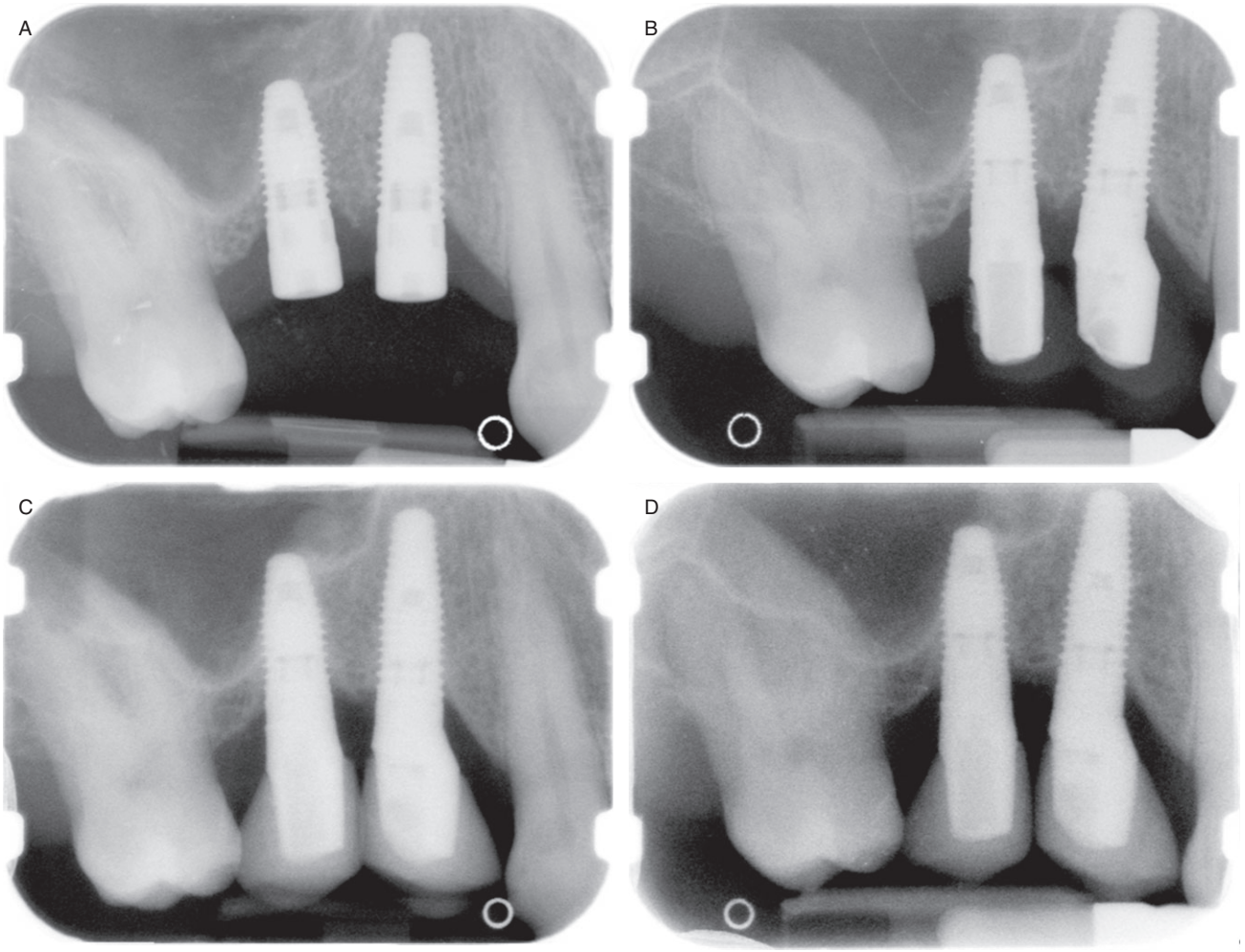

Figure 3 Radiographic documentation of a clinical case of two adjacent implants inserted in position 14–15 supporting single-tooth rehabilitations. *A*. Periapical radiograph soon after implant insertion; *B*. Periapical radiograph at loading phase, 6 months after surgery; *C*. Periapical radiograph taken 1 year after loading; *D*. Periapical radiograph taken 6 years after loading. The peri-implant bone level showed minimal change as compared with the loading phase.

bone type during implant site preparation may somehow lead to a systematic difference in bone type scoring between different surgical teams. Furthermore, the use of GBR procedures, as well as any modification to the standard surgical protocol, represents confounding variables whose effect on the marginal bone loss should be taken into account.

Achilli and colleagues compared immediate loading and early loading (after 6 weeks) protocols in a total of one hundred twenty Replace tapered implants supporting 54 fixed bridges in 51 patients with posterior edentulous mandible.[18] No implant failed after 12 months of loading. Peri-implant bone resorption was 1.24 ± 0.88 mm for immediately loaded implants (33 bridges) and 1.19 ± 1.01 mm for early-loaded implants (21 bridges). Also in that study, the mean peri-implant bone loss values were higher than in the present study, but in both groups, the period between implant placement and loading was shorter than the present one in which a conventional loading protocol was adopted.

Nickenig and colleagues compared Nobel Replace implants with different collar configurations.[19] Seventy implants with rough microthreaded collar and 63 with smooth collar were used for the rehabilitation of posterior mandible in 34 patients. After 2-year follow-up, the mean marginal bone resorption around implants with smooth collar was 1.1 mm, significantly higher than around implants with rough collar (0.5 mm).

Five- and 7-year data have been published of a study on 38 patients, demonstrating good long-term results for TiUnite implants under immediate loading protocol.[20,21] Fifty-one fixed prostheses (30 partial dentures,

20 single crowns, and one mandibular complete denture) supported by one hundred two implants placed mainly in posterior regions of the jaws and primarily in soft bone quality were loaded the same day of intervention. GBR was performed in 66 sites (64.7%) with exposed implant threads. The overall cumulative implant survival rate was 97.1%. The mean marginal bone loss was 1.51 ± 1.00 mm after 7 years. Such value is higher than that reported in the present study but similar to the study by Achilli and colleagues[18] and the loading temporization was shorter than ours. In spite of the differences in protocol, the clinical results of the study by Glauser and colleagues[20,21] are comparable to ours, confirming the predictability of this implant system in the long term.

Many studies introduced confounding variables in the protocol such as GBR techniques, modified drilling techniques, anticipated loading protocols, or the treatment of specific regions of the jaws. The present study adopted a conventional loading protocol, following the manufacturer's instructions, and did not pose particular limitations to the patient selection except for being partially edentulous and not smoking 20 or more cigarettes/day. The dropout rate in the present study up to over 6 years was lower than 10%, as only three patients did not attend the scheduled recall program.

The only implant failure recorded was probably due to a lack of compliance of the patient, as suggested by her high value of full-mouth plaque score (around 25% at 6 and 12 months). In addition, she was a regular smoker. So, the authors may speculate that the main cause for this failure could not be ascribed to the implant system nor to the rehabilitation type (ST).

The conventional implant success criteria proposed by Albrektsson and colleagues in 1986 require that implants must display immobility, absence of peri-implant radiolucency, and marginal bone loss not exceeding 1.5 mm after the first year of loading and up to 0.2 mm yearly.[15] Furthermore, an implant system can be considered successful if 85% of the implants meet these criteria under loading for a period of at least 5 years.[15]

Buser and colleagues in 1991 proposed similar implant success criteria, without specifying the tolerated marginal bone loss over time: absence of disturbances, pain, foreign body sensation or altered sensitivity, absence of recurrent peri-implant infection in association with suppuration, absence of mobility, and absence of continuous radiotransparency along the implant profile.[22] In the present study, 95.9% of the implants met the success criteria established by Albrektsson and colleagues,[15] as one implant was lost and another one displayed a marginal bone loss exceeding 2 mm at 5 years. These longitudinal data, though referred to a limited sample size, may contribute to determine the successful performance of the Replace implant system. The relative high prosthetic complication rate should be evaluated considering that none of such events lead to a failure of the rehabilitation as all of them were easily solved.

In the present investigation, marginal bone loss around implants supporting partial bridges was significantly higher than around implants supporting single crown in the maxilla. The limited sample size however prevents generalization of this result. Indeed, scarce evidence exists in the literature concerning the difference in marginal bone loss between splinted multiunit reconstructions and single crowns. This topic would deserve further investigation and the present finding should be validated by prospective studies with a larger sample size. While splinting can be mandatory to enhance implant stability in case of immediate and early loading, it could be hypothesized that such expedient might not be necessary for single crown submitted to conventional loading protocol. Avoidance of splinting would also simplify oral hygiene procedures around single crown reconstructions.

CONCLUSION

Within the limitations of this study, it can be concluded that implants with oxidized microtextured surface placed mainly in posterior regions may achieve excellent long-term clinical outcomes in the rehabilitation of partial edentulism.

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