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Impact of the method of surface debridement and decontamination on the clinical outcome following combined surgical therapy of peri-implantitis: a randomized controlled clinical study

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Abstract

Objectives: The study aimed at investigating the impact of two surface debridement/decontamination (DD) methods on the clinical outcomes of combined surgical treatment of peri-implantitis.

Material and Methods: Thirty-two patients suffering from advanced peri-implantitis ($n = 38$ combined supra- and intra-bony defects) were treated with flap surgery, granulation tissue removal, and implantoplasty at buccally and supracrestally exposed implant parts. The intra-bony aspects were randomly allocated to surface DD using either (i) an Er:YAG laser (ERL) device, or (ii) plastic curets+cotton pellets+sterile saline (CPS). In both groups, the intra-bony component was augmented with a natural bone mineral and covered with a collagen membrane. Clinical and radiographic parameters were recorded at baseline and after 6 months of non-submerged healing.

Results: Two patients were lost during follow-up. At 6 months, ERL-treated sites failed to reveal higher reductions in mean bleeding on probing (ERL: 47.8 ± 35.5 *versus* CPS: 55.0 ± 31.1%) and CAL values (ERL: 1.5 ± 1.4 *versus* CPS: 2.2 ± 1.4 mm) when compared with the CPS group. Both groups exhibited a comparable radiographic bone fill at the intra-bony defect component.

Conclusion: The study failed to demonstrate a significant impact of the method of surface DD on the clinical outcome following combined surgical therapy of advanced peri-implantitis lesions.

Key words: bone graft; collagen membrane; implantoplasty; peri-implantitis; surgical regenerative therapy

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Conflict of interests and source of funding statement

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Surgical access to peri-implantitis lesions facilitates the removal of all granulation tissue from the defect area as well as a thorough debridement and decontamination of exposed implant surfaces (Lindhe & Meyle 2008). Animal studies have indicated that this approach was associated with a resolution of the inflammatory cell infiltrate, and in case of a submerged healing procedure, promotion of new bone fill and a certain re-establishment of new bone-to-implant contact (BIC) (Hall et al. 1999, Machado et al. 2000, Schou et al. 2003, Persson et al. 2004, Schwarz et al. 2006b). Previous experimental data also suggest that the adjunctive use of bone augmentation procedures

and the principle of guided bone regeneration (GBR) may be associated with an improved histological outcome of therapy (Claffey et al. 2008, Renvert et al. 2009). From a clinical point of view, however, this beneficial effect appeared to be potentially influenced by either the physico-chemical properties of bone graft substitutes or the configuration of the peri-implant defect (Schwarz et al. 2008, 2009b, 2010) In particular, while various types of bone graft substitutes were proven to be associated with clinical and radiological improvements over a period of 6–12 months (Schwarz et al. 2006a, Roos-Jansaker et al. 2007), a predictable long-term stability (i.e. 2 and 4 years) of these promising results could, so far, only be documented for a natural bone mineral (NBM), which was covered with a native collagen membrane (CM) (Schwarz et al. 2008, 2009b). In this context, it must be stressed that bone grafting techniques primarily attempt to fill and subsequently obstruct the osseous defect, rather than to address disease resolution (Lindhe & Meyle 2008). The latter aspect might primarily be achieved by a proper method of surface decontamination. However, the currently available animal and human studies on surgical treatment of peri-implantitis failed to point to a superiority of any single approach for surface decontamination (i.e. cotton pellets soaked in sterile saline, chemical agents, air abrasives, lasers) (Claffey et al. 2008, Renvert et al. 2009). When considering the impact of defect configuration on the clinical outcome of surgical regenerative therapy of peri-implantitis lesions using NBM+CM, best results could be achieved in circumferential-type (referred to as Class Ie) intra-bony defects (Schwarz et al. 2010). In contrast, both semicircumferential- (referred to as Class Ib) and circumferential- (referred to as Class Ic) type defects exhibiting a buccal dehiscence showed significantly lower changes in mean probing pocket depths (PD) and clinical attachment level (CAL) gains after 6 months of non-submerged healing. A site-level analysis has pointed to lowest PD and CAL changes at the midbuccal aspect of Class Ib and Class Ic groups (Schwarz et al. 2010). Based on these findings, one might speculate that NBM was not sufficiently stabilized in the dehiscence area of Class Ib and Class Ic defects, thus favouring a dispersion of the bone graft particles. Because a stabilization of particulated bone grafts might also be challenging at supracrestally exposed implant surfaces, currently available clinical concepts for the management of the supracrestal defect (i.e. Class II) component used a surgical elimination of pathological peri-implant pockets in combination with an implantoplasty to reduce the risk for a re-infection in this area (Romeo et al. 2005, 2007). It has been reported that peri-implantitis lesions in humans most commonly featured a combined defect configuration including a Class II (79%) as well as an intra-bony aspect (i.e. Class I). Even though Class Ie showed the highest frequency (55.3%), buccal dehiscences occurred in 13.3–15.8% (Classes Ic and Ib, respectively) of the implants (Schwarz et al. 2007). At the time being, there are no clinical data available reporting on the combined surgical resective (i.e. implantoplasty) and regenerative treatment of Class I+II peri-implantitis defects.

Therefore, the present randomized controlled clinical trial aimed at investigating the impact of two surface debridement/decontamination (DD) methods [i.e. Er:YAG laser *versus* plastic curets+cotton pellets soaked in sterile saline (CPS)] on the clinical outcome of a combined surgical resective (i.e. Classes Ib, Ic, and II) and regenerative (i.e. Class I) treatment of peri-implantitis.

Materials and Methods

Study population and design

The study population consisted of 32 partially edentulous patients (11 men and 21 women; mean age 60.8 ± 10.9 years) exhibiting a total of $n = 38$ implants (Table 1), all suffering from moderate to advanced (i.e. combined Class I and Class II defects) peri-implantitis (Mombelli & Lang 1994). All patients attended the Department of Oral Surgery, Heinrich Heine University, Düsseldorf, Germany for surgical treatment procedures.

Before participation, each patient was given a detailed description of the procedure and was required to sign informed consent forms. The study was in accordance with the Helsinki Declaration of 1975, as revised in 2000 and the study protocol was approved by the ethics committee of the Heinrich Heine University.

Before the start of the experimental part of the study and in order to reduce the signs of inflammation (i.e. suppuration and pus formation), the study implants received a single course of non-surgical instrumentation using plastic curets (Straumann, Waldenburg, Switzerland) combined with an antiseptic pocket irrigation using 0.2% chlorhexidine digluconate solution (Corsodyl®, GlaxoSmithKline Consumer Healthcare, Bühl, Germany) (CHX) and subgingival application of CHX gel 0.2% (Corsodyl® Gel). At 2 weeks after initial therapy, all patients were treated with access flap surgery, granulation tissue removal, and implantoplasty at both buccally (i.e. Classes Ib and Ic) and supracrestally (i.e. Class II) exposed implant surfaces. The remaining intra-bony aspects (i.e. Classes Ib, Ic, and Ie) were randomly allocated to surface DD using either (i) ERL or (ii) CPS. In both groups, the intra-bony component was augmented with NBM and covered with CM. Clinical and radiographic parameters were recorded at baseline and after 6 months (i.e. primary endpoint of a follow-up period

Table 1. Distribution of different implant systems in both groups at baseline

Group	ANK	AST	BRA	CAM	ITI	KSI	REP	TSV	XIV	NI
CPS ($n = 16$)	1	0	2	1	6	0	0	3	2	1
ERL ($n = 19$)	0	1	4	1	3	1	1	2	1	5

ANK, Ankylos® (cylindrical screw, microrough surface), Dentsply Friadent, Mannheim, Germany; AST, Astra Dental Implant System® (cylindrical screw, microthread, nanotype surface), Astra Tech Dental, Mölndal, Sweden; BRA, Brånemark System® (cylindrical screw, machined surface), Nobel Biocare AB, Göteborg, Sweden; CAM, Camlog Screw Line® (cylindrical screw, microrough surface), Camlog Biotechnologies AG, Basel, Switzerland; ITI, ITI® (cylindrical screw, microrough surface), Institut Straumann AG, Basel, Switzerland; KSI, KSI Bauer Schraube® (conical screw, machined surface), KSI GmbH, Bad Nauheim, Germany; REP, NobelReplace® (tapered screw, microrough surface), Nobel Biocare AB, Göteborg, Sweden; TSV, Tapered Screw Vent® (tapered screw, microrough surface), Zimmer Dental, Freiburg, Germany; XIV Xive® (cylindrical screw, microrough surface), Dentsply Friadent, Mannheim, Germany; NI, Non-identifiable implant systems.

of 24 months) of non-submerged healing (Fig. 1).

Patient selection

For patient selection, the following inclusion criteria were defined (Schwarz et al. 2010): the (1) presence of at least one screw-type titanium implant exhibiting either a Class Ib (i.e. buccal dehiscence+semicircular bone resorption to the middle of the implant body), Class Ic (i.e. buccal dehiscence+circular bone resorption under maintenance of the lingual compacta), or Class Ie (i.e. circular bone resorption under maintenance of the buccal and oral compacta) defect configuration with a PD of >6 mm and an intra-bony component of >3 mm as estimated clinically [i.e. bone sounding using a periodontal probe (PCP 12, Hu-Friedy, Chicago, IL, USA)] and radiologically, (2) Class II $\geqslant 1$ mm, (3) no implant mobility, (4) single tooth and bridgework restaurations without overhangings or margins, (5) no evidence of occlusal overload (i.e. occlusal contacts revealed appropriate adjustment), (6) the presence of at least 2 mm of keratinized peri-implant mucosa to facilitate a re-positioning of the mucoperiosteal flap at the augmented areas, (7) treated chronic periodontitis and proper periodontal maintenance care, (8) a good level of oral hygiene [plaque index (PI) <1 (Löe 1967)], (9) no systemic diseases that could influence the outcome of the therapy [i.e. diabetes (HbA1c <7), osteoporosis, bisphosphonate medication], and (10) non-smoker or light smoking status in smokers (<10 cigarettes per day). Hollow cylinder implants were excluded from the study.

Clinical measurements

The following clinical measurements were performed immediately before surgery (baseline), and 6 months after treatment using a periodontal probe (PCP 12): (1) PI (Löe 1967), (2) bleeding on probing (BOP), evaluated as present if bleeding was evident within 30 s after probing, or absent, if no bleeding was noticed within 30 s after probing, (3) PD measured from the mucosal margin to the bottom of the probeable pocket, (4) mucosal recession (GR) measured from the implant neck (IN) to the mucosal margin, and (5) CAL measured from IN to the bottom of the probeable pocket. The primary outcome variable was CAL. All measurements were made at six aspects per implant: mesiovestibular (mv), midvestibular (v), distovestibular (dv), mesiooral (mo), midoral (o), and distooral (do) by one blinded and previously calibrated investigator. Pre- and postoperative non-standardized radiographs at 6 months were taken with the long cone paralleling technique and evaluated descriptively by the same blinded investigator (N.S.).

Configuration assessment of peri-implant bone defects

During open flap surgery, the supraalveolar, circumferential, and intra-bony components of the defects (Schwarz et al. 2010) were measured by one blinded and previously calibrated investigator (N.S.) (Fig. 2):

1. supraalveolar component – s(a) of the defect, measured as the maximum linear mesial or distal distance from the borderline between the bony and the transmucosal part (BTB) of the implant to the alveolar bone crest,
2. circumferential component – s(c) of the defect, measured as the linear distance from the vestibular – s(c-v), mesial – s(c-m), distal – s(c-d), and the oral – s(c-o) bone wall of the defect to the implant surface, and
3. intra-bony component of the defect, measured as the linear distance from the alveolar bone crest to the bottom of the defect (v, m, d, o).

The baseline defect characteristics in both groups are presented in Table 2.

Intra-examiner reproducibility

Five patients, each showing two implants with PDs $\geqslant 4$ mm on at least

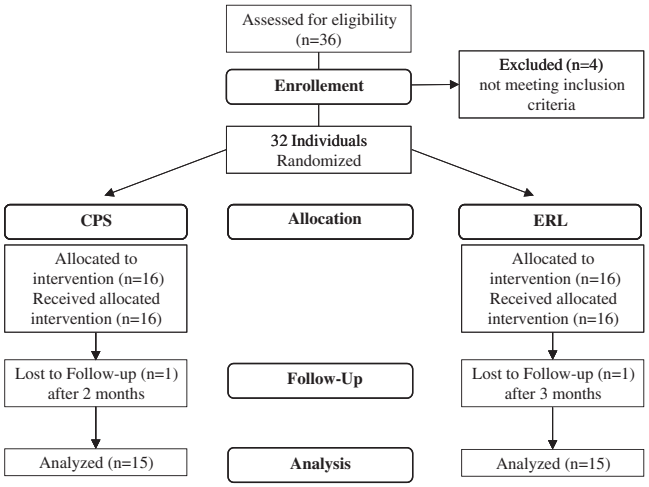

Fig. 1. A consort E-flowchart of the enrolment, allocation, follow-up, and analysis.

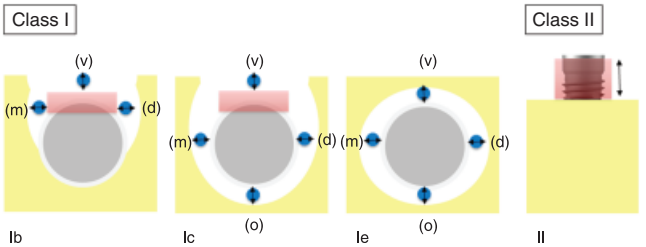

Fig. 2. Intra-operative assessment of the defect components. Class I: intra-bony component. Class Ib (i.e. buccal dehiscence+semicircular bone resorption to the middle of the implant body). Class Ic (i.e. buccal dehiscence+circular bone resorption under maintenance of the lingual compacta). Class Ie (i.e. circular bone resorption under maintenance of the buccal and oral compacta): intra-bony component (i), blue circles; circumferential (i.e. width) component s(c), arrows; m, mesial aspect; d, distal aspect; b, buccal aspect; o, oral aspect. Class II: supraalveolar component s(a), arrow. The red rectangles indicate the surface areas undergoing an implantoplasty.

one aspect, were used to calibrate the examiner. The examiner evaluated the patients on two separate occasions, 48 h apart. Calibration was accepted if measurements at baseline and at 48 h were within a millimetre at >90% of the time.

Randomization procedure

Supra- and intra-bony defect components were estimated before surgery on radiographs and by performing transmucosal bone sounding. According to a computer-generated protocol (RandList® DatInf GmbH, Tübingen, Germany), all defect sites were randomly assigned to the following methods of surface decontamination: (i) ERL or (ii) CPS.

The randomization process resulted in comparable mean values of all investigated clinical parameters at baseline in both groups (Table 3). Furthermore, the number of smokers was almost comparable in both groups (i.e. five in the ERL and three in the CPS group).

For the given sample size of 15 patients (two drop outs) per group, an 85% power detecting a 1 mm difference in CAL was calculated (Power and Precision, Biostat, Englewood, USA). For the power analysis, a standard normal distribution was assumed. The probability of a Type I error was set at 0.001. Sigma (0.75) was estimated based on the standard deviations observed in previous studies (Schwarz et al. 2006a, 2008).

Treatments

Mucoperiosteal flaps were raised buccally and orally by means of intracrevicular incisions under local anaesthesia. Subsequently, all granulation tissue was completely removed from the defect area and the implant surfaces by means of plastic curets (Straumann® Dental Implant System) (Fig. 3a). Implantoplasty at both buccally (i.e. Classes Ib and Ic) and supracrestally (i.e. Class II) exposed implant surfaces was performed in a way as to completely planish the threatened areas and smoothen the structured implant surface using diamant burrs (ZR Diamonds, Gebr. Brasseler GmbH & Co. KG, Lemgo, Germany) and arkansas stones under copious irrigation with sterile saline. Particular care was taken to completely remove any titanium deposits/dust from the surrounding tissues (Fig. 3b). According to the randomization code, DD of the remaining implant surface areas was either performed using CPS or ERL. In the CPS group, the plastic curets (Straumann® Dental Implant System) were used in a way as to completely remove all mineralized deposits by a chipping action. Afterwards, soaked cotton pellets were homogeneously adapted to all exposed implant surface areas and used under moderate pressure to remove all remaining non-mineralized deposits, which was followed by a thorough irrigation with sterile saline. An ERL device (elexxion delos, elexxion AG, Radolfzell, Germany) emitting a pulsed infrared radiation at a wavelength of 2.940 nm was selected for laser treatment. The laser beam was guided onto the exposed implant surfaces under water irrigation with a specially designed periodontal handpiece and a lancet-shaped sapphire tip emitting a lateral laser beam (experimental duros tip, elexxion AG). Laser parameters were set at 100 mJ/pulse (11.4 J/cm^2), 10 Hz, and pulse energy at the tip was approximately 90 mJ/pulse. The fibre tip was guided in a semicircular motion from coronal to apical parallel to the implant surface in the contact mode (Fig. 3c). In both groups, NBM (BioOss® spongiosa granules, particle size 0.25–1 mm, Geistlich, Wolhusen, Switzerland) was applied in a way as to homogeneously fill the intra-bony defect component. Before its application, the graft material was moistened in sterile saline for 5 min. Following grafting, a bioresorbable type I/III CM of porcine origin (BioGide®, Geistlich) 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 (Fig. 3d and e). Neither sutures nor pins were used for membrane fixation or stabiliza-

Table 2. Distribution and baseline defect characteristics in mm (mean ± SD)

Group	Class Ib	Class Ic	Class Ie	s(a)	s(c)	i
CPS ($n = 16$)	4	6	6	2.5 ± 1.1	2.7 ± 0.6	2.3 ± 1.3
ERL ($n = 19$)	4	6	9	2.2 ± 1.2	2.6 ± 0.8	2.9 ± 1.5

Comparisons between groups (unpaired *t*-test): NS, respectively. s(a) – supraalveolar component; s(c) – circumferential component (i.e. width); i – intrabony component.
CPS – plastic curets+cotton pellets soaked in sterile saline; ERL – Er:YAG laser.

Table 3. Clinical parameters (mean ± SD) at baseline and 6 months for the CPS ($n = 15$ patients) and ERL ($n = 15$ patients) groups

	Baseline	6 Months	Difference	*p* value*
Plaque index				
CPS	0.7 ± 0.6	1.2 ± 0.9	0.5 ± 0.6	$p<0.05$
ERL	0.7 ± 0.5	1.1 ± 0.9	0.4 ± 0.5	$p<0.01$
	NS		NS	
Bleeding on probing				
CPS	100 ± 0.0%	45.0 ± 31.2%	55.0 ± 31.1%	$p<0.001$
ERL	93.3 ± 18.7%	45.5 ± 33.0%	47.8 ± 35.5%	$p<0.001$
	NS		NS	
Probing depth				
CPS	5.5 ± 1.8 mm	3.1 ± 0.6 mm	2.4 ± 1.5 mm	$p<0.001$
ERL	5.1 ± 1.6 mm	3.4 ± 0.6 mm	1.7 ± 1.4 mm	$p<0.001$
	NS		NS	
Mucosal recession				
CPS	1.2 ± 1.2 mm	1.4 ± 1.3 mm	0.2 ± 0.3 mm	$p<0.05$
ERL	1.3 ± 0.9 mm	1.5 ± 1.0 mm	0.2 ± 0.2 mm	$p<0.05$
	NS		NS	
Clinical attachment level				
CPS	6.7 ± 2.2 mm	4.5 ± 1.4 mm	2.2 ± 1.4 mm	$p<0.001$
ERL	6.4 ± 2.0 mm	4.9 ± 1.1 mm	1.5 ± 1.4 mm	$p<0.001$
	NS		NS	

Comparisons between groups (unpaired *t*-test): NS, respectively.
CPS – plastic curets+cotton pellets soaked in sterile saline; ERL – Er:YAG laser.
*Comparisons within groups (paired *t*-test).

tion. Finally, the mucoperiosteal flaps were repositioned coronally and fixed with vertical or horizontal mattress sutures in a way to ensure a non-submerged healing procedure. All treatments were performed by the same experienced surgeon (F.S.).

Postoperative care

Postoperative care consisted of rinsing with a 0.2% chlorhexidine digluconate solution (Corsodyl®, GlaxoSmithKline Consumer Healthcare, Bühl, Germany) twice a day for 2 weeks. The sutures were removed 10 days after the surgery. Recall appointments to control oral hygiene and wound healing were scheduled every second week during the first 2 months after surgery and monthly during the short-term observation period of 6 months. A supragingival professional implant/tooth cleaning and reinforcement of oral hygiene were performed at 1, 3, and 6 months after therapy (N.S.).

Statistical analysis

The statistical analysis was performed using a commercially available software program (PASW Statistics 18.0, SPSS Inc., Chicago, IL, USA). Mean values and standard deviations were calculated for each variable and group using the patient as a statistical unit. The data rows were examined with the Kolmogorow–Smirnow test and proven to be normally distributed. For the statistical evaluation of the changes within groups over time, the paired *t*-test was used. The unpaired *t*-test was used for between-group comparisons of the changes in mean values from baseline to 6 months. The alpha error was set at 0.05.

Results

A total of $n = 30$ patients (i.e. two patients refused to continue follow-up due to personal reasons after 2 and 3 months, respectively) terminated the observation period of 6 months and served for the statistical analysis (CPS: $n = 15$ patients exhibiting $n = 16$ implants; ERL: $n = 15$ patients exhibiting $n = 19$ implants). The postoperative wound healing was considered as generally uneventful in both groups. In particular, no complications such as allergic reactions, swellings, abscesses or infections were observed throughout the whole study period. A slight pigmentation of the implant supporting soft tissues, potentially caused by residual titanium particles, was only observed in one patient. All sites revealed an exposure of CM at the transmucosal aspect of the wound area. These areas were associated with healthy soft tissue conditions and underwent a fast degradation of CM, thus resulting in an almost complete soft tissue coverage after 10–14 days of healing (Fig. 3f and g).

The mean PI and BOP values as assessed in both CPS and ERL groups at baseline and after 6 months are summarized in Table 3. These values did not reveal a statistically significant difference between the groups at baseline (NS; unpaired *t*-test, respectively). CPS- and ERL-treated patients revealed a significant increase in mean PI values at 6 months ($p < 0.05$, $p < 0.01$; paired *t*-test, respectively) without showing any significant difference between groups (NS; unpaired *t*-test, respectively). Mean BOP values were significantly reduced in both groups after 6 months of healing ($p < 0.001$; paired *t*-test, respectively). Even though mean BOP reductions tended to be higher in the CPS group, the differences to ERL-treated patients did not reach statistical significance (NS; unpaired *t*-test, respectively) (Table 3). Defect-related changes of mean BOP scores after 6 months of healing in both groups are presented in Fig. 4a. In particular, CPS- and ERL-treated sites tended to reveal higher mean BOP reductions at Class Ic+II ($61.0 \pm 35.9\%$ and $58.5 \pm 37.5\%$, respectively) and Class Ie+II ($52.4 \pm 31.2\%$ and $38.8 \pm 41.6\%$, respectively) defects when compared with Class Ib+II defects ($39.0 \pm 34.8\%$ and $33.2 \pm 40.7\%$, respectively). This was particularly true for CPS-treated sites (Fig. 4a).

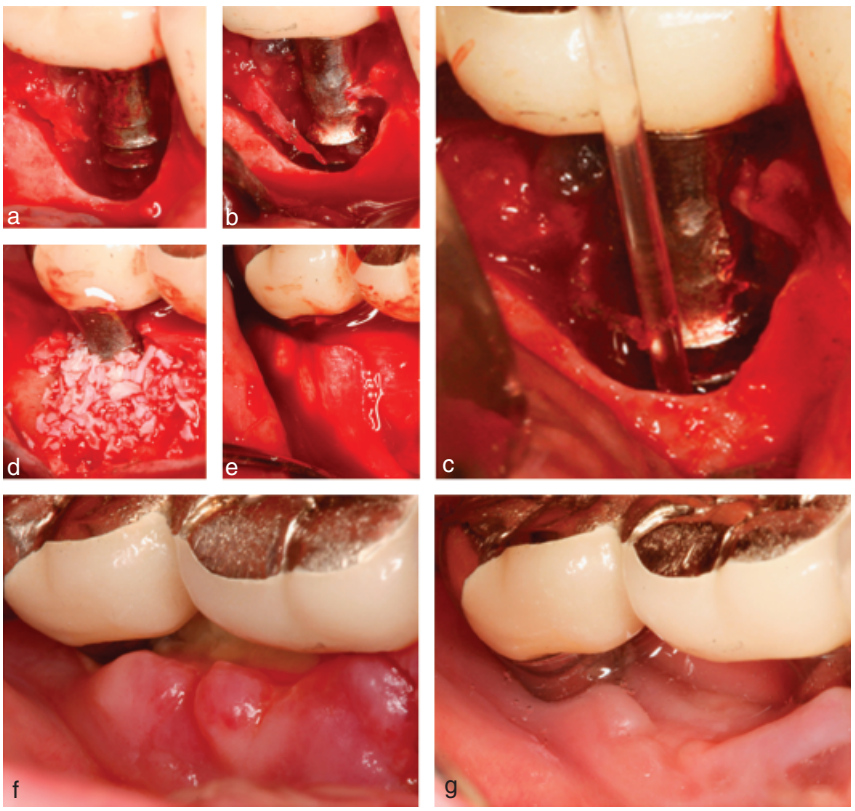

Fig. 3. Combination therapy at Class I and Class II defect components. (a) Defect situation (Class Ib+II) after granulation tissue removal. (b) Implantoplasty was performed at buccally (i.e. Classes Ib and Ic) and supracrestally exposed implant surfaces. (c) Debridement and surface decontamination of the remaining implant surface areas were randomly performed by either CPS or ERL (as demonstrated here). (d) Collagen membrane (CM) was firstly applied at the lingual aspect and the entire defect area was homogeneously augmented with natural bone mineral (NBM). (e) Application of CM at the corresponding buccal aspect to stabilize NBM. (f) Wound healing at suture removal showing a slight exposure of CM. (g) Uneventful soft tissue healing at 6 months.

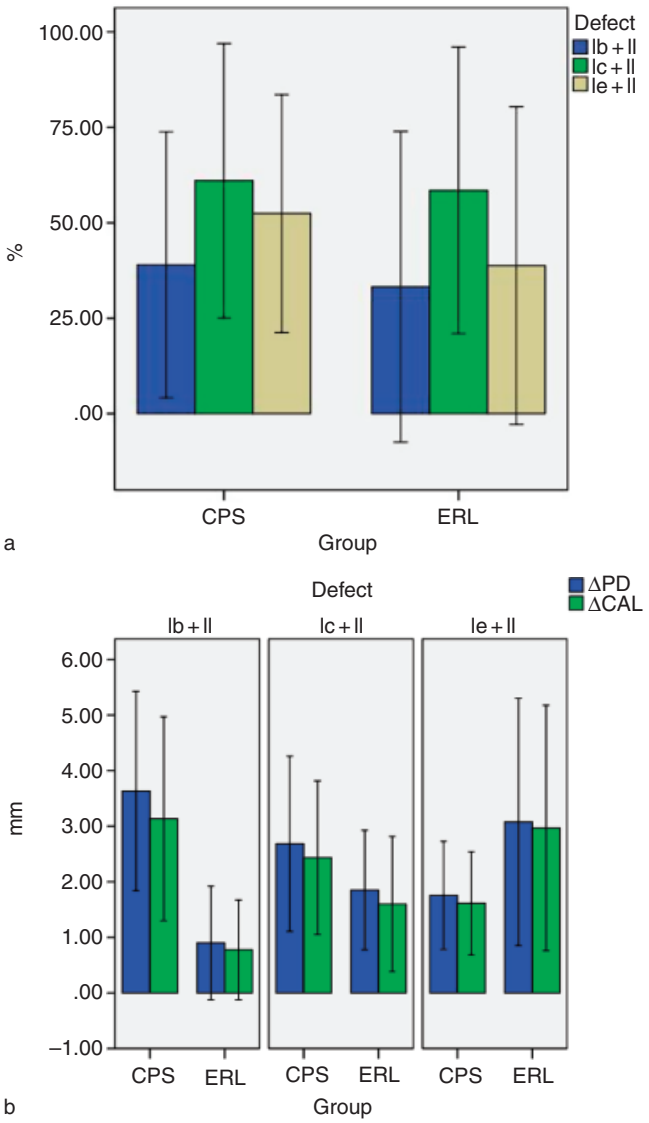

Fig. 4. Defect-related changes (Δ) of mean (± SD) clinical parameters from baseline to 6 months ($n = 35$ implants) at CPS- and ERL-treated sites. (a) Bleeding on probing (%). (b) Probing depth and clinical attachment level (mm).

The mean PD, MR, and CAL values in both groups at baseline and after 6 months of healing are summarized in Table 3. These values did not reveal a statistically significant difference between the groups at baseline (NS; unpaired *t*-test, respectively). Both CPS- and ERL-treated sites exhibited a significant reduction of mean PD and CAL values at 6 months ($p < 0.001$; paired *t*-test, respectively). Even though mean PD reductions and CAL gains tended to be higher in the CPS group, between-group comparisons of the differences in mean PD and CAL values at 6 months were statistically not significant (NS; unpaired *t*-test, respectively) (Table 3). Defect-related changes of mean PD and CAL values after 6 months of healing in both groups are presented in Fig. 4b. In particular, it was observed that CPS-treated sites revealed highest PD reductions and CAL gains at Class Ib+II defects (3.6 ± 1.8 and 3.1 ± 1.8 mm; respectively), which was followed by Class Ic+II (2.7 ± 1.6 and 2.4 ± 1.4 mm, respectively) and Class Ie+II (1.7 ± 0.9 and 1.6 ± 0.9 mm, respectively) defects. In contrast, ERL treated sites revealed highest PD reductions and CAL gains at Class Ie+II defects (3.1 ± 2.2 and 2.9 ± 2.2 mm, respectively), which was followed by Class Ic+II (1.8 ± 1.1 and 1.6 ± 1.2 mm, respectively) and Class Ib+II defects (0.9 ± 1.0 and 0.8 ± 0.9 mm, respectively) (Fig. 4b). A site-level analysis of defect-related changes in mean PD values at 6 months in different groups is presented in Fig. 5a and b. Both CPS- and ERL-treated defects revealed comparable and almost homogeneous PD changes at all buccal and lingual aspects. This was particularly true for Class Ic+II defects (Fig. 5a and b).

The frequency distribution of CAL gains at 6 months in both groups is shown in Table 4. While all patients in the CPS groups revealed a CAL gain of at least 1 mm, a total of two patients (13.3%) in the ERL group were characterized by either unchanged or even decreased (-0.5 mm) CAL values. The majority of CPS-treated patients revealed a CAL gain of 2 mm (40.0%). A CAL gain of 3 and >4 mm was observed in a total of five patients, corresponding to 33.3%. In the ERL group, the majority of the treated patients revealed a CAL gain of 1 mm (46.7%). A CAL gain of 3 and >4 mm was observed in a total of three patients, corresponding to 20.0% (Table 4).

At 6 months, descriptive radiographic analysis revealed a decreased translucency in the former peri-implant defect area for a total of 15 sites in the CPS group, and for 14 sites in the ERL group (Fig. 6).

Discussion

The present randomized, controlled clinical trial was primarily designed to investigate the impact of surface decontamination on the outcome of a combined surgical resective/regenerative therapy of moderate to advanced peri-implantitis defects. Basically, it was observed that both treatment procedures resulted in comparable and statistically significant short-term clinical improvements as evidenced by PD reductions and CAL gains. Even though these changes tended to be higher in the CPS group when compared with the ERL group, the differences did not reach statistical significance. When interpreting the site-level analysis in both CPS and ERL groups, it was noted that all aspects investigated (i.e. mb, b, db, mo, o, do) revealed comparable and almost homogeneous defect-related changes of mean PD values. However, an obvious reverse effect of ERL and CPS on mean PD and CAL changes was noted when the defect classes were

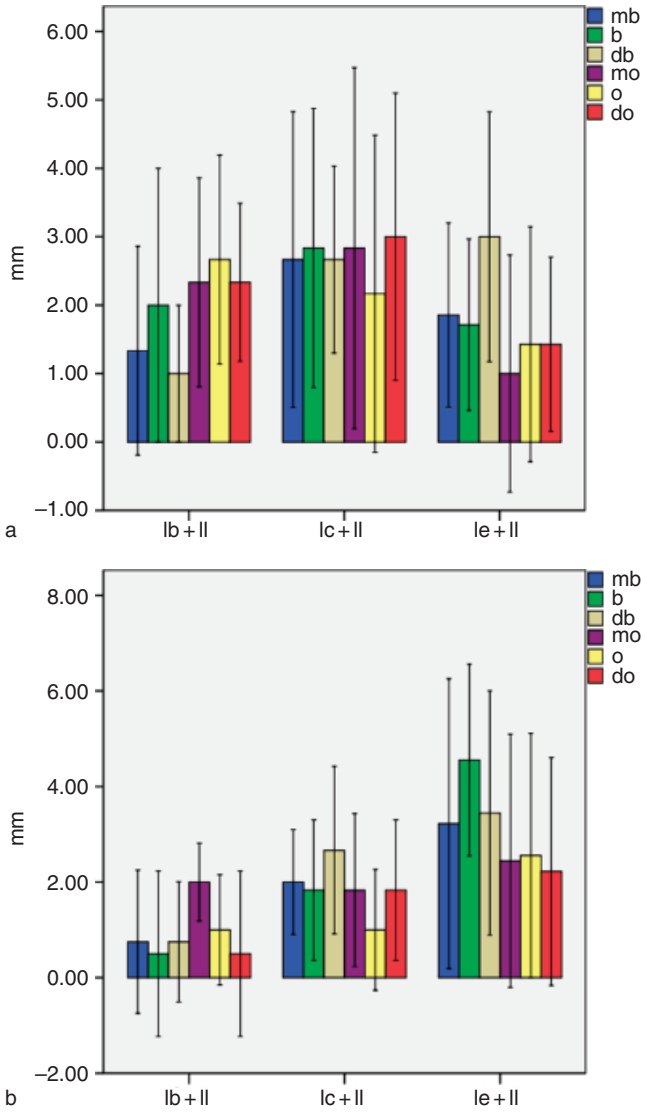

Fig. 5. Site-level analysis of defect-related changes (Δ) in mean probing depth (PD) values from BL to 6 months at six aspects: mesiobuccal (mb), midbuccal (b), distobuccal (db), mesiooral (mo), midoral (o), and distooral (do) ($n = 35$ implants). (a) CPS and (b) ERL.

Table 4. Frequency distribution of CAL gain after 6 months in the CPS ($n = 15$ patients) and ERL ($n = 15$ patients) groups

CAL gain (mm)	CPS		ERL	
	no.	%	no.	%
0	0	0	2	13.3
1	4	26.7	7	46.7
2	6	40.0	3	20
3	3	20	2	13.3
>4	2	13.3	1	6.7

CPS – plastic curets+cotton pellets soaked in sterile saline; ERL – Er:YAG laser.

taken into consideration. While the ERL group revealed highest PD and CAL changes at Class Ie defects, these changes were most pronounced at Class Ib defects in the CPS group. These differences in defect-related outcomes between both groups may, to a certain extent, point to a higher efficiency of ERL for DD of larger surface areas exposed to a less accessible defect configuration (i.e. Class Ie) when compared with CPS. At the time being, these are the first clinical data reporting on the surgical application of ERL for surface DD of peri-implantitis defects. In this context, it must be emphasized that both experimental and clinical data have indicated that this type of laser seemed to be capable of effectively removing bacterial deposits from either smooth or rough titanium implants without injuring their surfaces (Kreisler et al. 2002, Schwarz et al. 2009a). In particular, ERL irradiation of contaminated (i.e. *Streptococcus sanguinis*) dental implant surfaces exhibiting various microtopographies was associated with a high bactericidal potential, thus suggesting its suitability to serve as a potential tool for surface decontamination (Kreisler et al. 2002). When evaluating and comparing the efficacy of both ERL and CPS for debridement of biologically contaminated moderately rough titanium surfaces, it was observed that significantly lowest residual plaque biofilm (RPB) areas were observed following ERL application ($5.8 \pm 5.1\%$). In contrast, hand instrumentation using plastic curets resulted in mean RPB areas ranging from $58.5 \pm 4.9\%$ to $61.1 \pm 11.4\%$ (Schwarz et al. 2005, 2006c). From a clinical point of view, however, it must be emphasized that the removal of non-mineralized plaque biofilms, collected in vivo using an intraoral splint system (Schwarz et al. 2005, 2006c), may not reflect the biologic contamination encountered at chronic peri-implantitis defects. While sterile saline failed to reveal a significant bactericidal effect against adhering bacteria on titanium surfaces (Gosau et al. 2010), the additional influence of a cotton pellet on surface DD using hand instruments, as used in the CPS group of the present study, has not been addressed in the current literature. However, previous studies have indicated that a combination of systemic antibiotics and CPS during surgical therapy without the addition of a bone filler or GBR resulted in a resolution of experimentally induced peri-implantitis lesions, as evidenced by bone defect fill and re-osseointegration (Persson et al. 2001, 2004). Interestingly, the use of a carbon dioxide laser and hydrogen peroxide had no apparent effect on the outcome of therapy, because both groups revealed comparable new BIC values at either machined (laser: 21%; control: 22%) or moderately rough implant surfaces (laser: 74%; control: 84%) (Persson et al. 2004). In contrast, surface DD using ERL (12.7 J/cm^2) resulted in higher new BIC values (44.8 *versus* 14.8%) when compared with hand instrumentation using plastic curets+local application of metronidazole gel during open flap surgery of experimentally induced peri-implantitis in dogs (Schwarz et al. 2006b). The results noted for CPS-treated defects at 6 months are, to a certain extend, in accordance with the data of a

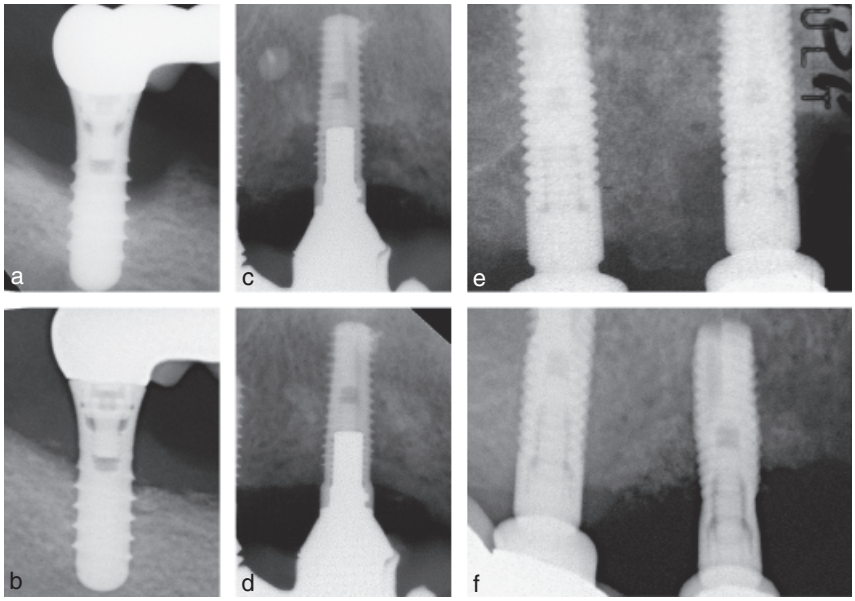

Fig. 6. Representative non-standardized radiological views at baseline and after 6 months of healing in both groups. CPS (Class Ic+II – refer to Fig. 2): (a) baseline and (b) 6 months. CPS (Class Ic+II): (c) baseline and (d) 6 months. ERL (Class Ic+II): (e) baseline and (f) 6 months.

previous study investigating the impact of defect configuration (i.e. Class Ib, Class Ic, and Class Ie defects exhibiting a Class II component of $\leqslant 1$ mm) on the clinical outcome of surgical regenerative therapy of per-implantitis lesions using a combination of CPS and NBM+CM (Schwarz et al. 2010). After 6 months of transmucosal healing, mean PD changes ranged from 1.4 ± 0.5 mm at Class Ib defects to 1.3 ± 0.7 mm at Class Ic defects and 2.9 ± 0.3 mm at Class Ie defects. The corresponding mean CAL changes ranged from 0.9 ± 0.8 mm at Class Ib defects to 0.9 ± 0.7 mm at Class Ic defects and 2.5 ± 0.5 mm at Class Ie defects (Schwarz et al. 2010). When interpreting the defect-related changes of mean clinical parameters in the CPS group of the present study, it was noted that highest PD reductions and CAL gains were observed at Class Ib+II defects, which was followed by Class Ic+II and Class Ie+II defects. In contrast, ERL-treated sites revealed highest PD reductions and CAL gains at Class Ie+II defects, which was followed by Class Ic+II and Class Ib+II defects. There might be several reasons to explain the discrepancy noted between both studies. First of all, it must be emphasized that the present protocol aimed at including moderate to advanced peri-implantitis defects exhibiting a Class II component of $\geqslant 1$ mm. Accordingly, it is impossible to estimate to what extent a larger variation in defect configurations and sizes may have contributed to the more heterogeneous outcome of defect-related PD and CAL changes in either CPS or ERL groups. Secondly, an implantoplasty was performed at both buccally (i.e. Classes Ib and Ic) and supracrestally (i.e. Class II) exposed implant surfaces to reduce the potential risk for a re-infection in these areas. The scientific rationale for this approach was based on the observation that surgical regenerative treatment using NBM+CM resulted in lowest PD and CAL changes at the mb- aspect of Class Ib and Class Ic groups (Schwarz et al. 2010). Accordingly, it was hypothesized that the present combined surgical resective/regenerative therapy may result in more predictable clinical improvements at Class Ib and Ic defects than a regenerative approach alone. This observation, however, needs to be supported by a controlled clinical trial aimed at investigating the impact of a combined surgical resective/regenerative therapy of peri-implantitis defects. So far, the beneficial influence of an implantoplasty on the clinical and radiological outcome of surgical therapy of peri-implantitis has only been reported in one comparative study (i.e. two publications). In particular, apically repositioned flap surgery combined with a modification of the implant surface (i.e. implantoplasty) resulted in significantly improved PD and CAL changes as well as less marginal bone loss over a period of 36 months when compared with apically repositioned flap surgery alone (Romeo et al. 2005, 2007). Unfortunately, the authors did not report on the specific defect characteristics but indicated that an implantoplasty has been conducted at all exposed surface areas, thus suggesting a close similarity to the surgical procedure as used in the present study. Considering disease resolution as the primary objective of surgical treatment of peri-implantitis, one must keep in mind that both CPS and ERL groups exhibited not only statistically significant but also defect-dependent BOP reductions after 6 months of healing. Because surgical regenerative therapy of peri-implantitis using NBM+CM resulted in clinical improvements (i.e. BOP, PD, CAL) over a period of 4 years (Schwarz et al. 2009b), one might hypothesize that the long-term stability of the clinical results obtained in the present study is primarily dependent on proper oral hygiene (Lindhe & Meyle 2008) rather than the method of surface decontamination. In this context, it must be stressed that despite a stringent postoperative care, mean PI scores significantly increased in both groups at 6 months. This observation may point to a need to further develop effective home care cleaning techniques for patients suffering from peri-implantitis.

Within its limitations, the present study failed to demonstrate a significant impact of the method of surface DD on the clinical outcome following combined surgical therapy of advanced peri-implantitis lesions.

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Clinical Relevance

Scientific rationale for the study: The method of surface DD is considered to have a significant impact on the clinical outcome of surgical (i.e. implantoplasty+regenerative) therapy of peri-implantitis lesions.
Principal findings: The present results have indicated that surface DD using either an Er:YAG laser device, or plastic curets+cotton pellets soaked in sterile saline followed by the application of an NBM in combination with a native CM at the intra-bony aspect of advanced peri-implantitis lesions resulted in significant but comparable PD reductions and CAL gains after 6 months of non-submerged healing.
Practical implications: The method of surface DD might not be considered as an important factor significantly influencing the outcome following combined surgical therapy of advanced peri-implantitis lesions.