

Implants with an Oxidized Surface Placed Predominately in Soft Bone Quality and Subjected to Immediate Occlusal Loading: Results from a 7-Year Clinical Follow-Up

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ABSTRACT

Purpose: The purpose of this clinical follow-up was to document the 7-year outcome of immediately loaded implants exhibiting an oxidized surface.

Material and Methods: Thirty-eight patients received a total of 51 implant-supported fixed prostheses. The restorations were supported by 102 implants, the majority of which were placed in posterior regions (88%) and primarily in soft bone quality (76%). Radiographic examinations were performed at prosthesis insertion, at 1- and 6-month follow-ups, and annually at the 1- through 5-year follow-up visits. Marginal peri-implant soft tissue evaluations were conducted at all these follow-ups. This report presents the results after at least 7 years of loading.

Results: After 7 years of prosthetic loading, the cumulative implant survival rate was 97.1% and the mean marginal bone remodeling was -1.51 mm (SD 1.00, $n = 73$) with significantly more initial remodeling at sites having received marginal guided bone regeneration procedures. A low rate of biological and technical complications was detected after 7 years of function. The quantification of intrasulcular plaque sampling showed no significant difference between teeth and implants.

Conclusion: The 7-year follow-up data indicate that the introduced immediate loading protocol is a successful treatment alternative also including regions exhibiting soft bone conditions.

KEY WORDS: dental implants, immediate loading, immediate restoration, long-term, marginal bone level, microbiota, oxidized surface

INTRODUCTION

Recent developments in implant therapy aim to simplify clinical protocols. A main focus is on the reduction of the number of surgical interventions and the overall duration of treatment time, thereby improving patient acceptance. Consequently, a steadily increasing number of protocols for immediate implant loading or

immediate implant restoration for different indications have been published.^{1–13} In principle, the documented outcomes indicate that overall performance may be similar to that published for traditional, staged protocols. Nevertheless, the majority of the reports are based on short-term results and limited to implant survival or implant success.

The use of moderately rough surfaces may contribute to the maintenance of primary implant stability at immediately loaded/restored implants.¹⁴ It has been suggested that these surfaces help in reducing the time required to achieve secondary stability by speeding up bone formation at the implant–bone interface, thus reducing the overall time at risk following implant surgery.^{15–18} Moreover, these surfaces may also have a beneficial impact in areas of soft bone quality where the viability of immediate loading protocols has been questioned.^{1,19,20}

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Since the clinical implementation of implants with moderately rough surfaces, some authors have expressed concerns that the roughened surface becomes partly exposed to the marginal soft tissue compartment or even to the oral cavity.^{21,22} Up to now, short-term studies demonstrated unequal outcomes. Whereas some authors demonstrate no surface effect on initial plaque accumulation,²³ other reports claim that rough surfaces may induce increased plaque accumulation²¹ resulting in inflammation of the surrounding soft tissues.²² Moreover, there is only sparse knowledge on the intrasulcular microbiota around implants being in function for more than 5 years.²⁴ Consequently, the clinical impact of moderately rough implant surfaces in contact with the marginal soft tissues or exposed intraorally requires further investigation.

Published data on immediate implant loading indicate that these implants show a marginal bone resorption that is equal to or slightly reduced when compared with bone level changes around implants for which loading has been delayed.^{8–10,25–30} In addition, following the first year of function, marginal bone levels for implants placed with immediate/early loading protocols have been reported to be as stable over time as for delayed loaded implants.^{11,12,31–34}

Marginal bone remodeling at implants placed in the native bone or in the regenerated bone (guided bone regeneration, GBR) using a conventional late loading protocol has been shown to be similar over the first 5 years.³⁵ However, there is a lack of long-term data on implants placed in combination with GBR and loaded immediately.

When focusing on implant-supported partial prostheses placed according to conventional delayed loading protocols and reviewing systematically the available long-term literature, a substantial incidence of technical and biological complications has been reported.³⁶ Up to now, there is sparse knowledge with respect to adverse biological and technical events related to immediate implant loading or restoration protocols. The aim of this report is to present the 7-year follow-up data of immediately loaded, moderately rough implants with regard to implant success/survival, marginal hard and soft tissue reactions, intrasulcular microbiota, as well as biological and technical complications.

The research hypothesis was that the clinical outcome with the proposed immediate loading protocol, using slightly tapered and moderately rough

implants, would be comparable with a delayed loading protocol.^{37,38} Furthermore, it was hypothesized that the intrasulcular microbiota is comparable with that found at neighboring natural abutments.²³

MATERIALS AND METHODS

Clinical follow-ups were conducted at a single centre in Switzerland with approval of local ethical committee for this prospective study. The patients with the outcome reported from 1, 4, and 5 years of follow-up were recalled for ordinary check-up. Detailed description of surgical and prosthetic protocol in the prospective study has been presented in the 1-year follow-up report.³⁹ Clinical and radiological examinations, intrasulcular plaque sampling, and registration of any adverse event/complication were included in the ordinary clinical check-up 7 years following implant placement.

The prospective study protocol called for consecutively enrolled patients provided stated inclusion and exclusion criteria were considered.³⁹ In particular, smoking and local regenerative procedures in connection with implant treatment were accepted, whereas patients with ongoing parafunctional habits were excluded.

The study population was composed of 38 patients; whereof 17 females and 21 males, with a mean age of 52 years (range 19–77) at the time of treatment. Eleven patients (29%) were smokers. One hundred two screw-shaped, slightly tapered two-piece implants (Brånemark System® Mk IV, Nobel Biocare AB, Gothenburg, Sweden) exhibiting a moderately rough oxidized surface (TiUnite, Nobel Biocare AB, Gothenburg, Sweden) were placed, whereof 38 in the maxilla and 64 in the mandible. Implant distribution according to bone quality and quantity⁴⁰ is displayed in Table 1.

In 66 sites with exposed implant threads, GBR was performed. Autogenous bone harvested from site preparation and if further volume was required, a mixture of autogenous bone and a xenograft (Bio-Oss®; Geistlich Pharma AG, Wolhusen, Switzerland) was placed to support the resorbable collagen membrane (Bio-Gide®; Geistlich Pharma AG) covering the exposed area. The implants were prosthetically loaded at the day of implant placement with a provisional restoration. Metal- or fiber-reinforced frameworks and acrylic veneering were applied for fixed partial restorations. Provisional acrylic crowns were used for single-tooth restorations. Full contact in centric occlusion was

TABLE 1 Implant Distribution According to Bone Quality and Quantity⁴⁰

Bone Quantity	Bone Quality				Total Number of Implants
	1	2	3	4	
A	—	—	5	—	5
B	—	16	36	22	74
C	—	7	10 (3)	5	22 (3)
D	—	1	—	—	1
E	—	—	—	—	—
Total	—	24	51 (3)	27	102 (3)*

*Number of failed implants within brackets.

ensured and excursive contacts were avoided whenever possible. Cantilevers and pontics were avoided in the restorations whenever possible. Fifty-one restorations were connected to the 102 implants. The distribution of implants and prosthesis placed in the maxilla and mandible according to type of indication is listed in Table 2.

Follow-up examinations were performed 2, 4, and 6 weeks, 2, 3, and 6 months, and 1, 2, 3, 4, 5, and 7 years following implant placement/loading.

Intraoral radiographic examinations were taken at the time of implant insertion, 1 and 6 months, and 1, 2, 3, 4, 5, and 7 years following implant placement. The radiographs were taken perpendicular to the implant axis with a long-cone paralleling technique. During the entire 7-year follow-up period, an independent radiologist at the University of Gothenburg performed the evaluation of the marginal bone level at mesial and distal implant surfaces. The reference point used for the radiographic evaluation was the abutment/implant interface.

The peri-implant mucosa was evaluated as either normal (score 0), bleeding on superficial probing (score 1), or spontaneous bleeding mucosa (score 2). The plaque accumulation was evaluated and recorded as either no visible plaque (score 0) or visible plaque (score 1) in the gingival area. The assessments were made on the buccal and lingual surfaces at the 4-week follow-up and at all subsequent follow-up visits.

At the ordinary clinical 7-year check-up following implant placement, implant stability was assessed for 17 implants supporting single crowns. However, individual implant stability was not assessed on implants in multiple implant restorations since the restorations were not removed. The clinical examinations of peri-implant mucosa and plaque were conducted and registered as in

the prior prospective study protocol. Intrasulcular bacterial sampling was performed at both implants and neighboring teeth at the buccal sulcus using sterile paper points. Quantification of the total bacterial load (TBL) and of four marker species (Aa: *Actinobacillus actinomycescomitans*, Bf: *Bacteroides forsythus*, Pg: *Porphyromonas gingivalis*, and Td: *Treponema denticola*) using DNA probes was conducted (IAI PadoTest 4-5, Institut für Angewandte Immunologie, Switzerland). At the 7-year follow-up, all biological and technical adverse events were recorded.

The implants had to meet the following criteria to be regarded as successful, a modification of the proposal by Albrektsson and colleagues^{41,42}: no radiolucent zone around the implant; the implant acted as an anchor for the functional prosthesis; confirmed individual implant stability; and no suppuration, pain, or ongoing pathologic processes.

Descriptive statistics, including mean values and standard deviations, were used for presentation of the results. An actuarial life table method⁴³ was used for evaluation of the cumulative success rate of the implants up to and including 5 years. For the 7-year follow-up, the life table addresses cumulative survival rate as individual implant stability was not confirmed in case of multiple implant support of the restoration. The marginal bone remodeling for implants in grafted and non-grafted sites was compared using the Mann-Whitney *U* test. Wilcoxon signed rank test was used for comparing quantification of intrasulcular plaque sampling at implants and teeth. Commercial available statistical software (SPSS® 17.0, SPSS, Inc., Chicago, IL, USA) was used for the statistical analysis.

RESULTS

Thirty of the 36 patients completing the prospective 5-year study attended the ordinary 7-year check-up. One patient with two implants had died prior to the 7-year check-up, three patients with altogether 10 implants had moved abroad and were not available for the recall visit, and two patients with, altogether, five implants were not motivated to attend the 7-year check-up.

During the entire 7-year observation period, three implants were recorded as failures, resulting in a cumulative implant survival rate of 97.1%. These failed implants, all in one patient, were lost shortly after implant surgery because of flap dehiscence with

TABLE 2 Number of Prostheses and Implants per Indication

	Indication					
	Single Anterior Maxilla	Single Posterior Maxilla	Single Posterior Mandible	Partial Posterior Maxilla	Partial Posterior Mandible	Complete Mandible
Reconstructions	5	7	8	10	20	1
Implants	5	7	8	26	51	5
Failures	—	—	—	3	—	—

TABLE 3 Life Table Implants

Time Period	Implants	Failed	WD	CSR %
Placement >> 1 year	102	3	0	97.1
1 >> 2 years	99	0	4	97.1
2 >> 3 years	95	0	5	97.1
3 >> 5 years	90	0	0	97.1
5 >> 7 years	90	0	17	97.1
7 years	73	—	—	—

CSR = cumulative survival rate; WD = withdrawn implants.

suppuration in a GBR area around a three-unit prosthesis supported by three implants. The three implants had to be removed along with the grafting material at the 2-month follow-up. The life table analysis is presented in Table 3.

The 30 patients, who attended the ordinary 7-year check-up, featured 36 restorations supported by 73 implants. The mean follow-up time for all implants was 7 years and 5 months (range 83–96 months).

The results from the radiographic evaluation of marginal bone levels over time are presented in Figure 1. Seven years following implant loading, the mean change in marginal bone level was -1.51 mm (SD 1.0, $n = 73$), Table 4. Most of the marginal bone remodeling occurred during the first year of loading. The mean marginal bone resorption from 5 to 7 years was limited to 0.04 mm (SD 0.88, $n = 67$), Figure 2. Implants exhibiting a marginal bone remodeling exceeding 2 mm during the first year of loading demonstrated steady state of the mean bone level over time following 1-year follow-up, Figure 3. Comparing non-grafted versus grafted implant

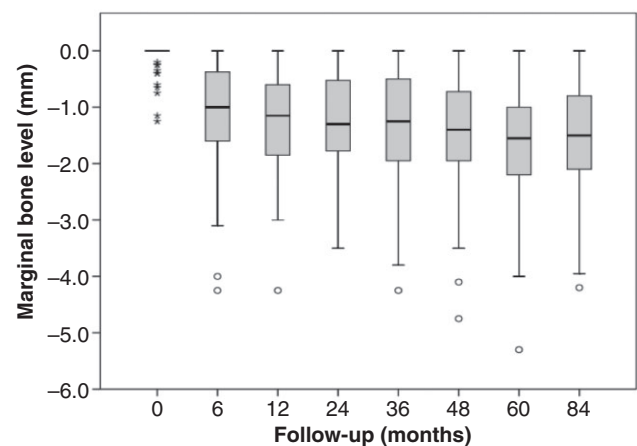


Figure 1 Box plot with all bone level measurements over time.

TABLE 4 Marginal Bone Loss between Implant Placement (Loading) and 1 and 7 Years Follow-Up

Marginal Bone Loss (mm)	All Sites		Grafted Sites		Non-Grafted Sites	
	Loading to 1 Year	Loading to 7 Years	Loading to 1 Year	Loading to 7 Years	Loading to 1 Year	Loading to 7 Years
<0	—	—	—	—	—	—
0 (%)	12	8	6	2	23	16
0.1–1.0 (%)	38	26	41	17	31	39
1.1–2.0 (%)	34	34	32	41	37	26
2.1–3.0 (%)	15	25	19	29	9	19
3.1–4.0 (%)	—	6	—	10	—	—
4.1–5.0 (%)	1	1	2	2	—	—
Total numbers of implants	98	73	63	42	35	31
Mean value (mm)	1.16	1.51	1.29	1.84	0.93	1.06
SD (mm)	0.85	1.00	0.89	0.94	0.74	0.90

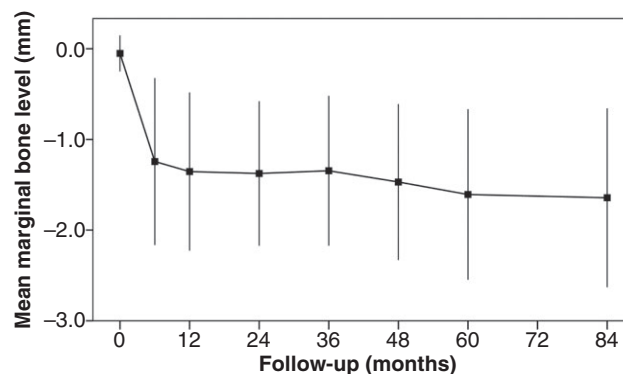


Figure 2 Marginal bone level (mean value) plotted over time for all implants with readable radiographs at baseline and at 5- and 7-year follow-up ($n = 67$). Error bars: ± 1 SD. Error bars = SEM.

sites, statistical analysis of the bone remodeling demonstrated a significantly larger bone remodeling for the grafted sites from implant insertion to 6 months, $p = .019$, and from insertion to 7-year follow-up, $p < .001$ (Mann-Whitney test), Figure 4 and Table 4.

Accumulation of plaque and bleeding on probing data reported over the entire follow-up period are displayed in Tables 5 and 6. Over the follow-up period, a high percentage of the implant sites have been reported with no visible plaque. As a mean for the entire study period, the absence of visible plaque was slightly more frequent on the buccal as compared with the lingual surface. Bleeding on probing showed a similar pattern over the study period.

The quantification of intrasulcular plaque sampling was tested (Wilcoxon signed ranks test) comparing implants versus teeth, Figure 5. There was no statistical significant difference with regard to the TBL and the four marker species, Table 7.

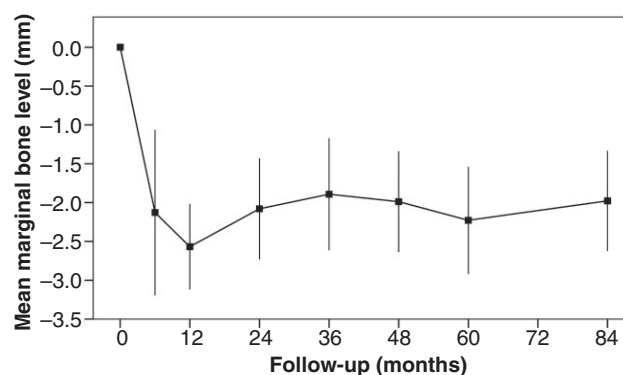


Figure 3 Marginal bone level (mean value) plotted over time for all implants with bone loss > 2 mm during the first year and readable radiographs at baseline and at 5- and 7-year follow-up ($n = 14$). Error bars: ± 1 SD. Error bars = SEM.

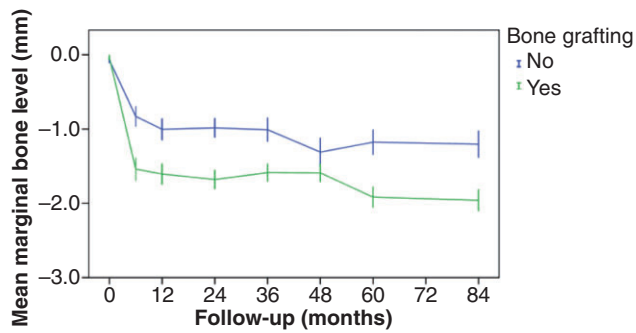


Figure 4 Marginal bone level plotted over time for all implants with readings at baseline and at 5- and 7-year follow-up (no grafting $n = 28$, grafted $n = 39$). Error bars: ± 1 SE. Mean values presented with error bars = SEM.

TABLE 5 Absence of Visible Plaque (%) Including All Available Date from Each Visit

Time	<i>n</i>	Implant Positions with No Visible Plaque (%)
4 weeks	92	76
6 weeks	92	67
2 months	96	71
3 months	95	65
6 months	97	70
1 year	99	58
2 years	92	73
3 years	90	81
4 years	86	78
5 years	85	75
7 years	73	82

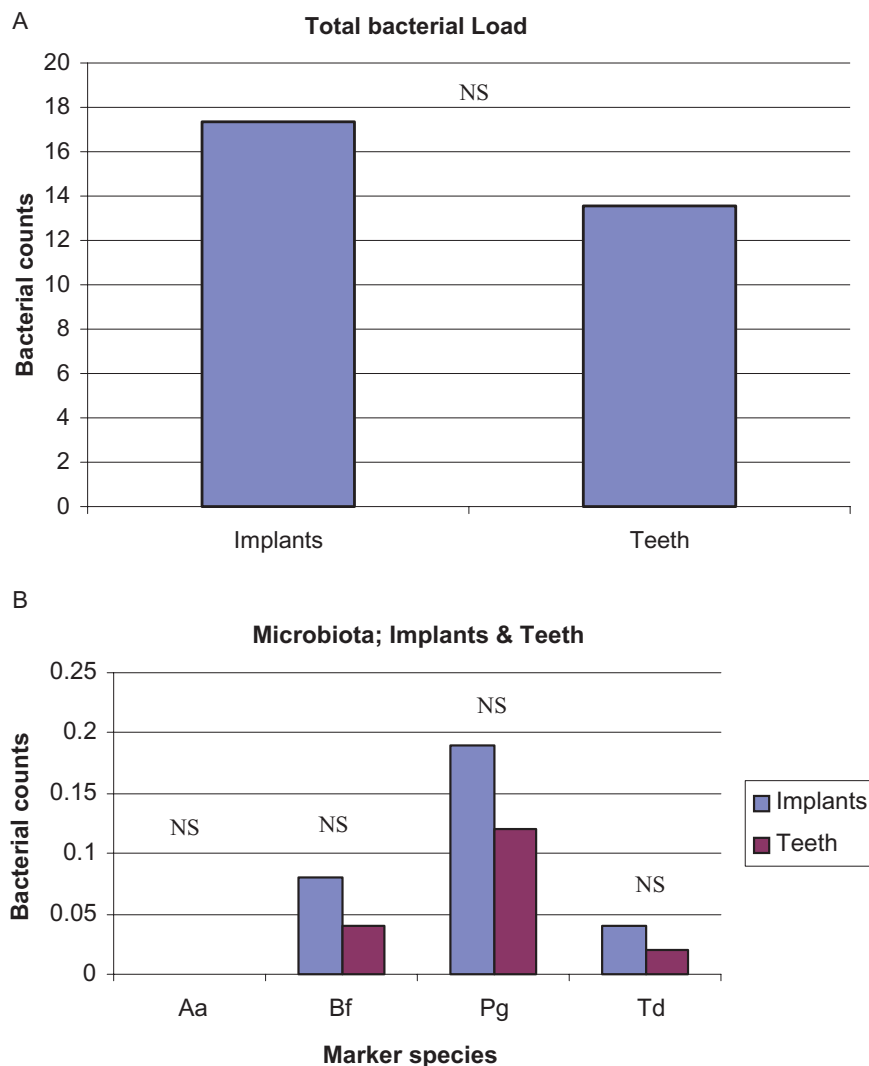


Figure 5 Microbiological analysis at the 7-year check-up indicating the respective number of counted bacteria in millions. (A) Total bacterial load at implants ($n = 73$) and teeth ($n = 35$). (B) Comparison for Aa, Bf, Pg, and Td between implants and teeth.

Aa = *Actinobacillus actinomycetemcomitans*; Bf = *Bacteroides forsythus*; Pg = *Porphyromonas gingivalis*; Td = *Treponema denticola*.

TABLE 6 Absence of Bleeding on Probing (%) Including All Available Data from Each Visit

Time	n	Implant Positions with No Bleeding on Probing (%)
4 weeks	57	73
6 weeks	66	73
2 months	79	73
3 months	76	64
6 months	82	74
1 year	92	56
2 years	92	70
3 years	90	77
4 years	86	66
5 years	85	74
7 years	73	86

At the 7-year check-up, no serious adverse event was reported. The following nonserious complications were registered: extensive toothbrushing, thin buccal mucosa with a high labial fraenum, and a local infection around an implant had resulted in mucosal recessions in three patients; in one patient, the filling of the occlusal screw access hole was redone, minor porcelain chipping was treated with chair-side polishing in two patients; and in two patients, minimal washout of cement of the palatal vent hole was noted with no treatment required.

DISCUSSION

Within the 7 years of follow-up period, three out of 102 implants were recorded as early failures because of a postoperative infection in adjacent area. Thereafter, no additional implants were lost, rendering an implant

survival rate of 97.1% after 7 years. This demonstrates that oxidized, moderately rough surface implants used as immediate anchorage for prostheses may integrate with the same predictability as documented for the traditional staged loading protocol,^{37,38} thereby supporting the research hypothesis. Considering that the majority of the implants were placed in posterior regions as well as in soft bone quality conditions, initial as well as long-term outcome was not jeopardized. Moreover, it can be assumed that the reason for the three failures was not related to the immediate loading protocol or implant surface *per se* as the implant losses occurred following a flap dehiscence with suppuration in a GBR area. The present study, initial marginal bone remodeling leveled off during the first year of function. At the 12-month evaluation, a mean (SD) change of 1.2 (0.9) mm ($n = 98$) was noted for the bone level.³⁹ This result is in accordance with the reported mean marginal bone resorption by Calandriello and colleagues²⁵ and Vanden Bogaerde and colleagues²⁶ following 12 to 18 months. Moreover, the mean marginal bone level within the present study remained fairly stable up to 7 years, thereby fulfilling the criteria for long-term marginal tissue stability as proposed by Albrektsson and colleagues^{40,41} Furthermore, 98 out of 99 implants at the 1-year follow-up and 73 out of a possible 73 at the 7-year time point could be radiographically evaluated, indicating high reliability of the data. Finally, the present data are consistent with existing long-term data on implants placed to support fixed partial dentures and loaded using a conventional, staged protocol.^{27–30}

On average, an exposure of the coronal moderately rough surface to the supracrestal connective tissue compartment of 0.8 mm resulted due to a mean marginal bone remodeling of 1.2 mm occurring during the first year of loading. Since there was only minimal change in marginal bone level between the 1- and the 7-year measurements, it can be concluded that the moderately rough surface *per se* did not negatively affect the marginal tissue response. This is further supported when focusing on the long-term pattern of bone remodeling around implants exhibiting more than 2 mm of bone remodeling during the first year when no further trend for pronounced remodeling was detected (Figure 3).

In a split-mouth study, Benic and colleagues investigated marginal bone remodeling at implants placed in the native bone versus implants placed in combination with local regenerative measurements (GBR).³⁵ They

TABLE 7 Statistics on Microbiota, Comparing Bacterial Accumulation between Implants and Teeth

	p
TBL (total bacterial load)	.064
Aa	1.000
Bf	.112
Pg	.494
Td	.839

Wilcoxon signed rank test, significant differences ($p < .05$).

Aa = *Actinobacillus actinomycetemcomitans*; Bf = *Bacteroides forsythus*; Pg = *Porphyromonas gingivalis*; Td = *Treponema denticola*.

found no difference during the 5-year study period. In the present study, initial marginal bone remodeling during the first 6 months was significantly more pronounced for the group of implants having received marginal GBR as compared with the group of implants placed in the native bone. A possible explanation could be that according to the study protocol, the suprastructures at all implants were several times removed during the early healing phase for measuring implant stability on an individual basis. As the locally applied regenerative measurements are immature during this early stage of healing, the stability of the marginal GBR volume may be reduced. Hence, this repeated intervention might have provoked a more pronounced marginal hard tissue retraction at these sites. A further reason for more pronounced marginal remodeling within the GBR group could be that the marginally applied regenerative volume is per se more prone to healing- and maturation-related volume contraction as the native bone.

With regard to early microbial colonization of the "pristine" peri-implant pocket, Quirynen and colleagues reported that a complex microbiota was established within the first week after connection to the intraoral environment. Following 7 days of undisturbed plaque accumulation, the detection frequency for most species was nearly identical in plaque samples from peri-implant pockets compared with samples from the reference teeth.²³ Furthermore, in a group of 213 subjects including 976 Brånemark System implants being in function for 9 to 14 years, Renvert and colleagues detected no marked difference in microbial profile between implants and teeth.²⁴ These findings are in line with the microbiological analysis conducted in the present study at the 7-year follow-up, where also no significant difference with regard to TBL or the frequency of four marker species could be detected.

With reference to adverse events related to implant-borne prostheses, the incidence of biological and technical complications has been reported when systematically reviewing the literature over the long-term clinical studies on delayed loaded implants.³⁶ In particular, technical complications were reported on average for 21.3% of all fixed partial dentures, and biological complications occurred on average in 8.6% during the first 5 years in function. At the 7-year follow-up for this patient population, biological complications were noted for three restorations (8.3%) not requiring any

extensive interventions. Cleaning and reinstruction for oral hygiene were conducted. For five restorations (13.9%), technical complications were noted, whereof one required a refilling of the occlusal screw access hole, two required minor polishing, and two required no intervention. Annual recall examinations including evaluation of occlusion and professional oral hygiene as well as the use of torque control devices to fix abutments and prostheses may have had a positive impact in keeping a low rate of complications. The small number of biological complications encountered in this study is also in line with results from a systematic review on marginal soft tissue aspects at implants subjected to immediate loading or immediate restoration.⁴⁴ In particular, the reviewers concluded that once immediately loaded or restored implants integrate successfully, they appear to show a longitudinal soft tissue reaction with regard to dimensional as well as morphologic aspects comparable with those of conventionally loaded implants. Nevertheless, further clinical studies are still needed to verify the long-term results of the current report.

CONCLUSION

Within the limitations of this study, it is concluded that the applied immediate loading protocol using a slightly tapered implant design with an oxidized, moderately rough surface texture is a successful treatment modality also including regions exhibiting soft bone quality. The 7-year outcome is similar to that documented for delayed loading protocols.

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