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Surgical therapy of peri-implantitis lesions by means of a bovine-derived xenograft: comparative results of a prospective study on two different implant surfaces

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Abstract

Objectives: The aim of this prospective study was to evaluate a regenerative surgical treatment modality for peri-implantitis lesions on two different implant surfaces.

Materials and Methods: Twenty-six patients with one crater-like defect, around either TPS (Control) or SLA (Test) dental implants, with a probing depth (PD) $\geqslant 6$ mm and no implant mobility, were included. The implant surface was mechanically debrided and treated using a 24% EDTA gel and a 1% chlorhexidine gel. The bone defect was filled with a bovine-derived xenograft (BDX) and the flap was sutured around the non-submerged implant.

Results: One-year follow-up demonstrated clinical and radiographic improvements. PDs were significantly reduced by 2.1 ± 1.2 mm in the Control implants and by 3.4 ± 1.7 mm in the Test implants. Complete defect fill was never found around Controls, while it occurred in three out of 12 Test implants. Bleeding on probing decreased from $91.1 \pm 12.4\%$ (Control) and $75.0 \pm 30.2\%$ (Test) to $57.1 \pm 38.5\%$ ($p = 0.004$) and $14.6 \pm 16.7\%$ ($p = 0.003$), respectively. Several deep pockets ($\geqslant 6$ mm) were still present after surgical therapy around Controls.

Conclusions: Surface characteristics may have an impact on the clinical outcome following surgical debridement, disinfection of the contaminated surfaces and grafting with BDX. Complete fill of the bony defect seems not to be a predictable result.

Key words: biomaterial; bone substitute; defect fill; peri-implantitis; surgical treatment

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Conflict of interest and source of funding statement

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During the last few years, biological complications around dental implants have become a frequent finding in patients (Berglundh et al. 2002, Roos-Jansåker et al. 2006, Lindhe & Meyle 2008, Fransson et al. 2009, Koldsland et al. 2010, Roccuzzo et al. 2010, Lang & Berglundh 2011). According to Zitzmann & Berglundh (2008), peri-implantitis is characterized by inflammatory lesions in peri-implant tissues and an associated loss of supporting bone.

Various protocols have been suggested in the treatment of peri-implantitis. Non-surgical procedures alone, however, appear to be insufficient to resolve peri-implantitis lesions (Renvert et al. 2008), while surgical procedures may promote access for the removal of bacteria on the implant surface. Nevertheless, Claffey

et al. (2008) reported that data obtained from case series and animal experiments indicate that no single cleaning method including chemical agents used during surgical treatment of peri-implantitis was proven to be superior.

The outcome of the surgical treatment of peri-implantitis at implants with different types of surfaces has been evaluated in animal experiments. Persson et al. (2001) reported that resolution occurred following surgical treatment at implants with both smooth and SLA surfaces. Parlar et al. (2009) showed that the treatment of peri-implantitis with decontamination method resulted in considerably more bone fill around an SLA implant than TPS. More recently, Albouy et al. (2011) demonstrated that the resolution of peri-implantitis following surgical treatment is possible but the outcome of treatment is influenced by implant surface characteristics.

Surgical treatment of peri-implantitis lesions has been evaluated in several clinical studies (Behneke et al. 2000, Khoury & Buchmann 2001, Leonhardt et al. 2003, Romeo et al. 2005, 2007, Schwarz et al. 2006, 2009, 2010, Roos-Jansåker et al. 2007a, b, Wiltfang et al. 2010). Two systematic reviews based on RCTs (Kotsovilis et al. 2008, Esposito et al. 2010) failed, however, to determine which is the most effective way to treat peri-implantitis.

Apart from surface decontamination, it seems useful, in crater-formed defects, to correct the anatomical conditions for improving plaque control and for eliminating the favourable environment for anaerobic bacteria by means of bone-regenerative procedures (Schwarz et al. 2010). The most recent literature research on the subject, to the best of our knowledge (Sahrmann et al. 2011), aimed to assess the available literature for regenerative treatment using bone-graft substitutes and membranes. A large heterogeneity concerning disinfection protocols and regenerative materials used and the high percentage of low-quality studies rendered a meta-analysis impossible. Well-controlled trials are needed to determine predictable protocols for the successful treatment of peri-implantitis using the GBR technique.

The aim of this prospective study was to evaluate and compare the healing, following regenerative surgery, after decontamination of implants, by means of a bovine-derived xenograft, in defects around implants of two different surfaces.

Materials and Methods

Patient population

From January 2008 to June 2009, 26 patients (10 males and 16 females; mean age: 60 ± 7.9 years; four smokers), who presented a peri-implantitis crater-like lesion with a probing depth (PD) of ≥ 6 mm and no implant mobility, were consecutively enrolled from those attending the principal investigator's private practice (Fig. 1). The specialist practice receives referrals from general dental practitioners, specialists in orthodontics, specialists in maxillo-facial surgery and physicians, mainly located in the North-west of Italy.

Patients had been treated, in the previous years, for periodontitis and had subsequently received therapy by means of dental implants of two different surfaces, i.e. titanium plasma-sprayed surface (TPS) and sand-blasted large grit and acid-etched surface (SLA) (Straumann Dental Implant System, Straumann AG, Basel, Switzerland). All implants supported only cemented fixed dental prostheses. Patients had been recalled at various intervals, depending on the initial diagnosis and the results of the therapy (Mombelli & Lang 1998), for supporting periodontal therapy. Motivation, reinstruction, instrumentation and treatment of re-infected sites were performed as needed. Patients had been placed on an individually tailored maintenance care programme, including continuous evaluation of the occurrence and the risk of disease progression.

All patients had complied with the recall programme until evaluation of the peri-implantitis. Hollow cylinder and hollow screw implants were not included in the study. Only one implant defect per patient was included in the study (Table 1). The baseline demographic and clinical characteristics of the patients, divided into two groups according to the implant surface, are represented in Table 2. Each patient was provided with a detailed description of the procedure. They were also informed that their data would be used for statistical analysis and gave their informed consent to the treatment. No ethical committee approval was sought to start this observational study, as it was not required by national law or by ordinance of the local inspective authority. The prospective study was performed in accordance with the principles stated in the Declaration of Helsinki and the Good Clinical Practice Guidelines.

Surgical procedures

Each patient underwent scaling and root planing and professional implant cleaning after receiving personalized oral hygiene instructions. No surgery was performed before the re-assurance of good motivation and compliance from each single patient, full-mouth plaque score (FMPS) < 20% and full-mouth bleeding score (FMBS) < 20%.

All surgeries were performed by one surgeon (M. R.) with 20 years of experience in periodontal surgery. The area selected for surgery was anaesthetized with mepivacaine plus epinephrine 1:100,000. Full-thickness, mucoperiosteal flaps were raised by means of intracrevicular incisions. Subsequently, all granulation tissue was completely removed from the defect area and the implant surfaces were thoroughly debrided using plastic curettes (Straumann

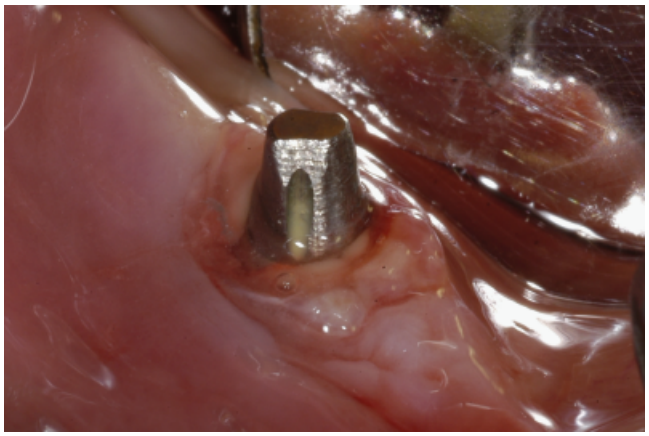

Fig. 1. Inflammation and pus around the implant, at baseline.

AG) (Fig. 2). Following cleaning, the exposed implant was covered with EDTA 24% (Prefgel Straumann AG) for 2 min. and a Chlorhexidine 1% gel (Corsodyl dental gel, GlaxoSmithKline, Baranzate, Italy) for 2 min. Then the implant and bony surfaces were thoroughly rinsed with sterile physiologic saline. A bovine-derived xenograft (BDX) (BioOss® Collagen, Geistlich, Wolhusen, Switzerland) was applied in a way as to homogeneously fill the intrabony defect component (Fig. 3). Before its application, the graft material was moistened in sterile saline. If the area had no keratinized tissue, following grafting, a connective tissue graft was trimmed and adapted over the entire defect so as to cover 2–3 mm of the surrounding alveolar bone and to ensure stability of the graft material. Finally, the flap was repositioned coronally and fixed with sutures to ensure a non-submerged healing procedure (Fig. 4).

Post-surgical care

Patients were instructed to take 1 g of amoxicillin and clavulanic acid twice a day for 6 days, starting at least 1 h before surgery, and non-steroidal analgesics, as needed. Immediately after surgery, the patients applied ice packs on the treated area, and it was recommended that these be kept in place for at least 4 h. Patients were advised to discontinue tooth brushing and to avoid trauma at the site of surgery for 3 weeks. They were also instructed to use a 0.2% chlorhexidine digluconate rinse for 1 min. three times a day for the same period of time. Patients were seen after 7 days and then weekly for the first month to monitor healing. The sutures were removed after 14 days. After the healing phase, patients were placed on an individually tailored maintenance care programme. Motivation, reinstruction, supragingival instrumentation and antiseptic therapy were performed as needed.

Clinical assessments

The outcome variables for this study were PD reduction, bleeding on probing (BOP) reduction and bone defect (BD) fill.

Immediately before surgery and 12 months post-operatively, a calibrated examiner (F. B.), blinded to the initial classification of the patients, collected the following parameters by means of a periodontal probe (XP23/UNC 15, Hu-Friedy, Chicago, IL, USA): PD according to Fiorellini & Weber (1994) at the mesial, distal, buccal and palatal/lingual aspects of each implant (Fig. 5). At the same time and sites, the presence of

Table 1. Data on patients, defect location, implant type, months in function

n	Sex	Age	Smoking	Site	Implant type	Months in function
1	M	56		25	∅4.1 × 10 mm TPS	80
2	F	53		31	∅3.3 × 12 mm TPS	63
3	M	68		21	∅4.1 × 10 mm SLA	22
4	F	66		35	∅4.1 × 10 mm TPS	98
5	M	55		46	∅4.1 × 08 mm SLA	14
6	F	55		14	∅4.1 × 10 mm TPS	20
7	F	60		24	∅ 4.1 × 10 mm SLA	58
8	M	68		27	∅4.8 × 08 mm SLA	44
9	F	67		26	∅4.1 × 10 mm TPS	114
10	M	58	Yes	13	∅ 4.1 × 10 mm SLA	54
11	F	70		23	∅4.1 × 08 mm TPS	96
12	F	56		37	∅4.8 × 08 mm SLA	69
13	F	79		35	∅4.1 × 10 mm TPS	60
14	M	60		26	∅4.1 × 10 mm TPS	24
15	F	54		26	∅4.1 × 10 mm TPS	58
16	F	63		31	∅4.1 × 10 mm TPS	90
17	F	46	Yes	17	∅4.8 × 10 mm SLA	34
18	M	51	Yes	46	∅4.1 × 12 mm TPS	49
19	F	71		17	∅4.8 × 10 mm SLA	78
20	M	64	Yes	35	∅4.1 × 12 mm TPS	84
21	F	57		36	∅4.1 × 08 mm TPS	92
22	F	56		27	∅4.1 × 08 mm SLA	54
23	F	56		14	∅4.1 × 10 mm SLA	49
24	F	63		46	∅4.1 × 10 mm SLA	24
25	M	45		36	∅4.1 × 12 mm TPS	120
26	M	62		36	∅4.8 × 10 mm SLA	52

Table 2. Baseline demographic and clinical parameters in Control (TPS) $N = 14$ and in Test (SLA) $N = 12$, means ± SD, numbers (%)

	Control	Test	*p*
Female (%)	9 (64.3)	7 (58.3)	0.99
Age	59.9 ± 7.0	60 ± 8.8	0.98
Smoke (%)	2 (14.3)	2 (16.7)	0.99
FMPS (%)	30.5 ± 9.1	27.5 ± 7.5	0.33
FMBS (%)	29.4 ± 7.6	26.8 ± 10.4	0.21

FMPS, full-mouth plaque score; FMBS, full-mouth bleeding score.

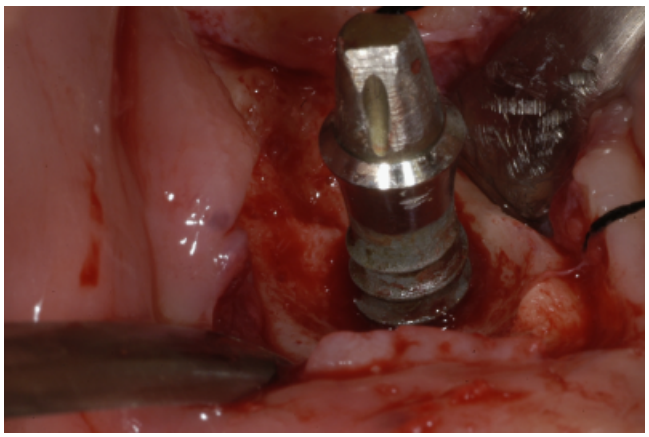

Fig. 2. Peri-implantitis lesion after the removal of granulation tissue and before decontamination of the implant surface.

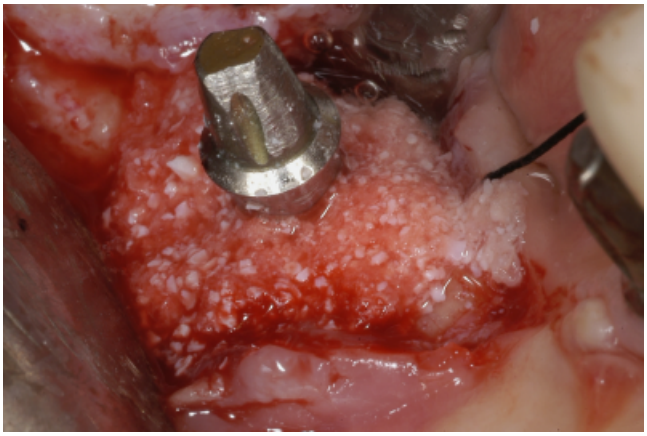

Fig. 3. Bovine-derived xenograft applied around the peri-implantitis defect.

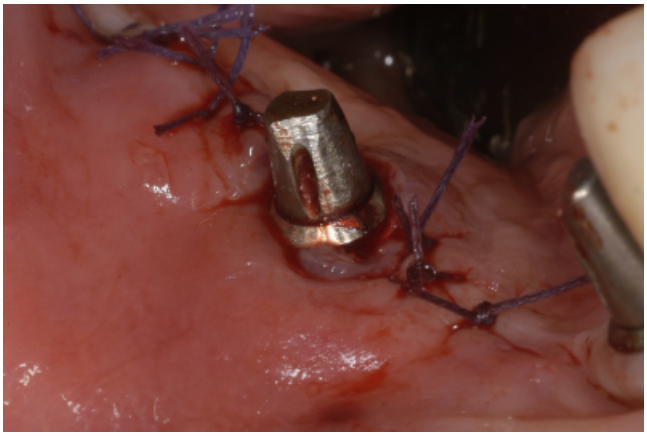

Fig. 4. Non-submerged suture of the flap.

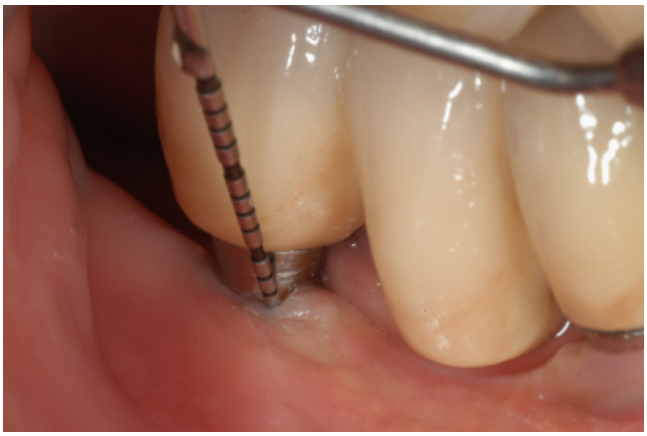

Fig. 5. Clinical situation and probing around the implant at the 1-year follow-up.

dental plaque (Pl), of BOP and of pus was recorded. Figures were rounded off to the nearest millimetre. At the same time, the distance between the base of the implant shoulder and the most coronal visible bone-to-implant contact (BL), measured in millimetres, both at the mesial and at the distal aspect of each implant, was calculated using standardized periapical intraoral films with a long cone technique (Roccuzzo et al. 2001, Bornstein et al. 2005). The 12-month BL values were compared with the baseline values according to the technique described previously by Roccuzzo et al. (2008) and the radiographic BD fill was calculated.

Statistical analysis

Each patient contributed with one peri-implantitis lesion and was, therefore, regarded as the statistical unit. Data were expressed as mean ± SD or percentages. The statistical distribution of the quantitative measures was found to be non-gaussian (Shapiro–Wilk test) and non-parametric tests were used. Comparison between the two groups was performed by means of Fisher's exact test for qualitative variables, and the Mann–Whitney rank-sum tests for quantitative variables. Pre- and post-surgery recordings were conducted using exact McNemar test or the Wilcoxon matched-pairs signed-rank test. All the tests were two-tailed. The level of significance was set at 5%.

Results

In all patients, surgery and immediate healing proceeded without complications and with minimal post-operative discomfort. No patient dropout and no implant removal were registered during the first 12 months of observation. The clinical parameters in both the groups at baseline and at the 1-year evaluation are summarized in Tables 2–4.

In the Control group, PD decreased from 7.2 ± 1.5 to 5.1 ± 2.0 mm, corresponding to a statistically significant reduction of 2.1 ± 1.2 mm ($p = 0.001$). In the Test group, PD decreased from 6.8 ± 1.2 to 3.4 ± 1.0 mm, corresponding to a statistically significant reduction of 3.4 ± 1.7 mm ($p = 0.003$). A statistically significant difference in PD reduction was found between the two groups ($p = 0.04$).

Controls presented on average 3.1 ± 1.1 sites per patient with PD ⩾ 6 mm at baseline and 1.2 ± 1.7 sites at 1 year ($p = 0.002$). Test implants presented 2.8 ± 1.1 mean sites per patient with PD ⩾ 6 mm at baseline, which all disappeared at the 1-year evaluation ($p = 0.002$). Even though the reduction was greater in the Test group, the difference between the two groups did not reach statistical significance.

At baseline, BOP was present around 91.1 ± 12.4% of the Control and

Table 3. Clinical parameters around the implants at baseline and 1 year after treatment in both groups, means ± SD, numbers (%)

	Baseline	Post-op	*p* value
Probing depth (mm)			
Control	7.2 ± 1.5	5.1 ± 2.0	0.001
Test	6.8 ± 1.2	3.4 ± 1.0	0.003
Number of sites per patient with PD⩾6 mm			
Control	3.1 ± 1.1	1.2 ± 1.7	0.002
Test	2.8 ± 1.1	0	0.002
Bone level (mm)			
Control	3.9 ± 1.6	2.2 ± 1.3	0.001
Test	3.0 ± 0.9	1.1 ± 0.8	0.002
Bleeding on probing at the implant site (%)			
Control	91.1 ± 12.4	57.1 ± 38.5	0.004
Test	75 ± 30.2	14.6 ± 16.7	0.003
Plaque at the implant site (%)			
Control	64.3 ± 25.4	30.4 ± 24.4	0.003
Test	45.8 ± 25.7	16.7 ± 16.3	0.01
Pus			
Control	10 (71.4%)	4 (28.6%)	0.01
Test	4 (33.3%)	0 (0%)	0.04

Table 4. Results of treatment in both groups, means ± SD, numbers (%)

	Control	Test	*p*
Probing depth reduction (mm)	2.1 ± 1.2	3.4 ± 1.7	0.04
Reduction of number of sites per patient with PD⩾6 mm	1.9 ± 1.6	2.8 ± 1.1	0.10
Bone defect fill (mm)	1.6 ± 0.7	1.9 ± 1.3	0.99
Complete bone defect fill	0/14 (0%)	3/12 (25%)	0.09
BOP reduction	19/56 (33.9%)	29/48 (60.4%)	0.007
Plaque reduction	19/56 (33.9%)	14/48 (29.1%)	0.59
Pus elimination	6/10 (60%)	4/4 (100%)	0.25

BOP, bleeding on probing.

75.0 ± 30.2% of the Test implant sites. At the 1-year examination, the values decreased significantly to 57.1 ± 38.5% ($p = 0.004$) and to 14.6 ± 16.7% ($p = 0.003$), respectively. The difference between the two groups was statistically significant ($p = 0.007$).

In the Control group, the mean BL decreased from 3.9 ± 1.6 to 2.2 ± 1.3 mm, corresponding to a reduction of 1.6 ± 0.7 mm ($p = 0.001$). In the Test group, BL decreased from 3.0 ± 0.9 to 1.1 ± 0.8 mm, corresponding to a reduction of 1.9 ± 1.3 ($p = 0.002$). Both reductions were statistically significant, but the difference between the two groups was not statistically significant. Complete BD fill was never found in the Control group, while it occurred in three out of 12 in Test group. However, no statistically significant difference was found between the two groups.

At baseline, plaque was found around 64.3 ± 25.4% of the Control and 45.8 ± 25.7% of the Test implants. At the 1-year examination, plaque was present around 30.4 ± 24.4% ($p = 0.003$) and 16.7 ± 16.3% ($p = 0.01$), respectively. The reduction was statistically significant in both groups. The difference between the Test and the Control groups, however, did not reach statistical significance.

Before treatment, pus was present around 10 implants of the Control implants and four of the Test implants. At the end of the observation period, all Test implants healed, while four of the Control implants did not. After the 1-year examination, two of these four TPS implants presented deep pockets with pus and were subsequently removed.

Discussion

The aim of this prospective study was to evaluate the results of regenerative surgery by means of BDX in peri-implant defects around implants of two different surfaces. The outcome variables were PD reduction, BOP reduction and BD fill.

The proposed treatment was effective in reducing the mean pocket depth, even though it produced better results in the Test group. In particular, the mean PD decrease was 2.1 ± 1.2 mm in the Control group and 3.4 ± 1.7 mm in the Test group, with a statistically significant difference between the groups ($p = 0.04$). No deep pockets (PD⩾6 mm) were detected in the Test implants at the end of the observation period, while 1.2 ± 1.7 mean sites were still present in the Control implants. From a clinical point of view, this result seems to be quite interesting, even though the difference did not reach statistical significance, probably due to the small sample size of the two groups. It is not possible to draw definitive conclusions, but these positive preliminary results encourage further investigation with a similar protocol.

The surgical therapy was also effective in reducing the proximal BDs, especially in the Test implants. In particular, complete defect fill occurred around 25% of the SLA implants while it was never found around TPS implants. The mean defect fill (measured mesially and distally at each implant) was 1.6 ± 0.7 mm in the Control group and 1.9 ± 1.3 mm in the Test group, with a difference that did not reach significance. Two TPS implants out of 14 were removed, at the end of the follow-up period, as a consequence of the persistence of deep pockets.

Behneke et al. (2000) presented a report on 25 ITI screw implants in 17 patients, with air polishing of the surface, and corticocancellous bone grafts or particulate bone placed into the peri-implant osseous defects, allowing transmucosal healing. Two of the 25 cases resulted in a negative outcome of the procedure. The results of this study suggested that the use of autogenous bone grafts appears to be an efficacious treatment approach for restoring the bone loss caused by peri-implantitis. The success of the treatment was attributed to the use of autogenous bone as an augmentation material with the possibility of maintenance of cellular viability and rapid revascularization. It must be stated, however, that the possibility of the placement of a block into a defect depends on the morphology of the defect and may be quite difficult under some anatomic circumstances. On the other hand, the spongy consistency of BDX Collagen, used in the present study after moistening in sterile saline,

allowed simple trimming and easy adaptation of the material to the peri-implant defects.

Khoury & Buchmann (2001) concluded that submerged healing of autogenous bone grafts, with and without the application of barriers, in advanced peri-implant disease represents an appropriate treatment regimen to augment the open creater-formed defects, and is significantly associated with the long-term stability of peri-implant health. The advantage of the technique presented in the present study is that healing seems to occur without the need for the removal of the prosthetic restoration in order to submerge the implant reducing time and the cost of treatment. It must be stated, however, that a minimal amount of keratinized tissue was considered necessary for the successful application of the technique. Therefore, in areas with no keratinized mucosa, a connective tissue graft was trimmed and adapted to ensure stability of the graft material. Test and Control implants were, using the adopted technique, similar in all aspects, except for the implant surface. This was particularly interesting from a statistical point of view, as bias and variability were reduced to minimal levels. It would be useful in the future to assess whether the quality of the soft tissue, i.e. keratinized tissue *versus* alveolar mucosa, may influence the treatment outcomes of peri-implantitis, as previous studies have not taken this parameter into careful consideration.

Leonhardt et al. (2003) treated 26 implants demonstrating peri-implantitis in nine periodontally compromised partially dentate individuals (five smokers) by means of surgical exposure of the lesions and cleaning using hydrogen peroxide. No attempt was made to regenerate the BD, while an antibiotic regimen was started according to a susceptibility test of target bacteria. The treatment was successful in 58% of the implants treated during the 5-year follow-up period. Smoking seemed to be a negative factor for treatment success. On the contrary, Serino & Turri (2011) found no difference in the mean number of implants with peri-implantitis at the 2-year examination between smokers and non-smokers. In the present study, the number of smokers was too limited (four out of 26) to draw any conclusions.

The question of whether submerged healing and/or the application of a membrane may have resulted in more pronounced BD fill is still open. Roos-Jansåker et al. (2007b) presented one study on regenerative surgical treatment modality for peri-implantitis using submerged healing in 12 patients. After surgical exposure of the defect, the implant surface was treated using 3% hydrogen peroxide. The BDs were filled with a bone substitute and a resorbable membrane was placed over the grafted defect. The implant was then covered by flaps and submerged healing was allowed for 6 months. PD was reduced by 4.2 mm and a mean defect fill of 2.3 mm was obtained. In the same year, the same author Roos-Jansåker et al. (2007a) presented a prospective cohort study using a bone substitute with or without resorbable membranes punched and fixed over the implant by the abutment. There was no significant difference between the two groups. No sufficient data are present to arrive at definitive conclusions on this subject. In the present study, it was decided not to use the membrane in order to keep the procedure as simple as possible, in agreement with data showing that the placement of Bio-Oss Collagen alone in fresh extraction sockets may counteract post-extraction ridge reductions (Araújo & Lindhe 2009). More recently, Araújo et al. (2011) demonstrated that the placement of Bio-Oss Collagen in the void between the implant and the buccal–approximal bone walls of fresh extraction sockets provided additional amounts of hard tissue at the entrance of the previous socket and improved the level of marginal bone-to-implant contact.

A similar protocol, without the use of a membrane, was recently described by Wiltfang et al. (2010), who presented the results in 36 cases of peri-implantitis-induced bone loss (depth $>$ 4 mm) who were followed for 1 year. The implants were decontaminated with an etching gel and the defects were filled with autologous bone mixed 1:1 with a xenogenic bone graft. The BDs after treatment revealed a mean reduction of 3.5 mm compared with the values from 5.1 mm before surgery to 1.6 mm 1 year after treatment. The average reduction of the PD was 4 mm. PDs of more than 4 mm were present in seven implants.

Regarding BOP, at baseline, bleeding was found at 91.1 $\pm$ 12.4% of the sites compared with 57.1 $\pm$ 38.5% after treatment ($p = 0.004$), in the Control group and at 75.0 $\pm$ 30.2% of the sites compared with 14.6 $\pm$ 16.7% after treatment ($p = 0.003$), in the Test group. The improved bleeding scores for both groups indicate a clinically healthier situation after therapy in accordance with Lang et al. (1990) and Roos-Jansåker et al. (2007a, b).

It is interesting to note that at the 1-year evaluation, both FMPS (21.0 $\pm$ 6.8% *versus* 19.5 $\pm$ 5.2%) and FMBS (20.6 $\pm$ 6.0% *versus* 18.6 $\pm$ 6.1%) were reduced to an acceptable level, with no statistical difference between the two groups. This may indeed suggest that the study outcome is not related to oral hygiene but somehow to implant surface characteristics.

The question about the ideal protocol for a bactericidal effect against adhering bacteria is still open. Schou et al. (2003) indicated that the simplest method involving chlorexidine and saline should be the preferred implant surface preparation method. A recent paper by Gosau et al. (2010) revealed that several antiseptics seemed to be able to reduce the total amount of microorganisms accumulating on titanium surfaces, supporting the additional use of antibacterial agents in peri-implant therapy. Similarly, Schwarz et al. (2011) failed to demonstrate a significant impact of the method of surface decontamination on the clinical outcome following combined surgical therapy of advanced peri-implantitis lesions. The two-step procedure (EDTA $\pm$ chlorhexidine gel) used in this research has never been described before and has been selected because it presents the advantage of low cost and easy use. Its real efficacy, however, can be confirmed only by controlled bacterial studies.

Unlike the studies of Schwarz et al. (2006, 2009), where several implant types and implant surfaces were investigated, this research evaluated the outcome of the same surgical protocol on implants that differ by only one variable of interest, i.e. surface characteristics. While the TPS surface has S_a values of approximately 3.1 μm, SLA has S_a values of approximately 2.0 μm (Buser et al. 1999). In a recent systematic review, prepared for the Seventh European Workshop on Periodontology, Renvert et al. (2011) revealed that only a few studies provided data on how implant surfaces influence peri-implant disease, with no evidence that implant surface characteristics can have a significant effect on the initiation of peri-implantitis. In animals, it is demonstrated (Albouy et al. 2011) that the

resolution of peri-implantitis following surgery is possible and that the outcome of treatment is influenced by implant surface characteristics, but no comparative clinical research has confirmed this difference in humans. The preliminary results of this study seem to confirm data from a recent research on mandibles of dogs (Parlar et al. 2009), where the treatment of peri-implantitis with the decontamination method resulted in considerably more bone fill around an SLA implant than TPS. In clinical practice, of course, the amount of re-osseointegration on a previously plaque contaminated surface cannot be evaluated (Renvert et al. 2009).

In conclusion, the antimicrobial and surgical technique described resulted in a clinical healthier situation around many of the treated implants so that their function could be fully maintained. Moreover, the treatment around SLA implants presented better final results, even though the reason for this is not fully understood. The time in function of the implants varied considerably from 14 to 120 months. The impact of this variable is also completely unknown. Nevertheless, these preliminary results seem to suggest that the clinical decision of whether implants should be removed or treated may also be based on the surface characteristics. Ideally, this should be established on large well-designed RCTs with a long duration of follow-up. Practical and ethical reasons, however, make RCTs possible only after preliminary information, from lower quality studies, is available. Within its limits, mainly the lack of classification of the defects (Schwarz et al. 2010) and the relatively small sample size, the present pilot study represents a step in the definition of the ideal protocol for the treatment of peri-implant defect.

Finally, more years of observation are necessary to verify whether an osseous defect fill with incomplete ''re-osseointegration'' is sufficient to ensure favourable long-term maintenance of the implants.

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Clinical Relevance

Scientific rationale for the study: In animal studies, the treatment of peri-implantitis is influenced by the surface characteristics of the implants. Limited information on the regenerative possibilities in peri-implantitis lesions around implants of different surfaces is available in humans. The objective of this clinical trial is to test the efficiency of a surgical protocol in defects around TPS and SLA implants.

Principal findings: Surgical regenerative treatment by means of BDX resulted in clinical and radiographic significant improvements after 1 year, particularly around SLA implants. Complete fill of the bony defect seems not to be a predictable outcome.

Practical implications: Surface characteristics might be considered as a clinical parameter potentially influencing the outcome following surgical regenerative therapy of peri-implantitis lesions after decontamination of implants and grafting with BDX. These preliminary results provide an ethical base to perform randomized-controlled clinical studies to investigate various methods for the decontamination of implant surfaces and grafting materials. In the meantime, the clinical decision of whether implants should be removed or treated by means of decontamination and regenerative procedure may be based on several factors, including surface characteristics.