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Research Study: Periodontal Tissue Regeneration Following Er:YAG and Nd:YAG Laser Treatments

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ABSTRACT

In periodontal therapies, healing typically occurs through the formation of a long junctional epithelium or a new connective tissue attachment to the previously diseased root surface. Certain procedures have the potential to also induce the restoration of lost alveolar bone, periodontal ligament and cementum.

Nd:YAG and Er:YAG lasers have been found to be useful for periodontal debridement, ablation, vaporization, hemostasis, and disinfection effects as well as biological effects such as image-biomodulation. In this paper we present evidence, based on the review of the published scientific literature, that periodontal tissue regeneration may be expected to be induced when the LightWalker laser is used to perform Er:YAG and Nd:YAG periodontal procedures which are FDA-cleared for the device. The review follows the guidelines for obtaining the US FDA 510(k) clearance for a medical device, and the guidelines of the European Medical Device Directives.

Key words: Laser periodontics, Er:YAG, Nd:YAG, TwinLight, WPT.

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I. INTRODUCTION

Lasers, when used for various periodontal procedures, can provide distinct advantages over the traditional mechanical means, such as easy ablation of smaller volumes of tissue, hemostasis (which, in turn, offers better visualization of the surgical field), sterilization of the incision or target surface area and less post-treatment tissue edema and swelling [1-4]. For many procedures the use of a laser can also be considered a minimally invasive technique, resulting in lesser discomfort than with traditional approaches [1]. Furthermore, lasers may have biostimulatory effects (i.e. image-biomodulation), which are reported to result in better wound healing compared to traditional approaches [1]. There is also a developing body of evidence indicating that laser periodontal therapy may have the beneficial side-effects of reducing inflammatory mediators, such as interleukin-1b, interleukin-6, tumor necrosis factor-a and matrix metalloproteinase-8 [1].

Different types of lasers have been used to perform periodontal procedures. However, there are two laser wavelengths, Er:YAG and Nd:YAG, that merit special attention due to their proven safety and efficacy in periodontal treatments [5]. Most commercially available dental laser devices are capable of delivering only one of these high-power periodontal laser wavelengths, however, there is currently a laser device which includes both wavelengths within the same device (LightWalker®, manufactured by Fotona).

The Er:YAG wavelength of 2,940 nm coincides with the absorption peak of water and is also effectively absorbed by the hydroxyl radical component of calcium hydroxyapatite [1, 4]. Consequently, the wavelength of the Er:YAG laser is a good choice for the ablation of oral soft tissues and modification of dental hard tissues, including bone. The LightWalker's FDA-cleared Er:YAG laser periodontal procedures include [6]:

a) Sulcular debridement;
b) Removal of subgingival calculi in periodontal pockets with periodontitis by closed or open curettage; and
c) Removal of granulated tissue

The 1,064-nm wavelength of the Nd:YAG laser exhibits low absorption in water, is minimally absorbed by bone, cementum, dentin, calculus and enamel but is readily absorbed by pigmented soft tissues [1, 4]. In addition, the Nd:YAG wavelength is absorbed by hemoglobin and thereby is effective in coagulation and hemostasis during soft-tissue surgical procedures. The LightWalker's FDA-cleared Nd:YAG laser periodontal procedures include [6]:

a) Sulcular debridement or soft-tissue curettage (removal of diseased or inflamed soft tissue in the

periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss, and tooth mobility);
b) Laser-assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium);
c) Implant recovery; and
d) Hemostasis

In periodontal therapies, healing typically occurs through the formation of a long junctional epithelium or a new connective tissue attachment to the previously diseased root surface [1]. Certain procedures have the potential to also induce the restoration of lost alveolar bone, periodontal ligament and cementum (the surface layer of the root) [1, 3, 5].

In this study, we set out to determine, based on the review of the published scientific literature, whether LightWalker's FDA-cleared Nd:YAG and Er:YAG laser periodontal procedures have the potential to induce periodontal tissue regeneration

II. MATERIALS AND METHODS

LightWalker is FDA cleared and CE marked, which ensures that it's technical characteristics and performance are already in compliance with the essential requirements of the FDA and European Medical Device Directive (MDD 93/42/EEC). Therefore, the safety and efficacy of the reviewed laser periodontal procedures and the LightWalker device have already been established.

The study method used to evaluate the LightWalker's potential for inducing periodontal tissue regeneration was based on the US FDA requirements for obtaining a 510(k) clearance for a medical device [7]. A 510(k) premarket clearance is based on a demonstration made to the FDA that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR 807.92(a)(3)) that is not subject to premarket approval (PMA). The device is compared to one or more similar legally marketed devices that support their substantial equivalency claims. A legally marketed device, as described in 21 CFR 807.92(a)(3), is a device that was legally marketed prior to May 28, 1976 (preamendment device), for which a PMA is not required, or a device which has been reclassified from Class III to Class II or I, or a device which has been found SE through the 510(k) process. The legally marketed device(s) to which equivalence is drawn is commonly known as the "predicate."

Substantial equivalence means that the evaluated device is at least as safe and effective as the predicate. A device is substantially equivalent if, in comparison to a predicate it:

i) has the same intended use as the predicate; and

ii) has the same technological characteristics as the predicate; or the difference in the technological characteristics do not raise new questions of safety and effectiveness;

A claim of substantial equivalence does not mean the analyzed and predicate devices must be identical. Substantial equivalence is established with respect to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labeling, biocompatibility, standards, and other characteristics, as applicable.

In this review, the substantial equivalence was determined using the standard clinical evaluation method [8], based on the assessment and analysis of published clinical data on Nd:YAG and Er:YAG periodontal dental treatments and devices. The clinical evaluation was based on a comprehensive analysis of available clinical data relevant to periodontal tissue regeneration. This includes data specific to LightWalker, and as well any data relating to the devices established as equivalent to LightWalker by the evaluation.

A published research review was carried out in order to establish the laser device performance characteristics and prescribed treatment protocols required to achieve periodontal tissue regeneration. Basic medical texts and review articles were used to provide description, natural course and consequences of the medical condition concerned, the potential different clinical forms, stages and severities of the conditions, and the frequency in the general population as well as a description of the available therapeutic options. In order to include the latest findings regarding the risks and benefits of the available treatment options, a separate literature search of the databases was conducted. The most recent reviews returned by this search, as well as any reviews returned by searches for data on the clinical evaluation, were examined. The data generated through literature searching was related either directly to LightWalker or to equivalent devices. The equivalence of LightWalker to the device used in a particular study providing data that was considered to be relevant to the clinical evaluation, was demonstrated for each such study recovered by the literature search for periodontal tissue regeneration.

Equivalence was assessed on multiple levels:

a) Clinical equivalence. To consider two devices to be equivalent according to clinical characteristics, they should be used for the same clinical condition, for the same intended purpose, at the same site in the body, in a similar population and not be foreseen to deliver significantly different performances. If a device application or patient group were found to be substantially different from those of the LightWalker, the study was excluded from further analysis.
b) Technical equivalence. Clinical effect is achieved through laser-tissue interaction, where the only technical characteristics relevant to the clinical properties of periodontal lasers are those of the laser beam itself, and not of a particular laser device. During the determination of equivalence, the different laser beam parameters / properties were taken into consideration and compared in the tables accompanying the summary of each supporting research article, reporting on the results of a clinical study conducted with LightWalker or an equivalent device.

III. RESULTS

What follows below are the results of the clinical evaluation listed separately for each analyzed FDA-cleared periodontal indication for LightWalker.

a) Nd:YAG laser sulcular debridement

In publications [9, 10], a successful use of the LightWalker's Nd:YAG laser was reported for stimulating the growth of osteoblasts and inducing alveolar bone regeneration. A fixation and preservation of the tooth and its functions were achieved without any surgical or other invasive medical methods.

In another study where a Smarty-A Nd:YAG laser (manufactured by DECA, Italy) was used, it was shown that the laser treatment was as effective as surgical flap debridement in promoting bone regeneration [11]. Radiographic images taken at 2, 4, 6 and 12 months from treatment of the sites having undergone surgical or laser treatment showed that the lack of bone support at each site before therapy tended to improve at the follow-up examinations, up to an appreciable recovery of the bone component [11].

In yet another study [12], made with a Genius Nd:YAG laser (manufactured by Genius, Denmark), measurement of standardized vertical bitewing X-rays at 12-39 months (median 20 months) indicated alveolar bone gain of 0.07 mm in scaling and root planing when an Nd:YAG laser was used, compared to bone loss when only mechanical scaling and root planing was performed, the difference being significant [12].

Table 1 shows a comparison of laser treatment parameters as used in studies [9-12], and laser treatment parameters for LightWalker Nd:YAG sulcular debridement, cleared under K070355, K101817 and K121508.

Table 1: Comparison of Nd:YAG laser treatment parameters used for sulcular debridement.

Nd:YAG laser	Sulcular debridement			
	Study [10]	**Study [11]**	**Study [12]**	**K121508**
Device	Fidelis/ LightWalker Fotona Slovenia	Smarty-A DECA Italy	Genius Dental, Genius Denmark	LightWalker Fotona, Slovenia
Wavelength	1064 nm	1064 nm	1064 nm	1064 nm
Spot size	300 µm fiber	300 µm fiber	NA	300 - 360 µm fiber
Power	1.75 - 2.25 W	0.6-1.5 W	4 W	1 - 4 W
Energy	115-150 mJ	60-150 mJ	80 mJ	50 - 400 mJ
Pulse duration	100 - 350 µs	100-300 µs	350 µs	100 µs
Frequency	15 Hz	10-15 Hz	50 Hz	10 - 20 Hz

Conclusion: Published research demonstrates that periodontal tissue regeneration may be expected to be induced when sulcular debridement is being performed using FDA-cleared LightWalker Nd:YAG laser parameters for this indication.

b) Nd:YAG laser-assisted new attachment procedure

In this procedure, also called the LANAP procedure, an Nd:YAG laser is used in the first step for the initial pocket de-epithelialization (sulcular debridement), followed by the second step during which scaling and root planing is performed using ultrasound instrumentation, and finished by the third step for final fibrin clotting (hemostasis), again using the Nd:YAG laser.

In one of the first LANAP studies [13], results indicated a period of continued reduction in pocket depths over the first year, a period of healing, and long-term stability of results out to 3 years. There was also evidence of bone regeneration.

In a controlled human tooth extraction study [14], the microscopic structure of the post-LANAP tissues were examined. Teeth that were scheduled for removal

were treated with LANAP, allowed to heal for three months and extracted. The teeth were sectioned, stained and examined in the microscope to test the hypothesis of regeneration. The study results showed growth of new bone and new connective tissue.

In another, human-extracted tooth study [15], nine months post-LANAP results were examined. Evidence of periodontal regeneration being induced was reported.

Table 2 shows a comparison of laser treatment parameters as used in studies [13-15], and laser treatment parameters for the LightWalker Nd:YAG laser-assisted new attachment procedure cleared under K070355.

Table 2: Comparison of Nd:YAG laser treatment parameters used for laser-assisted new attachment procedure.

Nd:YAG laser	**Laser-assisted new attachment procedure**			
	Study [13]	**Study [14]**	**Study [15]**	**K070355**
Device	Periolase, Millennium Dental Technol. USA	Periolase Millennium Dental Technol. USA	Periolase, Millennium Dental Technol. USA	Fidelis/ LightWalker Fotona, Slovenia
Wavelength	1064 nm	1064 nm	1064 nm	1064 nm
Spot size	320 μm fiber	NA	360 μm fiber	300 - 360 μm fiber
Power	3W - 4.8 W	3W - 4 W	4W	1.5 - 4.5 W
Energy	150- 240 mJ	150- 200 mJ	200 mJ	60-200 mJ
Pulse duration	150 μs - 635μs	150 μs - 635μs	100 μs - 650μs	100-650 μs
Frequency	20 Hz	20 Hz	20 Hz	10-50 Hz

Conclusion: Published research demonstrates that periodontal tissue regeneration may be expected to be induced when a laser-assisted new attachment procedure is being performed using FDA-cleared LightWalker Nd:YAG laser parameters for this indication.

c) Er:YAG laser removal of subgingival calculi, removal of granulated tissue and sulcular debridement

Shwartz et al. [16, 17] reported new cementum formation accompanied by the formation of a periodontal ligament. Similarly, in a combined sulcular and root-surface debridement procedure, Mizutani et al. [18] reported new bone formation using Er:YAG laser.

In Aleksic et al. [19], it was reported that Er:YAG stimulates the proliferation of osteoblasts and enhances bone healing and regeneration. In Pourzarandian et al. [20], histological and TEM examination showed faster initial bone healing after Er:YAG laser irradiation.

In [20] Cranska reported post-op bone regeneration following a peri-implantitis treatment with LightWalker Er:YAG laser. It should be noted that the management of peri-implant mucositis and peri-implantitis is similar to the treatment of conventional periodontal disease [1]. A major difference is that the implant is not surrounded by periodontal ligament and, therefore, the blood supply to the tissue around the implant is missing.

Table 3 shows the comparison of laser treatment parameters as used in studies [17-18], and laser treatment parameters for LightWalker Er:YAG removal of subgingival calculi, removal of granulated tissue and sulcular debridement (cleared under K070355, K101817and K121508).

Table 3: Comparison of Er:YAG laser treatment parameters used for the removal of subgingival calculi, removal of granulated tissue, and sulcular debridement.

Er:YAG laser	**Removal of subgingival calculi Removal of granulated tissue Sulcular debridement**			
	Study [17]	**Study [18]**	**Study [18]**	**K121508**
Device	KEY II, KaVo Germany	Delight HOYA ConBio USA	Powerlase/ LightWalker Fotona Slovenia	LightWalker Fotona, Slovenia
Wavelength	2940 nm	2940 nm	2940 nm	2940 nm
Spot size	0.5 x 1.65 mm or 0.5 x 1.1 mm	0.4 – 0.7 mm	1 mm	0.3 – 1 mm
Energy	160 mJ	30 – 350 mJ	200 mJ	up to 200 mJ
Pulse duration	250-500 μs	200 μs	50 μs	100 - 1000 μs
Frequency	10 Hz	30 Hz	15 Hz	10-40 Hz

Conclusion: Published research demonstrates that periodontal tissue regeneration can be expected to be induced when Er:YAG laser removal of subgingival calculi, removal of granulated tissue and/or sulcular debridement is performed using FDA-cleared LightWalker Er:YAG laser parameters for these indications.

IV. DISCUSSION

Based on the positive published results of both Er:YAG laser therapy and Nd:YAG laser therapy, a natural next step is to combine both therapies into a

single periodontal laser treatment. This has been done with the "TwinLight procedure", a combined Nd:YAG/Er:YAG laser treatment available with LightWalker [21-27]. Based on the published results and clinical reports, this complementary dual-wavelength procedure promises to become the procedure of choice when it comes to minimally invasive, efficient, and safe non-surgical periodontal treatment. It should be noted that a recently published multi-center retrospective report provided clinical evidence, based on before and after radiographic images, for periodontal tissue regeneration following the TwinLight procedure performed with the LightWalker laser [28].

It is worth noting that the "laser-assisted new attachment procedure" represents a combined treatment consisting of the FDA-cleared Nd:YAG laser sulcular debridement procedure (1st step), the standard SRP (mechanical scaling and root planing) procedure (2nd step) and the FDA-cleared Nd:YAG hemostasis (3rd step). The TwinLight procedure also integrates the FDA-cleared Er:YAG removal of calculi with the 2nd step of the procedure.

V. CONCLUSIONS

In conclusion, our scientific literature review has demonstrated that periodontal tissue regeneration may be expected to be induced when the LightWalker laser is used to perform Er:YAG and Nd:YAG periodontal procedures which are FDA-cleared for the device [6]. This has been recently confirmed by a multi-center retrospective study of bone regeneration following the TwinLight periodontal procedure [28].

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