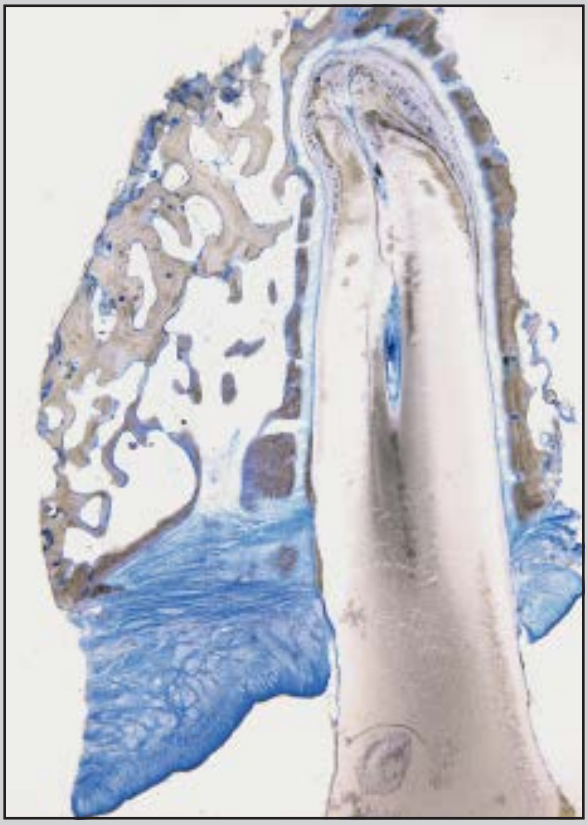
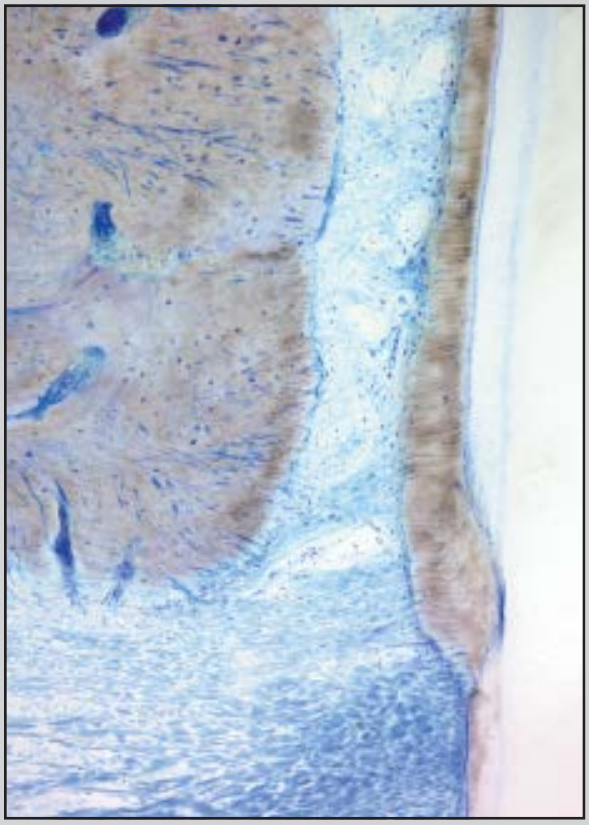
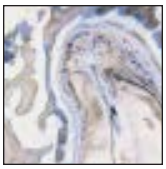




A Prospective 9-Month Human Clinical Evaluation of Laser-Assisted New Attachment Procedure (LANAP) Therapy



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This investigation was designed and implemented as a single-center, prospective study to evaluate the clinical response to the Laser-Assisted New Attachment Procedure (LANAP). Eight patients with advanced periodontitis were enrolled and treated with full-mouth LANAP therapy and monitored for 9 months. Full-mouth clinical measurements, including clinical attachment level (CAL), probing depth (PD), and recession, were provided at baseline and after 9 months of healing by a single calibrated examiner, including a total of 930 sites and 444 sites with initial PD equal to or greater than 5 mm. Clinical results for the 930 sites measured pre- and postoperatively revealed that mean PD was reduced from 4.62 ± 2.29 mm to 3.14 ± 1.48 mm after 9 months (P < .05). CAL decreased from 5.58 ± 2.76 mm to 4.66 ± 2.10 mm (P < .05) and recession increased from 0.86 ± 1.31 mm to 1.52 ± 1.62 after 9 months (P < .05). For the subset of 444 sites with initial PD greater than or equal to 5 mm, the PD decreased from 6.50 ± 2.07 mm to 3.92 ± 1.54 mm (P < .05) and CAL decreased from 7.42 ± 2.70 mm to 5.78 ± 2.06 mm (P < .05). As demonstrated by the clinical evaluation, the majority of treated sites demonstrated clinical improvement. LANAP therapy should be further investigated with long-term clinical trials to compare the stability of clinical results with conventional therapy. (Int J Periodontics Restorative Dent 2014;34:21–27. doi: 10.11607/prd.1848)

There is a desire among patients and clinicians to treat periodontal disease effectively with minimally invasive therapies.[1] Recent publications have focused on surgical therapy with minimally invasive flap approaches.[2] Many patients and clinicians decline to use these effective conventional surgical procedures due to perceived and real side effects such as root exposure, gingival recession, and postoperative discomfort. This often leads to the selection of nonsurgical therapies for treatment of advanced periodontal diseases, resulting in insufficient resolution of the disease.[3,4]

Laser-Assisted New Attachment Procedure (LANAP) therapy, having been initially introduced more than 15 years ago, is becoming more commonly accepted among clinicians as additional research emerges.[5,6]

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An initial histologic report provided evidence of new attachment for LANAP-treated teeth with new cementum and inserting Sharpey fibers.[7] This was confirmed by a recent study documenting human proof of principle for periodontal regeneration with new cementum, periodontal ligament, and alveolar bone adjacent to previously diseased root surfaces.[8] In addition to histologic documentation, it is necessary to understand the clinical response to therapy.

Currently, there is limited evidence as to the clinical efficacy of LANAP. There are no published direct comparative prospective or retrospective studies. As clinicians begin to further scrutinize this therapy and evaluate how to integrate it into clinical practice, data regarding clinical response to treatment are needed. Ongoing multicenter randomized prospective studies comparing LANAP to conventional surgical and nonsurgical therapies may provide additional information regarding the efficacy of LANAP in the future.

This report presents the response to LANAP for eight patients treated prospectively and followed for 9 months posttreatment.

Method and materials

This investigation was designed and implemented as a single-center, prospective clinical study, and a subgroup of the data has previously been presented documenting the potential for periodontal regeneration.[8] Subjects provided informed consent according to the Declaration of Helsinki of 1975, as revised in 2000, and were enrolled from May 1, 2010, through June 30, 2010. Eligibility required subjects to be between the ages of 18 and 70 years and have at least one tooth diagnosed and prescribed for extraction, with greater than or equal to 7-mm probing depth and radiographic suggestion of a 4-mm or deeper infrabony defect. Subjects were excluded from entry into the study if they *(1)* had congenital or metabolic bone disorders, immunosuppressive therapy, or a disease that may affect wound healing; *(2)* were current smokers (within 6 months of entry into the study); or *(3)* were pregnant or planning pregnancy during the course of the study. In addition, subjects with a history of active periodontal surgical treatment or scaling and root planing during the last 12 months were also excluded.

Prior to enrolling patients, the periodontal examiner participated in a calibration training session. Probing depth and recession depth were measured and attachment levels calculated. Levels of intraexaminer reliability were found to be within prespecified limits with greater than 90% repeatability.

Full-mouth attachment levels were then recorded prior to delivering local anesthesia. Full-mouth treatment LANAP therapy was provided in a single visit one arch at a time.

Surgery

The minimally invasive laser periodontal surgical therapy was provided using a neodymium:yttrium-aluminum-garnet (Nd:YAG) 1064 nanometer laser (PerioLase MVP-7, Millennium Dental Technologies) as previously reported. Full-mouth clinical measurements for probing depth, recession depth, mobility, and furcation grade were accomplished according to the calibration protocol prior to administering local anesthesia. The laser was first used on a setting of 4.0 W, 100-μs pulse duration, and 20 Hz. It was passed from the gingival margin to the base of the pocket parallel to the root surface and moved laterally and apically to remove the diseased pocket epithelium and decontaminate the pocket. This was accomplished for all surfaces of the pocket for teeth in one arch. The teeth were aggressively scaled and root planed with piezo-ultrasonic instrumentation. Four or five piezo tips (Piezon Master 400, EMS, and Piezosurgery, Mectron) were used on each root surface with repetitive cleaning until the roots were smooth and there was no longer visual or tactile evidence of remaining calculus. The root preparation was performed from the coronal aspect of the teeth apical to the level of the periodontal ligament. A second pass with the laser on a setting of 4.0 W, 650-μs pulse duration, and 20 Hz was performed from the apical extent of the defect to the gingival margin. The surgical sequence was

repeated for the second arch. Occlusal adjustment with selective grinding and extracoronal or intracoronal splinting of teeth to reduce mobility was provided immediately postsurgery and as needed at follow-up visits.

Patients were given postoperative instructions and medications, including: 0.12% chlorhexidine mouthrinses (bid) for 4 weeks, modified tooth brushing to protect against dislodging the fibrin clot (ie, patients were instructed to only brush coronal tooth surfaces for the first 2 weeks postsurgery), oral antibiotics (amoxicillin, 500 mg every 8 hours for 7 days), and anti-inflammatory analgesics for pain relief as needed (ibuprofen, 600 mg every 6 hours).

Patients were seen for follow-up care and oral hygiene instruction at 7, 14, 28, 42, and 56 days. The surgical sites were inspected and gently cleaned with chlorhexidine-soaked gauze, and teeth were gently cleaned supragingivally. Prophylaxis was provided and hygiene reviewed with the patient at 2.5, 4, 5.5, 7, and 8.5 months.

At 9 months, full-mouth clinical measurements were performed, including probing depth (PD), recession depth, clinical attachment level (CAL), mobility, and furcation grade.

Statistical analysis

Means and SDs were calculated for all quantitative data from each clinical parameter, and paired *t* tests were used to contrast clinical parameters (PD, recession, and CAL) at 9 months postsurgery with those at baseline. To evaluate the response to the therapy, changes in PD and CAL were computed and further transformed into categories (increase: > 0; no change: 0; and decrease: < 0), and their frequencies were calculated showing percentages in each category. This step was repeated using the sites where PD at baseline was more than 5 mm. A linear regression analysis was carried out to calculate the critical PD value, where the initial PD value below which loss of attachment occurred as a result of treatment and above which gain of attachment level resulted.[9] Statistical significance was set at a level of .05. All statistical analyses were performed with commercially available software (SPSS version 19, IBM).

Results

Eight patients were enrolled in the study and treated with full-mouth LANAP therapy. All patients healed uneventfully with no significant adverse events related to the LANAP surgical treatment. The mean total energy used per patient was 6,034 J, with a mean of 3,344 J for the mandibular arch and 2,691 J for the maxillary arch. Some patients experienced increased dentinal sensitivity during the first 4 weeks postoperatively, which then decreased to within normal limits.

Full-mouth clinical measurements pre- and posttreatment were obtained on a total of 930 sites. Mean PD reduction was statistically significant, reducing from 4.62 ± 2.29 mm to 3.14 ± 1.48 mm after 9 months ($P < .05$, paired *t* test) (Fig 1a). The CAL decreased from 5.58 ± 2.76 mm to 4.66 ± 2.10 mm ($P < .05$, paired *t* test) (Fig 1b). Recession increased from 0.86 ± 1.31 mm to 1.52 ± 1.62 mm after 9 months ($P < .05$, paired *t* test) (Fig 1c). Statistical analysis revealed that 73% of all sites had decreased PD, 21% had no change, and 6% increased (Fig 2a); 58% of sites gained attachment, 24% had no change, and 18% lost attachment (Fig 2b). Those sites that initially had PDs of 4.88 mm or greater were more likely to gain attachment, and that value was calculated to be the critical PD.

The subset of 444 sites with initial PDs greater than or equal to 5 mm were analyzed. For this subset, PD decreased from 6.50 ± 2.07 mm to 3.92 ± 1.54 mm ($P < .05$, paired *t* test) and CAL decreased from 7.42 ± 2.70 mm to 5.78 ± 2.06 mm ($P < .05$, paired *t* test). Eighty-eight percent of sites with initial PD greater than or equal to 5 mm decreased PD, 9% had no change, and 3% increased (Fig 2c). Seventy-four percent of sites in this subset gained attachment, 17% had no change, and 9% lost attachment (Fig 2d).

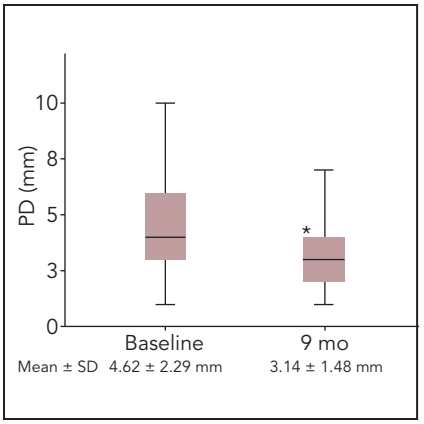


Fig 1a *PD change after 9 months in all sites (n = 930).*

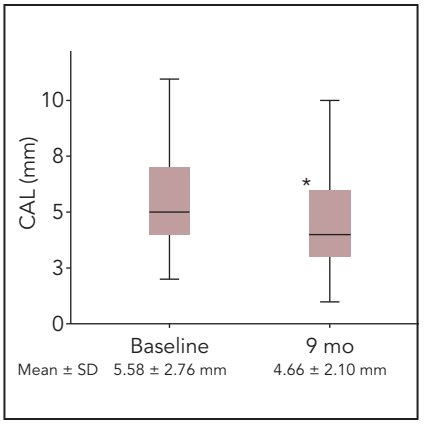


Fig 1b *CAL change after 9 months in all sites (n = 930).*

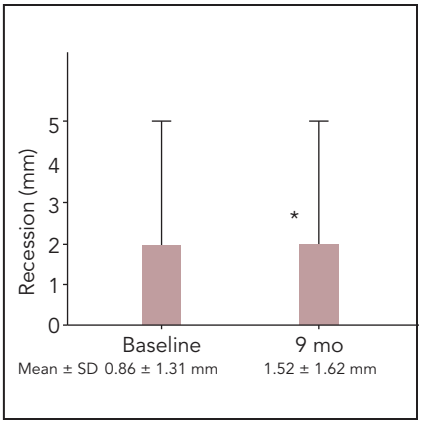
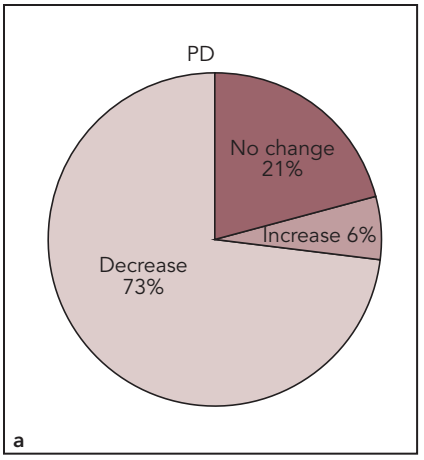
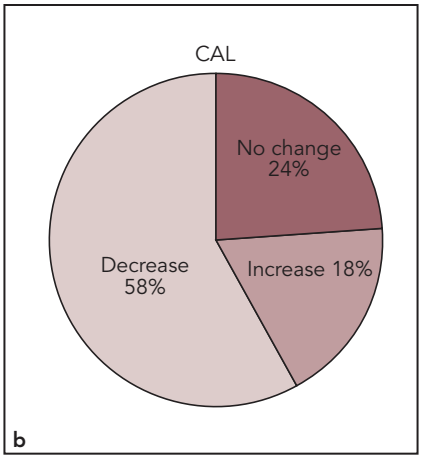
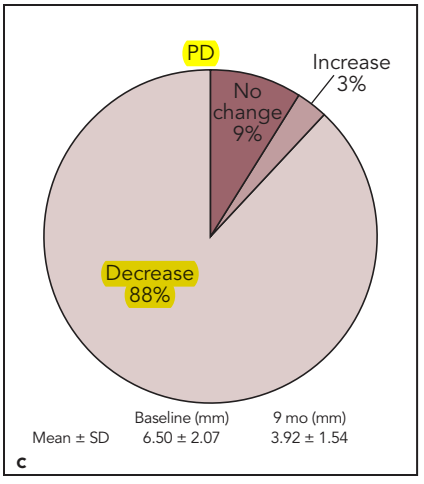


Fig 1c *Recession change after 9 months (n = 930).*







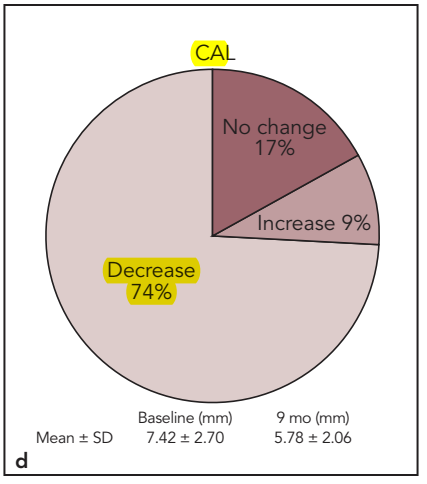


Fig 2a *Distribution of PD change after LANAP therapy (n = 930).*

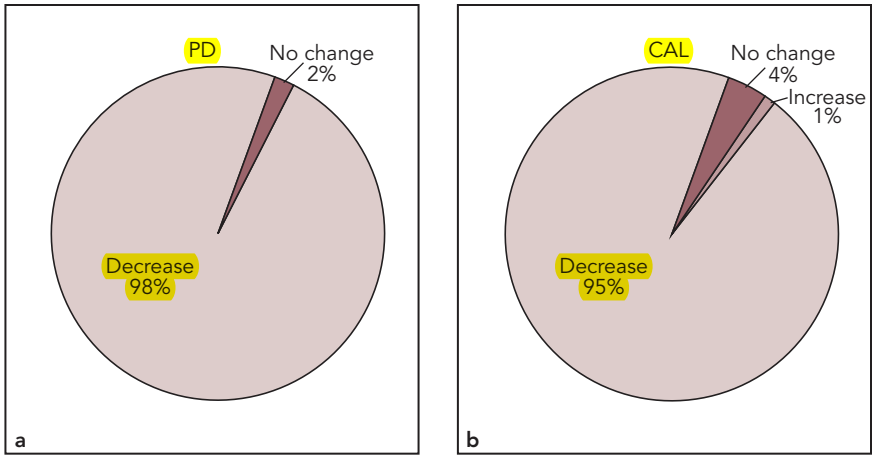
Fig 2b *Distribution of CAL change after LANAP therapy (n = 930).*

Fig 2c *Distribution of PD change in the sites with initial PD of 5 mm or more (n = 444).*

Fig 2d *Distribution of CAL change in the sites with initial PD of 5 mm or more (n = 444).*

Fig 3a *Distribution of PD change in the sites with initial PD of 7 mm or more (n = 150).*

Fig 3b *Distribution of CAL change in the sites with initial PD of 7 mm or more (n = 150).*



Discussion

This report presents the clinical evaluation for 8 patients treated prospectively with full-mouth LANAP therapy, for which a subset of teeth evaluated histologically has been previously reported.[8] There was statistically significant improvement for both CAL gain and PD reduction after evaluating the mean data from full-mouth measurements by the calibrated examiner. The response was generally positive, with 58% of all sites gaining attachment (24% of sites had no change) and 73% of sites demonstrating PD reduction (21% of sites had no change). This trend was more evident when only PD ≥ 5 mm at baseline was used for analysis. The subset of sites with PD greater than or equal to 5 mm responded favorably to LANAP therapy, with 97% of the sites for PD demonstrating clinical improvements or stability (no change or a decrease) and 91% of the sites for CAL demonstrating a gain or no change.

Lindhe et al described the critical PD for which periodontal therapy resulted in either gain or loss of CAL.[9] In an attempt to replicate this analysis, the critical PD for the LANAP therapy for the present data set was calculated as 4.88 mm ($P < .05$) from univariate linear regression analysis. Therefore, sites with initial PD ≥ 4.88 mm are more likely to gain rather than lose attachment with LANAP therapy.

Systematic reviews have proven that clinical outcomes in terms of CAL gain and PD reduction in open flap debridement procedures were particularly effective in areas with initial deep PD (> 6 mm).[10] In the present study, the changes in PD in pockets greater than 5 mm amounted to 2.58 ± 2.13 mm, and CAL gain amounted to 1.64 ± 1.84 mm. These clinical results compare well with classical approaches of surgical debridement reported in the literature.[9,11] Although systematic reviews have questioned the superiority of Nd:YAG over conventional therapies, recent publications suggest that its adjunctive use may provide greater control of inflammation and provide positive clinical results.[12–15]

According to Philstrom et al, for more than 7 mm of initial PD, pocket reduction after scaling and root planing plus the flap procedure was 2.58 mm and CAL gain was 1.60 mm.[11] The present findings are well comparable to classic surgical therapy: pocket reduction and CAL gain based on the current study recalculated for more than 7 mm of initial PD found pocket reduction of 4.39 ± 2.33 mm and CAL gain of 2.96 ± 1.91 mm, substantially higher than the value reported in the literature.

The results of the present prospective study compare favorably to clinical data published with various laser protocols and support LANAP therapy as a valid alternative for the treatment of periodontal

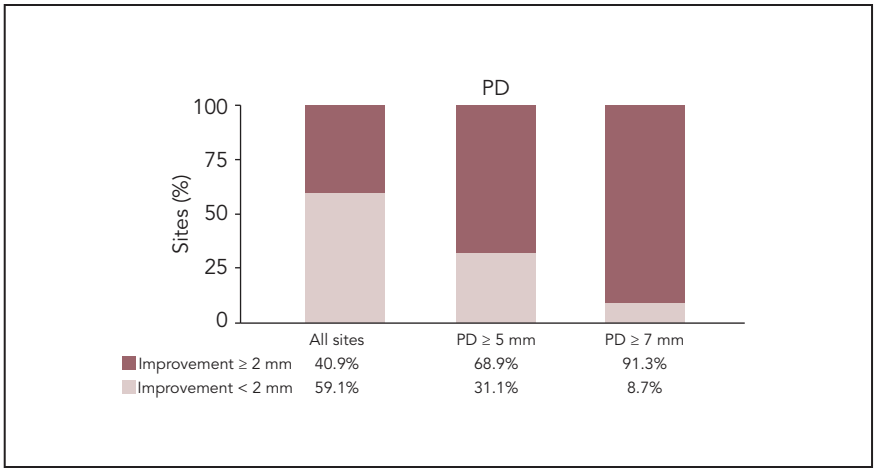


Fig 4a *Percentage of sites with greater than 2 mm of PD reduction based on baseline PD.*

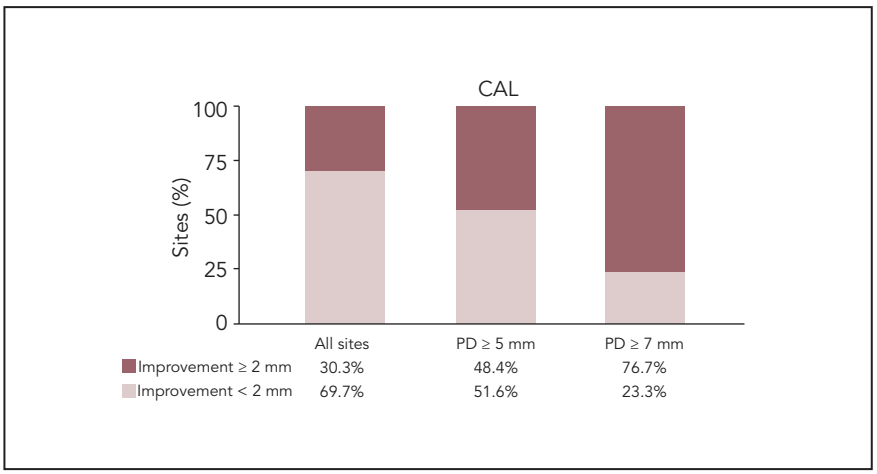


Fig 4b *Percentage of sites with greater than 2 mm of CAL reduction based on baseline PD.*

disease, with the advantages of having a minimally invasive approach.[15–17] For sites initially with ≥ 7 mm of PD, 91% had at least 2 mm of PD reduction and 77% had at least 2 mm of CAL gain (Figs 3 and 4). For sites initially with ≥ 5 mm of PD, 69% had at least 2 mm of PD reduction and 48% had at least 2 mm of CAL gain.

Conclusion

The clinical results from eight patients treated with full-mouth LANAP therapy demonstrate a favorable response in regard to CAL gain and PD reduction. There is a need for long-term comparative studies for LANAP with conventional controls to better characterize the therapy.

Acknowledgment

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