Clinical evaluation of a protocol of subgingival debridement with Er:YAG laser in comparison to ultrasonic debridement: a randomized clinical trial

Valutazione clinica di un protocollo di detartrasi sottogengivale con Er:YAG laser in confronto con la detartrasi con ultrasuoni: uno studio clinico randomizzato:

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Summary

Objective: The aim of this parallel controlled randomized clinical trial was to evaluate the clinical efficacy of ultrasonic subgingival debridement in combination with Er:YAG laser as compared to full mouth ultrasonic subgingival debridement alone, after one year, in patients with initial to moderate chronic periodontitis. **Material & Methods:** 40 patients diagnosed with mild to moderate periodontal disease were randomly allocated to a subgingivally scaling with ultrasounds+Er:YAG laser (test group) or with just ultrasounds (control group). Patients were clinically evaluated at baseline and 1, 3, 6 and 12 months after treatment. **Results:** No differences could be seen between groups for probing pocket depths (PPD), clinical attachment levels (CAL), bleeding on probing (BOP), plaque index (PI) or recession (REC). A trend could be seen in the test group to have a higher reduction in the PPD values, a smaller proportion of pockets with a PPD≥4 mm and smaller proportion of open pockets (PPD≥4mm+BOP) at the 12 months evaluation. **Conclusion:** The treatment of periodontitis combining ultrasounds and an Er:YAG laser resulted in similar results than those obtained with the conventional treatment with ultrasounds.

Riassunto

Obiettivo: l'obiettivo di questo studio clinico parallelo controllato e randomizzato è stato quello di valutare l'efficacia clinica di i detartrasi subgengivale con ultrasuoni in combinazione con Er:YAG, rispetto alla detartrasi subgengivale di tutta la bocca solo con ultrasuoni, controllata dopo un anno, in pazienti con parodontite cronica da iniziale a moderata. **Materiali e Metodi:** a 40 pazienti con diagnosi di malattia parodontale lieve-moderata è stato prescritto a caso uno scaling subgengivale con ultrasuoni + Er:YAG (gruppo sperimentale) o solo con gli ultrasuoni (gruppo di controllo). I pazienti sono stati valutati clinicamente all'inizio e a 1, 3, 6 e 12 mesi dopo il trattamento. **Risultati:** nessuna differenza poté essere osservata tra i due gruppi per quanto riguarda profondità di sondaggio delle tasche (PPD), livelli di attacco clinico (CAL), sanguinamento al sondaggio (BOP), indice di placca (PI) o recessione (REC). Nel gruppo di controllo potrebbe essere vista la tendenza di avere una maggiore riduzione dei valori di PPD, una percentuale più piccola di tasche con un PPD ≥ 4 mm e minore percentuale di tasche aperte (PPD ≥ 4mm + BOP) nella valutazione a 12 mesi. **Conclusione:** il trattamento della parodontite combinando ultrasuoni ed un laser Er: YAG ha portato a risultati simili a quelli ottenuti con il trattamento convenzionale con ultrasuoni.

Introduction

Periodontal diseases are highly prevalent chronic inflammatory conditions, with destructive periodontal diseases, namely periodontitis, affecting more than one third of the population (Brown 1989). In fact, periodontitis is the main cause of

tooth extraction in the developed world (Stephens et al. 1991). The treatment of periodontitis is mainly focused to eliminate the subgingival biofilm (Slots & Ting 1999). The mechanical removal of biofilms has shown to halt the progression of attachment loss, to improve gingival health and hence, to significantly reduce tooth loss (Axellson & Lindhe 1981, Knowles et al. 1979, Lindhe & Nyman 1984). This standard mode of periodontal therapy, scaling and root planing (SRP), is based on the use of curettes, scalers or ultrasonic instruments aimed to debride the affected roots, thus removing subgingival biofilm and calculus, and together with the reinforced oral hygiene by the patient, prevent the recolonization by bacteria from the supragingival biofilm. Different protocols have been used to perform non-surgical periodontal therapy. The traditional approach has been to instrument different areas of the mouth (usually quadrant-wise) at weekly, intervals during four consecutive weeks, thus combining scaling with oral hygiene motivation. An alternative approach, the so-called full mouth disinfection (Quirynen et al. 2006) consisted on whole mouth scaling within 24 hours with the adjunctive use of chlorhexidine. Alternatives also exist in terms of debridement methods: in the last decade, the use of lasers has been proposed in the treatment of periodontitis due to its inherent anti-infective and physical properties. While in the literature on lasers, there are more than 1000 types of lasers, just a few have been marketed and used in the dental clinical practice. Among them, Erbium YAG (Er:YAG) laser posses specific characteristics that may make it useful for non-surgical periodontal therapy. However, the clinical efficacy of Er:YAG lasers in non-surgical treatment of periodontitis has been evaluated in several clinical trials with controversial results. Due to this controversial results, further investigation is needed. We hypothesized that a new non-surgical periodontal treatment protocol based in the combination of Er:YAG laser with ultrasonic subgingival debridement may be more effective than a protocol based just on ultrasonic debridement. Thus, the aim of this randomized clinical trial was to evaluate the clinical efficacy of ultrasonic subgingival debridement in combination with Er:YAG laser, when compared to full mouth ultrasonic subgingival debridement alone, after one year, in patients with initial to moderate chronic periodontitis.

Material and Methods

The study was designed as a randomized, controlled, single-masked and parallel group, clinical trial of 12 months of duration (Figure 1), conducted at the Graduate Clinic of Periodontology at the Faculty of Odontology, University Complutense,Madrid, Spain, between 2008-2010. Approval of the study protocol was obtained by the Ethics Committee, and all participants provided informed consent before the start of the study.

Figure 1: The consort E-Flowchart
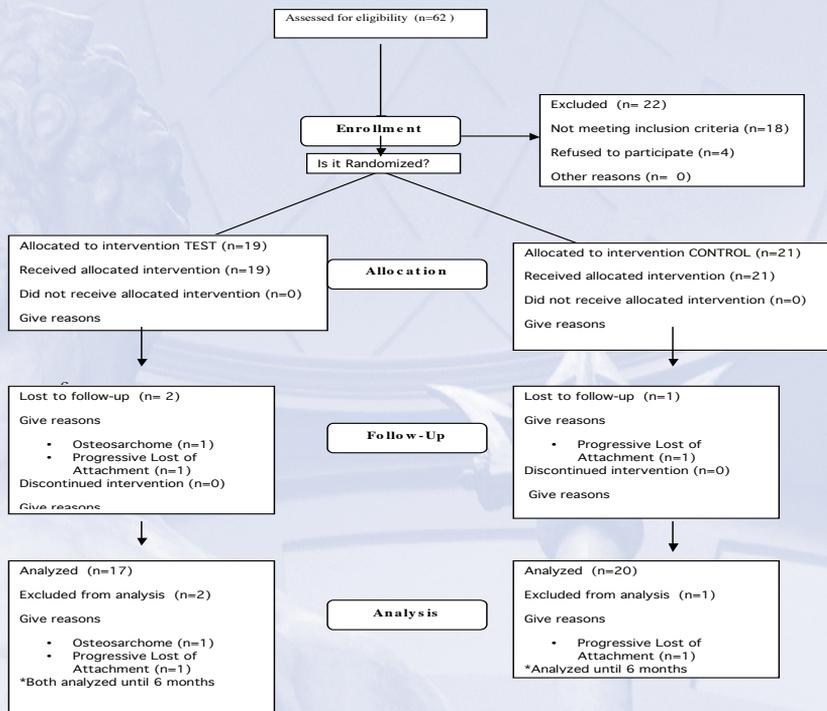
Patient sample

Consecutive patients diagnosed of mild to moderate chronic periodontitis according to the criteria described by Armitage (1999) were invited to participate in this study after a screening visit to evaluate inclusion-exclusion criteria, including full-mouth periodontal and radiographic evaluation. The following criteria were used in the selection of study subjects:

Inclusion criteria
- Age 25-80 years;
- A minimum of 4 teeth per quadrant;
- A least 4 teeth per quadrant with PPD≥5 mm;
- Radiographic bone loss between 30-50% in more than 30% of teeth;
- Good general health according to medical history and no allergies to local anesthetics;
- Willing to participate in the study.

Exclusion criteria
- Subgingival instrumentation within 12 months prior to the baseline examination;
- Use of systemic antimicrobials within 3 months prior to the start of the study;
- Medical conditions requiring prophylactic antibiotic coverage or prophylaxis;
- Ongoing drug therapy that might affect the patient's clinical response;
- Pregnant women.

Examinations

Full mouth clinical examinations were performed at baseline and 1, 6 and 12 months following the completion of the treatment protocol. All teeth and tooth sites (except wisdom teeth) were included in the examinations and the following variables were recorded at 6 sites per tooth: a) *Plaque score (PlI)*: absence/presence of plaque at the cervical part of the tooth as detected with the use of staining with erythrosine (Plac Control liquid, Dentaid, Cerdanyola, Spain); b) *Probing Pocket Depth (PPD)*: measured with Florida probe® (Florida Probe/Fp 32 Vs. 7.2.1/USA) with a controlled force of 25 gr and measured to the closest 0.5 mm; c) Bleeding on Probing (BoP): presence/absence of bleeding within 15 s following pocket probing; d) *Location of gingival margin (GM)*: the distance between the GM and a fixed reference point on the tooth (cemento-enamel junction, CEJ) or the margin of the restoration. A negative value was given when the GM was located coronal to the CEJ; e) *Relative Attachment level (RAL)*: it was calculated adding PPD and GM.

One blinded examiner (AO) performed all measurements. Before the start of the study, the examiner was trained and calibrated to achieve adequate levels of accuracy and reproducibility for the various clinical parameters and indices to be used.

If a lost of attachment ≥2 mm in ≥4 teeth was detected in any patient during the follow-up, the patient exited the study and was treated accordingly. The data from the last visit of the patient was then used for the analysis.

Patient enrolment procedure

The participants were stratified as smokers (current smokers and former smokers of <1 year) and non-smokers (never smoked and former smokers of >1 year). Patients accepting the protocol were randomized and assigned to the test or control groups, by means of a computer generated list. Allocation concealment was secured by having an external agent, not involved in the study, who assigned the patients immediately after baseline measurements, keeping the examiner blinded.

Treatment procedures

Figure 1 depicts study design. Before starting the treatment and after the screening evaluation, patients were given oral hygiene instructions and provided with the adequate devices, aiming at achieving optimal personal biofilm control. Patients were instructed to brush twice daily with the modified Bass technique using a manual medium softness toothbrush and interdental cleaning with dental floss or interdental brushes once daily. Reinforcement instructions were given, if necessary, at baseline and at the reevaluation visits. Each treatment protocol was carried out by a different therapist, being both graduate students in their third year. The had been previously trained in their assigned protocol, either full-mouth ultrasonic debridement plus ERG:YAG laser or ultrasonic debridement alone.

Test group: full mouth ultrasonic debridement plus Er:YAG-laser
The patients assigned to the test group received a full mouth subgingival debridement session (day 0) of 45-60 minutes

with a piezo-ceramic ultrasonic instrument (Minipiezon® EMS, Electo Medical System, Switzerland) using a piezon® tip (DS-001A, Electo Medical System, Switzerland) under profuse water irrigation and power settings between 50-80%. One week later (day 7) the sites with initial PPD ≥5 mm were treated with the Er:YAG laser + feedback system (Kavo Key Laser III, Germany). The laser device was set at a power of 160 mJ and a frequency of 10 Hz. The periodontal sapphire tip (blue light wedge/1.003.8602) was inserted in the pocket and laser was discharged whenever calculus was detected by the feedback system. The tip was moved across the pocket no more subgingival calculus were detected. Local anesthetic was only used if the patients required it. The use of anesthesia together with the time spent for laser treatment was recorded at each treatment phase.

Control group: ultrasonic debridement
The patients in the control group were treated in two sessions, carrying out subgingival debridement of two quadrants at each visit. In the first session (day 0) were treated during 45-60 minutes using of the same ultrasonic device as in the test group. The second session (day 7) was performed in the same manner but for the left quadrants. Local anesthetics were used if necessary and the total treatment time ranged between 90 and 120 minutes.

Postoperative Care
At each follow up visit, all teeth from patients in both groups were supragingivally polished with a rubber cup (Copas profilaxis, DentaFlux, Spain) and a low abrasive polishing paste (Pasta de Profilaxis, DentaFlux, Spain). No intention was made to subgingivally debride the residual pockets or the bleeding sites. Motivation and reinforcement in the provided oral hygiene techniques were given at each visit if necessary.

Data analysis
To avoid the bias caused by treatment response and patients drop out, an intention to treat analysis (ITT) was performed. The primary outcome variable was changes in PPD. As secondary outcome variables, changes in RAL and BOP were selected. PlI was considered as a control outcome variable.
The patient was the unit of the analysis and hence, means, standard errors and 95% confidence intervals were calculated for each outcome variable in each patient at every visit. Normally distributed variables were evaluated by means of ANOVA.

Results
The screening process was performed from (month-year) to (month-year). As it is shown in figure 2, during this period of time, 62 consecutive patients were screened, and 18 did not fulfill the inclusion criteria. Among the suitable candidates, 44 were invited to participate in the study and 40 agreed to do so, and signed the informed consent. All patients completed the 6-month evaluation. Two patients in the test group and one patient in the control group were unable to attend the 1-year visit: in the test group, one patient left the study due to the development of an osteosarcoma; one patient in each group suffered progressive loss of attachment >2 mm in more than 4 teeth. With regards to the demographic variables, data can be seen in Table 1.

Table 1: Demographic characteristics of the patient sample

	TEST	CONTROL	TOTAL
Number of patients-baseline	19	21	40
Number of patients-12 m	17	20	37
Mean Age (Min:Max)	48.5 (37: 71)*	56.8 (39:71)*	52,8
Gender (Male:Female)	7:12	5:16	12:28
Smokers	10	7	17
Number of teeth	26.05	24.8	25.4

*: Statistical significant differences between groups at baseline.

Primary outcome variable (PPD): Table 2 depicts the changes in mean PPD between baseline and the different post-treatment visits for both treatment groups. At baseline, the mean PPD was similar in both groups. A significant reduction in the mean PPD when compared to baseline occurred at each visit for each treatment group. At the 12-month evaluation, the mean PPD in the test group was 2.48 mm and 2.71 mm in the control group, with a mean reduction of 0.52 mm and 0.36 mm, respectively.

PPD was stratified in shallow pockets (1-3 mm) and moderate to deep pockets (≥4 mm). Table 3 shows the frequency distribution of pockets ≥4 mm in both treatment groups at every visits. At baseline, there were no significant differences between groups. A significant reduction in the percentage of sites ≥4 mm occurred in both groups after therapy, although only the test group demonstrated a significant reduction at each time visit, when compared to baseline, whereas the control group only demonstrated significant differences between baseline and the 1-month evaluation. At end of the study there were significant differences (p=0.004) between the treatment groups for the mean percentage of sites with PPD ≥4 mm. When comparing the mean percentage of open pockets (PPD≥4+BOP) between groups, the test group experienced a statistical significant reduction between baseline and 12 months, while the control group did not demonstrate differences.

Table 2. Mean reductions of PPDs between baseline and the different time visits. They are expressed as mean, standard error (SE), 95% Confidence intervals (95% CI), and intergroup statistical evaluation (ANOVA, p value)

Changes in PPD (mm)	TEST				CONTROL				P value
	Mean	SE	95% CI		Mean	SE	95% CI		
Baseline PPD	3.07	0.07	2.91	3.22	3.11	0.07	2.95	3.26	0.7344
Baseline 1 month	-0.48	0.08	-0.64	-0.32	-0.42	0.07	-0.57	-0.27	0.598
Baseline 3 months	-0.50	0.08	-0.67	-0.33	-0.41	0.07	-0.57	-0.24	0.457
Baseline 6 months	-0.54	0.08	-0.71	-0.38	-0.45	0.08	-0.61	-0.29	0.448
Baseline 12 months	-0.52	0.09	-0.69	-0.34	-0.36	0.08	-0.52	-0.20	0.224

Table 3. Percent reductions of moderate to deep PPDs between baseline and the different time visits. Percentages are expressed as mean, standard error (SE), 95% Confidence intervals (95% CI), and intergroup statistical evaluation (ANOVA, p value). (PPD≥4mm)

Reductions in % of PPD ≥ 4 mm	TEST				CONTROL				P value
	Mean %	SE	95% CI		Mean %	SE	95% CI		
Baselin % of PPD≥ 4mm	29.75	1.74	26.30	33.20	30.32	2.00	26.34	34.29	0.8368
Baseline 1 month	-10.99	1.75	-14.55	-7.43	-9.21	1.66	-12.57	-5.84	0.4889
Baseline 3 months	-10.88	1.85	-14.65	-7.12	-8.94	1.75	-12.5	-5.38	0.4744
Baseline 6 months	-11.33	1.74	-14.88	-7.79	-8.89	1.65	-12.24	-5.55	0.3421
Baseline 12 months	-11.86	2.09	-16.12	-7.59	-6.24	1.91	-10.12	-2.35	0.0726

RAL: At baseline, the mean RAL was similar in both groups (3.81mm in the test group and 3.77 mm in the control). At the 12 months evaluation, the mean RAL in the test group was of 3.38 mm and 3.57 mm in the control group, with a mean reduction of 0.28 mm and 0.15 mm, respectively. The statistical analysis showed no differences within and between both groups at any time.

BOP: At baseline, there were not statistical significant differences between groups, with a mean value of 62% for the test group and 67% for the control. At the 12 months evaluation, the mean BOP in the test group was 28% and in the control group 30%. The test group experienced a significant reduction in the mean BOP when comparing baseline with each visit, while the control group experienced a significant reduction after the 1-month evaluation, with a mean reduction of 31% and 35%, respectively.

PlI: At baseline, both groups showed similar mean values of PlI, 61.6% in the test group and 60.5% in the control, and there was a continued improvement in the plaque levels during the entire period of the study. After 12 months, evaluation the PlI reached a level of 27.1% for the test group and 24.6% for the control. There were no statistical significant differences between groups in any study period and both groups showed a significant reduction between baseline and all the examination intervals.

Discussion

The present study demonstrated that, in patients with mild-moderate chronic periodontitis, the tested treatment approach resulted in significant clinical improvements up to one year of follow-up. The obtained results were not significantly different from the outcomes attained in the control group, where a standard non-surgical periodontal therapy was carried out. Both treatment approaches were effective in reducing PPD, BOP and PlI deposits even one year after the therapy. In regards to the main outcome measurement, PPD reduction, significant reductions were attained in the test group at each follow up visit. This tendency could not be seen, however, in the control group, where a small relapse between the 6-month and 1-year visit was noted. Table 4 shows the results of the different studies that have used the Er:YAG laser as initial periodontal therapy.

In summary we can conclude that both treatment protocols were effective in terms of PPD and BOP reduction. These clinical benefits were maintained over a year, taking into account that no additional treatment was performed in any of the groups. The statistical analysis demonstrated a trend to better clinical results in the test group, specially for PPD reduction and reduction of the proportion of sites ≥ 4mm, although these small benefits have to be weighed with the costs of the laser device and therefore, the cost-benefits of this mode of therapy must be carefully analyzed. Further studies with a larger sample sizes are necessary to evaluate the real efficacy of this proposed treatment protocol and to ascertain the added value of the Er:YAG laser application in the deep periodontal sites.

Study	PPD reduction	Bs-%PPD≥4	RAL changes	BOP changes	PI changes
Schwarz et al. 2001	Bs T:4,9/C:5,0 Laser: 2.0mm SRP: 1.6 mm	Not examined They selected PPD≥4 mm	Bs T:6,3/C:6,5 Laser: AG 1.9mm SRP: AG 1.0mm	Bs T:56%/C:52% Laser: -43% SRP: -29%	Bs T:1.0/C:1.0 Laser: -0.4 (1-3) SRP: -0.3 (1-3)
Schwarz et al. 2003a	Bs T:4,9/C:5,0 Laser: 1.6mm SRP: 1.3 mm	Not examined They selected PPD≥4 mm	Bs T:6,3/C:6,5 Laser: AG 1,4mm SRP: AG 0,7mm	Bs T:56%/C:52% Laser: -36% SRP: -24%	Bs T:1.0/C:1.0 Laser: +0.3 (1-3) SRP: +0.2 (1-3)
Schwarz et al. 2003b	Bs T:5.2/C:5.0 Laser: 2.0mm SRP: 1.7 mm	Not examined as PPD distribution	Bs T:6,9/C:6,6 Laser: AG 1.6mm SRP: AG 1.6mm	Bs T:58%/C:61% Laser: -44% SRP: -45%	Bs T:1.0/C:1.0 Laser: +0.3 (1-3) SRP: +0.2 (1-3)
Sculean et al. 2004	Bs T:5.2/C:5.2 Laser: 1.5mm SRP: 1.5 mm	Not examined They selected PPD>4 mm	Bs T:6,7/C:6.7 Laser: AG 1.1mm SRP: AG 1.1mm	Bs T:40%/C:46% Laser: -23% SRP: -31%	Bs T:0.8/C:0.8 Laser: -0.02 (1-3) SRP: 0.0 (1-3)
Tomasi et al. 2006	Bs T:6.0/C:5.8 Laser: 1.1mm SRP: 1.0 mm	Not examined They selected PPD>4 mm	Bs T:6,7/C:6.7 Laser: AG 0.6mm SRP: AG 0.4mm	Bs T:92%/C:92% Laser: -50% SRP: -52%	Bs T:10%/C:22% Laser: +9% SRP: +3%

Crespi et al. 2007	Bs T:5.4/C:5.1 PPD-5-6 mm L:2.8/SRP: 1.0 Bs T:7,9/C:7,1 PPD≥7mm L:4.8/SRP: 2.2	Just included PPD > 4mm. They sub-grouped in 5-6 & ≥7mm	Bs T:6.2/C:6.1 PPD-5-6 mm AG L:2.9/SRP: 1.3 Bs T:8.4/C:8.3 PPD≥7mm AG L:5.0/SRP: 2.0	Bs T:1.75/C:1.75 GI-Laser: -0.66 (1-3) GI-SRP: -0.74 (1-3)	Bs T:1.05/C:1.05 Laser: -0.24 (1-3) SRP: -0.23 (1-3)
Lopes et al. 2010	Bs S+L:6.4/ L:6.4/SRP:6.8/ Cor:6.2 S+L:2.19/L:1.6/ SRP:2.29	Not examined	BS+L:6.7/L:6.2/ SRP:7.2/Cor:6.8 AG S+L:1.1/L:0.7/ SRP:1.4	Bs-SL/L/SRP/C: 100% S+L:-68%/L: -62%/SRP:-68%/ Cor:-38%*	Bs-S+L:43,7/L:38/ SRP:52,4/ Cor:6,2 S+L:-23%/L: -20%/SRP:-22%
Rotundo et al. 2010	Bs S+L:5.1/L:5.2/ SRP:5.2/ Cor:5.3 S+L:1.2/L:0.7/ SRP:1.0/C: 0.7	Just included PPD≥ 4mm.	Bs S+L:5.7/L:6.2/ SRP:6.1/Cor:6.1 AG S+L:0.5/L:0.2/ SRP:0.5/Cor: 0.1	Bs S+L:71%/L 75% /SRP:73%/ Cor: 74% S+L:-18%/L: -17%/ SRP:-16%/ Cor:-10%	Bs S+L:63%/L 64%/ SRP:68%/ Cor: 72% S+L:-16%/L: -24%/SRP:-20%/ Cor:-22%

PPD: Probing pocket depth
RAL: Relative Attachment Level
BOP: Bleeding on Probing
PI: Plaque index
Bs: Baseline
T: Test
C: Control
L: Laser
SRP: Scaling and Root Planning

AG: Attachment Gain
GI: Gingival Index
S+L: Scaling+laser
Cor: Coronal Scaling

References

Crespi R, Cappare P, Toscanelli I, Gherlone E, Romanos GE. (2007) Effects of Er:YAG laser compared to ultrasonic scaler in periodontal treatment: A 2-year follow-up split-mouth clinical study. *Journal of Periodontology* 78, 1195-1200.

Lopes BMV, Theodoro LH, Melo RF, Thompson GMA, Marcantonio RAC. (2010) Clinical and microbiologic follow-up evaluations after non-surgical periodontal treatment with Erbium:YAG laser and scaling and root planing. J*ournal of Periodontology* 81, 682-691.

Rotundo R, Nieri M, Cairo F, Franceschi D, Mervelt J, Bonaccini D, Esposito M, Pini-Prato G. (2010) Lack of adjunctive benefit of Er:YAG laser in non-surgical periodontal treatment: a randomized split-mouth clinical trial. *Journal of Clinical Periodontology* 37, 526–533.

Sanz M, Teughels W; Group A of European Workshop on Periodontology. Innovations in non-surgical periodontal therapy: Consensus Report of the Sixth European Workshop on Periodontology. *Journal of Clinical Periodontology* 35(8 Suppl), 3-7.

Schwarz F, Sculean A, Georg T, Reich E. (2001a) Periodontal treatment with an Er: YAG laser compared to scaling and root planing. A controlled clinical study. *Journal of Periodontology* 72, 361-367.

Schwarz F, Sculean A, Berakdar M, Georg T, Reich E, Becker J. (2003a) Periodontal treatment with an Er: YAG laser compared to scaling and root planing. A 2-year follow-up Split-mouth study. *Journal of Periodontology* 74, 590-596.

Schwarz F, Sculean A, Berakdar M, Georg T, Reich E, Becker J. (2003b) Clinical evaluation of an Er:YAG laser combined with scaling and root planing for non-surgical periodontal treatment. A controlled, prospective clinical study. *Journal of Clinical Periodontology* 30, 26-34.

Sculean A, Schwarz F, Berakdar M, Romanos GE, Arweiler NB, Becker J. (2004) Periodontal treatment with an Er:YAG laser compared to ultrasonic instrumentation: a pilot study. *Journal of Periodontology* 75, 966-973.

Tomasi C, Schander K, Dahlen G, Wennström JL. Short term clinical and microbiologic effects of pocket debridement with an Er:YAG laser during periodontal maintenance. (2006). *Journal of Periodontology* 77: 111-118.

Wennström JL, Tomasi C, Bertelle A, Dellasega E. (2005) Full-mouth ultrasonic debridement versus quadrant scaling and root planing as an initial approach in the treatment of chronic periodontitis. *Journal of Clinical Periodontology* 32, 851–859.