1 2 3 4 5	William D. Holm, Bar #007412 Erik J. Stone, Bar #027805 JONES, SKELTON & HOCHULI, P.L.C. 2901 North Central Avenue, Suite 800 Phoenix, Arizona 85012 Telephone: (602) 263-1700 Fax: (602) 200-7804 wholm@jshfirm.com estone@jshfirm.com		
6 7	Attorneys for Plaintiff Medical Dental Advanced Technologies Group, LLC		
8	UNITED STATES DISTRICT COURT		
9	DISTRICT OF ARIZONA		
10	Medical Dental Advanced Technologies NO.		
11	Group, LLC, COMPLAINT		
12	Plaintiff,		
13	V.		
14	Technology4Medicine, LLC, a Wyoming Limited Liability Company; and Lares Research, Inc., a California corporation,		
15	Defendants.		
16	Detendants.		
17	Plaintiff Medical Dental Advanced Technologies Group, LLC ("MDATG"),		
18	for its Complaint against Defendants Technology4Medicine, LLC ("Tech4Med") and		
19 20	Lares Research, Inc. ("Lares") (collectively, "Defendants"), alleges as follows:		
21	THE PARTIES 1. MDATG is an Arizona corporation with its principal place of		
22			
23	business located in Scottsdale, Arizona.		
24	2. Tech4Med is, upon information and belief, a Wyoming limited		
25	liability company with its principal office located in Robertson, Wyoming. Upon		
26	information and belief, Tech4Med transacts interstate business in Arizona and elsewhere.		
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3. Lares is, upon information and belief, a California corporation with its principal place of business located in Chico, California. Upon information and belief, Lares transacts interstate business in Arizona and elsewhere.

JURISDICTION AND VENUE

- 4. This is an action for patent infringement, trademark infringement, and declaratory judgment. This action arises under the patent and trademark laws of the United States and the common law of Arizona.
- 5. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) because this action arises under the patent laws of the United States, 35 U.S.C. § 271 et seq. (Patent Infringement), as well as the Lanham Act, 15 U.S.C. §§ 1114 (Trademark Infringement) and 1125 (Unfair Competition and False Description). This Court also has jurisdiction over the related declaratory judgment claim under 28 U.S.C. § 1367.
- 6. This Court has personal jurisdiction over Defendants because Defendants have committed acts of infringement in this District in violation of 35 U.S.C. § 271 and 15 U.S.C. §§ 1114 and 1125 and have placed infringing products and services into the stream of commerce with the knowledge and/or understanding that such products are used and sold in this District. Defendants derive substantial revenue from the sale of infringing products and services distributed within this District, and/or expect or reasonably should expect their actions to have consequences within this District. Defendants have purposefully availed themselves of the rights and privileges of conducting business in Arizona. Defendants have committed torts in or directed at a resident of this District and are therefore subject to personal jurisdiction in this District.
- 7. Defendants have committed intentional acts for which they knew or should have know would cause harm to a resident of this District.
- 8. Venue is proper in this district under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claims occurred in this District and because Defendants are subject to personal jurisdictions in this District.

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FACTUAL BACKGROUND

- 9. MDATG and its members, including Dr. Enrico DiVito, D.D.S., P.C. ("Dr. DiVito"), have spent substantial time, effort, and expense over the last several years pioneering new technologies involving the use of lasers and other energy sources to treat conditions and diseases affecting root canals, periodontal tissues, and other dentistry. In particular, these technologies use new laser-generated light energy modalities to enable treatment of certain conditions in a remarkably facile manner with astoundingly improved outcomes.
- 10. On June 14, 2011, United States Patent No. 7,959,441 ("the '441 Patent") was duly and lawfully issued by the United States Patent and Trademark Office ("USPTO"). The '441 Patent relates to an invention of a device and method of laser dentistry, including the laser treatment of teeth and gums. MDATG applied for the '441 Patent on February 9, 2007, under Application No. 11/704,655. The '441 Patent is attached to this Complaint as Exhibit A.
- 11. MDATG owns all substantial right, title, and interest in the '441 Patent, and holds the right to sue and recover damages for infringement of the '441 Patent, including past infringement.
- 12. On July 19, 2011, United States Patent No. 7,980,854 ("the '854 Patent") was duly and lawfully issued by the USPTO. The '854 Patent relates to an invention of a device and method of laser dentistry, including the laser treatment of teeth and gums. MDATG applied for the '854 Patent on February 28, 2009, under Application No. 12/395,643. The '854 Patent is attached to this Complaint as Exhibit B.
- 13. MDATG owns all substantial right, title, and interest in the '854 Patent, and holds the right to sue and recover damages for infringement of the '854 Patent, including past infringement.
- 14. On June 5, 2009, MDATG filed for trademark protection with the United States Patent and Trademark Office for its trademark/service mark "PIPS," with serial number 77753385 (the "PIPS Mark").

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- 15. In developing and promoting its new technologies, MDATG branded aspects of its new technologies with the PIPS Mark, which has rapidly built substantial and widespread recognition and goodwill both domestically and internationally as the next "big thing" in the use of laser technology in endodontics, periodontics, and other dental/medical arenas.
- 16. On March 15, 2009, MDATG entered into a license agreement for the purpose of licensing to Lares certain patents and patent applications held by MDATG (the "License Agreement").
- 17. Pursuant to the License Agreement, MDATG granted limited rights to Lares relating to certain MDATG patents, including the '441 Patent and the '854 Patent. The License Agreement, however, did not grant any rights to use the PIPS Mark.
- 18. Pursuant to Paragraph 17.2 of the License Agreement, the License Agreement could not be assigned by Lares "without the written consent of [MDATG]" except as a result of a sale, consolidation, or reorganization of Lares.
- 19. Pursuant to Paragraph 19 of the License Agreement, the License Agreement would be interpreted in accordance with the laws of the state of Arizona and each party to the License Agreement consented to jurisdiction and venue in the state of Arizona.
- 20. Upon information and belief, on or about July 20, 2011, without any prior notice to MDATG, Lares purportedly assigned the License Agreement to Tech4Med in violation of Paragraph 17.2 of the License Agreement.
- 21. The purported assignment by Lares to Tech4Med was an invalid assignment, as it was not part of a sale, consolidation, or reorganization of Lares. Furthermore, MDATG did not provide written consent to the purported assignment, as is required under Paragraph 17.2 of the License Agreement.
- 22. Since Lares' invalid assignment of the License Agreement to Tech4Med, Lares has voluntarily abandoned any and all rights it may have once had

under the License Agreement. As a result, the License Agreement has been terminated by Lares and/or is now void.

- 23. Upon information and belief, since Lares' invalid assignment of the License Agreement to Tech4Med, Tech4Med has engaged in infringing conduct, including the unauthorized manufacture, use, sale, and offering for sale of products, machines, and/or methods which fall within the scope of the '441 Patent, the '854 Patent, and the PIPS Mark.
- 24. In particular, upon information and belief, Tech4Med's infringing conduct includes putting on, sponsoring, or otherwise participating in classes, seminars, etc. where others are shown, taught, or given assistance in carrying out procedures or methods which fall within the scope of the '441 Patent, the '854 Patent, and the PIPS Mark.
- 25. In addition, Tech4Med has been working to create the inaccurate impression among clinicians and businesses in the dental industry that Tech4Med has a close business relationship with Dr. DiVito and MDATG relative to the '441 Patent, the '854 Patent, and the PIPS Mark.
- 26. In particular, upon information and belief, Tech4Med has been improperly marketing MDATG's new technologies in conjunction with the unauthorized use of the PIPS Mark to promote, host, and profit from various dental seminars, all of which infringes upon MDATG's intellectual property rights.
- 27. Additionally, Tech4Med has been using Dr. DiVito's likeness, without permission or authorization, to market MDATG's new technologies in conjunction with the PIPS Mark to promote, host, and profit from various dental seminars, all of which infringes upon MDATG's intellectual property rights.
- 28. Upon information and belief, Tech4Med's infringing conduct is intentional and willful.

29. Tech4Med profits from this infringement.

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30. MDATG has not authorized Tech4Med to make, use, sell, or offer to sell the '441 Patent, the '854 Patent, or the PIPS Mark.

FIRST CAUSE OF ACTION (Tech4Med's Infringement of the '441 Patent)

- 31. MDATG incorporates by reference each of the allegations previously set forth in this Complaint as if fully set forth and alleged herein.
- 32. As set forth above, MDATG is the owner of the '441 Patent and holds all rights flowing from its ownership of the '441 Patent.
- 33. In violation of 35 U.S.C. § 271, Tech4Med has infringed the '441 Patent literally and/or under the doctrine of equivalents by using, making, performing, selling, or offering to sell the patented claims that fall within the scope of the '441 Patent without MDATG's permission or authorization.
- 34. Among the infringing conduct is Tech4Med's manufacturing products that fall under the claims of the '441 Patent and selling them in the industry.
- 35. MDATG has suffered damages as a result of Tech4Med's infringement of the '441 Patent.
- 36. Unless and until enjoined by this Court, Tech4Med will continue to infringe the '441 patent. Tech4Med's infringement is causing and will continue to cause MDATG irreparable harm, for which there is no adequate remedy at law. Under 35 U.S.C. § 283, MDATG is entitled to a permanent injunction against further infringement.

SECOND CAUSE OF ACTION (Tech4Med's Infringement of the '854 Patent)

- 37. MDATG incorporates by reference each of the allegations previously set forth in this Complaint as if fully set forth and alleged herein.
- 38. As set forth above, MDATG is the owner of the '854 Patent and holds all rights flowing from its ownership of the '854 Patent.
- 39. In violation of 35 U.S.C. § 271, Tech4Med has infringed the '854 Patent literally and/or under the doctrine of equivalents by using, making, performing,

selling, or offering to sell the patented claims that fall within the scope of the '854 Patent without MDATG's permission or authorization.

- 40. Among the infringing conduct is Tech4Med's manufacturing products that fall under the claims of the '854 Patent and selling them in the industry.
- 41. MDATG has suffered damages as a result of Tech4Med's infringement of the '854 Patent.
- 42. Unless and until enjoined by this Court, Tech4Med will continue to infringe the '854 patent. Tech4Med's infringement is causing and will continue to cause MDATG irreparable harm, for which there is no adequate remedy at law. Under 35 U.S.C. § 283, MDATG is entitled to a permanent injunction against further infringement.

THIRD CAUSE OF ACTION (PIPS Trademark Infringement – Against Tech4Med)

- 43. MDATG incorporates by reference each of the allegations previously set forth in this Complaint as if fully set forth and alleged herein.
- 44. As alleged above, Tech4Med has and currently is wrongfully using the PIPS Mark in interstate commerce without the consent of MDATG.
- 45. Tech4Med's wrongful use of the PIPS Mark is likely to cause confusion, mistake, and deception among the public as to the identity and origin of the PIPS Mark and all associated goods and services.
- 46. Tech4Med's wrongful use of the PIPS Mark constitutes trademark infringement under section 32 of the Lanham Act, 15 U.S.C. § 1114.
- 47. As a proximate result of Tech4Med's wrongful use of the PIPS Mark, MDATG has suffered and will continue to suffer great damage to its business, goodwill, reputation, profits, and the strength of its mark. The injury to MDATG is and continues to be ongoing and irreparable. An award of monetary damages alone cannot fully compensate MDATG for its injuries and MDATG lacks an adequate remedy at law.
- 48. MDATG is entitled to a permanent injunction against Tech4Med as well as all other remedies available under the Lanham Act, including, but not limited to,

1	compensatory damages, treble damages, disgorgement of profits, and costs and attorney	
2	fees.	
3	49. Tech4Med's wrongful use of the PIPS Mark has been and continues	
4	to be deliberate, willful, and wanton, making this an exceptional case within the meaning	
5	of 15 U.S.C. § 1117.	
6	FOURTH CAUSE OF ACTION	
7	(Federal Unfair Competition, False Designation of Origin, Passing Off and False Advertising – Against Tech4Med)	
8	50. MDATG incorporates by reference each of the allegations previously	
9	set forth in this Complaint as if fully set forth and alleged herein.	
10	51. The PIPS Mark is used and owned by MDATG in connection with	
11	goods and services relating to lasers and laser tips for medical purposes, namely, for use	
12	in performing dental and endodontic services, including root canal procedures, periodontal	
13	treatment services, and dental restorative treatment services.	
14	52. MDATG's PIPS Mark is a distinctive mark and has become	
15	associated with MDATG and thus exclusively identifies with MDATG's business,	
16	products, and services.	
17	53. Tech4Med has improperly used the PIPS Mark without the consent	
18	of MDATG. Specifically, Tech4Med has wrongfully designated, passed off, and	
19	advertised its association with the PIPS Mark and associated goods and services in	
20	connection with promoting, sponsoring, and conducting seminars relating to the PIPS	
21	Mark.	
22	54. Tech4Med's wrongful use of the PIPS Mark has deceived consumers	
23	into believing that Tech4Med's promotion of PIPS goods and services originate from, are	
24	sponsored by, or otherwise approved by MDATG, all in violation of section 43(a) of the	
25	Lanham Act, 15 U.S.C. § 1125(a).	

Tech4Med's wrongful use of the PIPS Mark constitutes false

designation of origin, passing off and false advertising in connection with products and

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services distributed in interstate commerce, all in violation of section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

- 56. Tech4Med's wrongful use of the PIPS Mark has caused irreparable injury to MDATG's goodwill and reputation. The injury to MDATG is and continues to be ongoing and irreparable. An award of monetary damages alone cannot fully compensate MDATG for its injuries and MDATG lacks an adequate remedy at law.
- 57. MDATG is entitled to a permanent injunction against Tech4Med, as well as all other remedies available under the Lanham Act, including, but not limited to, compensatory damages; treble damages; disgorgement of profits; and costs and attorney fees.

FIFTH CAUSE OF ACTION (Declaratory Relief)

- 58. MDATG incorporates by reference each of the allegations previously set forth in this Complaint as if fully set forth and alleged herein.
- 59. There is an actual controversy of sufficient immediacy and concreteness relating to the legal rights and duties of MDATG and its legal relations with the Defendants under the License Agreement to warrant relief under 28 U.S.C. § 2201.
- 60. Specifically, MDATG seeks a declaratory judgment with regard to the ongoing rights and duties of MDATG under the License Agreement.
- 61. MDATG contends that Lares' purported assignment of the License Agreement to Tech4Med was invalid and in violation of the written provisions of the License Agreement. Accordingly, Tech4Med is not a proper licensee under the License Agreement.
- 62. Furthermore, MDATG contends that Lares has voluntarily abandoned any and all rights it may have had under the License Agreement. As a result, the License Agreement is now terminated and/or void.

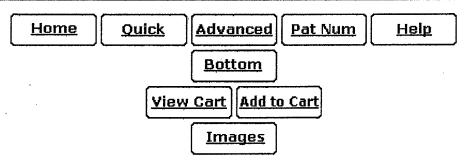
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Ţ	PRAYER FOR RELIEF		
2	WHEREFORE, MDATG respectfully requests that this Court enter		
3	judgment in favor of MDATG and prays that this Court grant the following relief:		
4	a. A judgment that the '441 and '854 Patents are valid and		
5	enforceable.		
6	b. A judgment that the '441 and '854 Patents are infringed by		
7	Tech4Med's manufacture, offers to sell, sales, or uses;		
8	c. A judgment declaring that the purported Lares' assignment of		
9	the License Agreement was invalid;		
10	d. A judgment declaring that the License Agreement is now		
11	terminated and/or void.		
12	e. A judgment permanently enjoining Tech4Med, its affiliates		
13	and subsidiaries, and each of its officers, agents, servants and employees and those acting		
14	in privity or concert with them, from making, using, offering to sell, selling, or importing		
15	products claimed in any of the claims of the '441 and '854 Patents, and from causing or		
16	encouraging others to use, sell, offer for sale, or import products that infringe any claim of		
17	the '441 and '854 Patents, until after the expiration date of the '441 and '854 Patents,		
18	including any extensions and/or additional periods of exclusivity to which MDATG is or		
19	may become entitled to;		
20	f. A judgment awarding damages under 35 U.S.C. § 284 in an		
21	amount sufficient to compensate MDATG for its damages arising from infringement by		
22	Tech4Med, including, but not limited to, lost profits and/or a reasonable royalty, together		
23	with pre-judgment and post-judgment interest, and costs;		
24	g. A judgment awarding treble damages for willful infringement		
25	by Tech4Med, pursuant to 35 U.S.C. § 284;		
26	h. An accounting and/or supplemental damages for all damages		
27	occurring after any discovery cutoff and through this Court's decision regarding the		
28	imposition of a permanent injunction;		
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1	i. A judgment ordering Tech4Med, its agents, officers,		
2	employees, representatives, successors, assigns, attorneys, and all other persons acting for,		
3	with, by, through, or under its authority, be permanently enjoined from using the PIPS		
4	Mark, or any colorable imitation thereof;		
5	j. A judgment awarding MDATG all applicable damages under		
6	15 U.S.C. § 1117, including actual damages suffered by MDATG, Tech4Med's profits		
7	and costs incurred;		
8	k. A judgment ordering Tech4Med to prepare an accounting of		
9	its profits derived from its wrongful conduct pursuant to 15 U.S.C. § 1117;		
10	1. A judgment declaring that this case is exceptional and		
11	awarding MDATG its reasonable costs and attorney fees pursuant to 35 U.S.C. § 285 and		
12	15 U.S.C. § 1117; and		
13	m. Such further and other relief as this Court deems just and		
14	proper.		
15	JURY DEMAND		
16	Pursuant to Rule 38 of the Federal Rules of Civil Procedure, MDATG		
17	respectfully demands a jury trial of all issues triable to a jury in this action.		
18	DATED this 17 th day of August, 2012.		
19	JONES, SKELTON & HOCHULI, P.L.C.		
20	By s/ Erik J. Stone		
21	William D. Holm Erik J. Stone		
22	2901 North Central Avenue, Suite 800 Phoenix, Arizona 85012		
23	Attorneys for Plaintiff Medical Dental Advanced Technologies Group, LLC		
24	riavancea reciniciogies Group, Elec		
25	ORIGINAL electronically filed this 17 th day of August, 2012.		
26	tills 17 day of August, 2012.		
27	s/ Vicki Jones		
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Exhibit A

USPTO PATENT FULL-TEXT AND IMAGE DATABASE



(1 of 1)

United States Patent

7,959,441

Glover, et al.

June 14, 2011

Laser based enhanced generation of photoacoustic pressure waves in dental and medical treatments and procedures

Abstract

A laser tip, and method for the use thereof, is described for utilization in medical and dental applications. Specifically, a tip with an increased photoacoustic wave emission capability is formed by beveling the tip and further enhanced by stripping the adjacent sheath. Preferably, this conic and/or stripped tip section is surface modified, for example, by texturing, derivatization or metalization. In the field of endodontics the tip is inserted into a solution that has been introduced into a root canal and the pulsed laser is fired. The resulting generation of an enhanced photoacoustic wave propagates through the solution. These photoacoustic waves turbulently clean the interior of the root and lateral canal systems and/or causes cell lysis and dissolution of inorganics in biotic systems.

Inventors: Glover; Douglas L. (Phoenix, AZ), DiVito; Enrico E. (Scottsdale, AZ), Tubbs; Kemmons A.

(Mesa, AZ), Colonna; Mark P. (Whitefish, MT)

Assignee: Medical Dental Advanced Technologies Group, L.L.C. (Scottsdale, AZ)

Appl. No.: 11/704,655

Filed: February 9, 2007

Related U.S. Patent Documents

Application Number

Filing Date

Patent Number

Issue Date

60840282

Aug., 2006

Current U.S. Class:

433/224; 433/29

Current International Class:

A61C 5/02 (20060101)

Field of Search:

433/29,224

References Cited [Referenced By]

ZII	Patent	Documents
$\mathbf{v}_{\bullet o}$	T CHOUSE	TOCATION

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<u>4676586</u>	June 1987	Jones et al.
<u>4985027</u>	January 1991	Dressel
<u>5116227</u>	May 1992	Levy
<u>5173049</u>	December 1992	Levy
<u>5188532</u>	February 1993	Levy
<u>5267995</u>	December 1993	Doiron et al.
<u>5324200</u>	June 1994	Vassiliadis et al.
5639239	June 1997	Earle
<u>5968039</u>	October 1999	Deutsch et al.
<u>6162052</u>	December 2000	Kokobu
<u>7261561</u>	August 2007	Ruddle et al.
2001/0041324	November 2001	Riitano
2002/0090594	July 2002	Riitano et al.
2002/0183728	December 2002	Rosenberg et al.
2003/0013064	January 2003	Zirkel
2003/0236517	December 2003	Appling
2004/0038170	February 2004	Hiszowicz et al.
2004/0193236	September 2004	Altshuler
2004/0224288	November 2004	Bornstein
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Primary Examiner: Rodriguez; Cris L Assistant Examiner: Rosen; Eric

Attorney, Agent or Firm: Luedeka, Neely & Graham, P.C.

Parent Case Text

This application is a provisional application Ser. No. 60/840,282 filed on Aug. 24, 2006.

Claims

What is claimed is:

1. A method for providing a photoacoustic wave therapy for use in endodontic treatments of tooth interiors comprising: (a) providing a laser system; (b) providing a laser fiber optic operatively coupled to the laser system, said laser fiber optic being substantially cylindrical and untapered from adjacent a proximal end to adjacent a tip

which tapers from a circumference of the laser fiber optic to an apex with a surrounding generally conical wall, defining a surrounding generally conical outer surface of said tip and further where the laser fiber optic contains a sheath extending from adjacent the proximal end of the laser fiber optic to a terminus edge thereof spaced proximally from the beginning of said tapered tip and spaced proximally from said apex of said tapered tip toward said proximal end by a distance of from about 2 mm to about 12 mm so that at least the surface of said fiber optic is uncovered over substantially the entirety of said tapered tip and over at least the portion of an outer surface of the substantially cylindrical and untapered part of said fiber optic extending from adjacent said terminus edge to the beginning of the tapered tip; (c) delivering a treatment liquid into a root canal in a tooth; (d) submerging at least the tip and the uncovered portion of the outer surface of the substantially cylindrical and untapered part of said laser fiber optic into the treatment liquid so that substantially no laser light may be emitted from the outer surface of said fiber optic into any open space above an upper surface of the liquid in the canal; (e) treating the interior of the root canal by pulsing a laser through the fiber optic so that laser light is emitted from surfaces thereof uncovered by said sheath generally omnidirectionally to create a series of photoacoustic waves which propagate from said surfaces generally omnidirectionally through the treatment liquid in the interior of the root canal and into contact with adjacent root canal wall surfaces in order to disintegrate material in the root canal, while preserving, cleaning and disinfecting reticular surfaces of the aforesaid adjacent root canal wall surfaces relative to their condition prior to treatment as aforesaid; (f) withdrawing the tip of the laser fiber optic from the treatment liquid; and (g) sealing the root canal.

- 2. The method according to claim 1 where substantially the entire surface of the tapered tip is uncovered.
- 3. The method according to claim 1 where the tapered tip is a surface modified tip comprising a textured surface, a frosted surface, or a derivatized surface.
- 4. The method according to claim 1 where the laser fiber optic has no cladding or sheath adjacent to the tip.
- 5. The method of claim 1, wherein the treatment liquid comprises an EDTA solution.
- 6. The method of claim 1, wherein the treatment liquid comprises water.
- 7. A method for providing a photoacoustic wave therapy for use in dental or periodontal treatments comprising:

 (a) providing a laser system; (b) providing a laser fiber optic operatively coupled to the laser system, said laser fiber optic being substantially cylindrical and untapered from adjacent a proximal end to adjacent a tip-which tapers from a circumference of the laser fiber optic to an apex with a surrounding generally conical wall, defining a surrounding generally conical outer surface of said tip and further where the laser fiber optic contains a sheath extending from adjacent the laser system to a terminus edge thereof spaced proximally from the proximal end of said tip and spaced proximally from said apex of said tapered tip toward said laser system by a distance of from about 2 mm to about 12 mm so that at least the surface of said fiber optic is uncovered over substantially the entirety of said tapered tip and over at least a portion of an outer surface of the substantially cylindrical and untapered part of said fiber optic extending from adjacent said terminus edge to the beginning of the tapered tip; (c) delivering a treatment liquid into a root canal, sulcus or tissue space in a mouth; (d) submerging the tip and the uncovered portion of the laser fiber optic into the treatment liquid; (e) treating the interior of the root canal, sulcus or tissue space by pulsing a laser through the fiber optic so that laser light is emitted therefrom generally omnidirectionally to create a series of photoacoustic waves which propagate from the outer surface of the fiber optic from at least the portion of the surface extending from the terminus edge to the apex, said waves

propagating generally omnidirectionally through the treatment liquid in the interior of the root canal, sulcus or tissue space and into contact with root canal wall surfaces or other adjacent surfaces, tissues, or structures so as to cause disintegration of material in the treatment liquid in the canal, sulcus, or tissue space while preserving, cleaning, and disinfecting internal surfaces of the aforesaid adjacent root canal wall and other adjacent surfaces, tissues, or structures relative to their condition prior to treatment as aforesaid; (f) withdrawing the tip of the laser fiber optic from the treatment liquid.

8. The method according to claim 7 where substantially the entire surface of the tapered tip is uncovered.

Description

FIELD OF THE INVENTION

The present invention is related to the field of dentistry, medicine and veterinary medicine. More specifically, the present invention is a method and device for rapid molecular modification of biological structures for dental, medical and veterinary procedures and/or treatments. Additionally, the present invention is an integration of lasers, photoacoustics, photoacoustic (PA) waves, and other sciences with treatments and procedures in dentistry, medicine and veterinary medicine.

BACKGROUND OF THE INVENTION

Recent advances in the fields of dentistry, medicine, and veterinary medicine necessitate functional and efficient implementation of therapies during exploratory and restructuring procedures. Approaches of interest combine efficiency and esthetics with the inherent utility of the investigative area. Of specific interest is the arena the dental root canals that while rapidly increasing in volume throughout the world have lagged in gaining concerted integration of recent scientific advancements.

When performing root canals it is desirable to efficiently debride or render harmless all tissue, bacteria, and/or viruses within the root canal system. As shown in FIG. 1A and FIG. 1B (FIG. 1B is a simplified representation of FIG. 1A), a tooth root 5 of the root canal system includes the main root canal 1 and all of the accessory or lateral canals 3 that branch off of the main canal 1 generally towards the jaw bone 7. Some of these accessory canals are very small and extremely difficult to reach in order to eliminate any bacteria and/or viruses. Such accessory canals 3 may bend, twist, change cross-section and/or become long and small as they branch off from the main canal 1, making them very difficult to access or target therapeutically.

The accepted dental procedure is to mechanically pull out the main canal nerve 1 thereby separating it from the accessory canal nerves 3 (which stay in place) then filing out the main canal 1 with a tapered file. This action leaves an undesirable smear layer along the main canal 1 and actually plugs some of the accessory canal 3 openings, which potentially trap harmful bacteria or other harmful maladies. This is very undesirable. The dentist must chemo-mechanically debride both main 1 and accessory canals 3, including the smear layer produced by the filing. Often this is done with a sodium hyperchlorite solution and various other medicaments that are left in the root canal system for 30 to 45 minutes. This current methodology does not necessarily debride or render harmless all of the accessory root canals 3 because of the difficulty in first cleaning off the smear layer then negotiating some of the smaller twisted lateral canals. As a result many treatments using this method fail over time

due to reoccurring pathology. This often requires retreatment and/or sometimes loss of the tooth.

Therefore, there is a present and continuing need for new and improved dental, medical, and veterinary procedures that address the above problems.

SUMMARY OF INVENTION

It is an object of the present invention to provide new medical, dental and veterinary devices, treatments and procedures.

It is another object of the present invention to provide a device for producing a photoacoustic wave used in endodontal treatment of tooth interiors comprising a laser system having a wavelength of at least 1500 nm and power of at least 0.5 Watt, a sheath coupled at one end to the laser system said sheath comprising a laser fiber optic and a treatment fluid lumen, both running the length of the sheath and exiting the sheath at a distal end, said laser fiber optic having a flat, blunt or modified tip and whereby inserting the tip into the treatment fluid delivered into root canal produces a photoacoustic wave as the laser is pulsed.

It is yet another object of the present invention to provide a method for endodontal treatment of tooth interiors comprising the steps of: providing a laser having a wavelength of at least 1500 nm and at least 0.5 Watt; providing a laser fiber optic coupled to the laser, said laser fiber optic having a flat, blunt or modified tip; inserting the tip of the laser fiber optic into a root canal in a tooth; treating the interior root canal by creating a photoacoustic wave front in the interior of the root canal using the at least 1500 nm at least 0.5 Watt laser energy; withdrawing the tip of the laser fiber optic from the root canal; and sealing root canal.

The novel features that are considered characteristic of the invention are set forth with particularity in the appended claims. The invention itself, however, both as to its structure and its operation, together with the additional objects and advantages thereof, will best be understood from the following description of the preferred embodiment of the present invention when read in conjunction with the accompanying drawings. Unless specifically noted, it is intended that the words and phrases in the specification and claims be given the ordinary and accustomed meaning to those of ordinary skill in the applicable art or arts. If any other meaning is intended, the specification will specifically state that a special meaning is being applied to a word or phrase. Likewise, the use of the words "function" or "means" in the Description of Preferred Embodiments is not intended to indicate a desire to invoke the special provision of 35 U.S.C. .sctn.112, paragraph 6 to define the invention. To the contrary, if the provisions of 35 U.S.C. .sctn.112, paragraph 6, are sought to be invoked to define the invention(s), the claims will specifically state the phrases "means for" or "step for" and a function, without also reciting in such phrases any structure, material, or act in support of the function. Even when the claims recite a "means for" or "step for" performing a function, if they also recite any structure, material or acts in support of that means of step, then the intention is not to invoke the provisions of 35 U.S.C. .sctn.112, paragraph 6. Moreover, even if the provisions of 35 U.S.C. .sctn.112, paragraph 6, are invoked to define the inventions, it is intended that the inventions not be limited only to the specific structure, material or acts that are described in the preferred embodiments, but in addition, include any and all structures, materials or acts that perform the claimed function, along with any and all known or later-developed equivalent structures, materials or acts for performing the claimed function.

DETAILED DESCRIPTION OF THE DRAWINGS

FIG. 1a and 1b illustrates a root canal system including the main root canal and all of the accessory or lateral canals that branch off of the main canal (1a). Some of these accessory canals are very small and extremely difficult to reach in order to eliminate any bacteria and/or viruses. Such accessory canals may bend, twist, change cross-section and/or become long and small as they branch off from the main canal, making them very difficult to access or target therapeutically. 1b is a simplified graphical representation of the same.

FIG. 2 is a Scanning Electron Micrograph (SEM) clearly illustrating internal reticular surfaces created by the present invention, which are preserved and sterilized for subsequent filling and embalming, i.e. using rubber, gutta-percha, latex, etc.

FIG. 3 is an illustration of a laser fiber tip preferably used according to the present invention.

FIG. 4 is an illustration of the system according to the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is useful for treating dental, medical, and veterinary problems; primarily dental surface preparations. The present invention uses enhanced photoacoustic wave generation in dental, medical, and veterinary application during procedures that otherwise face reoccurring infection, inefficient performance and at an increase in expenses. The result of this invention has the potential to increase the effective cleaning of the root canal and accessory canals and the potential to reduce future failures over time.

As shown in FIG. 3 and FIG. 4, the most preferred embodiment of the present invention utilizes an energy source which is preferably a pulsed laser energy that is coupled to a solution in such a fashion that it produces an enhanced photoacoustic pressure wave 8. The laser light is delivered using a commercially available laser source 10 and an optical light fiber 15 attached at a proximate end to the laser source 10 and has an application tip 20 at the distal end. The application tip 20 may be flat or blunt, but is preferably a beveled or tapered tip having a taper angle between 10 and 90 degrees. Preferably any cladding 24 on the optic fiber is stripped from approximately 2-12 mm of the distal end. The taper angle of the fiber tip 20 and removal of the cladding 24 provide wider dispersion of the laser energy 12 over a larger tip area and consequently produces a larger photoacoustic wave. The most preferred embodiment of the application tip 20 includes a texturing or deriviatization of the beveled tip 20, thereby increasing the efficacy of the conversion of the laser energy 12 into photoacoustic wave energy within the solution. A coupling ferrule 14 may be used to interchange different applicator tips. It should be noted that in the present invention this tapered tip 20, the surface treatment, and the sheath or cladding 24 stripping is not for the purpose of diffusing or refracting the laser light 12 so that it laterally transmits radiant optical light energy to the root surface. In the current invention these features are for the sole purpose of increasing the photoacoustic wave.

Herein derivatization means a technique used in chemistry that bonds, either covalently or non-covalently, inorganic or organic chemical functional group to a substrate surface.

It was found that the photoacoustic coupling of the laser energy to the solution provides enhanced penetration of the solution into the root canal and accessory canals, thereby allowing the solution to reach areas of the canal system that are not typically accessible.

The photoacoustic (PA) wave is generated when the laser energy transitions from the tip (usually quartz or similar material) of the laser device into the fluid (such as water, EDTA, or the like. The transmission from one medium to another is not 100% efficient and some of the light energy is turned into heat near the transition that the light makes from one media to the other. This heating is very rapid, locally heating some of the molecules of the fluid very rapidly, resulting in molecule expansion and generating the photoacoustic wave. In a pulsed laser, a wave is generated each time the laser is turned on, which is once per cycle. A 10 HZ pulsed laser then generates 10 waves per second. If the power level remains constant, the lower the pulse rate, the greater the laser energy per pulse and consequently the greater the photoacoustic wave per pulse.

The photoacoustic effect creates sound (pressure) waves that can potentially propagate throughout both the media and localized structure, e.g., the main root canal and the lateral or accessory canals. These sound waves provide vibrational energy, which expedites the breaking loose of and/or causing cell lysis of the biotics and inorganics in the root canal and lateral canal systems. In addition these vibrational waves help the propagation of the fluids into and throughout the main and lateral canal systems.

In general, light travels in a straight line, however, in a fluid light can be bent and transmitted around corners, but this transmission is minimal compared to the straight-line transmissibility of light. A sonic or shock wave on the other hand is easily transmitted around corners and through passages in a fluid. For example, air is a fluid. If you stood in one room and shined a bright light from that room into a hallway that was at right angles to that room, the intensity of the light would decrease the farther you go down the hallway. If you then went into a room at the end of the hallway and went to a back corner of the room, the light might be very dim. However, if while standing at the same location as the light source, you yelled vocally at the hallway, you could most likely hear the sound in the back corner of the back room. This is because sound is propagated spherically by the vibration of molecules instead of primarily in a straight line like light.

Although the laser light cannot turn corners easily and cannot propagate easily into the lateral canals, the sonic wave produced by the photoacoustic effect is easily transmitted through the lateral canals. Also, since the canals are tapered in a concave fashion, the photoacoustic wave will be amplified as it transverses toward the end of the lateral canals. Since the cross-sectional area of the lateral canals decreases as the wave traverses toward the canal end, the amplitude of the wave increases much as a Tsunami wave increases as it approaches a beach where the cross sectional area of the water channel constantly decreases.

The tip design can affect the magnitude and direction of the produced photoacoustic wave. A tapered tip has the effect of diverting the laser energy over the larger cone area (compared to the circular area of the standard tip) and thereby creating a larger photoacoustic wave. The same applies to any stripped sheath section of the tip.

Testing using a MEMS Pressure sensor:

A small plastic vial was fitted with a fluid connection (bottom of vial at right angles to axis of vial) that was close coupled hydraulically to a miniature MEMS piezo-resistive pressure sensor (Honeywell Model 24PCCFA6D). The sensor output was run through a differential amplifier and coupled to a digital Oscilloscope (Tektronics Model TDS 220). This model oscilloscope will hold a trace on the screen and allow a digital image to be taken of the trace. The vial and sensor were filled with water. The laser tip was submerged below the fluid level in the vial and fired (laser frequency was 10 HZ) at various power setting. A trace was recorded of the resulting

photoacoustic pressure waves.

A 170% increase in the photoacoustic wave was observed for the tapered and stripped tip versus the blunt-ended tip. A 580% increase in the photoacoustic wave was observed for textured (frosted) tapered/stripped tip versus the standard blunt-ended tip. The tapered tip has a greater exposed area than the blunt straight tip. The fiber optic is coated with a polyamide sheath, which reflects the laser beam internally, not allowing it to escape and propagating the laser energy down the fiber to the tip. On the straight or blunt-ended tip, the exposed area is the circular cross-sectional area of the end of the tip. On the tapered tip and textured tip the exposed area is the area of the tapered cone, which is greater than the exposed area of the blunt straight tip. This invention is on the ability of these features to increase the photoacoustic wave not to refract or redirect the radiant optical properties of the laser energy. In fact such radiant light energy can fuse the root canal wall surface making it impossible to clean and debride the small passages behind the fused areas.

During a previous experiment, fluid was placed into a Dampen dish located on a Formica surface. The laser tip was placed into the fluid and fired repetitively. The photoacoustic wave vibrated the Dampen dish on the Formica surface making an audible sound. For a specific tip this audible sound increased with an increasing power level of the laser. This implies that the audible sound is somewhat proportional to the amplitude of the photoacoustic wave. This was verified by placing a sound level meter one inch away from the Dampen dish and recording the dB level. Next, the laser power level was held constant and the tip was changed. The tapered and stripped sheath tip produced a greater photoacoustic wave than the standard straight or blunt-end tip. A tapered and stripped tip was then frosted or etched. This tip was tested and showed a greater photoacoustic wave generated than the non-frosted version. This was verified to be true at three different power levels. It would appear that since the power level was held constant, the photoacoustic wave amplitude would also be proportional to the exposed area and the surface treatment.

An increase in photoacoustic wave generation was seen by stripping the polyamide sheath away for 2-12 mm from the tapered end. Although laser light is coherent and travels in a straight line, some light bounces off of the polyamide sheath at an angle. As this light travels down the light path it continues bouncing off of the inside of the polyamide sheath and will eventually exit at an angle to the sheath once the sheath stops and exposes a non sheathed section. Therefore, some of the laser energy would also exit where the polyamide sheath has been removed, just upstream of the tapered tip. A tip with the sheath removed for 2 to 12 mm directly upstream of the tapered section was placed in the above-mentioned test set up.

The photoacoustic wave will propagate primarily perpendicular to the exposed surface and secondarily spherically with respect to the exposed surface. The standard straight end tip would have the PA wave propagating primarily in line with the tip. The tapered tip produced PA wave would be primarily propagated in a more lateral pattern. The tapered tip with the shinned sheath would propagate the PA wave in a more spherical pattern than the other two.

The standard straight blunt end tip would be less desirable because it directs the photoacoustic wave toward the apical end of the tooth and would have more propensities to drive the fluid from the nerve hole in the apical end and outward into the gum which could create medical complications. Since there may be lateral or accessory canals anywhere along the main root canal, it is more desirable to have a spherical wave distribution to direct waves to as many lateral canals as possible. Therefore the tapered tip with the skinned sheath produces a more desirable effect within the tooth.

Resultant Scanning Electron Micrographs (SEM's) show the reticular surface of the dentin to be devoid of infection and malady and allowing for rinsed removal of the debris elements.

The present invention also includes embodiments of the individual components, kits, methods, their manufacture, and their assembly into one singular procedure. Still further herein included are methods and processes for use of the individual components and the integration in biological applications.

All publications and patent applications are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference. Although the present invention has been described in some detail by way of illustration and example for purposes of clarity and understanding, it will be apparent that certain changes and modifications may be practiced within the scope of the appended claims.

The preferred embodiment of the invention is described above in the Drawings and Description of Preferred Embodiments. While these descriptions directly describe the above embodiments, it is understood that those skilled in the art may conceive modifications and/or variations to the specific embodiments shown and described herein. Any such modifications or variations that fall within the purview of this description are intended to be included therein as well. Unless specifically noted, it is the intention of the inventor that the words and phrases in the specification and claims be given the ordinary and accustomed meanings to those of ordinary skill in the applicable art(s). The foregoing description of a preferred embodiment and best mode of the invention known to the applicant at the time of filing the application has been presented and is intended for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise form disclosed, and many modifications and variations are possible in the light of the above teachings. The embodiment was chosen and described in order to best explain the principles of the invention and its practical application and to enable others skilled in the art to best utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated.

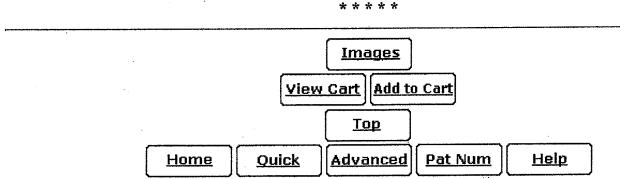
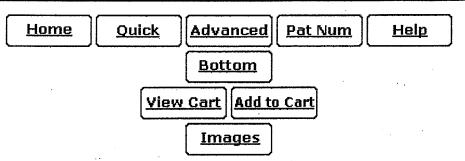


Exhibit B

USPTO PATENT FULL-TEXT AND IMAGE DATABASE



(1 of 1)

United States Patent

7,980,854

Glover, et al.

July 19, 2011

Dental and medical treatments and procedures

Abstract

A method treating a root canal in a tooth by introducing into the pulp chamber of a tooth and pulsing a laser light into the fluid reservoir so as to disintegrate pulp within the root canal without generation of any significant heat in said liquid fluid so as to avoid elevating the temperature of any of the dentin, tooth, or other adjacent tissue more than about 5.degree. C.

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Related U.S. Patent Documents

Application Number	Filing Date	Patent Number	<u>Issue Date</u>
11704655	Feb., 2007	•	
11895404	Aug., 2007		

Current U.S. Class:

433/224; 433/29

Current International Class:

A61C 5/02 (20060101)

Field of Search:

433/215,216,224,29 606/2-19 128/898

References Cited [Referenced By]

U.S. Patent Documents

		· · · · · · · · · · · · · · · · · · ·
<u>4676586</u>	June 1987	Jones et al.
<u>4985027</u>	January 1991	Dressel
<u>5116227</u>	May 1992	Levy
<u>5173049</u>	December 1992	Levy
<u>5188532</u>	February 1993	Levy
<u>5267995</u>	December 1993	Doiron et al.
5324200	June 1994	Vassiliadis et al.
5639239	June 1997	Earle
<u>5662501</u>	September 1997	Yagi
<u>5968039</u>	October 1999	Deutsch et al.
6162052	December 2000	Kokobu
<u>7470124</u>	December 2008	Bornstein
2002/0090594	July 2002	Ritano et al.
2002/0183728	December 2002	Rosenberg et al.
2003/0013064	June 2003	Zirkel
2004/0038170	February 2004	Hirszowicz et al.
2004/0193236	September 2004	Altshuler

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Parent Case Text

This application is a continuation-in part of pending application Ser. No. 11/704,655, filed Feb. 9, 2007, and of pending application Ser. No. 11/895,404, filed on Aug. 24, 2007, both of which claim priority to provisional application Ser. No. 60/840,282, filed on Aug. 24, 2006, all of which are incorporated herein by reference.

Claims

What is claimed is:

1. A method for treating a root canal in a tooth containing a crown portion extending to above a gum line and an elongate root integral with and projecting from the crown into the gum and an adjacent jaw bone, the root having a root canal containing pulp including nerve and other tissue in open communication with a pulp chamber in the crown, the method comprising: forming an opening in the crown into the pulp chamber dimensioned to enable working access to the root canal of said root for treatment thereof, removing pulp from said pulp chamber to provide an open area therein to gain access to pulp in said root canal, introducing liquid into at least said open area in said pulp chamber in an amount sufficient to provide a liquid reservoir, the upper level of which rises to an

immersion level, providing a laser system containing a source of a laser light beam and an elongate optical fiber connected to said source and configured to transmit said laser light beam to a tip portion thereof, said tip portion containing a tapered tip tapering to an apex with a surrounding conical wall, substantially the entire surface of which is uncovered so that said laser light beam is emitted therefrom generally omnidirectionally, substantially completely immersing at least said tip of said laser into said liquid reservoir, and pulsing said laser source at a power level of from about 0.1 W to about 1.5 W and at a pulse duration of from about 100 nanoseconds to about 1000 microseconds, at a pulse frequency of from about 2 Hz to about 25 Hz, and for a cycle time of from about 10 to about 40 seconds, wherein at least a substantial portion of the pulp in said pulp chamber and root canal is disintegrated into pulp material in admixture in and with said liquid and removing said liquid mixture containing said pulp material from the opening in the crown, rinsing, irrigating, and disinfecting said pulp chamber and root canal so as to provide substantially clean and substantially pulp-free dentin walls lining said chamber and root canal ready for filling, obturating said pulp chamber and root canal with a suitable filling material, wherein disintegration of pulp using the laser is accomplished without generation of any significant heat in said liquid so as to avoid elevating the temperature of any of the dentin, tooth, or other adjacent tissue more than about 5.degree. C.

- 2. The method of claim 1, wherein said tip is tapered convexly to an apex distally of the source.
- 3. The method of claim 1, wherein said tip is tapered concavely to an apex distally of the source.
- 4. The method of claim 1, wherein the pulse frequency is maintained constant.
- 5. The method of claim 1, wherein the pulse frequency is varied during each pulse cycle.
- 6. The method of claim 1, wherein the pulse frequency is maintained at about 15 Hz.
- 7. The method of claim 1, wherein the power level is maintained at about 1.5 Watts.
- 8. The method of claim 1, wherein the pulse duration is maintained substantially constant during each cycle at from about 50 to about 400 microseconds.
- 9. The method of claim 1, further comprising the step of removing at least part of the pulp from said root canal to make an opening in said root canal in flow communication with said open area in said pulp chamber prior to introducing the liquid into the open area.
- 10. The method of claim 1, wherein the optical fiber contains cladding in the form of a continuous sheath coating extending from the source to a terminus edge spaced proximally from said apex of said tapered tip toward said source by a distance of from about 2 mm to about 10 mm so that a surface of said optical fiber is uncovered over the entirety of said tapered tip and over any part of a cylindrical outer surface of said fiber between said terminus and the beginning of the tapered tip.
- 11. A method for treating a root canal in a tooth containing a crown portion extending to above a gum line and an elongate root integral with and projecting from the crown into the gum and an adjacent jaw bone, the root having a root canal containing pulp including nerve and other tissue in open communication with a pulp chamber in the crown, the method comprising: forming an opening in the crown into the pulp chamber dimensioned to

enable working access to the root canal of said root for treatment thereof, removing pulp from said pulp chamber to provide an open area therein to gain access to pulp in said root canal, introducing an aqueous solution into at least said open area in said pulp chamber in an amount sufficient to provide a liquid reservoir, the upper level of which rises to an immersion level, providing a laser system containing a source of a laser light beam and an elongate optical fiber connected to said source and configured to transmit said laser light beam to a tip portion thereof, said tip portion containing a tapered tip tapering to an apex with a surrounding conical wall, substantially the entire surface of which is uncovered so that said laser light beam is emitted therefrom generally omnidirectionally, substantially completely immersing at least said tip of said laser into said liquid reservoir, pulsing said laser source at a power level of from about 0.1 W to about 1.5 W and at a pulse duration of from about 100 nanoseconds to about 1000 microseconds, at a pulse frequency of from about 2 Hz to about 25 Hz, wherein at least a substantial portion of the pulp in said pulp chamber and root canal is disintegrated into pulp material in admixture in and with said aqueous solution, and removing said admixture containing said aqueous solution and pulp material from the opening in the crown and, rinsing, irrigating, and disinfecting said pulp chamber and root canal so as to provide substantially clean and substantially pulp-free dentin walls lining said chamber and root canal ready for filling, obturating said pulp chamber and root canal with a suitable filling material, wherein disintegration of pulp using the laser is accomplished without generation of any significant heat in said aqueous solution so as to avoid elevating the temperature of any of the dentin, tooth, or other adjacent tissue more than about 5.degree. C.

12. A method for treating a root canal in a tooth containing a crown portion extending to above a gum line and an elongate root integral with and projecting from the crown into the gum and an adjacent jaw bone, the root having a root canal containing pulp including nerve and other tissue in open communication with a pulp chamber in the crown, the method comprising: forming an opening in the crown into the pulp chamber dimensioned to enable working access to the root canal of said root for treatment thereof, removing pulp from said pulp chamber to provide an open area therein to gain access to pulp in said root canal, introducing an aqueous solution into at least said open area in said pulp chamber in an amount sufficient to provide a liquid reservoir, the upper level of which rises to an immersion level, providing a laser system containing a source of a laser light beam and an elongate optical fiber connected to said source and configured to transmit said laser light beam to a tip portion thereof, wherein cladding optic fiber adjacent the tip portion is spaced from about 2 mm to about 10 mm from the distal end of the tip portion, substantially the entire surface of the tip portion being uncovered so that said laser light beam is emitted therefrom generally omnidirectionally, substantially completely immersing at least said tip of said laser into said liquid reservoir, pulsing said laser source at a power level of from about 0.1 W to about 1.5 W and at a pulse duration of from about 100 nanoseconds to about 1000 microseconds, at a pulse frequency of from about 2 Hz to about 25 Hz, and for a cycle time of from about 10 to about 40 seconds, wherein at least a substantial portion of the pulp in said pulp chamber and root canal is disintegrated into pulp material in admixture in and with said aqueous solution, and removing said admixture containing said aqueous solution and pulp material from the opening in the crown, rinsing, irrigating, and disinfecting said pulp chamber and root canal so as to provide substantially clean and pulp-free dentin walls lining said chamber and root canal ready for filling, obturating said pulp chamber and root canal with a suitable filling material, wherein the disintegration of pulp using the laser is accomplished without generation of any significant heat in said aqueous solution so as to avoid elevating the temperature of any of the dentin, tooth, or other adjacent tissue more than about 5.degree. C.

Description

FIELD OF THE INVENTION

The present invention is related to the field of dentistry, medicine and veterinary medicine.

BACKGROUND OF THE INVENTION

In the field of dentistry, one of the most important and delicate procedures is that of cleaning or extirpating a diseased root canal to provide a cavity which is substantially free of diseased tissue and antiseptically prepared for a permanent embalming or obturation to seal off the area. When done properly, this step enables subsequent substantially complete filling of the canal with biologically inert or restorative material (i.e., obturation) without entrapping noxious tissue in the canal that could lead to failure of the therapy.

In a typical root canal procedure, the sequence is extirpation of diseased tissue and debris from and adjacent the canal followed by obturation. Often there is an intermediate filling of the canal with a calcium hydroxide paste for sterilization and reduction of inflammation prior to obturation and final crowning. In performing the extirpation procedure, the dentist must gain access to the entire canal, shaping it as appropriate. However, root canals often are very small in diameter, and they are sometimes quite curved with irregular dimensions and configurations. It is therefore often very difficult to gain access to the full length of the canal and to properly work all surfaces of the canal wall.

Many tools have been designed to perform the difficult task of cleaning and shaping root canals. Historically, dentists have used elongate, tapered endodontic files with helical cutting edges to remove the soft and hard material from within and adjacent the root canal area. Such root canal dental procedures often result in overly aggressive drilling and filing away of otherwise healthy dentin wall or physical structure of the tooth root, thereby unduly weakening the integrity or strength of the tooth. Additionally, when performing root canal procedures, it is desirable to efficiently debride or render harmless all dead, damaged, or infected tissue and to kill all bacteria, viruses and/or other undesirable biological material within the root canal system. Illustrations of a typical root canal system are shown in FIGS. 1A and 1B. The root canal system includes the main root canal 1 and many lateral or accessory canals 3 that branch off of the main canal 1, all of which can contain diseased or dead tissue, bacteria, etc. It is common during root canal procedure to mechanically strip out the main canal nerve, often tearing it away from the lateral canal nerves, much of which can then stay in place in the canal and become the source of later trouble. Thereafter, the main canal 1 is cleaned and extirpated with a tapered file. While it is desirable to extirpate all of the main and accessory canals in a root canal system, some of the lateral canals 3 are very small and extremely difficult to reach in order to remove tissue. Such lateral canals are often perpendicular to the main canal and may bend, twist, and change cross-section as they branch off from the main canal, making them practically inaccessible to extirpation with any known file or other mechanical device. Accordingly, lateral canals are often not properly extirpated or cleaned. Many times no effort is made in this regard, relying instead on chemical destruction and embalming processes to seal off material remaining in these areas. This approach is sometimes a source of catastrophic failure that can lead to loss of the tooth and other problems. Further, when the main canal is extirpated with a tapered file, this action can leave an undesirable smear layer along the main canal which can plug some of the lateral canal openings and cause other problems that trap noxious material against later efforts to chemically disinfect the canal.

Dentists can attempt to chemo-mechanically debride and/or sterilize both main and lateral canals using a sodium

hypochlorite solution or various other medicaments that are left in the root canal system for 30 to 45 minutes a time following primary mechanical extirpation of nerve and pulp tissue. However, this approach does not necessarily completely debride or render harmless all of the lateral root canals and material trapped therein because of the difficulty in cleaning off the smear layer and/or negotiating and fully wetting the solution into some of the smaller twisted lateral canals. As a result, many treatments using this method fail over time due to reoccurring pathology. This often requires retreatment and sometimes loss of the tooth.

Attempts have been made to reduce or eliminate the use of endodontic files and associated drawbacks by using lasers in the performance of root canal therapy. Some of these approaches involve burning away or carbonizing diseased and other tissue, bacteria, and the like within the canal. In these approaches, laser light is said to be directed or focused into or onto the diseased tissue, producing very high temperatures that intensely burn, carbonize, ablate, and destroy the tissue. These ablative treatments using high thermal energy to remove tissue often result in damage to the underlying collagen fibers and dentin of the root 5, even fusing the hydroxyapatite which makes up the dentin. In some cases, such treatments can cause substantial heating of the periodontal material and bone 7 surrounding the tooth, potentially causing necrosis of the bone and surrounding tissue. Additionally, the high temperatures in such treatments can melt the walls of the main canal, often sealing off lateral canals, thereby preventing subsequent treatment of lateral canals. Other attempts to use lasers for root canal therapy have focused laser light to a focal point within fluid disposed within a root canal to boil the fluid. The vaporizing fluid creates bubbles which erode material from the root canal when they implode. Such treatments which must raise the fluid temperature above the latent heat of vaporization significantly elevate the temperature of the fluid which can also melt portions of the main canal and cause thermal damage to the underlying dentin, collagen, and periodontal tissue. The damage caused to the tooth structure by these high energy ablative laser treatments weakens the integrity or strength of the tooth, similar to endodontic treatment utilizing endodontic files.

Therefore, there is a present and continuing need for minimally invasive, biomemetic, dental and medical therapies which remove diseased tissue and bacteria from the main root canal as well as the lateral canals of the root canal system while leaving the biological structures undamaged and substantially intact.

SUMMARY OF INVENTION

In accordance with one embodiment of the present invention, a method is provided for treating a root canal in a tooth containing a crown portion extending to above a gum line and one or more elongate roots integral with and projecting from the crown into the gum and an adjacent jaw bone. Each root has a root canal containing pulp including nerve and other tissue in open communication with a pulp or coronal chamber in the crown. An opening is formed in the crown into the pulp chamber dimensioned to enable working access to a canal of said one or more roots for treatment thereof. Pulp is removed from the pulp chamber to provide an open area therein to gain access to pulp in said canal and, optionally, remove at least part of the pulp from said canal to make an opening in said canal in flow communication with said open area in said pulp chamber. Liquid containing hydroxyl groups is dispensed into at least the open area in the pulp chamber in an amount sufficient to provide a liquid reservoir.

A laser system is provided containing a source of a laser light beam and an elongate optical fiber connected to said source and configured to transmit said laser light beam to a tip portion thereof. The tip may include a tapered tip tapering to an apex with a surrounding conical wall, substantially the entire surface of which is uncovered so that said laser light beam is emitted therefrom generally omnidirectionally. The optical fiber may also contain cladding in the form of a continuous sheath coating extending from the source to a terminus edge

spaced proximally from said apex of said tapered tip toward said source by a distance of from about 2 to about 10 millimeters so that the surface of said optical fiber is uncovered over the entirety of said tapered tip and over any part of a cylindrical outer surface of the fiber between the terminus and the beginning of the tapered end.

The tip of the laser is substantially completely immerse into the liquid reservoir, and pulsing said laser source at a power level of from about 0.1 W to about 1.5 W and at a pulse duration of from about 50 to about 1000 microseconds, at a pulse frequency of from about 2 Hz to about 25 Hz, and for a cycle time of from about 10 to about 40 seconds.

DETAILED DESCRIPTION OF THE DRAWINGS

FIGS. 1a and 1b illustrate a root canal system including a main or primary root canal and lateral and sub-lateral canals that branch off of the main canal. Some of these lateral canals are very small and extremely difficult to reach in order to eliminate any bacteria and/or viruses. Such lateral canals may bend, twist, change cross-section and/or become long and small as they branch off from the main canal, making them very difficult to access or target therapeutically.

FIG. 2 is a Scanning Electron Micrograph (SEM) clearly illustrating internal reticular canal wall surfaces following use of the present invention which, as can be seen, are preserved with no burning, melting, or other alteration of the canal wall structure or loss of its porosity after subtraction of the internal tissue. The surfaces retain high porosity and surface area and are disinfected for subsequent filling and embalming, i.e. using rubber, guttapercha, latex, resin, etc.

FIG. 3 is a graphical illustration of features of a laser fiber tip configured according to a preferred embodiment of the present invention.

FIG. 4 is a graphical illustration of a laser system according to an embodiment of the present invention.

FIG. 5 is a graphical illustration of an applicator tip of a laser system according to an embodiment of the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

A method and apparatus according to a preferred embodiment of the present invention uses a subablative energy source, preferably a pulsing laser, to produce photoacoustic energy waves in solutions dispensed in a root canal to effectively clean the root canal and lateral canals. In the context of this application, the term "subablative" is used to refer to a process or mechanism which does not produce or cause thermal energy-induced destruction of nerve or other native tooth structure, material or tissue, namely, that does not carbonize, burn, or thermally melt any tooth material. The pulsing laser in the inventive configuration of a preferred embodiment induces oscillating photoacoustic energy waves which emanate generally omnidirectionally from adjacent the exposed length of an applicator tip where light energy is caused to exit the surface of optical fiber material in many directions/orientations into adjacent fluid medium from a light energy source maintained at a relatively low power setting of from about 0.1 to no more than about 1.5 watts in order to avoid any ablative effects.

According to one embodiment of the present invention, a tooth is first prepared for treatment in a conventional

manner by drilling a coronal access opening in the crown of the tooth to access the coronal or pulp chamber and associated root canal. This may be performed with a carbide or diamond bur or other standard approaches for preparation of a tooth for root canal treatment known in endodontic practice after which the upper region above the entry of the canal into the chamber is generally emptied of pulp and other tissue. Thereafter, a first solution is slowly dispensed into the chamber, such as by use of a syringe or other appropriate mechanisms, with a small amount seeping and/or injected down into the individual root canals containing the as-yet unremoved nerves and other tissue. The first solution is preferably dispensed in an amount sufficient to fill the chamber to adjacent the top of the chamber. In other embodiments, portions of the nerve and other tissue in the canals may be removed using a broach or other known methods for removing a nerve from a root canal before the first solution is dispensed into the chamber and down into the root canals. In some embodiments, only a single solution may be used, although multiple solutions or mixtures may also be used as explained in more detail below.

The first solution preferably includes a compound containing molecules with at least one hydroxyl functional group and/or other excitable functional groups which are susceptible to excitation by a laser or other energy source in the form of rapidly oscillating photoacoustic waves of energy to assist with destructive subablative disintegration of root canal nerve tissue. It has been observed that certain fluids which do not contain excitable groups, such as xylene, do not appear to produce the desired photoacoustic wave when an energy source has been applied. In one embodiment of the invention, the first solution is a standard dental irrigant mixture, such as a solution of water and ethylenediamine tetraacetic acid (EDTA), containing hydroxyl or other excitable groups. In other embodiments of the invention, the hydroxyl-containing solution may be distilled water alone. In other alternate embodiments, solutions containing fluids other than water may be used, or various pastes, perborates, alcohols, foams, chemistry-based architectures (e.g. nanotubes, hollow spheres) and/or gels or a combination of the like may be used. Additionally, various other additives may be included in the solution. For example, and not by way of limitation, the first solution may include agents energizable by exposure to energy waves propagated through the solution from adjacent the fiber. These include materials selected from the group consisting of hydrogen peroxide, perborates, hypochlorites, or other oxidizing agents and combinations thereof. Additional additives believed to be energizable in the solution include materials selected from the group consisting of reducing agents, silanols, silanating agents, chelating agents, chelating agents coordinated or complexed with metals (such as EDTA-Calcium), anti-oxidants, sources of oxygen, sensitizing agents, catalytic agents, magnetic agents and rapidly expanding chemical, pressure or phase change agents and/or combinations of the like. The solution may also include dispersions or mixtures of particles containing nano- or micro-structures, preferably in the nature of fullerenes, such as nanotubes or bucky balls, or other nanodevices (including micro-sized devices) capable of sensitizing or co-acting with oxygenating, energizable, or activatable components in the solution/mixture, such as oxidative bleaching or other oxygenated agents. Various catalytic agents may be titanium oxide or other similar inorganic agents or metals. The first solution may also include additional effective ingredients such as surfactants or surface active agents to reduce or otherwise modify the surface tension of the solution. Such surface active agents may be used to enhance lubrication between the nerves and other intracanal tissue and the canals wall, as well as antibiotics; stabilizers; antiseptics; anti-virals; germicidals; and polar or nonpolar solvents; and the like. It is especially preferred that all materials used in the system be bio-compatible and FDA and otherwise approved, as necessary, for use in dental procedures. The amounts of any of the foregoing and other additives are generally very small in the order of a few percent by weight or only small fractions of percents. The majority of the solution/mixture is preferably water, preferably sterile triple distilled water for avoidance of undesirable or unaccounted for ionic effects.

An activating energy source is applied to the first solution contained in the coronal pulp chamber. In a preferred

embodiment, the activating energy source is a pulsing laser 10. The laser light energy 16 is delivered using a laser source 12 and an optical light fiber 14 attached at its proximate end to a laser source 12 and having an applicator tip 20 adjacent its distal end. The optical fiber 14 preferably has a diameter of from about 200 microns to about 400 microns. The diameter should be small enough to easily fit into the coronal pulp chamber and, if necessary, into a root canal itself, but large enough to provide sufficient energy via light carried therein to create a photoacoustic effect and to prevent avoidable leakage of light or loss of energy and damage to the tooth or the fiber tip. In a preferred embodiment, the laser source is a solid state laser having a wavelength of from about 700 nm to about 3000 nm, such as NdYAG, ErYAG, HoYag, NdYLF, Ti Sapphire, or ErCrYSGG laser. However, other suitable lasers sources may be used in various embodiments.

An appropriately dimensioned laser applicator tip 20 is preferably placed into the coronal chamber until it is at least fully immersed in the first solution. By "fully immersed" it is meant liquid level is even with the edge of the cladding or other covering on the optical fiber 14. Preferably, the distal most edge of any cladding or covering 18 on the optic fiber 14 adjacent the tip is spaced approximately 2-10 mm from the distal end of the distal end tip or end of the fiber, most preferably about 5 mm therefrom. As a result, up to about 10 mm and most preferably about 5 mm of the distal end of the fiber is uncovered. Preferably, all or substantially all of the length of this uncovered part of the tip end is immersed. If the uncovered part of the applicator tip is not fully immersed, sufficient energy may not be transferred to the fluid since light will be permitted to escape to the environ above the liquid surface. Accordingly, it is believed that spacing the distal-most or outermost end edge of the cladding more than about 10 mm should be avoided, as that can diminish the effectiveness of the system. In some applications, it may be necessary to provide a dam and reservoir around and above the opening in the tooth in order to increase the volume and level of fluid available for immersion of the uncovered area of the end of the fiber. The larger liquid volume and deeper immersion of the uncovered area of the tip end is believed to enable application of sufficient energy levels to produce the desired photoacoustic wave intensity in such instances. Such instances may include, for example, smaller teeth such as upper/lower centrals or teeth that are fractured off. In certain applications where a dam or reservoir is used it may be desirable to use a laser tip with more than 10 mm of space between the tip end and the cladding due to the larger volume of fluid.

It is a feature of the invention in a preferred embodiment that the distal-most end of the applicator tip be tapered to and end point, i.e. that the distal end have a "tapered tip" 22. Most preferably, the tapered tip has an included taper angle of from about 25 to about 40 degrees. The applicator tip 20 is therefore preferably not a focusing lens configured to concentrate light to a point in space away from the tip end. Such a configuration is believed to cause an ablative effect due to the high thermal energy created by the laser light focused to a point. Rather, the taper angle of the tapered fiber tip 22 and rearward spacing of the end of the cladding from the tip end in accordance with preferred embodiments of the invention are believed to enable a relatively wide dispersion of the laser energy for emission from a relatively large surface area of the tip all the way back to the edge of the cladding, not merely from the end of the laser fiber. An objective is to emit laser light generally omnidirectionally from the sides 24 and from the tapered area of the tapered tip 22, and consequently, to produce a larger or more omnidirectional photoacoustic wave propagating into surrounding liquid and adjacent material from substantially the entire exposed surface of the fiber optic quartz material. Among other things, this avoids and preferably eliminates any ablative effects associated with higher levels of focused or refracted radiant laser energy. The tip design in accordance with the invention is selected to provide a magnitude and direction of the photoacoustic wave in the surrounding fluid medium that exhibits a relatively sharp or high rise time at the leading edge of each pulse and which propagates through the fluid generally omnidirectionally from the exposed area of the end of the fiber. Accordingly, a tapered tip according to the invention has the effect of dispersing the laser

energy over the larger uncovered cone surface area and the rearwardly extending cylindrical wall surface (compared to a two dimensional generally flat circular surface area of a standard tip), thereby creating a much larger area through which the leading edges of the successive photoacoustic waves can propagate. In some embodiments, the exposed area of the fiber adjacent the tip end may include a texturing, such as frosting or etching, to increase the surface area and angular diversity of light emission for an even more comprehensive coverage of the photoacoustic wave energy within the solution and adjacent tissue.

When applying the laser to the first solution, applicants have discovered that it may be important to apply the laser energy to the solution so as to limit the creation of thermal energy. In the present invention, after the applicator tip is immersed in the first solution, laser energy is preferably applied to the first solution using subablative threshold settings, thereby avoiding any thermal-induced carbonization, melting, or other effects caused by a temperature rise above about 5 degree. C. in the dentin walls of the canal, apical portions of the tooth, or surrounding bone or tissue caused by the generation of significant thermal energy in the canal area or wall due to the ablative power settings used in prior attempts to perform root canal therapy with lasers. The practice of the present invention in accordance with its preferred embodiments causes an observable temperature rise in the solution of no more than a few degrees Centigrade and, as a result, no more than a few degrees Centigrade elevation, if any, of the dentin wall and other adjacent tooth structure and tissue. This is far below the standard constraint of avoiding any exposure of such material and tissue to more than 5 degree. C. increase in temperature for any significant period of time to avoid permanent damage in the same.

The inventors have found that relatively low power settings of from about 0.1 watt to about 1.5 watt and with a laser pulse duration of from about 100 nanoseconds to about 1000 microseconds, with a pulse length of about 50 microseconds most preferred, produces the desired photoacoustic effect without heating the fluid or surrounding tissue to produce any ablative or other thermal effect within or adjacent the root canal. A frequency of from about 5 to 25 Hz is preferred and a frequency of about 15 Hz is believed to provide optimal potentiation of harmonic oscillation of pressure waves in the fluid medium to disintegrate nerve and other tissue within the canal.

The particular preferred power level found to produce the ideal photoacoustic wave has a relationship to the approximate root volume of a particular tooth. The following chart (Table 1) shows what are believe to be preferred ranges of power levels for treatment of root canals in different types and sizes of teeth in accordance with the invention.

TABLE-US-00001 TABLE 1 Preferred Power Levels for Various Tooth Types Approx. Average Range of Preferred Tooth Type Root Volume (.mu.L) Power Levels (watts) Molar 177 0.5 to 1.5 Pre Molar 88 0.5 to 1.0 Cuspid 67 0.5 to 0.75 Laterals 28 0.25 to 0.5 Centrals 28 0.25 to 0.5 Lower Centrals 28 0.1 to 0.25

When the laser is immersed in the first solution, the laser is pulsed for a time preferably ranging from about 10 seconds to about 40 seconds, most preferably about 20 seconds. If the laser is pulsed for longer than about 40 seconds, excessive thermal energy can begin to develop in the fluid, potentially leading to deleterious heating effects in and around the tooth as described above. It has been found rather surprisingly that pulsing under the parameters of the invention causes a measurable temperature rise in the fluid medium of no more than a few degrees Celsius, if any, while still utterly destroying and/or disintegrating all nerve, pulp, and other tissue within the canal that also is observed to hydraulically self-eject from the canal during pulsing.

After the laser has been pulsed in the first solution, the first solution is allowed to stabilize and then laser pulsing treatment may be repeated again in the same or a different solution. In certain embodiments, the solution may be removed between repetitions of pulsing cycles of the laser to remove debris more gradually and to avoid any development or transfer of heat energy into the dentin surrounding wall or other adjacent structure. The coronal chamber and canal may be irrigated with a standard dental irrigant and solution may then be reinserted into the coronal chamber to perform an additional laser pulsing treatment. While any number of pulsing phases or cycles can be repeated, it is believed that a fully effective removal of all material within the canal can be achieved in less than about seven cycles.

To assist dentists in performing root canal treatments according to the present invention, a photoacoustic activity index has been developed which provides relationships between the various parameters, machine setting, and the like which have been found to be important in the practice of the inventive procedure. Factors which appear important in the practice of the invention include the power level, laser pulse frequency, the pulse duration, the proportion of average excitable functional groups per molecule in the first solution, the diameter of the laser optical fiber, the number of pulsing cycles repeated in completing an extirpation procedure, the duration of each cycle, the viscosity of the first solution, and the distance between the tip and the end of the cladding. Coefficients have been determined which relate deviations of certain of the above factors from what is believed to be the ideal or the most preferred factor value. Tables of these coefficients are shown below:

TABLE-US-00002 Preferred Range Power Density Approx. Average of Power Levels Coefficient Tooth Type Root Volume (uL) (watts) (DPD) Molar 177 0.5 to 1.5 1 Pre Molar 88 0.5 to 1.0 1 Cuspid 67 0.5 to 0.75 1 Laterals 28 0.25 to 0.5 1 Centrals 28 0.25 to 0.5 1 Lower Centrals 28 0.1 to 0.25 1

TABLE-US-00003 Frequency Pulses per Second Coefficient C(fq) (Value in HZ) 0.4 2 HZ 0.6 5 HZ 0.9 10 HZ 1 15 HZ 0.5 20 HZ 0.2 25 HZ

TABLE-US-00004 Pulse Duration Pulse Duration Coefficient C(pw) Value in micro sec (.mu.s) 1 <50 0.9 50 0.7 100 0.3 150 0.2 200 0.1 1000

TABLE-US-00005 Average quantity of Hydroxyl excitable groups Coefficient C(hy) per fluid molecule 1 >2 0.9 2 0.7 1 0.5 Part or Mixture 0 none

TABLE-US-00006 Fiber Diameter Fiber Diameter Coefficient C(fd) Value in microns 0.8 >400 1 400 0.8 320 0.5 200 0.3 <200

TABLE-US-00007 Repetition Cycle Repetition Cycles Coefficient C(rp) (repetitions) 0.3 >7 0.5 6 0.7 5 1 4 0.9 3 0.6 2 0.3 1

TABLE-US-00008 Cycle Duration Cycle Duration Coefficient C(sa) (Value in seconds) 0.2 >40 0.6 40 0.9 30 1 20 0.5 10 0.2 <10

TABLE-US-00009 Viscosity Fluid Viscosity Coefficient C(vs) (Centipoise) 1 <1 0.9 1 0.1 >500 0.05 >1000

TABLE-US-00010 Cladding Distance Between Terminus Separation Length of Cladding and Apex of Coefficient C(sl) Tip Value in millimeters (mm) 0.4 2 0.6 3 0.9 4 1 5 0.9 >5 0.3 >10

A practitioner may input coefficients from the above tables correlating to equipment, setting, and material parameters into the following equation: Photoacoustic Activity Index ("PA"

Index)=DPD.times.C(fq).times.C(pw).times.C(hy).times.C(fd).times.C(rp).ti- mes.C(sa).times.C(vs).times.C(sl) If the resulting PA Index value is greater than about 0.1, more preferably above about 0.3, then the equipment and materials may generally be acceptable to produce an effective photoacoustic wave for disintegration and substantially complete and facile removal of all root canal nerve, pulp, and other tissue from within the canal. If the PA Index is below about 0.1, it may indicate a need to modify one's equipment setup, setting, and method parameters in order to more closely approach the desired PA index of 1 or unity.

Using the invention parameters and procedures, root canal tissue and other material to be removed or destroyed is not believed to be removed or destroyed via thermal vaporization, carbonization, or other thermal effect due primarily to exposure to high temperatures, but rather through a photoacoustic streaming of and other activities within liquids in the canal which are laser activated via photon initiated photoacoustic streaming (PIPS). A photoacoustic wave with a relatively high leading edge is generated when the laser light transitions from the exposed surface of the fiber optic material into the solution. The laser light is believed to create very rapid and relatively intense oscillations of waves through the solution emanating from the interface of the exposed surface of the fiber optic and the surrounding liquid. The rapid, intense microfluctuations in the light energy emitted is believed to cause rapid excitation and/or expansion and de-excitation and/or expansion of hydroxyl-containing molecules adjacent the exposed surface of the fiber generating, among other things, photoacoustic waves of energy which propagates through and into the root canal system and oscillates within the system. These intense photoacoustic waves are believed to provide substantial vibrational energy, which expedites the breaking loose of and/or cell lysis and other effects to bring about a rapid and facile degradation/disintegration of substantially all tissue in the root canal and lateral canal systems immersed in the solution. The pulsing photoacoustic energy waves in combination with the chemistry of the fluid also is believed to cause intense physically disruptive cycling of expanding and contracting of nerve and other tissue which porositizes, expands, and ultimately disintegrates the nerve and other tissue in the canal without any significant thermally induced carbonization or other thermal effects of the same so that the resulting solution/mixture containing nerve and other tissue remains is observed to be self-ejected or basically "pumped" by a hydraulic effect out of the canal.

The photoacoustic effect creates energy waves that propagate throughout the fluid media in the main root canal and into the lateral canals, thereby cleaning the entire root system. The use of a substantially incompressible fluid medium causes the waves produced by the photoacoustic effect to be instantly transmitted through the lateral canals. Also, since the canals are tapered in a concave fashion, the photoacoustic wave is believed to be amplified as it transverses toward the end of the lateral canals for further intensification of the destruction towards apical or cul de sac areas.

In certain embodiments of the invention, a second dissolution solution may be added to the canal after treatment with the energy source/first solution. This dissolution solution chemically dissolves and/or disintegrates any remaining nerve structure or other debris that may remain in the main canal or in any lateral canals. Preferred dissolution solutions include hypochlorite, sodium hypochlorite, perborate, calcium hydroxide, acetic acid/lubricant/doxycycline and other like nerve tissue or matrix dissolving substances such as chelating agents (EDTA) and inorganic agents such as titanium oxides.

Finally, after desired tissue has been removed from the tooth interior, the canal may be irrigated to remove any

remaining debris and remaining solution, and then obturated with a material of choice, such as gutta percha, root canal resin, etc., according to standard practices in the industry.

Qualitative experimentation was performed placing a fluid into a Dampen dish located on a Formica surface. The laser applicator tip was placed into the fluid and fired repetitively. The photoacoustic wave vibrated the Dampen dish on the Formica surface making an audible sound. For a specific tip this audible sound increased with an increasing power level of the laser. This was verified by placing a sound level meter one inch away from the Dampen dish and recording the dB level. This implies that the power level is proportional to the amplitude of the photoacoustic wave. Next, the laser power level was held constant and the tip was changed. The tapered tip and a tip with a stripped sheath produced a greater photoacoustic wave than the standard flat tip. A tapered, stripped tip was then frosted or etched. This tip was tested and showed a greater photoacoustic wave generated than the non-frosted version. This was verified to be true at three different power levels. It would appear that since the power level was held constant, the photoacoustic wave amplitude would also be proportional to the exposed area and the surface treatment.

In a quantitative investigation of the applicator tip a MEMS Pressure sensor was utilized to measure the photoacoustic wave amplitude. This testing has shown a dramatic increase in the photoacoustic wave propagation caused by changes in the geometry and texturing of the tip. The inventors have also discovered that stripping of the cladding from the end of the applicator tip results in increases in the photoacoustic wave effect. In this regard, a small plastic vial was fitted with a fluid connection that was close coupled hydraulically to a miniature MEMS piezo-resistive pressure sensor (Honeywell Model 24PCCFA6D). The sensor output was run through a differential amplifier and coupled to a digital Oscilloscope (Tektronics Model TDS 220). The vial and sensor were filled with water. Laser tips having varying applicator tip configurations were fully submerged below the fluid level in the vial and fired at a frequency of 10 HZ. The magnitude of the photoacoustic pressure waves was recorded by the pressure sensor.

A 170% increase in pressure measured from generation of the photoacoustic waves was observed for the tapered tip versus the standard blunt-ended tip. A 580% increase in pressure measured from generation of the photoacoustic wave was observed for textured (frosted) tapered tips versus the standard blunt-ended tip. Rather than emitting in a substantially linear direction, the frosting disperses the light omnidirectionally causing excitation and expansion of more fluid molecules.

An increase in photoacoustic wave generation was seen by stripping the polyamide sheath away from about 2 mm to about 10 mm from the tapered end. Although laser light is coherent and typically travels substantially in a straight line, some light bounces off of the polyamide sheath at an angle. As this light travels down the light path it continues bouncing off of the inside of the polyamide sheath and will eventually exit at an angle to the sheath once the sheath stops and exposes a non sheathed section. Therefore, some of the laser light would also exit where the polyamide sheath has been removed, upstream of the tapered tip end. A tip with the sheath removed for 2 to 10 mm directly upstream of the tapered section was placed in the above-mentioned test set up and showed markedly better production of photoacoustic waves.

In various other embodiments of the invention, energy sources other than lasers may be used to produce the photoacoustic waves including, but not limited to, other sources of light energy, sonic, ultrasonic, photo-acoustic, thermo-acoustic, micromechanical stirring, magnetic fields, electric fields, radio-frequency, and other exciter mechanisms or other similar forms that can impart energy to a solution. Some of these sources penetrate the

tooth structure externally. Additional subablative energy sources may be used to create other types of pressure waves in a solution, such as chemoacoustic waves (shock waves created by rapid chemical expansion creating shock and pressure waves). Such waves can be created for example by loading the nanoparticles with a chemical that expands rapidly upon excitation, coating nanoparticles with a hard shell (e.g. polyvinyl alcohol), and activating the chemistry with an energy source such as optical, ultrasonic, radio-frequency, etc. As the activating chemical expands, pressure builds up in the hard shell, when the shell bursts it creates a shock wave that can propagate throughout the fluid similar to a photoacoustic wave. Additionally, a photoacoustic wave can be the activating energy source for producing the chemoacoustic wave.

Further, the present invention may be used for various procedures other than root canal treatment, such as for treatment of dental caries, cavities or tooth decay. Additionally, the present invention may be usable for treatments of bone and other highly networked material where infection is problematic, e.g. dental implants, bone infection, periodontal disease, vascular clotting, organ stones, scar tissues, etc. Adding a tube structure around the tip which might be perforated and will allow introduction of a fluid around the tip that will allow the photoacoustic waves to be directed into more difficult areas that do not contain fluid volume such as periodontal and gum tissue. This would be considered a type of photoacoustic transmission tube. This application process may also be used in other soft tissue applications where it is necessary to expand the diseased tissue or material to allow more rapid access and penetration to healing agents, chemicals or biologicals; i.e. antibiotics, peptides, proteins, enzymes, catalysts, genetics (DNA, mRNA or RNA or derivatives) or antibody based therapeutics or combinations thereof. In some cases, the present methodology may be used to rapidly dissolve or destroy diseased tissue areas. Additionally, the present invention may be used to expand diseased tissue in an abscess, allowing for extremely rapid and efficient penetration of healing or biological agents. The porosity created in the tissue by photoacoustic waves may allow for rapid infusion with the subsequent chemical species that can impose destruction, healing or cleaning or a combination of these events. The speed of this healing action may allow medical procedures that currently are not viable because of extensive time required for standard healing processes, i.e., sometimes adjacent tissue is infected because the original infection cannot be controlled more rapidly than the infection propagates. In this case, expanding the diseased tissue to enhance porosity may allow near instantaneous access for the medication, e.g., antibiotic or other agents.

Furthermore, the present invention may be applied to begin, construct or stage the activation of cells and/or tissues, including the area of transplantation and use in stem or primordial cells accentuation, their attachment and/or stimulation for growth and differentiation. The present invention is also believed to be usable to activate cells, e.g., progenitor, primordial or stem cells, to promote inherent nascent bone or tissue growth and differentiation, as well as in transplantation where stem or primordial cells are accentuated in their attachment and stimulated for growth and differentiation.

In one of the alternate embodiments of this invention, nanotubes or other micro-structures can be moved around in a therapeutic fluid by applying a magnetic field. An alternating or pulsed magnetic field could impart significant motion and stirring of the therapeutic fluid. Since the field would penetrate the entire tooth, the stirring action would also occur throughout the lateral or accessory canal system. These moving micro-particles would also act as an abrasive on any bacteria, virus, nerve material, or debris within the canal system. The effect would be a more thorough circulation of the fluid throughout the canal system to provide superior cleaning and debridement of the canal system. Magnetic material can also be inserted into, adsorbed onto, or absorbed into the nanotube or other microstructure increasing its magnetic moment.

TiO.sub.2 or other similar compounds can be activated and made bactericidal by exposing them to UV light or by inserting them in an electric field. Once excited these can destroy bacteria and other organic compounds such as remaining nerve tissue. Such compounds can be part of a therapeutic and can be activated by a UV light source pointed toward the therapeutic fluid, a UV source dipped into the fluid, or a UV laser source. These TiO.sub.2 or other similar compounds can also be activated by an alternating or pulsed electric field. One means to supply such an electric field could be by an external device that would bridge the tooth. Since the field propagates throughout the entire tooth it would also react TiO.sub.2 or other similar compounds within the accessory or lateral canals. This action could also be combined with the micro-particle based motion action mentioned above. This combination would more thoroughly clean and debride the canals. Since electric fields are generated externally and penetrate the entire root structure they could be used several months or on a yearly basis after the tooth is sealed to reactivate the titanium oxide and its bactericidal properties.

The foregoing description of preferred embodiments for this disclosure has been presented for purposes of illustration and description. The disclosure is not intended to be exhaustive or to limit the various embodiments to the precise form disclosed. Other modifications or variations are possible in light of the above teachings. The embodiments are chosen and described in an effort to provide the best illustrations of the principles of the underlying concepts and their practical application, and to thereby enable one of ordinary skill in the art to utilize the various embodiments with various modifications as are suited to the particular use contemplated. All such modifications and variations are within the scope of the disclosure as determined by the appended claims when interpreted in accordance with the breadth to which they are fairly, legally, and equitably entitled.

