

Adjunctive clinical effect of a water-cooled Nd:YAG laser in a periodontal maintenance care programme: a randomized controlled trial

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Slot DE, Timmerman MF, Versteeg PA, van der Velden U, van der Weijden FA. Adjunctive clinical effect of a water-cooled Nd:YAG laser in a periodontal maintenance care programme: a randomized controlled trial. *J Clin Periodontol* 2012; 39: 1159–1165. doi: 10.1111/jcpe.12007.

Abstract

Background: Various laser systems are currently available for intra-oral use. Neodymium:Yttrium–Aluminium Garnet lasers (Nd:YAG) have been approved by the US Food and Drug Administration for soft tissue treatment in the oral cavity. **Objectives:** The aim of this study was to test whether the use of a water-cooled Nd:YAG laser during a maintenance care programme as an adjunct to supragingival and subgingival debridement (scaling and root planing, SRP) with hand and ultrasonic instruments results in clinical improvement compared with SRP alone. **Material and Methods:** This study was an examiner-blind, randomized and controlled clinical trial using a split-mouth design. Thirty subjects were selected, originally diagnosed with moderate to severe generalized periodontitis, following a periodontal maintenance care programme (PMC). Immediately after SRP in two randomly assigned contra-lateral quadrants, all pockets ≥ 5 mm were additionally treated with a Nd:YAG laser (1064 nm, 4W, 250- μ sec pulse). Clinical assessments [probing pocket depth PPD, bleeding on pocket probing (BOPP)] were performed pre-treatment and at 6 months. Based on these assessments, the periodontal inflamed surface area (PISA) was calculated. **Results:** At 6 months, the clinical parameters had significantly improved for both regimens. No statistically significant differences between treatment modalities were observed for PPD and BOPP scores at any time. PISA scores supported these findings. **Conclusions:** In residual pockets ≥ 5 mm, treated in a PMC, the adjunctive use of an Nd:YAG laser does not provide a clinically significant additional advantage.

Key words: laser; maintenance care recall programme; Nd:YAG; periodontitis; RCT; scaling and root planning; treatment; ultrasonic

Accepted for publication 11 August 2012

Conflict of interest and source of funding statement

The authors declare that they have no conflict of interest. This study was self-funded by the Clinic for Periodontology, Utrecht, The Netherlands.

Laser therapy has bactericidal and detoxification effects, and it can remove epithelial lining, granulation tissue, plaque and calculus within the periodontal pocket with low mechanical stress and without leaving a

smear layer on root surfaces (Claffey & Polyzois 2008). These effects may potentially improve healing. Among dentists and dental hygienists in the Netherlands, a Nd:YAG laser with water and air coolant is often used

as an adjunct to the non-surgical treatment of periodontitis, as suggested by Lioubavina-Hack (2002). In a recent "in vitro" study, this particular Nd:YAG laser has been shown to have a bactericidal effect (Kranendonk et al. 2010). A recent "in vivo" study (Slot et al. 2011) investigated the effect of the water-cooled Nd:YAG laser when used for initial periodontal treatment as an adjunct to supragingival and subgingival debridement by scaling and root planing (SRP). Immediately after instrumentation, the total number of colony-forming units (CFU) was significantly reduced compared to the pre-instrumentation baseline for both groups, regardless of the treatment regimen. After 3 months, no added clinical effect was achieved with the additional use of the Nd:YAG laser over SRP alone.

Periodontal stability in the dentition is reflected by a minimal number of residual pockets following the initial periodontal therapy. Periodic monitoring of the periodontal status and appropriate maintenance procedures should be part of a long-term treatment plan in the management of chronic periodontitis (Hancock 1996). In-office periodontal maintenance at 3- to 4-month intervals can be effective in maintaining periodontal stability in most patients (Ramfjord 1993, AAP 1997). The presence of high numbers of residual pockets has been associated with the risk of disease progression (Badersten et al. 1990, Claffey et al. 1990). Lang et al. (1990) suggested that individuals with residual pockets (≥ 5 mm) may be regarded as having a risk for recurrent disease. Therefore, during periodontal maintenance visits, pockets with a probing depth ≥ 5 mm are carefully instrumented (SRP) to remove subgingival biofilm. Under maintenance conditions, it may be hypothesized that the bactericidal benefit of the Nd:YAG laser may offer an adjunctive clinical benefit. At present, the adjunctive effect of this water-cooled Nd:YAG laser during periodontal maintenance care is unknown. Therefore, the aim of this study was to test whether the use of a water-cooled Nd:YAG laser in pockets ≥ 5 mm during a supportive periodontal maintenance care programme (PMC) as an adjunct to hand and ultrasonic

instruments would result in greater clinical improvement than obtained with SRP alone.

Material and Methods

Ethical aspects

The study protocol was approved by the Medical Ethics Committee of the Academic Medical Center in Amsterdam (MEC# 02/270). All voluntary participants were informed of the outline, purpose and duration of the study and signed an informed consent form. Allocation concealment was achieved by providing the treatment assignment in sequentially numbered opaque sealed envelopes (SNOSE). This study was conducted in accordance with the CONSORT guidelines (Schulz et al. 2010, available at: <http://www.consort-statement.org/consort-statement/overview0/>).

Study population

For this study, all participants had been referred previously by their general dentists to a clinic specializing in periodontal therapy (Clinic for Periodontology, Utrecht). The final enrolment decision was determined by an experienced periodontist during regular follow-up visits after the patients had been actively involved in a regular supportive PMC for >1 year and had visited a dental hygienist at least once every 4 months. PMC included the reinforcement of oral hygiene instructions based on individual needs regarding optimal plaque control.

The following inclusion criteria were used:

- ≥ 30 years of age;
- systemically healthy (not pregnant);
- a minimum of three natural teeth in every quadrant;
- regarding the clinical diagnosis before active periodontal treatment, moderate-to-severe generalized periodontitis characterized by:
 - presence of ≥ 1 site per quadrant with a probing pocket depth (PPD) of >6 mm and interproximal attachment loss of ≥ 3 mm;
 - presence of bleeding on pocket probing (BOPP);
 - radiographic evidence of alveolar bone loss.

- the following clinical characteristics at the start of the study:
 - presence of ≥ 2 sites per quadrant with a PPD of ≥ 5 mm and interproximal attachment loss of ≥ 2 mm;
 - presence of BOPP;
 - radiographic evidence of alveolar bone loss.

The exclusion criteria were (acute) oral lesions, necrotizing ulcerative periodontitis, antibiotic use for any purpose within 6 months prior to entering the study and orthodontic braces.

Clinical assessments

The following measurements were performed prior to the PMC appointment and after a 6-month evaluation period:

- PPD determined using a manual probe (PQW 10-mm probe with Williams calibration; Hu-Friedy® Hu-Friedy Inc., Leimen, Germany);
- recession (REC) distance from the marginal gingiva to the cemento–enamel junction;
- BOPP (Van der Velden 1979).

All clinical measurements were obtained at six sites (mesio–buccal, buccal, disto–buccal, mesio–lingual, lingual and disto–lingual) around each tooth and were rounded to the nearest millimetre. All clinical measurements were performed by a calibrated examiner and experienced periodontist who was blinded to the treatment regimen. Access to previous assessment data was not allowed during the course of the study.

Clinical procedure

This study was an examiner-blind, randomized, and controlled 6-month clinical trial using a split-mouth design. After the eligibility to enter the study was established, the patients were scheduled for their first appointment. A medical-history form that included smoking habits and smoking history was completed. An experienced dental hygienist performed all treatments. All residual pockets ≥ 5 mm were supragingivally and subgingivally (SRP) debrided

using a piezoelectric ultrasonic unit (Piezon Master; EMS, Nyon, Switzerland) at a moderate setting using appropriate tips. In addition, where deemed appropriate by the dental professional, hand instruments were used (Hu-Friedy®).

After the completion of SRP, additional laser treatment assignments were revealed to the dental hygienist in an envelope (SNOSE). Immediately thereafter, depending on the randomization, all residual pockets with a depth of ≥ 5 mm among the two randomly assigned contra-lateral quadrants were additionally treated with the Nd:YAG laser. The opposing contra-lateral quadrants received no additional treatment. Randomization was based on a predetermined computer-generated set of random numbers that was obtained via www.random.org.

For additional laser therapy, a solid-state crystal Nd:YAG laser (Genius Periodontal A/S, Copenhagen, Denmark) was used in the randomly allocated quadrants (SRP +Nd:YAG). Before the laser system was set up for this study, the system was serviced and tested to ensure that it worked according to the manufacturer's specifications. The details for the settings of this water-cooled Nd:YAG laser are presented in Slot et al. (2011). The fibre tip was held with light pressure in contact with the tissue and aligned parallel to the tooth. The "perio" setting of the laser was used to adjust the power and cooling to enable smooth instrumentation. The length of the round flexible 0.6-mm laser fibre (0.2826 mm^2) emerging from the handpiece tip was adjusted to correspond to the periodontal pocket probe measurements. Small horizontal excursions were made approximately ± 2 mm along the gingival margin that penetrated no deeper into the pocket than the probing depth. The laser was applied for no more than 60 s per site. Remnants of gingival tissue were removed using a manual curette. All laser procedures were performed with protective eyewear for both the patient and dental hygienist. When debris was visible, the fibre tip was cleaned at the discretion of the operator to maintain its optical properties.

Following instrumentation, all supra-gingival surfaces were polished.

In addition, all patients received personalized instruction in oral hygiene procedures, including brushing and inter-dental cleaning. After treatment, the subjects were requested to rinse for 2 weeks, twice daily for 30 s, with 15 ml of a mouthwash containing 0.12% chlorhexidine (Perio-aid®; Dentaaid, Houten, The Netherlands). No other treatment was provided until the next appointment. Six months after this visit, which represented the end of the study period, all clinical measurements were recorded again. Figure 1 presents a flow diagram that represents the passage of the patients throughout this clinical trial.

Questionnaire

After the treatment, a questionnaire was provided to each subject for post-operative evaluation as a secondary outcome measurement (Table 1). The patients were asked to complete the questionnaires at home at the end of the same day to evaluate their perception of pain, swelling and bleeding after treatment. The patients were asked to indicate the specific quadrants of the mouth where the aforementioned outcomes were observed. In addition, the patients were asked to report the number of analgesic tablets taken. Subjects were asked to return the questionnaire the next day by mail.

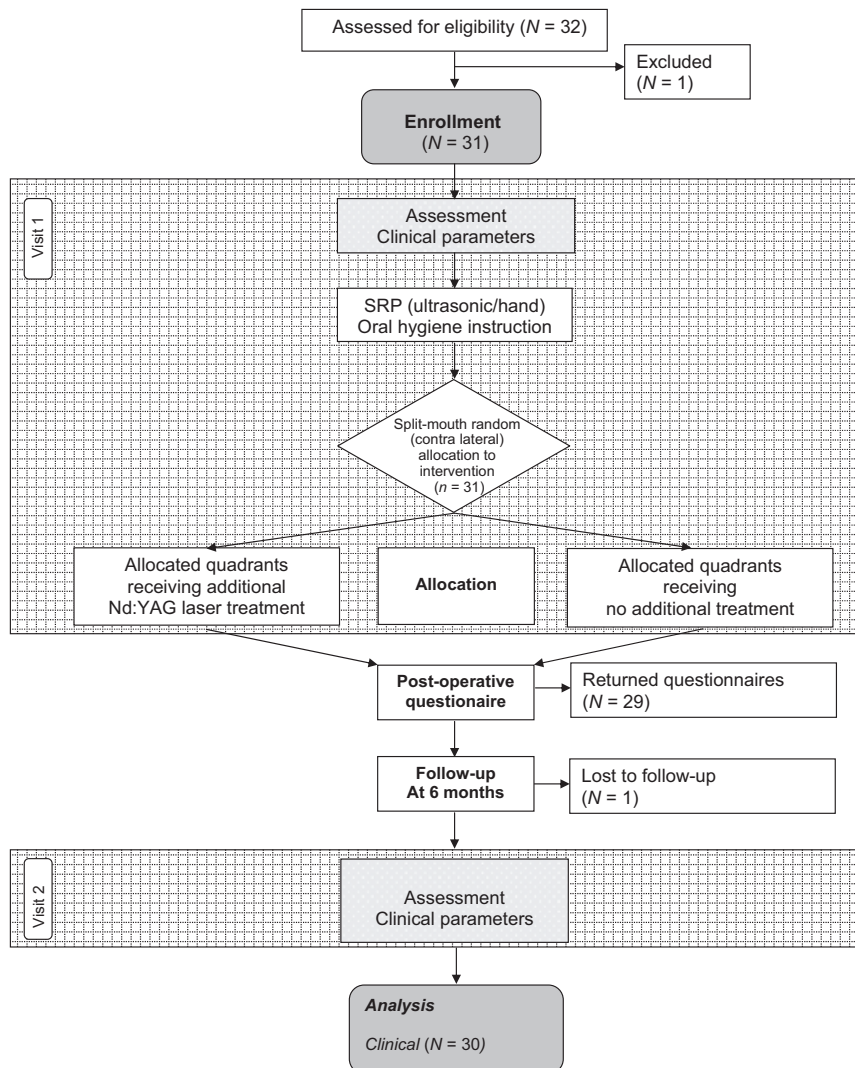


Fig. 1. Flowchart depicting subject enrolment and measurements.

Power and statistical analysis

Probing pocket depth and BOPP were the primary response variables. For PPD reduction, the present design was able to discern a difference (δ) of 0.5 mm between therapies with a standard deviation of 0.7 (as derived from Slot et al. 2011), given a Type I error of $\alpha = 0.05$ and a power of $\geq 80\%$. For the clinical measurements, a patient-level response variable was calculated for each parameter by separately computing the mean scores per patient at baseline and at the end of the trial for each intervention. The statistical analysis was performed by D.E.S. and M.F.T. both of whom were blinded to the randomization. The percentage of pockets with a depth of ≥ 5 mm was enumerated. Furthermore, for the PPD measurements, an overall mean value was calculated for the treated sites initially measuring ≥ 5 mm. Statistical testing for normality with respect to the distribution of the outcome of clinical parameters was performed using the Kolmogorov–Smirnov test. Multivariate analysis was conducted to determine the effect of smoking on treatment outcomes. The periodontal inflamed surface area (PISA) score was also calculated after the PPD data and the incidence of BOPP were entered into a PISA spreadsheet that was publically available from www.parsprototo.info (Nesse et al. 2008). Parametric and non-parametric tests were performed where appropriate with an “intention to treat” approach. $p < 0.05$ was defined as significant.

The questionnaires were evaluated using non-parametric chi-square tests to compare the outcomes of the two treatment regimens.

Results

Clinical findings

In total, 32 (14♂, 18♀) chronic periodontitis patients enrolled for more than 1 year in PMC were included. One subject failed to appear at the first appointment before the start of the study, whereas another subject was excluded after failing to attend the final assessment because of scheduling conflicts (Fig. 1). In total, 13 men and 17 women with a mean

age of 48.7 (± 11.3) years (range: 39–65 years) completed the study. All enrolled patients completed the study with a mean follow-up time of 6 months. No serious adverse effects of the laser treatment were observed or reported by the patients.

All clinical parameters were normally distributed. Post-hoc analysis revealed that the present study ($N = 30$) was sufficiently powered ($\beta = 1.0$) to discern a difference of 0.5 mm ($p < 0.05$) with an average SD of 0.52. At baseline, both sets of contra-lateral quadrants (SRP+Nd:YAG versus SRP) were found to be balanced with respect to the clinical parameters (PPD, BOPP, REC) (Table 2). After 6 months, all of the parameters had significantly improved compared to the baseline for both regimens. No statistically significant differences for the investigated parameters were found at any time between the two treatment modalities. The only significant difference ($p = 0.009$) was observed between the groups that manifested as an increase in the number of sites with visible gingival recession relative to the cemento–enamel junction. For the laser-treated quadrants, the number of sites increased by 0.7, whereas in the control quadrants, the number of sites decreased by 0.05. Twelve of the subjects were smokers and had been smoking for up to 40 years with a calculated burden of 42 pack-years. Eighteen of the subjects were non-smokers, among whom 11 were former smokers and quit 1–17 years earlier. An additional seven patients had never smoked. A subanalysis of the impact of smoking on treatment outcome revealed no significant differences with regard to the treatment used.

A similar pattern was observed for the PISA score (Table 3). The intra-group changes were significant, whereas the inter-group comparison failed to show any significant differences between the baseline and the completion of the trial ($p = 0.210$). The mean reduction in the PISA score in the laser-treated quadrants was

12.72 mm², whereas the equivalent in the control group was 16.90 mm².

Questionnaires

Table 4 shows the answers to questionnaires that were completed by 29 subjects. When post-operative bleeding, swelling or pain was reported on the day of treatment, it was more frequently observed in the quadrants receiving adjunctive laser therapy ($p \leq 0.01$). In total, only four patients reported the use of analgesics for continued pain arising from the provided treatment.

Discussion

The collective evidence gathered in systematic reviews suggests that the effect of the Nd:YAG laser for the treatment of chronic periodontitis may be comparable to SRP with regard to the reduction of subgingival microflora (Cobb 2006, Schwarz et al. 2008) and also with parameters associated with periodontal inflammation (Slot et al. 2009, Cobb et al. 2010). The AAP stated in their Statement on the Efficacy of Lasers in the Non-Surgical Treatment of Inflammatory Periodontal Disease that there is minimal evidence to support use of a laser for the purpose of subgingival debridement, either as a monotherapy or adjunctive to SRP (AAP 2011). This study evaluated the adjunctive effect of treatment with a water-cooled Nd:YAG laser during periodontal maintenance in the clinical setting. However, no adjunctive effect was observed. Thus, based on the present clinical results and those of a previous study (Slot et al. 2011), the water-cooled Nd:YAG laser appears to have no adjunctive beneficial role in subgingival debridement, either during the initial periodontal treatment or during supportive periodontal maintenance care. With respect to the use of other laser types as a non-surgical but supportive periodontal maintenance

Table 1. Questions used for the post-operative questionnaire

| Paraphrase | Complete question |
|---------------------|---|
| Bleeding | Did you experience any bleeding in the treated sites today? |
| Swelling | Did you experience any swelling in the mouth today? |
| Post-operative pain | Did you experience any post-operative pain in the mouth today? |
| Analgesics | Did you use any analgesics for pain in the treated sites today? |

Table 2. Means (SD) and analyses of all clinical parameters during the study for both treatment modalities for sites with a baseline pocket depth ≥ 5 mm.

| N = 30 | SRP+Nd:YAG | | | SRP | | | p-value* | 95% CI |
|------------------------------|-------------|-------------|--------------|-------------|-------------|--------------|----------|---------------|
| | baseline | end | difference | baseline | end | difference | | |
| Mean PPD ≥ 5 mm | 5.39 (0.32) | 4.42 (0.60) | -0.97 (0.58) | 5.46 (0.36) | 4.61 (0.53) | -0.85 (0.45) | 0.245 | [-0.10; 0.35] |
| No. of sites PPD ≥ 5 mm | 11.2 (5.0) | 5.6 (3.7) | -5.6 (3.5) | 10.6 (5.5) | 5.7 (3.6) | -4.9 (3.3) | 0.373 | [-0.9; 2.2] |
| Mean BOPP ≥ 5 mm PPD | 0.51 (0.27) | 0.49 (0.31) | -0.20 (0.21) | 0.51 (0.23) | 0.43 (0.25) | -0.07 (0.24) | 0.347 | [-0.13; 0.04] |
| Mean REC | 0.94 (0.98) | 1.00 (0.97) | +0.08 (0.32) | 0.81 (0.67) | 0.79 (0.79) | -0.02 (0.38) | 0.203 | [-0.06; 0.25] |
| No. of sites REC | 5.0 (4.5) | 5.7 (5.2) | +0.7 (1.6) | 4.8 (3.9) | 4.7 (3.9) | -0.05 (1.8) | 0.009 | [-2.2; -0.2] |

*Statistical comparison of the incremental change (difference) between groups (Wilcoxon test). PPD, probing pocket depth; REC, recession; SRP, scaling and root planing.

Table 3. Mean (SD) Periodontal Inflamed Surface Area (PISA) scores before treatment (base) and at follow-up (end) for both treatment modalities

| N = 30 | SRP+Nd:YAG | | | SRP | | | p-value* |
|---------------------------|-----------------------|---------------|---------------|-----------------------|---------------|---------------|----------|
| | baseline [§] | end | difference | baseline [§] | end | difference | |
| PISA mm ² | 50.40 (49.57) | 37.68 (44.29) | 12.72 (28.25) | 45.03 (37.97) | 28.13 (24.46) | 16.90 (24.56) | 0.210 |
| Within group [¶] | | | p = 0.009 | | | p = 0.001 | |

*Between-group differences (Wilcoxon test).

[¶]Baseline-end within-group comparisons (Wilcoxon test).

[§]Baseline comparison between groups not significant (Wilcoxon test).

Table 4. Results from the post-operative questionnaire

| N = 29 Paraphrase | N (%) of patients who reported post-operative complaints | No. of quadrants associated with post-operative complaints | | |
|----------------------|--|---|-----|----------|
| | | SRP+Nd:YAG | SRP | p-value* |
| Bleeding | 13 (45%) | 14 | 4 | 0.010 |
| Swelling | 14 (48%) | 17 | 3 | 0.001 |
| Post-operative pain | 24 (83%) | 28 | 11 | 0.001 |

*Chi-square test.

nance therapy, recent results from a cohort study (Krohn-Dale et al. 2012) and a multicentre study (Ratka-Krüger et al. 2012) indicate that the Er:YAG (used as a monotherapy during supportive periodontal care) provides clinical and microbiological outcomes similar to those of a traditional (ultrasonic) sonic scaler. The effect of an Nd:YAG laser in supportive periodontal maintenance therapy as monotherapy still needs to be established.

Periodontal inflamed surface area has been proposed as a classification system for periodontitis that quantifies the amount of inflamed periodontal tissue and, as such, indicates the systemic inflammatory burden. PISA probably quantifies the amount of inflamed periodontal tissue for each individual patient more accurately

than any other classification technique currently in use (Nesse et al. 2008). The PISA scores support the finding that the Nd:YAG laser does not provide an adjunctive treatment effect over mechanical periodontal therapy.

The increase in number of sites with recession appears to be a potentially adverse effect that does not justify the use of Nd:YAG laser on a routine basis. Among the collective evidence concerning the use of Nd:YAG during non-surgical periodontal therapy (Cobb et al. 2010, Schwarz et al. 2008, Slot et al. 2009), only one systematic review (Slot et al. 2009) reported on gingival recession. From their comprehensive search, only one article was retrieved (de Andrade 2008) that reported on recession in both study groups (i.e., SRP with or without additional Nd:YAG treat-

ment). An increase was observed in the distance of the gingival margin to the cemento-enamel junction, although statistically significant differences were not observed between the groups. This observation is in line with the present results, where the mean change in recession failed to show differences between the groups. Gingival recession was only assessed in case the gingival margin was located apical to the cemento-enamel junction. As such, no recession was measured when the gingival margin was located coronal to the cemento-enamel junction, which may result in the underestimation of the effect of the laser on gingival recession in the SRP+Nd:YAG-treated quadrants and may have negatively influenced the total clinical attachment loss.

Following the initial periodontal treatment using hand and ultrasonic instruments with or without the additional use of the Nd:YAG laser, a patient may experience a degree of pain and swelling in addition to post-operative sensitivity to high and low temperatures. In a previous study (Slot et al. 2011), post-operative pain determined using a questionnaire was more pronounced in the SRP+Nd:YAG group. Similar observations were evident from this study, where

the Nd:YAG-treated quadrants presented with significantly more bleeding, swelling and post-operative pain. Moreover, regarding patient perception, the post-operative experience of bleeding, swelling and pain was more pronounced in those quadrants additionally treated with Nd:YAG laser. Patient comfort and acceptance of dental treatment is not a commonly researched topic in dentistry; however, one study assessed this issue for orthodontic removable retainers (Wong & Freer 2005) and observed a strong relationship between comfort level and compliance. Consequently, it may be assumed that using Nd:YAG laser as an adjunct for periodontal therapy, either during the initial periodontal treatment or maintenance care, may result in patient abstinence from further clinical treatment. Contrary results with the Er:YAG laser show that during supportive periodontal treatment, painful sensations can be reduced as compared to sonic scaler instrumentation (Braun et al. 2010).

Limitations

- The Nd:YAG treatment alone is not evaluated in this study. Monotherapy could hypothetically result in a similar effect as PMC, based on recent work done with the Er:YAG laser (Krohn-Dale et al. 2012, Ratka-Krüger et al. 2012).
- The selected subjects were clients of a private periodontal clinic who, after the completion of active periodontal treatment, were treated in a PMC. Periodontal clinics and their staff are trained to treat and motivate patients with periodontitis and realize a high level of periodontal stability in general (Costa et al. 2012). The present results can therefore be generalized to practices and dental-care professionals with periodontitis patients who are motivated to undergo regular periodontal maintenance care.
- The laser system that was used was serviced and tested before the start of the experiment. However, there was no external con-

trol of the laser parameters during treatment within the present experimental design because the infrared radiation and the effects of the laser-tissue interactions were not visible, which implies that there was no control that ensured the effective performance of the tested system.

- The patients were not blinded with respect to treatment modality, which may have affected the patient assessment of the novel instrument.

Conclusion

No significant differences between laser-supported SRP and regular SRP were observed for any of the clinical parameters. An analysis of clinical parameters according to the PISA scores also supports these findings. Consequently, during a PMC, no clinical advantage was achieved with the additional use of the water-cooled Nd:YAG laser.

Acknowledgements

The authors thank Dr. Spiros Paraskevas and Dr. Natasha V. Lioubavina-Hack for their input and suggestions regarding the design of the study protocol. The authors also thank Gerard Flint from the Ricana Company for his help with setting up the laser treatment.

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Clinical Relevance

Scientific rationale for the study: The Nd:YAG laser has a potential bactericidal effect. At present, the clinical effect of water-cooled Nd:YAG lasers in a periodontal maintenance care programme is unknown.

Principal findings: The adjunctive use of the Nd:YAG laser after SRP during a maintenance care

programme did not provide additional benefits. The estimate of the periodontal inflamed surface area (PISA) supports this observation.

Practical implications: The results of this study are applicable to patients with diagnoses of moderate-to-severe adult periodontitis who are motivated to attend a maintenance care programme regularly. The clinical results did not show an advanta-

geous effect of adding a laser treatment to conventional periodontal maintenance care. The use of the Nd:YAG laser as an adjunct to the subgingival debridement of residual pockets ≥ 5 mm is therefore not supported by clinical scientific evidence. The Nd:YAG laser treatment alone was not examined.