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Clinical effectiveness of photodynamic therapy in the treatment of periodontitis

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Abstract

Aim: A randomized-controlled clinical pilot trial was designed to evaluate photodynamic therapy (PDT) for its bactericidal potential and clinical effect in the treatment of periodontitis.

Material and Methods: Fifty-eight subjects with chronic periodontitis were included. Each subject exhibited at least three active periodontal pockets 5 mm or deeper, bleeding on probing and the presence of *Porphyromonas gingivalis*. Subjects were randomly assigned to a control group treated by subgingival ultrasound only or to a study group additionally treated by PDT. Baseline clinical values of gingival index, bleeding on probing, probing pocket depths and clinical attachment levels were recorded and re-evaluated 90 days later. Pathogen screening for *P. gingivalis*, *Tannerella forsythia* and *Treponema denticola* was conducted at baseline as well as 10, 42 and 90 days after treatment.

Results: *P. gingivalis* was significantly reduced in both groups (laser group: $p = 0.020$; control group: $p = 0.042$). No significant reductions of *T. forsythia* and *T. denticola* were observed in either group. For the microbial parameters, no significant difference was found between the laser and the control group. All clinical parameters were significantly reduced in both groups after treatment. The mean probing pocket depths decreased from 5.79 to 4.55 mm in the laser group and from 5.54 to 4.51 in the control group. The intergroup difference was not significant ($p = 0.82$). Bleeding on probing was reduced from 100% evaluated at baseline to 47% in the laser group and 59% in the control group. The intergroup difference was not significant ($p = 0.28$). No significant differences were observed in any other parameters.

Conclusion: Application of a single cycle of PDT was not effective as an adjunct to ultrasonic periodontal treatment. There were no extra reductions in pocket depths and bleeding on probing. With regard to eradicating bacteria, however, there are no additional effects as compared with conventional treatment alone.

Key words: eradication of bacteria; periodontal inflammation; photodynamic therapy; therapeutic soft laser; ultrasonic periodontal treatment

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Non-surgical treatment of periodontitis has traditionally been accomplished with hand instruments or ultrasonic devices to remove supra- and subgingival bacterial deposits, infected granulation tissue and pocket epithelium. The purpose of this strategy is to eliminate pathogens, thus avoiding progression of the inflammation with continuous attachment loss. To date, however, no consensus has been reached on whether ultrasonic treatment can eliminate periodontal pathogens (Jepsen et al. 1998, Schenk et al. 2000, Rhemrev et al. 2006). Recently, laser light therapy has been introduced in periodontal therapy in an attempt to improve the effectiveness and efficiency of root surface debridement and bacterial elimination.

High-power lasers (CO_2, Nd:YAG) have been advocated for soft and hard tissue surgery, because they offer

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ablation/vaporization, haemostasis and sterilization (Miyazaki et al. 2003). InGaAsP doide lasers have even been proposed as a diagnostic tool to detect subgingival calculus (Folwaczny et al. 2004). Other authors have suggested Er:YAG lasers to remove plaque and calculus (Schwarz et al. 2003a, b, Sculean et al. 2004a, b) or to perform surgical procedures on soft tissue (Sculean et al. 2004a, b). A bactericidal effect was reported for Er:YAG lasers in periodontal pockets (Schwarz et al. 2003a, b). The findings of a recent study would suggest that fluorescence feedback-controlled Er:YAG laser systems can be used to remove subgingival calculus without depleting the root cementum in clinically relevant amounts (Krause et al. 2007). A systematic review of currently available data has indicated that similar levels of safety and effectiveness can be expected with Er:YAG lasers as with conventional debridement (Schwarz et al. 2008).

A number of indications also seem to exist for low-power (diode) lasers. The use of low-level laser light therapy (LLLT) to improve wound healing was first described in a clinical setting almost four decades ago (Mester et al. 1971). Further investigations showed four different effects of LLLT, stimulating cell proliferation in addition to conferring anti-inflammatory, immunological and analgetic benefits. Lasers may also confer bactericidal (Moritz et al. 1998, Pfitzner et al. 2004) and biostimulatory effects, for example by stimulating gingival fibroblast proliferation (Almeida-Lopes et al. 2001). Irradiation with low-level laser reduces prostaglandin E2 (PGE2) production and may thus counteract the progression of gingivitis and periodontitis (Sakurai et al. 2000).

Photodynamic therapy (PDT) combines low-level laser light with a photosensitizing compound binding to target cells. When photoactivated, free radicals are formed that are toxic to bacterial cells. In vitro studies have shown that 99% of subgingival plaque samples were successfully destroyed by photodynamic means (Soukos et al. 2003) and that *Actinobacillus actinomycetemcomitans* can be photoinactivated by a red laser in the presence of malachite green (Prates et al. 2007). Reports on photodynamic eradication of periodontal pathogens in vivo have essentially been confined to animals such as rats (Kömerik et al. 2003) or dogs (Sigusch et al. 2005). A number of recent in vivo studies have dealt with the clinical effects of adjunctive antimicrobial PDT in periodontal treatment. Some of these authors have reported a positive effect on pocket depth reduction as well as improvements in clinical levels and bleeding on probing (Andersen et al. 2007, Braun et al. 2008). Others have not found any statistically significant differences with regard to changes in clinical attachment levels and pocket depth reductions when PDT was used in addition to scaling and root planing. Similar findings have been published with regard to the antibacterial effect of PDT in the treatment of chronic periodontitis. Again, no intergroup differences were found for additional PDT in comparison with scaling and root planing alone, even though the regimen with adjunctive PDT did result in better full-mouth bleeding scores (Chondros et al. 2008, Christodoulides et al. 2008).

The present clinical pilot trial was performed to investigate both the bactericidal potential and the clinical effects of PDT applied in conjunction with conventional ultrasonic treatment.

Table 1. Patient characteristics at baseline

	Laser group	Control group	*p*-value
Patients	30	28	
Sites	115	110	
Mean age	48.9 ± 9.9 SD	48.5 ± 11.0 SD	0.895
Gender			0.184
Women	16 (53%)	20 (71%)	
Men	14 (47%)	8 (28%)	
Smoking			0.425
Smokers	5 (17%)	2 (7%)	
Non-smokers	25 (83%)	26 (93%)	
Periodontitis risk test	13 (43%)	13 (46%)	1.000

Of 58 patients evaluated, 51/7 exhibited 4/3 periodontal pockets meeting the inclusion criteria. Thus a total of 225 pockets were evaluated. No significant differences betwenn the groups were obtained for any of the baseline characteristics.

Material and Methods

Patient selection

Fifty-eight subjects (36 women and 22 men) diagnosed with chronic adult periodontitis (moderate to severe as defined by the AAP) were enrolled in the study. Their mean age was 48.7 (25–67) years (Table 1). All subjects gave their informed consent. The study was in accordance with the Declaration of Helsinki (as amended in Edinburgh, 2000) and was approved in its present form by the institutional ethics commission (University of Graz, Austria). Only the following subjects were included: (i) those who had not been treated for periodontitis in the previous 2 years; (ii) had not received antibiotics within 12 months before the treatment; (iii) showed no evidence of systemic disease; (iv) showed at least three periodontal pockets 5–8 mm deep with positivity for *Porphyromonas gingivalis*; and (v) exhibited a plaque index of $<30\%$ upon completion of the initial oral hygiene programme. Patients were assigned to the laser or the control group based on a randomization list. The randomization protocol was carried out as an administrative task by staff who were not involved in the treatment of these patients.

In each patient, only the four deepest pockets not exceeding 8 mm were included in the analysis. Pockets exceeding 8 mm in depth were invariably excluded from the study. A total of 51 patients exhibited four sites meeting the inclusion criteria, while seven patients exhibited only three sites meeting the inclusion criteria. Hence, a total of 225 sites ($51 \times 4 + 7 \times 3$) were available for follow-up. These 225 sites (5–8 mm deep, bleeding on probing, positive screening for *P. gingivalis*) were followed up over a period of 3 months.

Oral hygiene programme

To ensure a sufficient level of plaque control, all subjects were initially enrolled in a hygiene programme and received oral hygiene instructions over 6 weeks before treatment. Depending on individual needs, two to four appointments were scheduled for this purpose, which also included supragingival ultrasonic treatment. Patients were not included in the study if their plaque index scores were $>30\%$ upon completion of the initial oral hygiene programme. Supragingival treatment was then repeated and oral hygiene was reinforced 10, 42 and 90 days after treatment.

Study design and treatment protocols

This study was primarily conducted to address the question of whether mechanical root debridement supported by adjunctive PDT results in greater bacterial load reduction than mechanical root debridement without PDT. Modified *P. gingivalis* counts served as the primary outcome variable. Secondary variables included changes in *Tannerella forsythia* and *Treponema denticola* counts as well as reductions in bleeding on probing, pocket depths and clinical attachment levels. Subjects *were randomly assigned* to receive subgingival treatment in either one of two groups. All subjects were treated by the same operator, who was not blinded, in a single-stage approach. Group 1 (control group) was managed with an EMS Piezon® Master 600 ultrasonic system (EMS Electro Medical Systems, Nyon, Switzerland). Ultrasonic treatment was conducted at maximum power, in accordance with the manufacturer's instructions. No other treatment was applied in this group. Full-mouth supra- and subgingival debridement was performed. Instrumentation was carried out for at least 1 min. at all sites (including the evaluated sites but all other sites as well) or until the operator felt that the root surfaces were adequately debrided and planed. This group included 29 subjects (20 women and nine men; mean age: 49.1 years) and 110 sites.

Group 2 (laser group) was managed by PDT in addition to ultrasonic treatment. To the authors' knowledge, the first photobiological system used in an attempt to reduce bacterial loads in human periodontitis was HELBO® Blue (Helbo Photodynamic Systems, Grieskirchen, Austria). This photosensitizer system was also used in the present study. It was applied to each site for 3 min. using a glass applicator featuring a soft-touch cannula. After rinsing with saline, the diode laser (Minilaser 2075 F Dent 680 nm, 75 mW, HELBO®) was applied to the mesial, distal, lingual and buccal surfaces of each site for 1 min. each. A consistent energy flow was maintained by applying a fibreoptic pocket probe (HELBO® 3D p) below the gingival level. The probe was inserted into the pockets and activated at the deepest point of the periodontal pocket, where it was left for 1 min. This was followed by an additional lateral movement combined with vertical movements in apical and coronal directions to obtain a higher intensity of radiation even in segments located at higher levels. This group included 29 subjects (16 women and 13 men; mean age: 48.2 years) and 115 sites.

Clinical parameters

Clinical parameters were analysed by a single experienced periodontist at baseline (i.e. after the pretreatment phase of 6 weeks) and 3 months after treatment. This investigator was not involved in providing treatment during the study. Intra-examiner calibration and reproducibility was ensured in calibration sessions at the beginning of the study, obtaining duplicate measurements of pocket depths, clinical attachment levels and bleeding on probing from randomly selected patients (about 10% of the total study population). Intra-examiner agreement was verified by calculating Cohen's κ coefficient. Ranging from 0.806 to 0.812, this coefficient predicted an excellent degree of reliability. Parameters included full-mouth plaque scores, probing pocket depths and clinical attachment levels. Bleeding on probing was assessed simultaneously with pocket depths by recording the presence or the absence of bleeding up to 30 s after probing with a manual periodontal probe (PCP 12, Hu-Friedy, Chicago, IL, USA). Each tooth was probed at the mesio-vestibular, mid-vestibular, disto-vestibular, mesio-oral, mid-oral and disto-oral aspects.

Pathogen screening was performed at baseline as well as 10, 42 and 90 days after treatment using the microDent® test system (Hain Diagnostika, Nehren, Germany). Sterile paper points (size 30) were introduced into each site and allowed to remain there for 30 s. All paper points from the various periodontal pockets were pooled to obtain multiple-site samples from each patient. They were placed in sterile transport vials and transferred to the laboratory for DNA analysis. They were screened for bacterial species of the red complex as described by Socransky et al. (1998), including *T. forsythia*, *P. gingivalis* and *T. denticola*.

Statistical analysis

A sample size of 28 subjects per group allows differences in the success rates of the primary outcome variable (change in the bacterial load of *P. gingivalis*) to be detected over a range from 70% (control group) to 35% (laser group) with 80% power and a significance level of 0.05 (calculated with PASS). Percentages, mean values, standard deviations and median values were used for descriptive data analysis. For group comparisons, continuous data were analysed using *t*-tests. If normality assumptions were not fulfilled, a Wilcoxon–Mann–Whitney test was used. Categorial data were analysed by χ^2 tests and, in the presence of expectation values <5, by Fisher's exact test. Data analysis was performed with SPSS 15 (SPSS Inc., Chicago, IL, USA) and StatXact 5 (Cytel Software Corp., Cambridge, MA, USA). PASS (NCSS, Kaysville, UT, USA) was used for power calculation.

Wilcoxon's test for paired samples was used to evaluate differences between baseline and 90 days after treatment. Both groups were separately evaluated and compared for intergroup differences (at baseline and after 90 days) using the Mann–Whitney *U*-test for independent samples.

Bacterial loads were evaluated by semiquantitative results and categorized as 0, (+), +, ++ and +++ ($<10^4$, $<10^5$, $<10^6$, $<10^7$ and $>10^7$ pathogens). For the purpose of this study, the categories were coded as 0, 0.5, 1, 2 and 3, respectively.

Results

The mean probing pocket depths at baseline were 5.79 mm (± 1.001 SD) in the laser group and 5.54 mm (± 1.153 SD) in the control group. After treatment, these values decreased to 4.55 mm (± 1.144 SD) and 4.51 mm (± 1.339 SD). The intergroup difference was not significant ($p = 0.82$; Table 2).

Clinical attachment levels decreased from 6.606 mm (± 1.370 SD) to 5.258 mm (± 1.410 SD) in the laser group and from 6.592 mm (± 1.230 SD) to 5.244 mm (± 1.480 SD) in the control group. Again, the intergroup difference was not significant ($p = 0.89$; Table 3).

Being an inclusion criterion, bleeding on probing was obviously positive in 100% of the evaluated sites at baseline. After treatment, the percentage of sites exhibiting bleeding on probing had declined to 47% in the laser group and to 59% in the control group. This difference was not statistically significant ($p = 0.28$).

Screening for subgingival pathogens did not reveal any significant intergroup

difference at baseline or 90 days after treatment. Figure 1 and Table 4 shows the distribution of pathogen species at both points in time. *P. gingivalis* was significantly reduced in both groups (laser group: $p = 0.016$; control group: $p = 0.041$). No significant reductions in *T. forsythia* and *T. denticola* were observed in either group.

Discussion

The results of this study show that statistically significant improvements of the parameters investigated were obtained in both treatment groups 3 months after completion of therapy. Intergroup differences were not observed for any of the parameters, although visibly larger reductions in bleeding on probing were seen in the study group with adjunctive PDT than in the control group. Good clinical results were also obtained in the control group, which is consistent with the findings documented for conservative treatment of chronic periodontitis by subgingival debridement (Loos et al. 1987, Van der Weijden & Timmerman 2002). Our results are not in keeping with a number of recent clinical investigations, which yielded significantly better results for scaling/root planing in conjunction with adjunctive PDT than for scaling/root planing alone. Andersen et al. (2007) observed probing depth reductions of 1.11 ± 0.53 or 0.74 ± 0.43 mm 12 weeks after scaling/root planing with or without adjunctive PDT, respectively. Braun et al. (2008) conducted a split-mouth study showing that the relative attachment levels after scaling/root planing were better with adjunctive PDT than without (-0.67 *versus* -0.35 mm). They concluded that adjunctive PDT is capable of improving the clinical outcomes of subgingival debridement in patients with chronic periodontitis. Another study used a split-mouth design to compare the clinical effect of scaling/root planing with or without additional LLLT in the absence of a photosensitizer (Quadri et al. 2005). This controlled clinical trial showed that adjunctive LLLT significantly reduced gingival inflammation in periodontal patients. Our own data do not confirm these findings, as our laser and control groups failed to exhibit

Table 2. Mean probing pocket depths before and after treatment

	Baseline	90 days after treatment
Laser group	5.792 ± 1.001 SD	4.550 ± 1.144 SD
Control group	5.539 ± 1.153 SD	4.509 ± 1.339 SD

Mean values are based on investigational teeth. The reductions in probing pocket depths between the first and fourth examinations were highly significant in both groups ($p < 0.001$).

Table 3. Mean clinical attachment levels before and after treatment

	Baseline	90 days after treatment
Laser group	6.606 ± 1.370 SD	5.258 ± 1.410 SD
Control group	6.592 ± 1.230 SD	5.244 ± 1.480 SD

Mean values are based on investigational teeth.

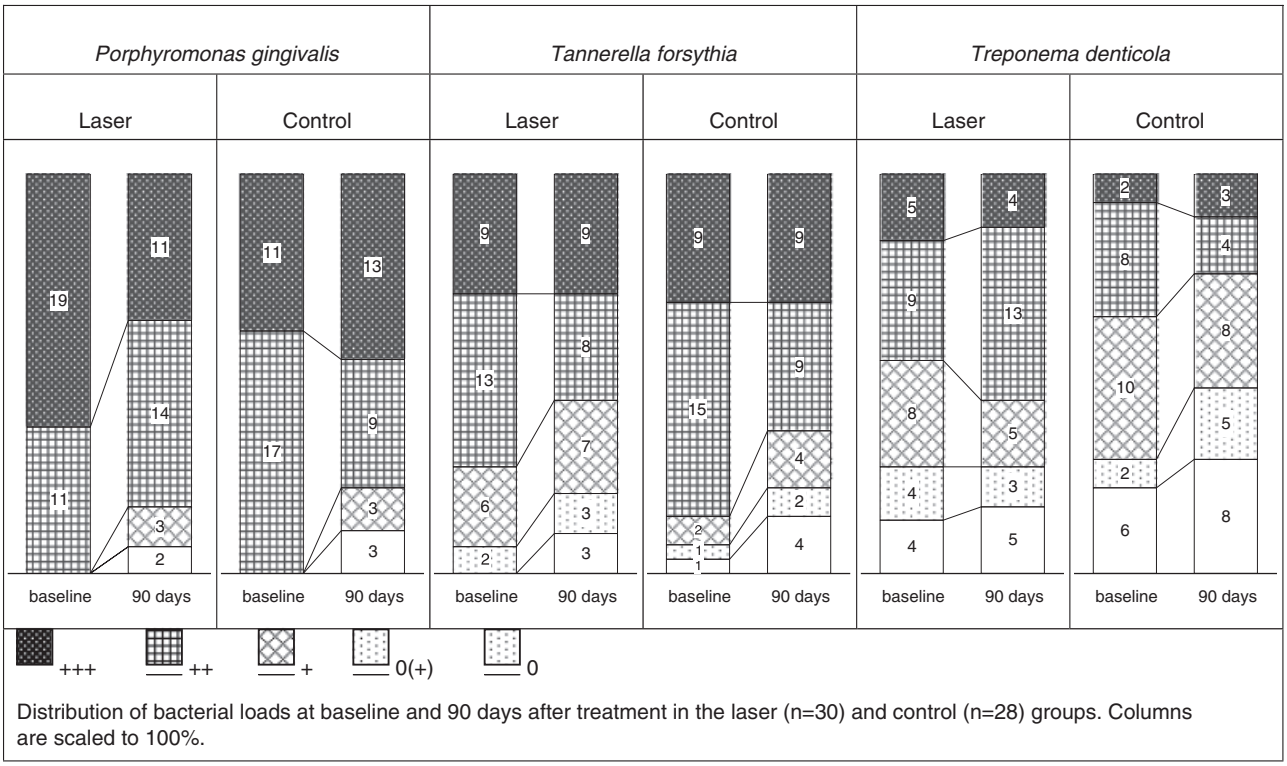

Fig. 1. Bacterial loads at baseline and after 90 days. Bacterial loads were assessed for each patient from pooled site specimens. The height of the columns is standardized to 100%; the counts in the columns represent the numbers of patients. Only *Porphyromonas gingivalis* showed a significant improvement over time. No significant differences were found between the laser and the control groups for any pathogen.

Table 4. Overview of pathogen screening

	Deterioration	No change	Improvement	Improvement within group	Difference between groups
Porphyromonas gingivalis					
Laser group	5 (17%)	10 (33%)	15 (50%)	0.020	$p = 0.694$
Control group	5 (18%)	12 (43%)	11 (39%)	0.042	
Tannerella forsythia					
Laser group	6 (20%)	12 (40%)	12 (40%)	0.100	$p = 0.944$
Control group	6 (21%)	12 (43%)	10 (36%)	0.094	
Treponema denticola					
Laser group	11 (37%)	11 (37%)	8 (27%)	0.895	$p = 0.259$
Control group	5 (18%)	12 (43%)	11 (39%)	0.194	

These screening results are based on all 58 patients. They were obtained from pooled specimens of each patient. ''Deterioration'' and ''improvement'' refer to increases and decreases in bacterial loads, respectively. Improvements of *P. gingivalis* were noted in both treatment groups. No significant intergroup differences were observed.

any significant intergroup differences in clinical pocket depth or attachment-level changes after treatment. This observation is in line with the results of an in vitro study, which showed that application of a diode laser did not promote new attachment of periodontal ligament cells in a significant way (Kreisler et al. 2001). The findings reported in this communication are in line with a previous study comparing four different modes of periodontal treatment, two of them involving PDT with or without scaling/root planing (Yilmaz et al. 2002). These approaches, which combined soft laser and methylene blue, failed to produce an extra clinical benefit over mechanical debridement alone. The results of a literature review by Meisel & Kocher (2005) would also suggest that adjunctive PDT does not reduce bacterial colonization of human periodontal pockets compared with ultrasonic treatment alone. Two randomized-controlled clinical trials were recently published, which yielded data very similar to our own (Chondros et al. 2008, Christodoulides et al. 2008). These studies included two groups of patients with chronic periodontitis treated by scaling/root planing. Again, one group received adjunctive PDT while the other did not. Several parameters were evaluated at baseline as well as 3 and 6 months after treatment, including probing depths, full-mouth bleeding scores, clinical attachment levels and microbiological screening for a variety of species (*Agregatibacter actinomycetemcomitans*, *P. gingivalis*, *Prevotella intermedia*, *T. forsythia*, *T. denticola*, *Parvimonas micra*, *Fusobacterium nucleatum*, *Campylobacter rectus*, *Eubacterium nodatum*, *Eikenella corrodens* and *Capnocytophaga* spp.). At 3 and 6 months, no significant differences between both treatment groups were observed based on clinical attachment levels, probing depths or bacterial loads, while full-mouth bleeding scores were significantly higher in the study group including adjunctive PDT. These findings are very similar to those of the present study. We, too, failed to observe significant intergroup differences with regard to any clinical or microbiological parameters after treatment. Our results only differ with regard to bleeding scores, which were found to be significantly different by Christodoulides et al. (2008) and Chondros et al. (2008). In fact, we noted visibly better improvements of this parameter in the PDT study group as well. These fell short of statistical significance, but it should be noted that bleeding on probing was not the main outcome variable of our investigation, meaning that this parameter was not in the focus of our power analysis. A separate study may be needed to make stronger statements about bleeding on probing.

The fact that our study and control groups showed similar levels of pathogen reduction suggests that the antibacterial effect we observed was due to ultrasonic rather than laser treatment. There is no consensus on whether ultrasonic treatment can eliminate periodontal pathogens. Data to this effect are available (Jepsen et al. 1998) but have been disputed by other authors (Schenk et al. 2000). Recent studies indicate that periodontal pathogens may not readily survive in the intrapocket environment created by ultrasonic treatment (Rhemrev et al. 2006). At any rate, our microbiological results confirm that subgingival ultrasonic instrumentation does indeed reduce the number of relevant microorganisms in periodontal pockets.

Our results argue against the notion that PDT may significantly add to the reduction of periodontal pathogens. Nor did it improve the clinical results of periodontitis therapy during the short-term observation period of 90 days. Both treatment modalities (ultrasound alone and ultrasound combined with PDT) were found to significantly reduce bleeding on probing. Visibly better results for this parameter were observed in the study group, although this difference fell short of statistical significance. In other words, there is a chance that PDT does reduce the degree of periodontal inflammation after all. It remains to be seen whether this effect has clinical potential justifying the use of PDT in the treatment of chronic adult periodontitis. Longitudinal trials are needed to investigate whether clinical parameters can be improved in the long term.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Table S1. Supporting information in accordance with the CONSORT Statement 2001 checklist used in reporting randomized trials.

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Clinical Relevance

Scientific rationale for the study: Various attempts have been made to find alternatives to the use of antibiotics in periodontal treatment. In vitro results suggest that PDT might offer such an alternative. However, few data from controlled clinical trials are available on the antibacterial efficacy of PDT in chronic periodontitis.

Principal findings: PDT provided in addition to ultrasonic therapy failed to improve probing depths, attachment levels and microbiological parameters compared with ultrasonic therapy alone.

Practical implications: Ultrasonic therapy of chronic periodontitis leads to good improvements of clinical parameters and effectively reduces periodontal pathogens. There is no extra benefit in combining ultrasonic therapy with adjunctive PDT.