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Ich bedanke mich bei den unten aufgeführten Kolleginnen und Kollegen für ihre wertvolle Mitarbeit, die sie in den vergangenen zwei Jahren geleistet haben.

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Nonsurgical treatment of aggressive periodontitis with photodynamic therapy or systemic antibiotics

Three-month results of a randomized, prospective,
controlled clinical study

Keywords: aggressive periodontitis, antibiotics, amoxicillin, metronidazole,
photodynamic therapy

Summary The aim of this randomized, controlled clinical study was to compare the short-term effects of nonsurgical periodontal therapy with the additional administration of systemic antibiotics (AB) and the same therapy with additional photodynamic therapy (PDT) in the treatment of patients with aggressive periodontitis (AP).

Thirty-six patients with AP received full-mouth nonsurgical periodontal treatment (SRP) and were then randomly divided into two groups of 18 subjects each. Group AB received amoxicillin and metronidazole three times a day for 7 days. Group PDT received two applications of PDT on the day of SRP as well as at follow-up after 7 days. The following clinical parameters were measured at baseline and 3 months after therapy: plaque index (PLI), bleeding on probing (BOP), probing depth (PD), gingival recession (GR), and clinical attachment level (CAL). After 3 months, PD was significantly reduced in both groups (from 5.0 ± 0.8 mm

to 3.2 ± 0.4 mm with AB, and 5.1 ± 0.5 mm to 4.0 ± 0.8 mm with PDT; both $p < 0.001$), while AB revealed significantly lower values compared to PDT ($p = 0.001$). In both groups, GR was not significantly changed. CAL was significantly reduced in both groups (PDT: 5.7 ± 0.8 mm to 4.7 ± 1.1 mm; $p = 0.011$; AB: 5.5 ± 1.1 mm to 3.9 ± 1.0 mm; $p < 0.001$) and differed significantly between the groups ($p = 0.025$).

The number of residual pockets ($PD \geq 4$ mm) and positive BOP was reduced by AB from 961 to 377, and by PDT from 628 to 394. Pockets with $PD \geq 7$ mm were reduced by AB from 141 to 7, and by PDT from 137 to 61.

After 3 months, both treatments led to statistically significant clinical improvements. The systemic administration of antibiotics, however, resulted in significantly higher reduction of PD and a lower number of deep pockets compared to PDT.

Introduction

The goal of periodontal treatment lies in reducing or eliminating the pathogens which initiate and cause the progression of periodontal disease (TELES ET AL. 2006). Mechanical surface treatments (scaling and root planing; SRP) and the associated removal of supra- and subgingival biofilm are considered the gold standard for treating inflammatory periodontal diseases, the aim being destruction of the bacterial biofilm, reduction of bacteria, and slowed recolonization by pathogenic microorganisms (HAFFAJEE ET AL. 1997, DARBY ET AL. 2001, SOUKOS & GOODSON 2011). However, in aggressive forms of periodontitis, treatment failure is common because the associated bacteria, such as *A. actinomycetemcomitans* and *P. gingivalis*, mostly cannot be eliminated, due to their tissue penetration ability (SAGLIE ET AL. 1988). Furthermore, aggressive periodontitis (local and generalized) is characterized by severe destruction of the periodontium, which can quickly lead to tooth loss (ARMITAGE 1999).

Because aggressive periodontitis is a less frequent form of periodontal disease, only a few studies on treatment alternatives are available in the literature (GUERRERO ET AL. 2005, MESTNIK ET AL. 2010). In addition to thorough cleaning of the surfaces of the teeth to reduce pathogenic microbes, antibiotics are also recommended (HERRERA ET AL. 2002, HAFFAJEE ET AL. 2003). Nevertheless, clinics often conduct nonsurgical therapy without added antibiotics, only using them after treatment has failed, so that antibiotics are rather seen as re-treatment than as a part of initial treatment (GUERRERO ET AL. 2005). In a study which compared the success of antibiotics in patients who received them as initial therapy with patients who received antibiotics only 6 months after SRP during the follow-up evaluation (placebo group from [GUERRERO ET AL. 2005]), it was found that the patients who received the initial antibiotic treatment had statistically significantly better values than the other group (GRIFFITHS ET AL. 2011). In general, it is postulated that periodontal treatment with adjuvant systemic antibiotics yields better results (MOMBELLI ET AL. 2011), and the need for surgical interventions decreases.

Due to the numerous side effects (especially gastrointestinal) of systemic antibiotic administration, the risk of developing resistant strains upon improper use, and negative patient attitudes toward antibiotics, the demand for antibacterial alternatives is rising. Thus, the challenge lies in evaluating new treatment alternatives which cause fewer side effects while effectively eliminating the pathogenic biofilm flora.

Photodynamic therapy (PDT) may be one such treatment alternative. It employs visible light (laser) and a dye (photosensitizer), the combination of which leads to the release of free oxygen radicals, which in turn can selectively destroy bacteria and their by-products (SHARMAN ET AL. 1999). Although PDT has been used in the field of medicine since 1904 for light-induced inactivation of cells, microorganisms, and molecules (VON TAPPEINER & JODLBAUER 1904), only in the last 10 years or so have clinical studies examined its application in the oral cavity. The current data show that treating chronic periodontitis with PDT alone vs. conventional SRP treatment has no additional benefit (SGOLA STRA ET AL. 2011). In contrast, combining PDT and SRP does provide an additional benefit, particularly in lesions with unfavorable anatomic conditions (SGOLA STRA ET AL. 2011, ATIEH 2010, MALIK ET AL. 2010). A clinical controlled study compared the effect of PDT alone (without subgingival SRP) with SRP in the treatment of aggressive periodontitis. Three months after therapy, both treatment types

showed similar success in terms of bleeding on probing (BOP) and probing depth as well as improved clinical attachment, which emphasizes the possible effect of PDT (DE OLIVEIRA ET AL. 2007). Based on these results, the question arises as to whether PDT could be an effective alternative to systemic antibiotics.

Thus, the purpose of this study was to examine and compare the efficacy of photodynamic therapy (PDT) and systemic antibiotics (AB) in addition to SRP in patients with aggressive periodontitis. The null hypothesis examined was that PDT would produce the same results as systemic antibiotics.

Materials and Methods

In accordance with the principles of the Declaration of Helsinki (Version VI, 2002) and after the study protocol had been approved by the Ethics Committee of Bialystok University (approval no. R-I-002/307/2009), the study was conducted at the Department of Periodontology, Medical Academy of Bialystok, Poland.

This was a single-center, examiner-blinded, randomized clinical study performed with parallel groups for an observation period of 3 months.

Subjects

Before starting the study, advantages and risks were explained to potential participants, who were included only after they had given written informed consent. Thus, 36 23- to 55-year-old patients who suffered from aggressive periodontitis were included and randomly (by flipping a coin) assigned to two parallel groups of 18 patients each.

Inclusion and exclusion criteria

The inclusion criterion for participation was aggressive periodontitis (ARMITAGE 1999). Patients were excluded if they had any systemic disease (e.g., wound healing dysfunctions, diabetes mellitus), were pregnant, allergic to antibiotics or the photosensitizer, or had taken antibiotics in the preceding 12 months. After being duly informed about the study, the subjects signed the consent forms.

Clinical Procedure

In one appointment, all subjects of both groups received thorough cleaning (scaling and root planing, SRP) of all pockets (≥ 4 mm) using not only ultrasound instruments (LM Instruments, Parainen, Finland) with a slim-line tip (PE-38, LM Instruments) and water cooling but also hand instruments (Gracey curettes, Hu-Friedy; Chicago, IL, USA).

On the day of SRP, the PDT group additionally received photodynamic therapy of all pockets (≥ 4 mm) and another application 7 days later. The teeth were moisture-isolated with cotton rolls, and the photosensitizer (based on phenothiazine chloride; HELBO® Blue Photosensitizer, Helbo Photodynamic Systems GmbH & Co KG; Wels, Austria) was applied into the pockets apically to coronally. After letting the photosensitizing agent sit for 3 min, the pockets were rinsed with sterile NaCl solution. Subsequently, the diode laser tip (HELBO® minilaser 2075Fdent, Helbo Photodynamic Systems GmbH & Co KG; wavelength 660 nm) was positioned down in the pocket, energy was activated, and the tip moved within the pocket for one minute.

In the antibiotic group (AB), subjects took 375 mg of amoxicillin and 250 mg of metronidazole each 3 × daily for 7 days, starting on the day of SRP (VAN WINKELHOFF ET AL. 1989).

Parameters examined

The primary parameter was probing depth (PD), which was measured at 6 sites on each tooth (mesiobuccal, buccal, distobuccal, mesiolingual, lingual, distolingual). Further parameters were gingival recession (GR) and the clinical attachment level (CAL), bleeding on probing (BOP, in %), and the SILNESS AND LÖE (1964) plaque index (PLI) at the treated sites (≥ 4 mm), as well as BOP and PLI on all of the patient's teeth (full-mouth BOP [FMBOP] and full-mouth PLI [FMPLI]). These parameters were also measured at 6 sites per tooth. Parameters were recorded at baseline and 3 months after SRP.

Statistical analysis

At the start of the study, a significance level of $\alpha=0.05$, a relevant average difference of 1 mm, and a power ($1-\beta$) of at least 0.90 were set in order to calculate the minimum number of necessary cases (at least 7 per group). A power calculation at the end of the study with the given number of cases and the given results yielded a power of 99.6%.

Statistical analysis was performed using IBM SPSS statistics 19 (IBM Company; Armonk, NY, USA). A total of 5,874 sites in all patients were examined; of these, 1,913 exhibited a PD of ≥ 4 mm which were treated as described above. The statistical unit was the patient. The primary parameter was the change in probing depth. The secondary parameters were changes in CAL, GR, BOP, PLI, FMBOP, and FMPLI. The data were checked for normal distribution using the Kolmogorov-Smirnov test. The two groups were compared using ANOVA. To compare examination time points (baseline and 3 months), Scheffé's F-test was employed, which takes the numerous pairwise comparisons with adjustments into consideration. For all statistical tests, significance was set at a 95% confidence level ($\alpha=0.05$).

Results

Of the 36 subjects admitted to the study, 35 returned for the 3-month follow-up (group AB 18, group PDT 17; recall rate 97.2%). All patients described having a complication-free healing period, which agreed with the clinical examinations. No side-effects – for instance, slight pain or a burning sensation as a consequence of laser treatment – were observed. Neither were side-effects of antibiotic administration observed, and none of the patients prematurely discontinued antibiotic use.

The 18 group AB subjects exhibited 1,086 sites with a PD ≥ 4 mm requiring treatment. In group PDT, there were 827 such sites.

The baseline data of the subjects are shown in Table I. A statistical comparison between groups showed the two groups to be statistically similar at baseline. Only the FMBOP (BOP of all teeth) showed significant differences between groups.

Mean values (\pm standard deviations) for the PD, GR and CAL parameters as well as the results of the statistical analysis are given in Table II. After 3 months, both groups demonstrated a significant reduction in PD ($p<0.001$). Group AB showed a significantly greater reduction compared to group PDT ($p=0.001$). At baseline, gingival recession (GR) values were very low and did not increase significantly after 3 months ($p>0.05$). There were no significant differences between groups at any time for this parameter ($p>0.05$). Both groups showed significant improvement in CAL ($p=0.011$ in group PDT, $p<0.001$ in group AB) and differed significantly from each other ($p=0.025$).

In a subanalysis, the number of sites was determined which showed a PD ≥ 4 mm and a BOP+, since these are generally considered during follow-up as pockets with treatment need.

In addition, the number of sites which had a PD ≥ 7 mm after completion of treatment was determined. This serves as a decisive criterion for deciding to take further surgical measures. It is evident from Table III that antibiotics led to a reduction in the number of pockets needing treatment (PD ≥ 4 mm BOP+) from 961 to 377. In the PDT group, the number of such pockets dropped from 628 to 394. At baseline, 141 sites with a PD of ≥ 7 mm were found in group AB. After 3 months, only

Tab. I Baseline data of patients in the photodynamic therapy (PDT) and systemic antibiotics (AB) groups; probing depth (PD), clinical attachment level (CAL), gingival recession (GR), plaque index (PLI), bleeding on probing (BOP), full-mouth PLI (FMPLI) and full-mouth BOP (FMBOP)

Parameter	PDT (N=17)	AB (N=18)	p-value
Age	37.4 \pm 8.0	34.7 \pm 9.1	0.380; n.s.
Gender			0.419; n.s.
Female	10 (59%)	13 (72%)	
Male	7 (41%)	5 (28%)	
PD (mm)	5.1 \pm 0.5	5.0 \pm 0.8	0.730; n.s.
CAL (mm)	5.7 \pm 0.8	5.5 \pm 1.1	0.564; n.s.
GR (mm)	0.6 \pm 0.7	0.5 \pm 0.6	0.614; n.s.
PLI	1.4 \pm 0.7	1.7 \pm 0.8	0.215; n.s.
BOP (%)	70.4 \pm 22.4	85.7 \pm 15.9	0.025*
FMPLI	1.0 \pm 0.7	1.5 \pm 0.8	0.063; n.s.
FMBOP (%)	52.4 \pm 22.7	74.2 \pm 20.7	0.006**
Statistical analysis between groups using ANOVA; n.s.: not significant, *: $p<0.05$, **: $p<0.01$			

Tab. II Probing depth (PD), gingival recession (GR) and clinical attachment level (CAL); pocket depth ≥ 4 mm. Means and standard deviations for photodynamic therapy (PDT) and systemic antibiotics (AB) groups

	PDT (N=17)	AB (N=18)	p-value between groups
PD (mm)			
Baseline	5.1 \pm 0.5	5.0 \pm 0.8	0.730; n.s.
After 3 months	4.0 \pm 0.8	3.2 \pm 0.4	0.001***
Baseline vs. 3 months	< 0.001***	< 0.001***	
GR (mm)			
Baseline	0.6 \pm 0.7	0.5 \pm 0.6	0.614; n.s.
After 3 months	0.7 \pm 0.7	0.6 \pm 0.8	0.972; n.s.
Baseline vs. 3 months	0.988; n.s.	0.866; n.s.	
CAL (mm)			
Baseline	5.7 \pm 0.8	5.5 \pm 1.1	0.564; n.s.
After 3 months	4.7 \pm 1.1	3.9 \pm 1.0	0.025*
Baseline vs. 3 months	0.011*	< 0.001***	
Statistical analysis between groups using ANOVA and between time points using Scheffé's F-test n.s.: not significant, *: $p<0.05$, ***: $p<0.001$			

7 such sites remained. In the PDT group, the number of sites with a PD of ≥ 7 mm decreased from 137 to 61 after 3 months.

Figures 1 to 4 depict the distribution of pockets across the individual patients in both groups.

Bleeding and plaque indices decreased significantly in both groups. The significant differences between the two groups observed at baseline were no longer present 3 months later (Tab. IV).

Tab. III Number of sites with probing depth (PD) ≥ 4 mm and bleeding on probing (BOP+) or PD ≥ 7 mm in AB and PDT groups

	Baseline	after 3 months	p-value baseline vs. 3 months
PD ≥ 4 mm and BOP+			
AB	961	377	$< 0.001^{***}$
PDT	628	394	0.270; n.s.
PD ≥ 7 mm			
AB	141	7	0.004^{**}
PDT	137	61	0.087; n.s.

Statistical analysis between groups using ANOVA
n.s.: not significant, **: $p < 0.01$, ***: $p < 0.001$

Tab. IV Bleeding on probing (BOP) and plaque index (PLI) at treated sites, full-mouth BOP (FMBOP) and full-mouth PLI (FMPLI) (means and standard deviations) for PDT and AB groups

	PDT (N=17)	AB (N=18)	p-value between groups
BOP (%)			
Baseline	70.4 \pm 22.4	85.7 \pm 15.9	0.025*
After 3 months	37.7 \pm 21.3	34.6 \pm 22.8	0.683; n.s.
Baseline vs. 3 months	$< 0.001^{***}$	$< 0.001^{***}$	
FMBOP			
Baseline	52.4 \pm 22.7	74.1 \pm 20.7	0.06*
After 3 months	25.5 \pm 15.9	25.8 \pm 13.4	0.961; n.s.
Baseline vs. 3 months	0.001^{***}	$< 0.001^{***}$	
PLI			
Baseline	1.4 \pm 0.7	1.7 \pm 0.8	0.215; n.s.
After 3 months	0.6 \pm 0.5	0.6 \pm 0.5	0.712; n.s.
Baseline vs. 3 months	0.004^{**}	$< 0.001^{***}$	
FMPLI			
Baseline	1.0 \pm 0.7	1.5 \pm 0.8	0.063; n.s.
After 3 months	0.4 \pm 0.4	0.4 \pm 0.4	0.994; n.s.
Baseline vs. 3 months	0.003^{**}	$< 0.001^{***}$	

Statistical analysis between groups using ANOVA, between time points using Scheffé's F-test
n.s.: not significant, *: $p < 0.05$, **: $p < 0.01$, ***: $p < 0.001$

Discussion

It has been scientifically proven that periodontitis is an infectious disease, the successful treatment of which is based on eliminating the infection (HAFFAJEE ET AL. 2003). The aim of the present study was to determine the efficacy of photodynamic therapy (PDT) compared to systemic antibiotics (AB) in addition to scaling and root planing (SRP) in patients with aggressive periodontitis.

In numerous studies it has been shown that treatment with the antibiotics metronidazole and amoxicillin in combination with SRP significantly improves the clinical results compared to treatment with SRP alone (HAFFAJEE ET AL. 2003, GUERRO ET AL. 2005, CIONCA ET AL. 2010, GRIFFITHS ET AL. 2011). Here, the use of systemic antibiotics offers the advantage that also tissue-penetrating pathogens in the tonsils or at the base of the tongue can be reached and successfully combated, thus eliminating or at least reducing periodontal pathogens to an undetectable level and controlling the infection (VAN WINKELHOFF ET AL. 1989, QUIRYNEN ET AL. 1995, VAN ASCHE ET AL. 2009). The problems associated with taking antibiotics, such as possible unpleasant side-effects, the risk of developing resistance, and the dependence on patient compliance for correct use, make it worth considering whether PDT can be a treatment alternative for patients with aggressive periodontitis.

The results of the present study show that both treatment approaches (SRP plus systemic antibiotics [AB] and SRP plus PDT) significantly improve the parameters examined: PD, CAL, PLI and BOP. Furthermore, a significant difference was observed between the two methods for PD and CAL, with the AB group showing better results for each parameter. The probability that pockets with a PD ≥ 4 mm and BOP+ as well as those with a PD ≥ 7 mm still required further treatment after 3 months was greater after PDT than after antibiotic treatment. In contrast, the clinical BOP parameter proved to be statistically similar between the two groups. This positive effect of PDT on BOP has also been reported in previous studies. One clinical, controlled study demonstrated that irradiation with a low-energy laser in conjunction with SRP led to a significant reduction of periodontal inflammation, as measured in that study by examining gingival crevicular fluid (GCF) values (QUADRI ET AL. 2005). Similarly, CHRISTODOULIDES ET AL. (2008) found that although one application of PDT in addition to SRP did not decrease PD or increase CAL, it did result in a significantly greater reduction in bleeding parameters than SRP alone.

In terms of gingival recession, neither a comparison of examination time points nor the two groups demonstrated a significant difference. Based on the results of this study, aggressive periodontitis should preferably be treated with SRP plus antibiotics rather than SRP plus PDT.

A direct comparison of results is not possible due to the lack of data from clinical controlled studies in which patients with aggressive periodontitis were given PDT.

The numerous side-effects associated with taking antibiotics, which can lead to patients discontinuing or rejecting antibiotic treatment, make it necessary to seek alternative therapies. Although PDT did not yield equal reductions in PD or the number of deep pockets (≥ 7 mm) after 3 months compared to antibiotics, on the whole, significant improvements in PD and CAL compared to baseline were observed during the study period. One advantage of PDT vs. AB may lie in the ability to repeat application (which is local as opposed to systemic) during the healing phase or after evaluation to reinforce the antibacterial effect. In contrast, systemic antibiotics should

Fig. 1 Distribution of pockets with probing depth (PD) \geq 4 mm and bleeding on probing (BOP+) in the systemic antibiotics group at baseline and after 3 months.

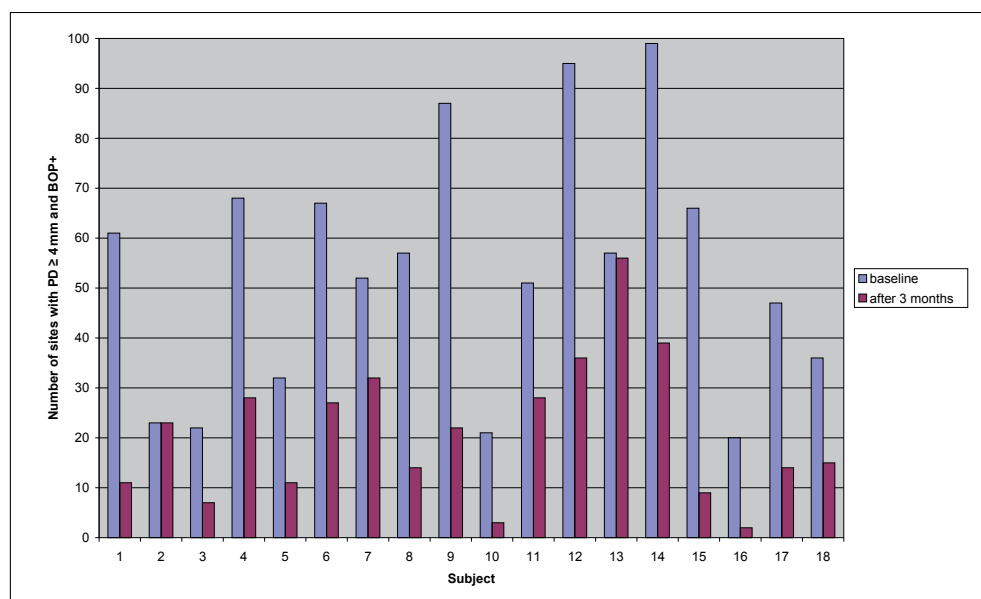
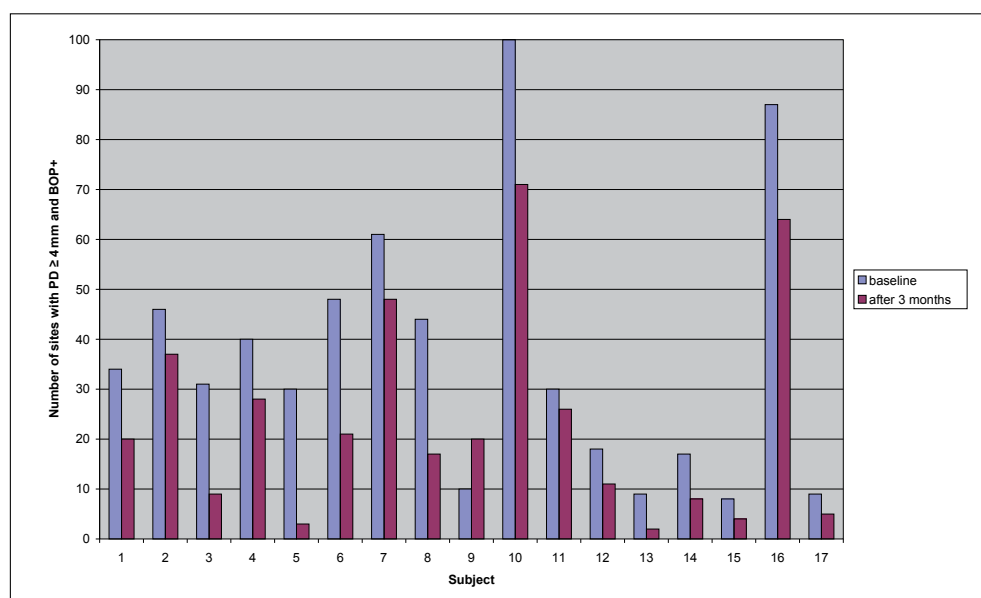


Fig. 2 Distribution of pockets with probing depth (PD) \geq 4 mm and bleeding on probing (BOP+) in the photodynamic therapy group at baseline and after 3 months.



only be taken for 7 to 10 days and may not be repeated at liberty. The possible clinical relevance of PDT was recently highlighted by the results of a randomized, controlled, clinical study on patients with peri-implantitis (SCHÄR ET AL. 2012). In that study, peri-implant pockets receiving nonsurgical treatment plus PDT were compared with those in which a local antibiotic was applied. Both treatment methods led to statistically and clinically significant improvement in PD and inflammation (i.e., BOP). No differences were found between the two types of treatment for any of the parameters examined, which permits the conclusion that both treatment protocols can lead to similar results.

Conclusions and Outlook

It can be concluded that after 3 months significant clinical improvement occurred after scaling and root planing both in combination with amoxicillin and metronidazole and with photodynamic therapy. Both treatment strategies led to statistically significant reductions in probing depth and gains in clinical attachment level after 3 months. Compared to photo-

dynamic therapy, systemic antibiotics produced a significantly higher reduction in probing depths and resulted in a significantly lower number of residual pockets with \geq 4 mm and bleeding on probing. Further long-term studies, especially on combined treatments, are necessary to more exactly determine the long-term potential of the methods tested here.

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Résumé

L'objectif de cette étude prospective clinique randomisée et contrôlée a été de comparer les effets à court terme du traitement non chirurgical associé à l'administration d'une antibiothérapie systémique (AB) ou associé à une thérapie photody-

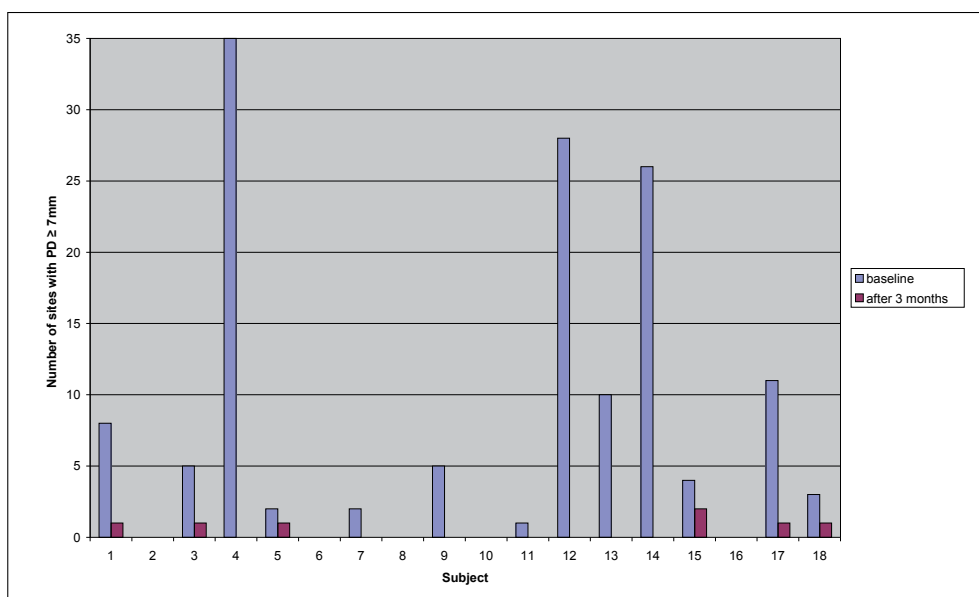


Fig. 3 Distribution of pockets with probing depth (PD) ≥ 7 mm in the systemic antibiotics group at baseline and after 3 months.

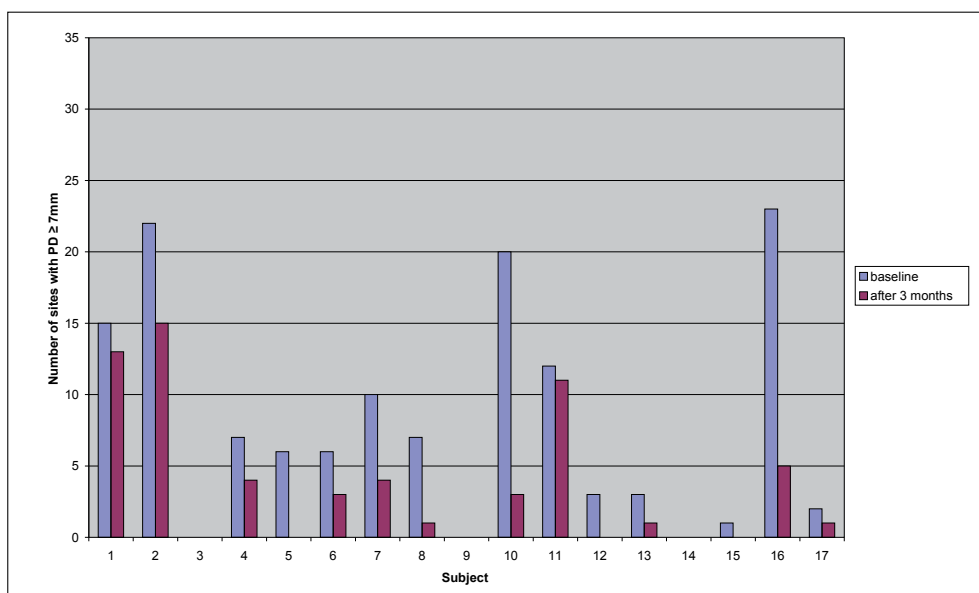


Fig. 4 Distribution of pockets with probing depth (PD) ≥ 7 mm in the photodynamic therapy group at baseline and after 3 months.

namique (PDT) dans le traitement des patients atteints d'une parodontite agressive (PA).

36 patients atteints de PA ont été soignés en une séance avec un traitement de curetage et lissage radiculaire (SRP), puis divisés d'une façon randomisée en deux groupes de 18 sujets chacun. Le groupe AB a reçu une antibiothérapie systémique d'amoxicilline combinée avec du metronidazol 3 \times par jour durant sept jours, tandis que les sujets du groupe PDT ont reçu la photothérapie ensemble avec le SRP, puis au 7^e jour. Les paramètres cliniques suivants ont été mesurés au début du traitement ainsi qu'à trois mois: indice de plaque (PLI), saignement au sondage (BOP), profondeur de poche (PD), récession gingivale (GR) et niveau d'attache clinique (CAL).

A trois mois, 35 patients ont pu être réévalués. La profondeur de poche PD avait significativement diminuée dans les deux groupes (de $5,0 \pm 0,8$ mm à $3,2 \pm 0,4$ mm avec AB, et $5,1 \pm 0,5$ mm

à $4,0 \pm 0,8$ mm avec PDT; $p < 0,001$, chacun). AB comparé à PDT révélait toutefois de valeurs significativement inférieures ($p = 0,001$). Aucun de deux groupes n'a eu un changement significatif pour GR. Les valeurs de CAL étaient significativement réduites (PDT: $5,7 \pm 0,8$ mm à $4,7 \pm 1,1$ mm; $p = 0,011$; AB: $5,5 \pm 1,1$ mm à $3,9 \pm 1,0$ mm; $p < 0,001$) avec une différence significative entre les deux groupes ($p = 0,025$).

Le nombre de poches résiduelles (PD ≥ 4 mm) avec BOP positif avait diminué de 961 à 377 avec AB, et de 628 à 394 avec PDT. Le nombre de poches ≥ 7 mm avait diminué de 141 à 7 avec AB, et de 137 à 61 avec PDT.

Les deux traitements montrent une amélioration clinique statistiquement significative après trois mois. Néanmoins, l'administration d'antibiotiques conduit à une réduction significativement plus importante des poches résiduelles (PD ≥ 4 mm) et profondes comparé au traitement PDT.

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