

Long-term retrospective case series

Laser-assisted protocol for the treatment of peri-implantitis

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Pulsed Nd:YAG dental lasers are surgical tools used to obtain specific surgical objectives as defined in the LANAP (laser-assisted new attachment procedure) for periodontitis and the LAPIP (laser-assisted peri-implantitis procedure) for peri-implantitis.

The LANAP using the PerioLase Nd:YAG laser (Millennium Dental Technologies) was introduced in 1998 as Laser ENAP,¹ and in 2004, the LANAP gained US Food and Drug Administration 510(k) clearance (No. K030290) for the claim "laser-assisted new attachment procedure (cementum-mediated periodontal ligament new attachment to the root surface in the absence of long junctional epithelium)". Subsequently, human histology studies^{2,3} established that the LANAP resulted in "periodontal regeneration—true regeneration of the attachment apparatus (new cementum, new periodontal ligament, and new alveolar bone) on a previously diseased root surface" (2016 510(k) clearance No. K151763).

The LAPIP emerged from the LANAP as a stand-alone procedure.⁴⁻⁷ The indication for the LANAP is moderate to advanced periodontitis,* whereas the LAPIP is indicated for peri-implantitis treatment.** The basic steps in the two protocols are the same and have adjustments for the whole mouth versus a single site, the responses to irradiation of root cementum versus implant titanium, and differences in surgical objectives.

A recent review of published studies of peri-implantitis laser treatment concluded that laser treatment enhances bone growth, but a quantitative analysis of bone-level changes is limited.⁹ The authors called for greater relevance and translation of the research findings to

the clinician. This report addresses those concerns with a detailed analysis of the clinical outcomes and a quantitative description of changes in radiographic density two to five years after undergoing a LAPIP in a private practice setting.

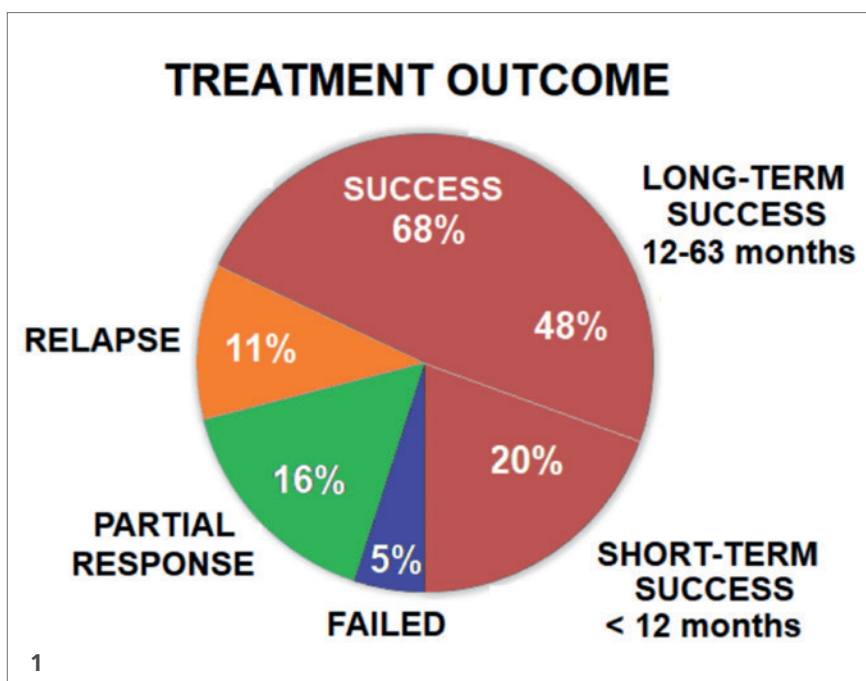


Fig. 1: Proportion of dental implants in each clinical treatment outcome category.

* Periodontitis: "Inflammation of the periodontal tissues resulting in clinical attachment loss, alveolar bone loss, and periodontal pocketing."⁸

** Peri-implantitis: "An inflammatory process around an implant which includes both soft-tissue inflammation and loss of supporting bone."⁸ Clinical signs include inflammation, bleeding on probing and suppuration. It progresses from peri-implant mucositis, which is confined to the soft tissue, to include PD > 4 mm and evidence of bone loss. Peri-implantitis often leads to progressive loss of osseointegration and eventual loss of the implant.

Dr Schwarz completed training in the LAPIP in September 2013. A retrospective analysis of the 222 sequential patients with 437 failing dental implants that were treated during the following three years was performed.⁷ That study was focused on the short-term efficacy of the LAPIP. A statistically significant reduction of clinical signs of erythema, bleeding and suppuration and reduced probing depth (PD) at the first follow-up visit (median period: 7.6 months; $P < 0.001$) was noted. The survival rate, the percentage of intact implants, was 94% over the longest follow-up period (median: 13.1 months) among those in the analysis.

Long-term clinical and radiographic data are presented from the same group of 222 patients. There was a continuum of responses, including long-term successes, partial responses with intact implants and implants lost after two years of maintenance with multiple treatments, as well as cases of successful treatments that relapsed after one to two years. Analysis of radiographic data from a sample of successfully treated implants provided a time course for bone regeneration.

Methods

Collection and analysis were performed of retrospective data, wherein patient records were sorted to find all patients in the practice who had undergone LAPIP treatment within the 37-month interval from the first treatment (October 2013) until the date of institutional review board approval (October 2016). A private institutional review board (Quorum Review) granted a waiver of informed consent and approved the retrospective data collection and analysis protocol. Later, the institutional review board approved the retrospective analysis of the long-term follow-up data that is included in this report. The original study was conducted according to standards established by the Declaration of Helsinki and Good Clinical Laboratory Practice Guidelines. Research standards established in

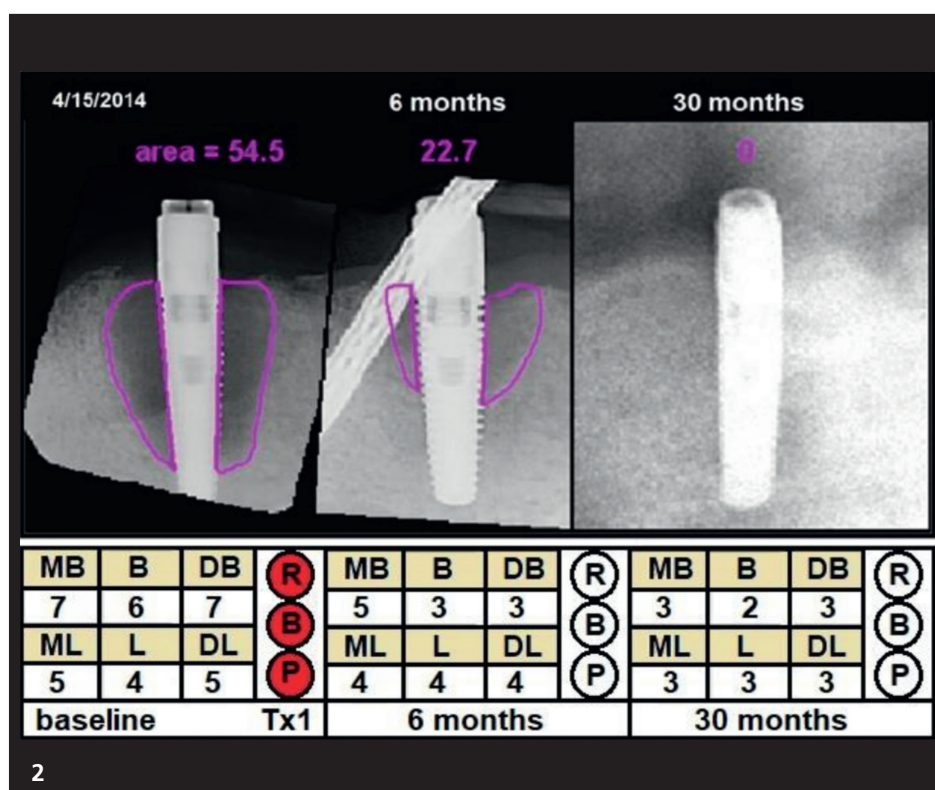


Fig. 2: Example of a successful treatment (Case 1), showing changes in radiographic defect (mm²), probing depth (PD; mm) and clinical signs from baseline to 30 months later. Violet = cross-sectional area; MB = mesiobuccal PD; B = buccal PD; DB = distobuccal PD; ML = mesiolingual PD; L = lingual PD; DL = distolingual PD; R = redness; B = bleeding; P = suppuration; Tx1 = first treatment.

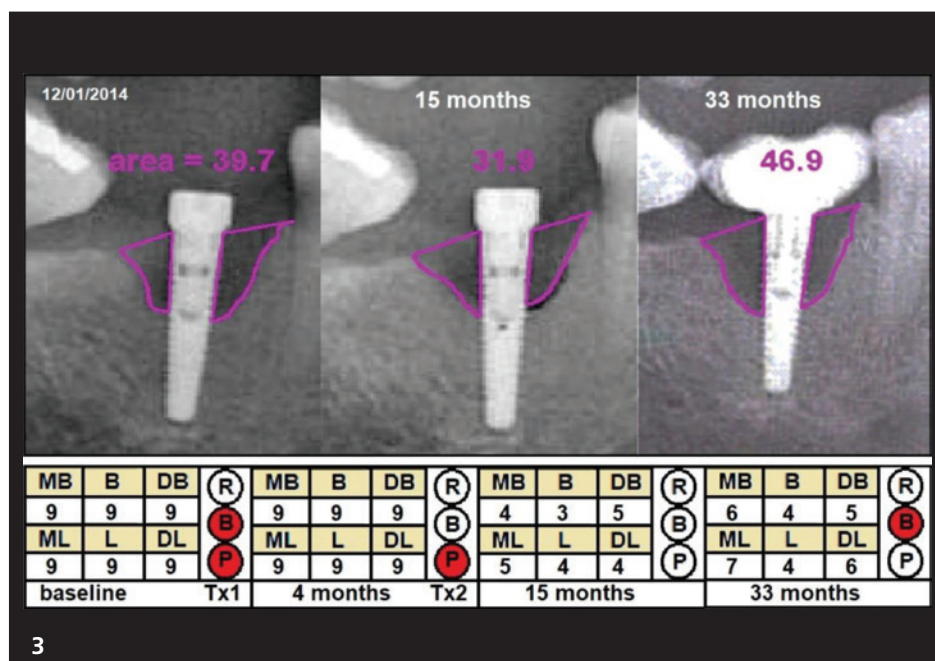


Fig. 3: Example of a partial response to treatment (Case 2), showing changes in radiographic defect (mm²), probing depth (PD; mm) and clinical signs from baseline to 33 months later. Violet = cross-sectional area; MB = mesiobuccal PD; B = buccal PD; DB = distobuccal PD; ML = mesiolingual PD; L = lingual PD; DL = distolingual PD; R = redness; B = bleeding; P = suppuration; Tx1 = first treatment; Tx2 = second treatment.

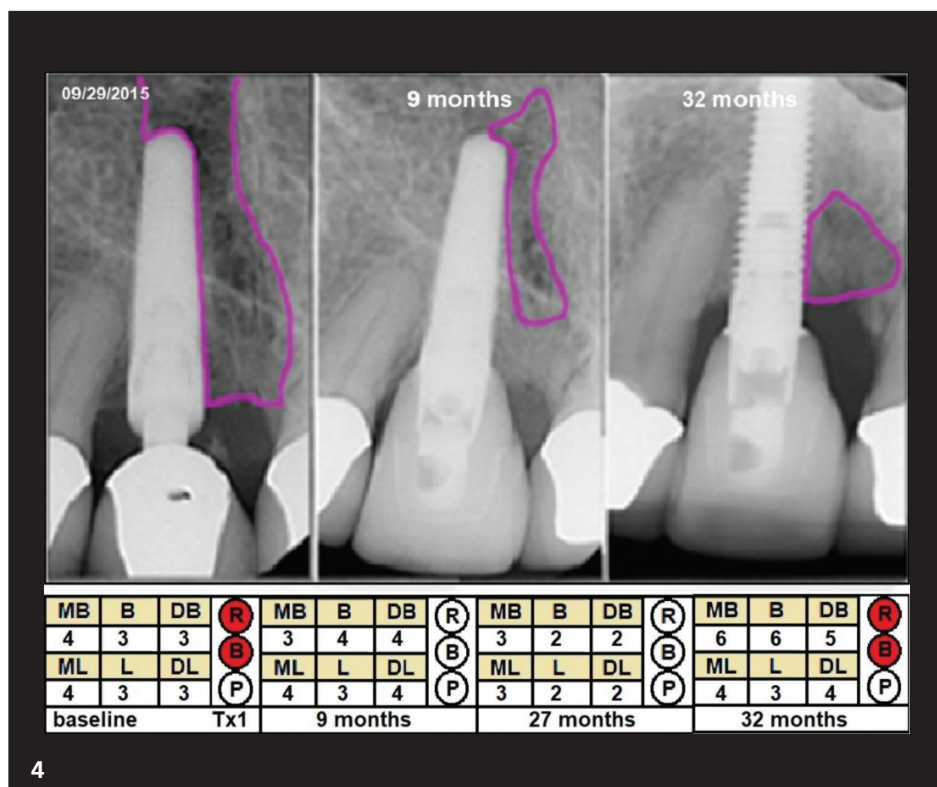


Fig. 4: Example of a successful single treatment that was without clinical signs for over two years, and then the implant presented with signs of reinfection (Case 3), showing changes in radiographic defect (mm²), probing depth (PD; mm) and clinical signs from baseline to 32 months later. Violet = cross-sectional area; MB = mesio-buccal PD; B = buccal PD; DB = disto-buccal PD; ML = mesio-lingual PD; L = lingual PD; DL = disto-lingual PD; R = redness; B = bleeding; P = suppuration; Tx1 = first treatment.

the original study were maintained in the current study.

The purpose of the original study was a precise statistical analysis of the initial clinical outcome of a single treatment, seeking to determine whether there was improvement or a lack of improvement at the first follow-up visit. A review was conducted of patients who received the treatment in the three years after the LAPIP training. All patients were included to eliminate selection bias. A staff member went through the medical records of each LAPIP patient and copied data into case report forms. Any identifying information was excluded, and the case report forms were sent electronically to the statistician for data entry and analysis. Data captured included laser settings, demographics, medical history, implant information, adverse events, PD (mm; for six pockets) and the presence of clinical signs (bleeding, erythema and/or suppu-

ration). Panoramic and/or periapical radiographs were available for analysis. The statistician excluded patients with missing data from the various analyses. The original group included 222 patients with 437 implants. That study enrolment closed in October 2016. Exclusion of patients with incomplete data resulted in 116 patients with 224 implants available for analysis, including 47% men and 53% women with a mean age of 65.8 years (range: 23–98 years).

Two years later (September 2018), a second look at the original group of patients was performed. Several patients had follow-up visits beyond the closing date of the original analysis. Case report forms of additional follow-up visits were collected, uploaded and added to the original data set. This resulted in 155 patients with 299 implants who had sufficient baseline and follow-up data to determine implant survival and clinical outcomes.

Laser dosimetry

The dental laser was a 6 W pulsed Nd:YAG laser (PerioLase MVP-7, Millennium Dental Technology) utilising an optical fibre that delivered high-energy pulses of light to the tissue. For the LAPIP, the fibre tip is inserted into the periodontal pocket. Parameters that are set on the control panel are energy per pulse up to 300 mJ; pulse duration, variable from 100 to 650 µs; and pulse repetition rate from 10 to 100 Hz. The duration of exposure is controlled with a foot switch.

The LAPIP details have been published elsewhere^{4–7} and are only summarised as follows for the protocol specifying surgical end points. Achieving those end points is what determines the dosimetry. In Step 2 of the protocol, the distal fibre tip is inserted into the periodontal pocket and passed around the implant several times to initially open the sulcus and then to remove the diseased pocket epithelium and disinfect the tissue, constituting Pass 1 with the laser.¹⁰ In Step 4 of the protocol, the fibre tip is inserted into the pooled blood within the sulcus and again passed around the implant, heating and congealing the blood and forming a fibrin clot, constituting Pass 2 with the laser.¹¹

Hence, real-time dosimetry is based on these clinical conditions. With a constant laser power (output), the time spent lasing within the sulcus determines the total energy delivered. In other words, a prescribed laser dose does not determine the treatment end point; rather, achieving the surgical end point determines the total joules. The surgeon understands that clinical conditions determine the precise laser parameters and the total energy delivered. However, exceeding the recommended dosimetry increases the risk of possible adverse effects.

The hard copy printout of the laser dose for Pass 1 and Pass 2 was available for 138 implants, and the mean total energy per implant was 285.8 J. This was divided between the two laser steps. Pass 1 mean total energy was 181.8 J, and Pass 2 mean total energy was 104.0 J. Energy was delivered according to the following formulas,

and sizable case-to-case variance was required to achieve the surgical end points:

- Pass 1 total joules delivered = $130 + (10 \times \text{aPD})$
- Pass 2 total joules delivered = $85 + (4 \times \text{aPD})$

These two formulas are not a prescription; they merely define the dosimetry used in this study. On average, Pass 1 required an initial 130 J for all implants, and Pass 2 required an initial 85 J. The formula specifies that the total joules per pass is related to the average probing depth (aPD; the average of six PD measurements). Consequently, to estimate the total energy, add ten times the aPD in joules to the initial values for Pass 1 and four times the aPD for Pass 2.

Radiographic analysis

Film radiographs were scanned and digitised and then the digital radiographs

were rotated, cropped and resized. Brightness and contrast were not adjusted. Images were arranged in chronological order to illustrate the sequential changes in radiographic density for each case. A technician skilled at reading dental radiographs outlined the radiographic defect and areas of change in subsequent images. The cross-sectional area of the defect within the outlines was measured using public domain software (ImageJ, National Institutes of Health freeware). As the dimensions of the implant were known, the areas were calibrated in square millimetres so that comparisons could be made over time and across cases. The sum of the defect areas on both sides of the implant is referred to as the cross-sectional area. Cross-sectional areas at follow-up visits of successful cases were converted to baseline percentage to estimate the time course of bone regeneration.

Results

The clinical outcome categories were defined as follows (Fig. 1):

- *Long-term success*: return to healthy PD and an absence of clinical signs
- *Short-term success*: patients with successful outcomes but without follow-up data beyond 12 months
- *Partial response*: failure to meet success criteria but the implant was still intact and stable
- *Relapse*: initial success and then return of clinical signs
- *Failed*: implant lost or removed.

The long-term responses to treatment can thus be divided into four general outcomes: successful response (Group 1), partial response (Group 2), spontaneous relapse (Group 3) and lost implant (Group 4). Summary statistics for each of the four groups are presented in this section, followed by one case from each group.

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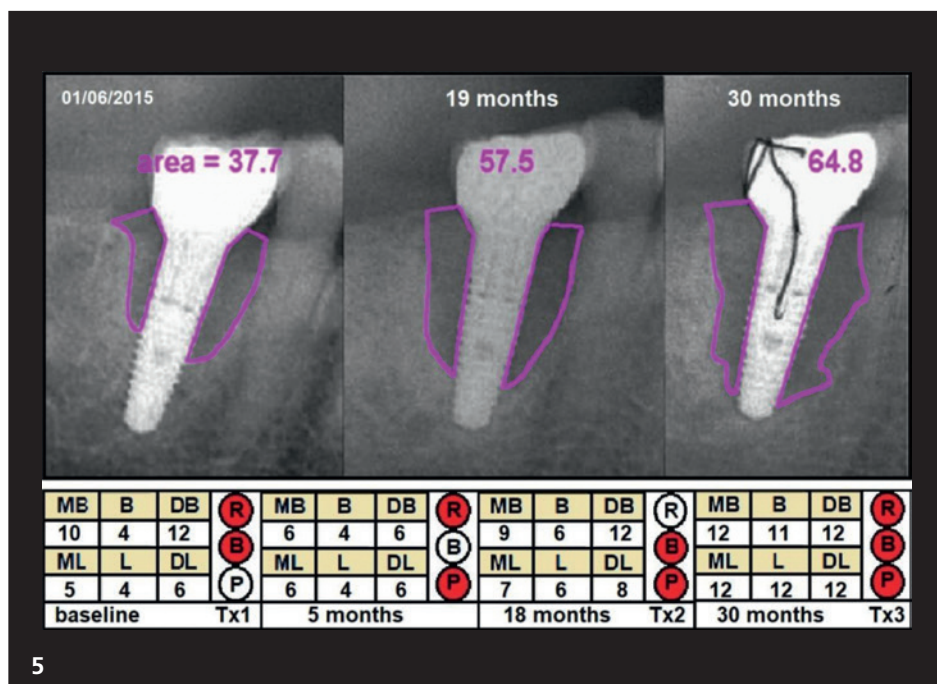


Fig. 5: Example of a lost implant (Case 4), showing changes in radiographic defect (mm²), probing depth (PD; mm) and clinical signs from baseline to 30 months later. Violet = cross-sectional area; MB = mesiobuccal PD; B = buccal PD; DB = distobuccal PD; ML = mesiolingual PD; L = lingual PD; DL = distolingual PD; R = redness; B = bleeding; P = suppuration; Tx1 = first treatment; Tx2 = second treatment; Tx3 = third treatment.

Group 1: Successful response

This was the most common response, 204 implants (68%) meeting the success criteria of post-treatment PD ≤ 4 mm and no clinical signs at follow-up visits. Most implants in this group (91%) achieved success after a single treatment. Others (7%) demonstrated a partial response and then success after a second treatment, and 2% achieved success after three treatments. The median follow-up period in this group was 18.8 months, and one implant was still successful at 63 months. At the time of the latest analysis, 48% of all implants still showed long-term success (12–63 months). The remaining 20% of successfully treated implants had follow-up periods of less than 12 months, so their long-term outcomes could not be determined. Most of these patients did not return for their scheduled hygiene visits.

Case 1 is an example from the group of successful treatments (Fig. 2). The patient was an 87-year-old man with a car-

diovascular condition and had implants in positions #32 and 42 that supported a mandibular overdenture. He presented with deep pockets (PD = 5.7 mm) accompanied by a large defect around implant #42. This had led to acute symptoms, including pain, erythema, bleeding, suppuration and swelling of the vestibule. At the pretreatment visit, the labial plate was mostly absent along the buccal aspect of the implant becoming exposed. At six months post-treatment, the clinical signs had resolved, the PD had reduced to 3.8 mm and the area of radiolucency had reduced too. At 30 months, the PD was 2.8 mm, and there was a complete absence of clinical signs.

Group 2: Partial response

Partial responders are implants that improved but still showed some clinical signs, had a PD > 4 mm and never achieved the success criteria. There were 47 implants (16%) in this category. Most were treated a second time at six or 12 months after

the first treatment, and several received a third treatment. They continued to exhibit clinical signs and had a PD > 4 mm. The median follow-up period in this group was 22 months.

Case 2 is an example of a partial response to treatment (Fig. 3). The patient was a 58-year-old man with Type 2 diabetes, hypertension and hyperlipidaemia and had had an implant (Nobel Biocare Tapered) placed in position #46 in July 2014. The patient presented in December 2014 with a PD of 9 mm around the implant, bleeding and suppuration and was treated with the LAPIP. At four months, there was no bleeding, but the PD was still 9 mm, and a second treatment was performed. At 15 months, the clinical signs had improved, and PD was reduced to an aPD of 4.2 mm. At 33 months, the implant was still intact; however, the PD had increased to 5.3 mm, and there was some bleeding on probing. The PD and clinical signs at follow-up visits did not allow this implant to reach the success criteria. Even though bone regeneration is unlikely with a defect this wide, the PD and clinical signs improved and remained improved for almost three years after the first LAPIP treatment, and the implant remained in function at the time of last follow-up.

Group 3: Spontaneous relapse

There were 32 implants (11%) with initially successful outcomes that demonstrated relapse with the return of inflammatory markers along with deeper PD. The medium time to relapse was 24 months (range: 11–43 months).

Case 3 is an example of a successful single treatment that was without clinical signs for over two years and then presented with signs of reinfection (Fig. 4). The 59-year-old female patient had an implant (Nobel Biocare Tapered; 3.5 × 16.0 mm) immediately placed in position #11. She had no risk factors for peri-implantitis, but four months later, at her first follow-up visit, the implant showed signs of redness and bleeding from 4 mm pockets. Subgingival cement was noted on the

periapical radiographs and was removed. The first LAIP treatment was performed in September 2015. At follow-up visits at nine, 15 and 27 months after the first treatment, all inflammatory markers were absent, and the PD showed progressive improvement, good bone fill being noted in the periapical radiographs. The apical radiolucency was absent, but a new defect had appeared coronally at 27 months. At 32 months, she showed significant relapse with redness and bleeding from pockets that had deepened beyond the pretreatment levels. Radiography revealed that the new defect had enlarged. The implant was subsequently retreated.

Group 4: Lost or removed implants

There were 16 implants (5%) that failed during the follow-up period. The median time to failure after the initial LAIP treatment was five months (range: one week to 31 months). Four implants were lost within the first month, six more by the first follow-up visit (five months), two at nine months, one at 18 months and three after two years of maintenance. One of the last was healthy but ordered extracted by the patient's physician.

Case 4 is among the lost implant cases (Fig. 5). The patient was an 81-year-old immunocompromised man with several medical conditions, including cardiovascular disease and a drug-resistant systemic infection. An implant (Nobel Biocare Tapered; 5 × 13 mm) had been placed in position #46, and he was seen six months later with an aPD of 6.8 mm, bleeding at four sites, erythema and radiographic evidence of bone loss. At the five-month follow-up visit, bleeding had resolved, and the aPD was reduced to 5.5 mm, but there was still redness and suppuration. By the 18-month visit, the condition had deteriorated. The aPD had increased to 8 mm, and there was bleeding and suppuration. At that time, the patient received a second LAIP treatment. At 30 months, one PD was 11 mm and the rest were 12 mm, and

there was an increase in the radiographic size of the defect. A third treatment was performed, and the laser dose was increased to 305 J at Pass 1 and 180 J at Pass 2 for that treatment. However, the implant was finally removed 31 months after the first treatment.

Change in radiographic density

Radiographs from all 299 implants were reviewed to identify interproximal vertical defects at baseline indicating bone loss. Many patients had panoramic radiographs of low resolution, and most bone loss was restricted to the buccal plate, which is not visible in transmission (periapical and panoramic) radiography. Only 21 cases were identified, and of these, ten provided measurable baseline and follow-up radiographs. Radiographic

data reflected a similar proportion of outcomes to the PD and clinical sign data. Out of the ten cases, one was from Group 3 (lost implant), two were from Group 2 (partial response) and seven were from Group 1 (successful cases). The cross-sectional areas of the seven successful cases were converted to a percentage of the baseline areas, and those values were plotted at their respective follow-up times (Fig. 6). The data fitted well to a decaying exponential function, $y = e^{-0.1x}$, which suggested that regeneration approached 98% by 36 months.

Discussion

The LAIP utilises the advantages of laser sulcular debridement (e.g. selective tissue removal, bacterial reduction, hae-

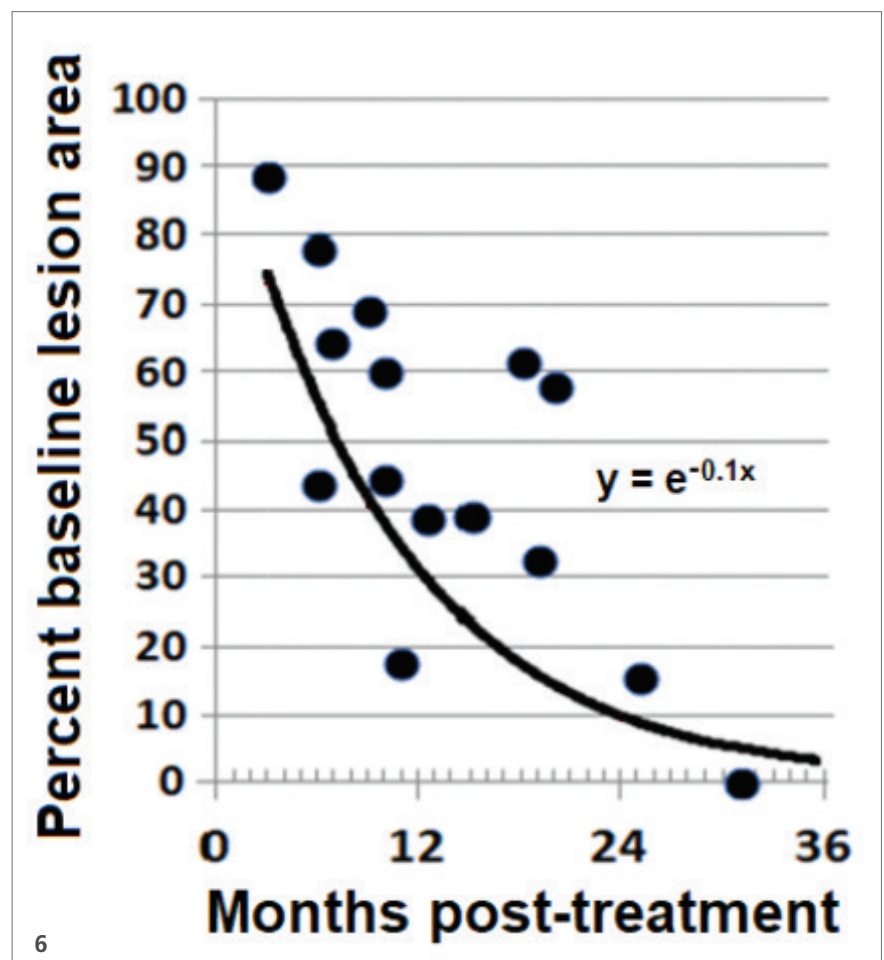


Fig. 6: Change in cross-sectional area of the defect as a percentage of the baseline area for seven implants from Group 1. Black circles = success.

mostasis, minimally invasive method) and embeds the laser components into a medically sound protocol that also includes implant debridement, occlusal adjustment, and detailed pretreatment and post-treatment procedures. Because of these additional therapeutic measures, the outcomes reported here may not be directly comparable with those of many controlled laser studies.

PD and clinical signs were analysed. Analysis of the short-term data from 116 patients with complete baseline and follow-up data determined that there was a statistically significant reduction in PD and clinical signs at the first follow-up visit (median: 7.6 months) after a single treatment. The aPD was reduced by 2.0 mm (5.4 mm reduced to 3.4 mm, $P < 0.001$), and clinical signs of erythema, bleeding and suppuration were reduced by 78–85% ($P < 0.001$). A recent prospective controlled trial of ten patients who were treated with the LAIP found similar results: a 1.9 mm PD reduction and decreased bleeding and suppuration.¹²

Several patients had follow-up visits after the short-term study had concluded. By the time of this long-term analysis, there were 155 patients with 299 implants available to determine long-term survival and response to therapy. The initial survival rate was 94% at 13.1 months (15 were lost out of the 264 implants). The long-term survival rate matched and surpassed the previous results, being 95% at 28.8 months (16 of the 299 implants were lost). In the long term, PD remained ≤ 4 mm, and clinical signs remained absent for 68% of the 299 implants. An additional 11% were initially successful, but then presented with a relapse at about two years post-treatment. Sixteen per cent of the 299 implants never achieved success but remained intact at 22 months.

The clinical healing curve indicated by the average rate of increase in radiographic density for successful cases demonstrated that, on average, bone fill is expected to be 25% complete by three months, 70% complete at one year,

90% complete by two years and 98% complete after three years. It is important to note that this study only sampled interproximal defects, and the analysis may thus not accurately reflect changes to labial bone.

Conclusion

One of the greatest challenges has been fighting a losing battle against peri-implantitis. The impact of the LAIP on treatment of peri-implantitis has been significant. Using other methods over 30 years of practice in the case of Dr Schwarz, achieving bone fill and eliminating all signs of inflammation have been challenging. These results describe the final stage of translation of an experimental protocol into clinical practice. An attempt to present an unbiased analysis of the real-world clinical outcomes, successful or not, has been accomplished. The results demonstrated would be typical for any clinician who has been properly trained and follows the protocol. Even a partial responder is a clinical success if the implant remains improved. Periodic retreatment of the partial responders and the relapses is a way to extend the time of functionality for the patient. The results of this study indicate that the LAIP offers a minimally invasive, repeatable way to regenerate bone and eliminate clinical signs of disease in most patients and to effectively manage the more difficult cases.

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Literature



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