Sulcular Debridement with Pulsed Nd:YAG.

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ABSTRACT

We present data supporting the efficacy of the procedure, laser sulcular debridement (laser curettage), as an important component in the treatment of inflammatory periodontal disease. Laser Assisted New Attachment Procedure™ (LANAP) is a detailed protocol for the private practice treatment of gum disease that incorporates use of the PerioLase pulsed Nd:YAG Dental Laser for laser curettage. Laser curettage is the removal of diseased or inflamed soft tissue from the periodontal pocket with a surgical dental laser. The clinical trial conducted at The University of Texas HSC at San Antonio, Texas, evaluated laser curettage as an adjunct to scaling and root planing. They measured traditional periodontal clinical indices and used a questionnaire to evaluate patient comfort and acceptance. The Texas data (N=10 patients) are compared with pocket depth changes following LANAP. LANAP data were obtained from a retrospective review of patient records at three private practices (N=65). No significant differences in post-treatment probe depth changes were found among the four centers indicating that the procedure produced consistent, favorable outcomes, and that results from controlled scientific clinical trials can be replicated in private practices. Reduction in pocket depths following laser treatment compare well with results obtained with scalpel surgery. The use of the laser offers additional benefits. We also present quantitative evidence from digitized radiographs of increased bone density in affected areas following LANAP.
Key words: Periodontitis, Nd:YAG dental laser, laser curettage, laser sulcular debridement, laser periodontal surgery, private practice.

1. INTRODUCTION

About 4,500 surgical dental laser systems are currently installed in dental offices in the United States.[1] It is unknown how many dentists actually use lasers to treat inflammatory periodontal disease, although the numbers are increasing steadily. This is surprising since there is currently only one published article of controlled clinical trials of laser sulcular debridement in a university-based study.[2] This clinical trial conducted at the University of Texas Health Science Center at San Antonio (UTHSCSA) examined the efficacy and safety of using pulsed Nd:YAG laser in the periodontal sulcus. In 1997, based on results from this study, American Dental Technologies, Inc. (Corpus Christi, TX) received market clearance from the FDA to claim that laser sulcular debridement (also known as laser curettage) was clinically safe and led to improved clinical indices of periodontitis including pocket depth reduction, attachment level gain, improved gingival index. reduced bleeding index and decreased tooth mobility. Since then several other laser companies have received similar FDA clearances.

We had observed promising results of Laser Periodontal Therapy on a case-by-case basis in our private practices.[3,4] and have published four case reports to illustrate a "typical" range of results.[5] Subsequently, we conducted a retrospective analysis of 65 patients receiving Laser Periodontal Therapy at three independent private dental practices. Pre- and post-treatment probing depths obtained from the patient records were reviewed as the clinical index. Pre- and post-treatment radiographs were also examined to evaluate changes in alveolar bone density.

Investigations performed in clinical trials under standardized conditions should reflect optimal outcomes that may not represent outcomes in private practice settings. In fact, it is often questioned if the private practitioner has the ability to reproduce published results on a predictable basis.[6,7] To address this issue, our retrospective results are compared to the prospective clinical trials data collected at UTHSCSA. Results are further compared to published results of other surgical and non-surgical therapies.

2. METHODS

Laser Periodontal Therapy® (LANAP) is a procedure developed within a practice setting specifically for the treatment of moderate to advanced periodontitis. A five-day certification program instructs clinicians in the LANAP technique. A general dentist and a periodontist who completed the training program subsequently contributed patient records to this study.

CENTER	INVESTIGATOR	LOCATION	LASER	# PTS.
CA	RHG and DKM	Cerritos, CA	PerioLase ®	21
OR	LEC	Eugene, OR	PerioLase ®	18
UT	LVT	Ogden, UT	PerioLase ®	26
UTHSCSA	University of Texas HSC	San Antonio, TX	PulseMaster ™	10

Pre-treatment examination, hygienic phase

All patients are initially assessed by taking medical history and charting plaque index, tooth mobility, and bleeding index. Probing depths are sampled at selected sites, pre-treatment radiographs are evaluated and indications for LANAP are determined. A periodontal maintenance program is initiated for each patient that includes initial supra-gingival scaling, instructions in personal oral hygiene and follow-up hygiene visits scheduled at three-month intervals. Immediately prior to LANAP, probing depths are charted at six sites around all teeth. Treatment may be administered to specific sites, a single quadrant or split-mouth (right or left / upper and lower quadrants). The schedule depends on practice style and the severity of the disease. It is customary to do split-mouth with 7-10 days between treatments, although one center (OR) completes full-mouth LANAP no more than three days from starting.

Dental Laser Systems

Three centers (CA, OR, and UT) used the PerioLase free-running (FR) pulsed Nd:YAG laser emitting near infrared radiation with a wavelength of 1064 nanometers. The range of laser parameters available with these systems included two pulse durations: a “short pulse” of 150 microseconds (μsec) and a “long pulse” of 635 μsec. Pulses can be delivered with a repetition rate of 10-50 pulses per second (10-50 Hz) and with pulse amplitudes of 30-400 millijoules (mJ). These settings are summarized clinically as average power in Watts, which is the total energy (Joules) delivered per second (Watts = Joules/second). Combinations of these laser settings produce an average power range of 0.3-8.00 Watts. The laser energy is delivered via a 320-micron diameter optical fiber that terminates in a custom-made laser handpiece. Laser energy is emitted from the distal tip of the fiber in contact with the tissue.

An equivalent pulsed Nd:YAG dental laser, the American Dental Technologies, Inc., PulseMaster™ Dental Laser System was used in the UTHSCSA clinical trial. This laser system had single pulse duration of 100 μsec and a range of average powers up to 6 Watts with a similar fiber optic delivery system.

Laser Periodontal Therapy

The entire procedure including local anesthesia, antibiotics, sub-gingival scaling and root planing, laser treatment and occlusal adjustment, is detailed elsewhere.[3-5] The first pass with the laser, referred to as laser “troughing,” is accomplished using the short duration 150μsec pulse. In practice the laser settings varied across patients and investigators, but at the three centers using the PerioLase all were within the range of 3.0 to 4.8 Watts to the tissue, as measured using a Molectron P-600 power meter. Approximate lasing time per tooth was one minute and total energy delivered (total light dose) was in the range of 10-15 Joules per mm pocket depth. *(Please note: exceeding 3.0 Watts average power is NOT recommended except for the experienced laser users.)*

Light dose, Joules per mm pocket depth, is similar to drug dose, mg per kg body weight, in that light dose defines the concentration of laser energy at the treatment site in a similar manner as drug dose defines the concentration of a drug in the tissues. Light dose is a very useful parameter inasmuch as certain clinical outcomes of laser surgery (e.g., adverse effects, bacteriocidal effects) are dose dependant.

Laser troughing effects sulcular debridement and de-epithelialization;[8] it is executed by continuously moving the fiber beginning at the gingival crest and working back and forth systematically stepping down to the base of the pocket. As lasing continues, the epithelial lining of the pocket and necrotic debris accumulate on the fiber tip. The fiber is withdrawn from the periodontal pocket periodically and the coagulum is removed by wiping the tip with wet gauze. An endpoint is reached when debris no longer accumulates.

Following laser troughing, standard scaling and root planing (S/RP) is accomplished first by using a piezo-electric scalar, then small curettes and root files to remove root surface accretions. Aggressive root planing is minimized. A second pass with the Nd:YAG Laser with the 635µsec “long pulse” finishes debriding the pocket, completes removal of epithelial tissue, provides hemostasis, and creates a “soft clot.”

The gingival tissue is compressed against the root surface to close the pocket and aid in formation and stabilization of a fibrin clot. When appropriate, occlusal trauma is adjusted with a high-speed handpiece, and mobile teeth are splinted.

The primary endpoints of LANAP are debridement to achieve complete removal of pocket epithelium and underlying infected tissue within the periodontal pocket and to facilitate removal of calcified plaque and calculus adherent to the root surface. The bacteriocidal effects of the pulsed Nd:YAG laser [9-16] and both intraoperative and post-operative use of antibiotic agents are exploited for the reduction of microbiotic pathogens within the periodontal sulcus and surrounding tissues. The wound is stabilized and occlusal trauma minimized to promote healing.

Patients are placed on a 3-month interval periodontal maintenance program. A complete follow-up periodontal evaluation with probing is done 6 to 12 months following initial treatment. No periodontal probing was done within the first 3 months because this may disrupt the healing process by physically traumatizing nonmatured gingival attachments. Teeth with pockets that remain ≥ 6 mm and exhibit inflammation (Gingival Index ≥2) may be re-treated.

UTHSCSA Clinical Protocol

The UTHSCSA Study [2] reported on 10 patients treated in a randomized, evaluator-blinded, spit mouth design. The protocol included oral hygiene, scaling and root planing (S/RP), and laser curettage. Following a hygienic phase applied to all quadrants, three treatment conditions of S/RP alone, S/RP plus laser, and no treatment were randomly assigned to three quadrants and the fourth quadrant received S/RP plus laser. A technique similar to LANAP was used, although laser parameters were constant. Pulse duration was 100 µsec, energy per pulse was 80 mJ, repetition rate was 25 Hz and average power was 2.0 W. A dosimetry table defined a light dose based on pocket depth and ranged from 6.6 to 10 Joules per mm pocket depth. There were two major differences between the UTHSCSA and LANAP protocols. UTHSCSA used a lower average power (consequently a lower light dose) and did not use a second pass with the 635 µsec “long pulse.”

All ten subjects were surveyed by the clinician immediately upon completion of the treatment appointment and then given a take-home questionnaire in order to assess the pain and comfort levels over time.

Probing depth: private practice

The probing depths were measured chair-side at six sites around all teeth using a Marquis Probe and values were entered onto periodontal charts by the investigator or a hygienist. Demographics, medical history, laser settings, laser dosimetry, probing depths, anesthesia and clinical observations were obtained by review of patient records. Subjects were selected for inclusion in analysis from records of all patients receiving LANAP who had full-mouth probing depths (PD) pre-treatment and post-treatment. Pre-treatment and post-treatment radiographs were digitized and analyzed with image processing software.

Statistical analysis

Probing depth charts were examined by an independent transcriber, entered into an Excel spreadsheet, and probe depth averages per patient and per follow-up interval were computed. Mean probe depth is computed as the arithmetic mean of all probing depths by pockets or by patient. Mean probe depth (MPD) changes represent the mean of the differences from baseline to follow-up. The large amount of data, 9214 probing depths, are grouped for analyses into 1-3 mm, ≥4 mm, 4-6 mm, ≥7 mm, 7-9 mm and ≥10 mm initial pocket depth categories for comparison with varied groupings in other studies. Original data from the UTHSCSA data sheets were transcribed into the same spreadsheet program to assure consistency among data sets. The UTHSCSA follow-up was controlled at 6-months ±7 days. Since retrospective follow-up data were not collected on a rigid schedule, “six-months” was defined as the interval greater than 90 days but less than 10 months for comparison of private practice with the UTHSCSA data.

Demographic data were compared among centers using analysis of variance (ANOVA) and chi-square procedures. Data on individual pocket depths were obtained prior to laser treatment and at the follow-up evaluation. Data were analyzed separately for each initial pocket depth at baseline and grouped for grouped pocket depths.

Data were summarized descriptively for the baseline pocket depth, follow-up depth, absolute change, and percent change from baseline. For analysis purposes, percent change was utilized rather than absolute change due to the dependence between amount of change and baseline value. Centers were compared using analysis of variance for a nested design for 4-6 and ≥7 mm pockets separately, with the factors: center, patients in centers, and pockets in patients. The patient was used as the unit of analysis, so center differences were compared to the patient in center variation, not the pocket variation. Center differences include differences between laser procedures. Contrasts between the centers were performed from the analysis of variance data made to test for differences between laser procedures.

Bone density analysis

Analog radiographs were digitized and analyzed with Emago© (Advanced Medical Devices, Richardson, TX) and Photoshop© software. In Emago (the pre-Treatment reference image and the post-Treatment images were balanced for differences in exposure and film processing characteristics with Gamma Correction. Gamma Correction is a computerized algorithm that modifies the gray level distribution of an image using the gray level distribution of another image as a reference. The software provides means of quantitative analysis of corrected radiographic densities through the use of density profiles. The density profiles in Figures 4A-D represent a plot of the gray value of each pixel along a line through the x-ray that is selected by the user. Each gray value represents the relative radiographic density at that point in arbitrary units. Emago© Constant projection geometry necessary for digital subtraction radiography is provided by consistently using individual bite blocks or other aiming techniques. Geometric Reconstruction is a useful alternative to obtaining before and after x-rays with identical projection geometry. Emago© Geometric Reconstruction produces a pair of images with identical image formation geometry by mapping the information contained in one image onto the projection plane of a reference image. After projection corrections and density analysis the two images were combined to produce one side-by-side image that was filtered in Photo Shop (contrast and sharpness) to enhance visualization of bony features.

3. RESULTS AND SIGNIFICANCE

Pocket depth reduction

Screening of over 200 private patient records provided 65 patients with full-mouth pre-operative and follow-up probing depths. In Figure 1 data from all patients at all follow-up times are sorted and combined into 3-4 months (3), 5-9 months (6), 10-15 months (12), 16-21 months (18), 22-29 months (24), and ≥30 months (36); and into 4-6 mm, 7-9 mm and ≥10 mm baseline pocket depths.

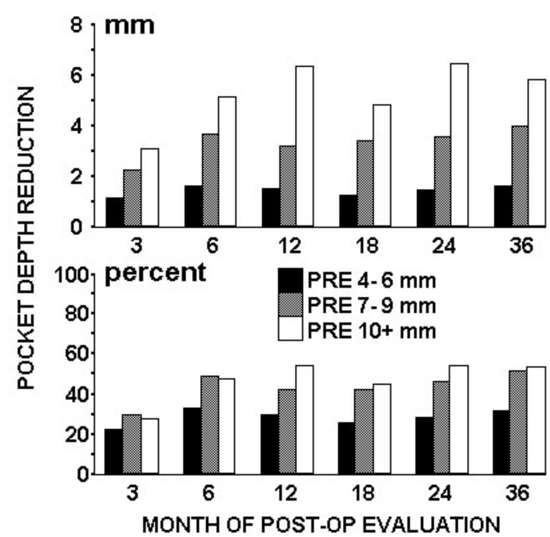

Figure 1. Mean pocket depth reduction in mm (top) and percent (bottom) as a function of post-treatment month following LANAP.

A trend in improvement (healing phase) is apparent during the first 12 months. Improvement remains fairly stable out to 3 years post-treatment. It is also apparent that deeper pockets do better than shallower pockets even if percent improvement is considered. These data include multiple evaluations and more than one treatment in many of the ≥6 mm pockets.

Probing depths at first follow-up (to eliminate effects of re-treatments) within 3-15 months were combined for the three centers that used the identical LANAP procedure (CA, OR, UT). Figure 2 shows the average mean probe depths ± 1.0 standard deviation grouped for each initial pocket depth. For reference the diagonal line in Figure 2, labeled "return to health," illustrates an ideal post-treatment pocket depth reduction to 3 mm. Also shown by the gray bars in Figure 2 are estimates [7] for pocket depth reductions expected following S/RP alone in 4-6 mm and 7-9 mm pockets (see also Figure 3), indicating that LANAP tends to be more efficacious than S/RP alone.

Private practice data were further culled to include only the first follow-up evaluation within 3-10 months to allow statistical comparison with the 6-month clinical trial data from the UTHSCSA Study. This yielded 42 patients from the practices. Including data from the Texas Study produced a total of 52 patients having 2832 pockets with depths ≥4 mm. Approximately one third of the patients were male and one quarter were smokers. Age ranged from 31 to 76 years of age with an overall mean of 52 years. Patients at UTHSCSA were approximately 10 years younger than patients from the other three institutions (p<.01). Baseline mean probe depths (MPD) at UTHSCSA were also significantly less (CA = 5.0mm, OR = 3.7mm, UT = 3.9mm, UTSHCSA = 3.1mm; UTHSCA vs. CA=UT p<0.001). Younger patients with shallower pockets indicates treatment of less advanced disease in the Texas study.

However, there were no significant differences among centers in clinical outcomes. The overall differences among centers in (MPD) changes are not statistically significant (4-6 mm: p=0.601; ≥7 mm; p=0.946), and the individual contrast comparing the clinical trial with private practice MPD's is also not statistically significant (4-6 mm: p=0.219; ≥7 mm: p=0.619).

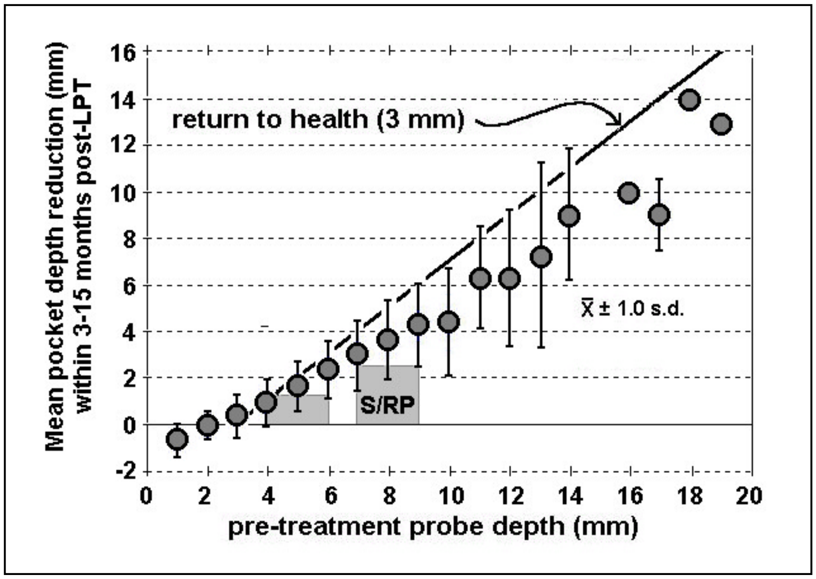

Figure 2. Mean probing depth change at the first follow-up within 3-15 months post-LANAP for each pre-treatment pocket depth. For data points without error bars: N=1. The diagonal line represents pocket depth reductions to 3 mm. Pocket depth reductions from S/RP alone are shown by the gray bars for 4-6 mm and 7-9 mm baseline probe depths (Cobb, 1997).

The percentage of pockets that improved range from 88% for 4 mm pockets to 96% for 8 mm pockets. For UTHSCSA 76% of the ≥4 mm treated pockets improved, compared with the other centers whose improvement rates ranged from 87% for CA to 96% for UT. All patients but one at CA (CA#13, MPD change = -0.3mm) showed overall improvement in mean percent change from pre-treatment. This patient's first evaluation was at 3 months post-treatment. At the subsequent 18-month evaluation this patient's MPD change was +1.2 mm for all pockets ≥4 mm.

There were 2311 pockets with initial probing depths of 4-6 mm in 42 patients treated with LANAP that showed least squares mean pocket depth reduction of 32.7% (1.55 mm), and 89.8% of these pockets had improved at the six-month evaluation. There were 350 pockets 7-9 mm in 37 LANAP patients that showed 45.5% reduction (3.44 mm) and 96.3% of these pockets improved. CA 4-6 mm pockets showed 33% mean improvement compared to 31% for OR, 34% for UT, and 23% for UTHSCSA.

All four centers gave extremely comparable results for ≥7 mm pockets with mean pocket depth reduction of 45% for both CA and OR, 46% for UT, and 47% for UTHSCSA. The ≥7 mm results show greater percent reductions than the 4-6 mm results (Figure 1). Although a wide variability in outcomes can be seen among patients, all patients showed overall mean improvement in measurements for these deep pockets.

Statistically valid tests for differences among various studies are typically not possible due to differences in study designs. However we can provide a graphic comparison of the results of laser procedures to those of clinical trials comparing various modalities of periodontal therapy. In Figure 3 are plotted results of probing depth reductions from various studies (black bars) reporting probing depth changes in 1-3 mm, 4-6 mm and ≥7 mm pockets.[7,17-21] Results of this study are shown by the gray bars and the Texas Study is shown by the white bars. In this comparison it is evident that pocket depth reductions following laser treatment are similar to those obtained from flap with osseous resection and Modified Widman Flap surgical procedures. Also compared in Figure 3 are results from clinical trials using antibiotic therapies and from scaling and root planing alone.

Gingival recession

At one center (OR) the height of the free gingival margin relative to the CES was carefully measured to evaluate post-operative recession. No measurable recessions of gingival margins associated with laser treated pockets were observed. This is consistent with anecdotal observations of investigators at the other centers.

Bone density
Clinical comparison of pre-treatment with post-LANAP radiographs suggest the formation of new bone. We have not completed the analysis that will indicate the frequency of this occurrence, but can suggest that it is not uncommon among LANAP patients. Figure 4A-D shows radiographs from four patients where we have conducted a preliminary radiographic density analysis. There is strong evidence for an increase in the density of interproximal alveolar bone following LANAP in these patients. In some cases we see new bony structures that suggest formation of new compact bone adjacent to the root surfaces (cribiform plate). This is evidence for remineralization and repair of the alveolar crest.

Pain and discomfort
All four clinicians in private practice agree, anecdotally, that patients seem to experience less pain and discomfort and to recover more rapidly when laser curettage is included in the treatment protocol than when it is not. This is consistent with the report of Gold and Valardi [8] and from results of the patient and clinician-administered survey in the UTHSCSA study (detailed in Dr. Neill's thesis (pg. 123-125):[22] All ten patients were comfortable at three hours post-treatment, including half of the patients reporting that they were extremely comfortable. The overall pain rating was 1.9 (little to no pain: 0-10 pt. scale). After 12 hours comfort levels improved with patients reporting little to no pain rated at 1.2. Patients included in their written comments a perceived added benefit with the laser and their "mouth felt cleaner and less irritation and bleeding after the tooth scraping."

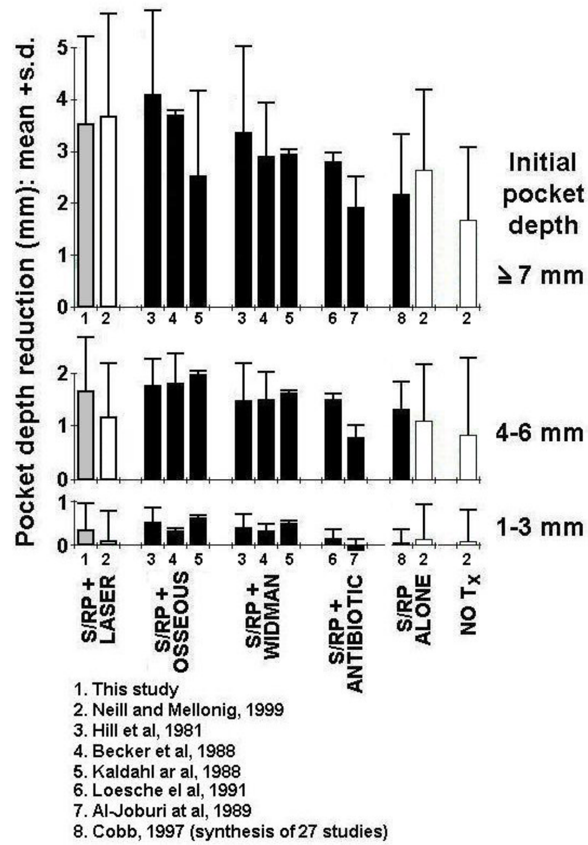

Figure 3. Comparison of pocket depth reductions for various studies using different modalities to treat periodontal disease. Gray bars: this study; white bars: UTHSCSA study.

4. CLINICAL RELEVANCE

Our retrospective analysis demonstrates that similar results of laser sulcular debridement obtained in a controlled randomized trial can be repeated in private practice. Furthermore, our analysis indicates that the LANAP technique and clinical outcomes can be successfully transferred to other practitioners through sufficient training.

A primary objective of this study was to statistically evaluate center differences in probing depth reductions between the clinical data and those data collected in a private practice setting. Although younger patients with less severe disease were included in the clinical trial, the clinical outcomes were remarkably similar. The statistical similarity of the groups allows us to infer that the improvement in all clinical indices (probing depth, attachment level, gingival index, bleeding index, tooth mobility and pathogen reduction) measured in the Texas study probably occurs in the private practice patients as well.

We have also seen evidence of minimal recession following LANAP, which is unlike the result of surgical flap procedures where similar pocket depth reductions are achieved partially through an apical repositioning of the gingival margin exposing the root surface to the oral environment. Additional benefits of the laser treatment over scalpel surgery include greater intraoperative hemostasis, greater post-treatment patient comfort, more rapid recovery, and high patient acceptance. It is not just laser sulcular debridement that accounts for the positive results from both the UTHSCSA Study and our private practices - 75 out of 75 happy patients - but a combination of laser treatment, scaling and root planing and good clinical management. Other important factors include rigorous training, proper dosimetry, and adherence to the treatment protocol.

There remain many unanswered questions. For example, what are the physiological processes that relate reduction of inflammation and destruction of oral pathogens with reattachment and increases in bone density? What are the specific laser/tissue interactions that occur during laser sulcular debridement and what leads to the sequence of cellular events that accompany soft tissue regeneration and bone remineralization? Answers to these questions will provide a logical basis for adjusting treatment protocols and dosimetry to maximize the clinical benefits.

5. ACKNOWLEDEGMENTS

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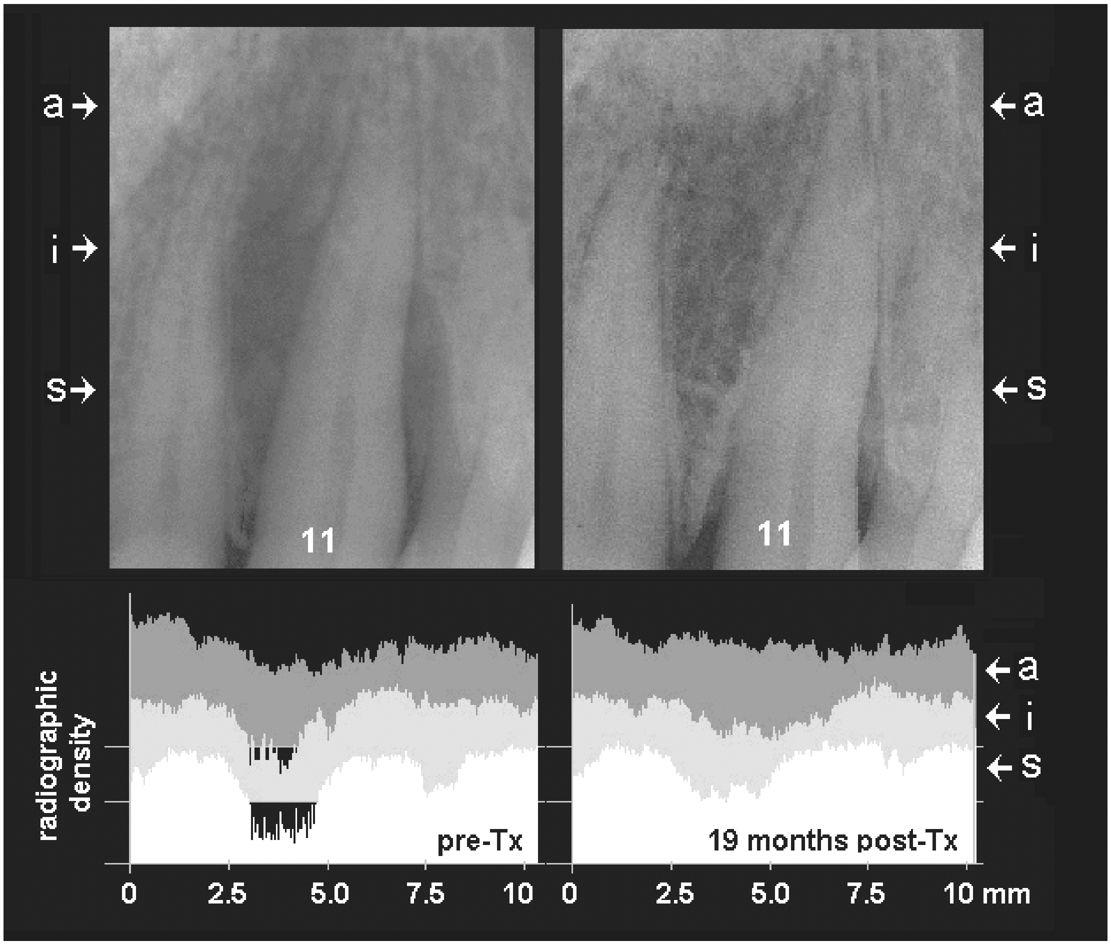
Figure 4 A-D. (Following 2 pages) Before and after LANAP radiographs from four patients. Note that gamma correction provides identical profiles for root dentin.

4A. Radiographic density histograms are measured at three locations: a, apical; i, intermediate; and s, superficial.

4B - C. Radiographic density is measured along the diagonal line shown on the radiographs. Also shown are before and after probing depths.

4D. A progressive change in radiographic density over time is illustrated at baseline, 9 months and 14 months post-LANAP.



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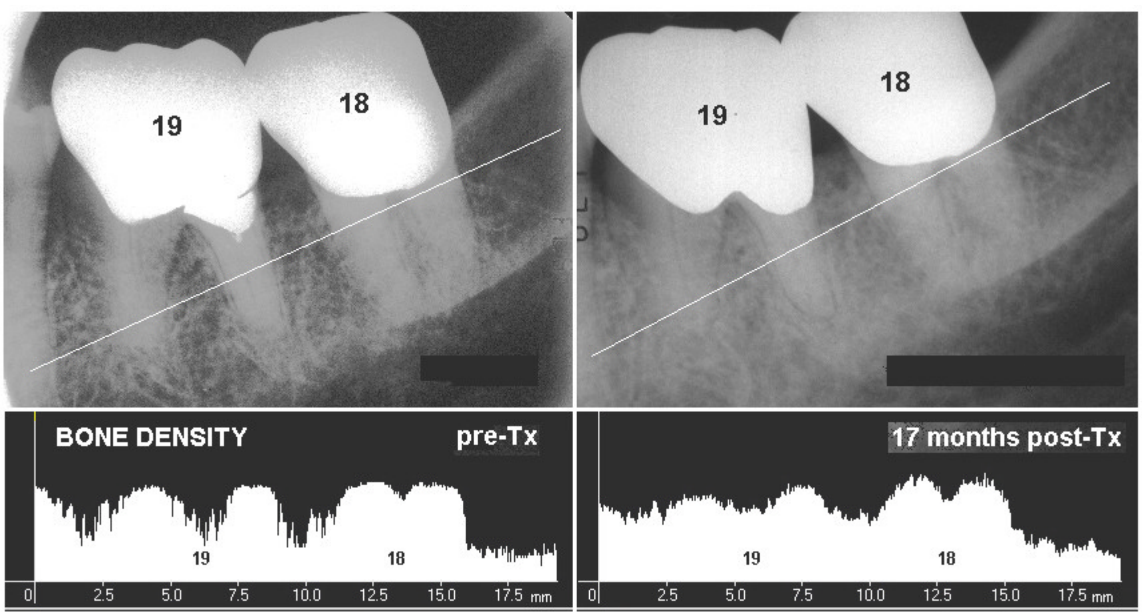
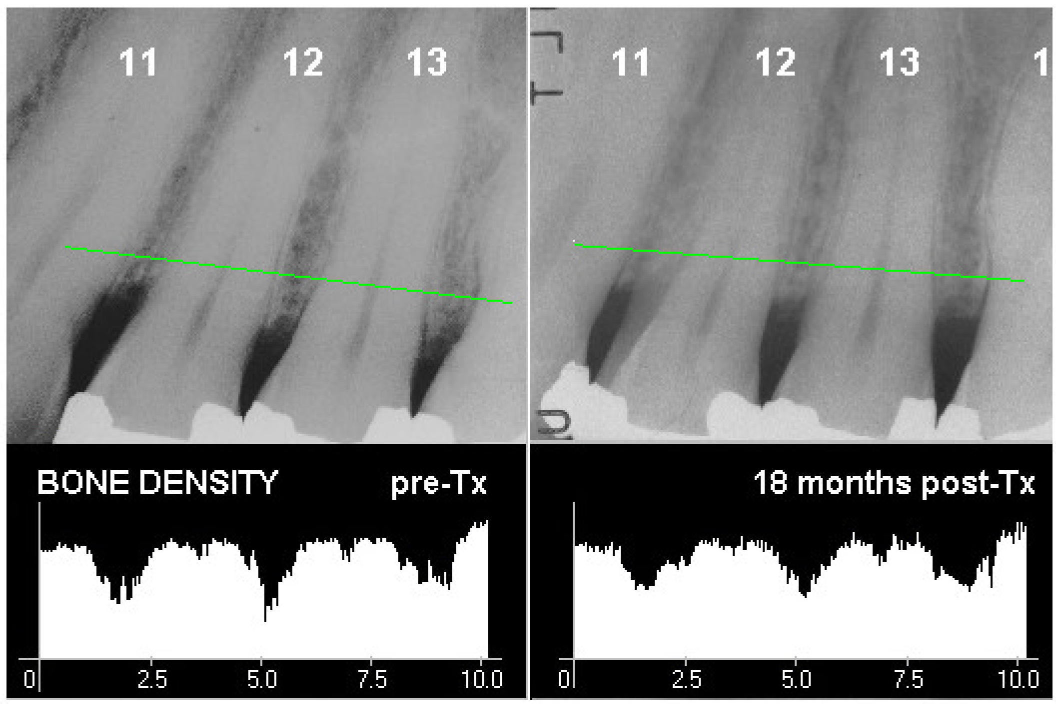


PROBING DEPTHS pre-Tx

20			19			18		
7	6	7	8	5	6	7	4	7
7	3	6	9	4	3	7	3	9

8 months post-Tx

20			19			18		
3	2	4	4	4	4	5	4	6
3	2	2	3	2	4	4	2	4



PROBING DEPTHS pre-Tx

12			13			14		
4	6	3	4	3	4	3	4	4
6	3	3	4	4	4	5	4	9

18 months post-Tx

12			13			14		
5	3	5	3	3	4	3	3	6
4	2	4	4	2	3	3	3	5