Pulsed Nd:YAG laser selective ablation of surface enamel caries: II. Histology and clinical trials.

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ABSTRACT

High intensity infrared light from the pulsed Nd:YAG dental laser is absorbed by pigmented carious enamel and not absorbed by normal enamel. Therefore, this system is capable of selective removal of surface enamel caries. Safety and efficacy of the clinical procedure was evaluated in two sets of clinical trials at three dental schools. Carious lesions were randomized to drill or laser treatment. Pulp vitality, surface condition, preparations and restorations were evaluated by blinded evaluators. In Study 1 surface caries were removed from 104 third molars scheduled for extraction. One week post-treatment teeth were extracted and the pulp was examined histologically. In Study 2 90 patients with 422 lesions on 376 teeth were randomized to laser or drill and followed for six months. There were no adverse events and both clinical and histological evaluations of pulp vitality showed no abnormalities. Caries were removed in all conditions. A significantly greater number of preparations in the drill groups vs. laser groups entered dentin (drill = 11, laser = 1, $p < 0.001$). This indicates that the more conservative laser treatment removed the caries but not the sound enamel below the lesion.

Keywords: Enamel caries, pulsed Nd:YAG laser, Er:YAG laser, histology, clinical trials, selective ablation,

1. INTRODUCTION

> *In the treatment of dental caries, complete removal of infected [tissue] is indispensable.*[1] *(Hosoda, 1984)*

> *Successful restorative dentistry in the future lies in the utilization of techniques and materials that allow us to do as little damage as possible during procedures made necessary by dental caries. ... The primary goal of restorative dentistry should be to seek out the most conservative approach possible in any restorative procedure.*[2] *(Simonsen, 1985).*

Dental caries refers to resorption or destruction of the calcified structure of the tooth, caused by bacterial action. The consequence of bacterial growth is proteolysis of the organic framework of the enamel by bacterial enzymes and acid decalcification of the enamel rods. A brown pigmentation appears in early lesions, mainly the result of pigmented bacteria associated with caries.

Current thinking in restorative dentistry advocates that all carious tissue should be removed from enamel. Unarguably, conservative dentistry mandates minimizing removal of sound enamel. Therefore, a technique for the selective removal of dental caries that conserves healthy tissue is indicated.

The use of the dental laser presents a new method for caries treatment. Selective ablation of surface enamel caries with laser

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energy has a potential that is not possible with the high-speed handpiece. Selective ablation of caries has been demonstrateded in extracted teeth with the argon fluoride laser,[3] 2nd harmonic alexandrite,[4] frequency tripled Nd:YAG,[5] pulsed Er:YAG[6] and clinically for the pulsed Nd:YAG.[7-10]

The low absorption of normal human enamel for the 1064 nm wavelength of the Nd:YAG causes high scattering and reflection and high ablation thresholds. At this wavelength dental caries has greater absorption and consequently lower ablation thresholds than normal enamel. This is an advantage for use of the pulsed Nd:YAG laser for caries removal since it provides a window of laser parameters that will remove carious enamel, leaving normal enamel intact.[5]

A side effect of both the laser and the dental drill is the production of heat that is conducted through enamel and dentin, potentially causing damage to the dental pulp. With pulsed laser energy (≈150μsec duration pulses) the target tissue is ablated before heat has time to be conducted to the pulp tissue. If the repetition rate is low (10-20 Hz), then the tissue has time to cool between pulses. Therefore, pulsing the laser beam can aid in avoiding thermal damage to the pulp.

We describe two clinical studies conducted under FDA regulations to evaluate the safety and efficacy of caries removal with the free running pulsed Nd:YAG dental laser. In Study 1 *in vivo* treatment of third molar caries was followed by extraction to evaluate pulp histology. Study 2 represents randomized, multicenter clinical trials. Both studies were conducted at Baylor College of Dentistry, The University of California at San Francisco, School of Dentistry and the University of the Pacific School of Dentistry.

2. METHODS

2.1 Clinical trials protocol and histologic evaluation of extracted third molars (Study 1).

2.1.1 Inclusion / exclusion criteria

Patients requiring third molar extraction whose teeth had pit and fissure caries located on occlusal or buccal surfaces, above the enamel-cementum junction were included in the study. The teeth were symptom free, fully developed and completely erupted. Non-carious, healthy, normal appearing teeth were used as controls for pulp vitality determinations. Teeth with radiographic evidence of periapical pathosis, incompletely formed roots, previous restorations, evidence of periodontitis or pulpitis, or clinical evidence of caries which had penetrated into dentin were excluded from the study.

2.1.2 Pulp vitality

Pulp condition was evaluated before and after treatment and at one week post-treatment when teeth were scheduled for extraction. A blinded, independent clinician reviewed the data and provide a pulpal diagnosis based on thermal and electrical pulp testing and radiographic appearance (Seltzer, 1975).

Prior to treatment the test teeth were isolated with cotton rolls, dried with sterile gauze and pulp tested. Thermal testing consisted of placement of an ice stick (0^{o}C) on the facial surface of the tooth for five seconds. No response or a response by the patient when the ice stick was removed was considered normal. Vitality was confirmed with an electrical pulp tester probe placed on the facial surface. A small current was passed through the tooth. Patients released a handheld button when a sensation was felt and a digital display recorded the level where the patient responded (0-80). Since the teeth were asymptomatic with absense of caries (control) or caries limited to enamel, a response at any level at 70 or below was considered normal.

2.1.3 Treatment groups

Prior to treatment patients were randomized to receive either laser or drill treatment. In the laser group a PulseMaster Dental Laser (American Dental Technologies, Southfield, MI) was used for treatments. The laser was set to deliver 100 mJ pulses at a repetition rate of 20 Hz, yielding an average power of 2.0 Watts. In the drill group the caries was removed with a 1/2 round carbide crosscut fissure (701) or pear-shaped (330) bur in a high-speed handpiece. Anesthesia was not used during either treatment unless requested by the patient

2.1.4 Clinical evaluations

After caries removal the treated surface was acid etched with orthophoshate acid. Prior to restoration teeth were evaluated for the following:

(1) Caries removal: Incomplete or complete removal of 1st degree caries.
(2) Enamel condition: Presence of cracking and/or fissures, surface debris and discoloration were noted.
(3) Preparation evaluation: Evaluation of the outline form, axial wall, cavosurface margin, retention, and overall preparation were rated according to the following scale:
    E = Acceptable, within criteria
    S = Acceptable, some deviation from criteria
    U = Major deviation from criteria, but correctable
    I = Not correctable
(4) Acid Etch Evaluation: Evaluation of acid etch per manufacturer recommendations as follows:
    E = Uniform frosty white
    U = Patchy or incomplete frosty white - re-etch to correct.
    I = Cannot achieve complete etch over surface of preparation

Preparations were restored with a hybrid resin (TPH) and the restoration evaluated.

(5) Restoration Evaluation - Surface, margin, retention, and whether the restoration is intact and serviceable at the follow-up using the above rating scale.

2.1.5 Histologic evaluation

After extraction, the apical 1/3 of each root was removed with a high speed handpiece with air/water coolant and the tooth placed in 10% formalin for fixation. Teeth were removed from formalin after three days and decalcified in 10% EDTA for two weeks, then dried and embedded in paraffin. Six micrometer sections were taken through the pulp chambers and stained with hematoxylin and eosin.

Two evaluators, blinded to the treatment condition, examined the slides at 250X. The condition of the pulp of each tooth was scored as follows:

0 = Normal pulpal tissue.
1 = Disruption of Odontoblastic layer with vasodilation.
2 = Superficial soft tissue involvement confined to cell-free zone and odontoblastic layer, evidence of polymorphonucleocytes (PMN).
3 = Deeper involvement past the odontoblastic layer into the central pulp.
4 = Pulp necrosis including the partial absence of the odontoblastic layer.
5 = Complete pulp necrosis.

2.2 Clinical trials protocol (Study 2)

The same criteria, design, techniques and investigators that were used in Study 1 were repeated in Study 2. However, teeth were not extracted, consequently, histology was not evaluated, and all teeth with surface caries were eligible for inclusion. As before, sites were discrete and independent of any previous restoration. Clinical evaluations were made prior to treatment, immediately following treatment, and at one week, one month, three month, and six month post-treatment follow-ups.

2.3 Methods of analysis

In Study 1, the laser or the drill was randomized within patients who had at least two affected teeth. Study 2 randomized patients to treatments, with the same treatment applied to all teeth within a patient. To compare results from these two studies, the tooth or site was used as the unit of analysis.

Age was compared between treatments using a two way analysis of variance, with the factors, center and treatment. Gender was compared between treatments using a Mantel-Haenszel summary chi-square test summed over centers; however the randomization was stratified on gender and no differences were expected. The treatment site was used as the primary unit of analysis. In most cases the treatment site was the tooth, but occasionally there were two or more distinct sites on a tooth which were treated and evaluated separately. Significance was determined using descriptive statistics summarized over the number of sites treated. For symptoms, thermal and electrical evaluations, and the pulp diagnosis, the tooth was used as the unit of analysis.

Proportions of patients with the preparation extending into the dentin were compared using Fisher's exact test.

Due to differences between centers in categorization of enamel condition, Fisher's exact test was used to compare the incidence of each between the drill and laser treatments by center. Restoration surface, margin, retention, and intact / serviceable evaluations were tabulated and compared using Mantel-Haenszel summary chi-square tests.

Electrical threshold and thermal stimulus data were converted to a response or no response value and compared between laser and drill using Mantel-Haenszel summary chi-square statistics, although most teeth recorded responses. Pulp diagnoses were compared similarly.

All other variables exhibited little or no variation from normal results, and were not statistically compared among treatments or centers.

3. RESULTS

3.1 Demographics, sample size: Study 1

In Study 1 one hundred and four third molars in thirty-one patients at three study centers were evaluated. Forty-three teeth were treated with the laser, thirty were treated with the drill, and thirty-one teeth were evaluated as controls.

Center	Baylor	UCSF	UOP	TOTAL
Patients				
Males	4	9	1	14
Females	6	5	6	17
Total	10	14	7	31
Teeth	C D L	C D L	C D L	C D L
	7 8 18	17 14 14	7 8 11	31 30 43

Table 1. Demographic summary: Study 1. C = control, D = drill, L = laser.

Table 1 summarizes the demographics of the patients plus the number of teeth treated or evaluated by center and treatment type. Significant differences among centers in ages were noted, ranging from a mean of 25 years at UCSF to a mean of 28 years at Baylor and a mean of 31 years at UOP. At UCSF more females than males were studied, while at the other two centers, males were more predominant.

Teeth were treated with 100 mJ pulses at a repitition rate of 20 Hz (2 Watts average power). The number of pulses ranged from 30 to 3737 with a mean of 930 and a median of 789 pulses. This represents 3 to 374 Joules of total energy, with an average of 80-90 Joules per treatment site.

3.2 Histology results.

The histological sections showed mild increased vascularity in three laser treated teeth, one drill treated tooth and one control tooth. Neither treatment caused a significant change in the architecture and morphology of the pulp. All other teeth were rated 0 (normal pulp). Differences among groups were not significant.

3.3 Clinical results.

3.3.1 Demographics, sample size: Study 2

Table 2 summarizes demographics of the patients and treatment sites from Study 2. No significant differences in ages or gender among centers or between treatment groups were noted. Table 2 also presents the number sites treated by center and by treatment. This includes only sites meeting study criteria. Some teeth had more than one discrete site. The laser was used to treat 215 sites on 190 teeth, while the drill was used for 207 sites on 186 teeth.

Center	Baylor	UCSF	UOP	TOTAL
Patients				
Males	6	19	11	36
Females	16	26	12	54
Total	32	45	23	90
Sites	D L	D L	D L	D L
	48 69	69 87	90 59	207 215

Table 2. Demographic summary: Study 2. C = control, D = drill, L = laser.

Pulp vitality, enamel condition, preparation and restoration evaluations from Study 1 and Study 2 were combined for analysis up to 1 week post-treatment. In all, 526 carious lesions in 121 patients were included. The laser was used on 258 sites, the drill was used on 237 sites and 31 teeth were evaluated as controls.

Follow up was completed on all patients at all times except for three patients. One patient missed the one week and one month evaluations, but was evaluated at three and six months. One patient missed the one week and three month evaluation, but was evaluated at one and six months. One other patient moved before the six month evaluation.

3.3.2 Safety - pulp vitality

All treated teeth remained asymptomatic through the evaluation period of Study 1. Only one event was reported, consisting of sensitivity to the laser in Study 1. It started at the beginning of laser treatment and lasted 30 seconds. This was considered to be related to general anxiety of the patient and not related to the treatment.

In Study 2, four drill-treated teeth became symptomatic (two to biting and one to cold) at one week post-treatment. One laser-treated tooth became symptomatic to biting at one week. A subsequent appointments the teeth had become asymptomatic.

All pulp evaluations for the controls and laser treated teeth were healthy (Table 3). At one week, one drill treated tooth in each study was diagnosed with reversible pulpitis. The Study 2 tooth was healthy at later evaluations and the Study I tooth had normal histology following extraction.

3.3.3 Efficacy - caries removed / caries into dentin

Enamel caries was removed completely for all laser and drill-treated teeth. In eleven drill-treated teeth and in only one laser-treated tooth the preparation penetrated into the dentin (Table 4). Results summed over both studies demonstrated a significant difference between laser and drill groups ($p < 0.004$).

All of these sites were then diagnosed as second degree caries and the preparation was completed with the drill. These teeth are not included in the summary analyses, although they were evaluated at all follow-up examinations.

		STUDY 1 extracted			STUDY 2 clinical trials			TOTAL		
One week		C	D	L	C	D	L	C	D	L
Baylor	H	7	8	18	22	48	69	29	56	87
	R	0	0	0	0	0	0	0	0	0
	I	0	0	0	0	0	0	0	0	0
UCSF	H	17	13	14	43	49	61	60	62	75
	R	0	1	0	0	1	0	0	2	0
	I	0	0	0	0	0	0	0	0	0
UOP	H	0	8	11	23	86	57	23	94	68
	R	0	0	0	0	0	0	0	0	0
	I	0	0	0	0	0	0	0	0	0
Total	H	24	29	43	88	183	187	112	212	230
	R	0	1	0	0	1	0	0	2	0
	I	0	0	0	0	0	0	0	0	0

1-6 Months		C	D	L	C	D	L	C	D	L
Baylor	H	---	---	---	22	48	69	22	48	69
	R	---	---	---	0	0	0	0	0	0
	I	---	---	---	0	0	0	0	0	0
UCSF	H	---	---	---	44	52	64	44	52	64
	R	---	---	---	0	0	0	0	0	0
	I	---	---	---	0	0	0	0	0	0
UOP	H	---	---	---	23	86	57	23	86	57
	R	---	---	---	0	0	0	0	0	0
	I	---	---	---	0	0	0	0	0	0
Total	H	---	---	---	89	186	190	89	186	190
	R	---	---	---	0	0	0	0	0	0
	I	---	---	---	0	0	0	0	0	0

TABLE 3. Pulp vitality / pulp diagnosis. C=Control, D=Drill, L=Laser, H=Healthy, R=Reversible pulpitis, I =Irreversible pulpitis

3.3.4 Post-treatment enamel evaluation

Table 5 presents a summary of the immediate post treatment enamel evaluation. One drill treated tooth in Study 1 had cracking. In Study 2, one laser treated tooth was initially reported to have cracking, but on further examination it was determined that the appearance was due to debris in the fissure (laser vs. drill, not significant: $p = 0.82$). Significant differences between laser and drill groups were obtained for remaining surface debris ($p < 0.001$) and discoloration ($p < 0.001$), which were much more prevalent in the laser group. The surface debris was removed by acid etch and any remaining discoloration was covered by the restoration.

3.3.5 Post-treatment preparation evaluation

The post treatment preparation evaluations were acceptable. However, in Study 2 at one center eight teeth in the first three patients randomized to the laser treatment lost the restorations at one week follow-ups. Procedural problems with the

restorative material were identified as the cause. One laser treated patient (3 sites) at another center also lost restorations. This patient had extremely poor dental hygiene and oral habits.

		STUDY 1		STUDY 2		TOTAL	
Caries into dentin		DRILL	LASER	DRILL	LASER	DRILL	LASER
Baylor	**NO**	**8**	**18**	**48**	**69**	**56**	**87**
	*** YES**	**0**	**0**	**0**	**0**	**0**	**0**
UCSF	**NO**	**14**	**14**	**69**	**87**	**83**	**101**
	*** YES**	**0**	**0**	**10**	**1**	**10**	**1**
UOP	**NO**	**7**	**11**	**90**	**59**	**97**	**70**
	*** YES**	**1**	**0**	**0**	**0**	**1**	**0**
Total	**NO**	**29**	**43**	**207**	**215**	**236**	**258**
	*** YES**	**1**	**0**	**10**	**1**	****11**	****1**

TABLE 4. Preparation penetrates into dentin. * According to protocol these sites were removed from the study. ** p < 0.004

4. DISCUSSION

4.1 Safety

Results from the evaluation of safety from these clinical trials were unremarkable. There was no abnormal histology and no loss of pulp vitality in either the laser or the drill groups. Thus, there were no unusual safety considerations and it is unlikely that the pulps suffered thermal damage as a result of laser treatment.

The safety of the laser procedure is consistent with previous reports. White, Goodis, and Daniels[11] studied the pulpal response, evaluated histologically, to pulsed Nd:YAG laser exposures on freshly extracted human third molars. Care was taken to ensure that specimens retained vital pulp tissues. Even with 100 mJ pulses at 20 Hz for 2 minutes (240 J total exposure, maximum used in the study) there was no observed pulpal disruption. Maximum exposure in the present study was 373 Joules.

It should be noted that following pulp vitality testing one drill treated tooth was diagnosed with a reversible pulpitis, although a review of the patient's records indicated that the tooth was asymptomatic. When the histology was evaluated none of the teeth at that center were judged to be inflamed. This supports the notion that there is little correlation between pulpal vitality testing responses, patient symptoms and histological appearance.

4.2 Efficacy

There were no unusual efficacy considerations either. Surface caries were completely removed with both laser and drill techniques in all instances. However, restoration evaluations revealed that special consideration should be given to materials used for filings when the laser is used since the defect will typically be smaller than with standard techniques.

Operators were instructed to remove all caries. To do this two different endpoints evolved for the two treatment conditions. For the drill the endpoint was visual: removal of all discolored enamel. For the laser the endpoint was auditory: cessation of a "popping" sound on laser impact.[12]

In this clinical study there was a high incidence of enamel discoloration in the Laser Group. Yet evaluators recorded that all caries had been removed. Infrared Spectroscopy of the site of enamel caries indicates that the discolored healthy enamel

remaining after laser ablation is indeed free of caries.[12] Consequently, the discoloration must refer to this layer of stained sound enamel below the lesion that was not removed by the laser. However, in the drill group there was no discoloration reported. This is because the visual endpoint for the drill is removal of all discolored tissue even if it is sound enamel.

In the drill group the preparation extended into the dentin in eleven teeth. In only one laser treated tooth did the preparation penetrate into the dentin, and treatment was completed using the drill. This significant difference is consistent with the above discussion. The drill, being more aggressive will remove healthy tissue below the lesion and increase the probability entering dentin. The laser represents the more conserving technique because it selectively removes the diseased tissue and does not remove healthy enamel.

In this study lesions were carefully selected according to the inclusion criteria. Consequently, none of the finished laser preparations had unsupported enamel. However, in clinical practice occasions may arise where unsupported enamel remains after caries removal necessitating modification of the preparation with the high speed handpiece.

		STUDY 1 extracted		**STUDY 2 clinical trials**		**TOTAL**	
Cracking		DRILL	LASER	DRILL	LASER	DRILL	LASER
Total	NO	28	43	207	214	235	257
	YES	1	0	0	0	**1**	**0**

Drill vs. laser: $p = 0.82$

		STUDY 1		**STUDY 2**		**TOTAL**	
Debris		DRILL	LASER	DRILL	LASER	DRILL	LASER
Baylor	NO	8	18	48	51	56	69
	YES	0	0	0	18	0	18
UCSF	NO	14	13	69	56	83	69
	YES	0	1	0	31	0	32
UOP	NO	7	8	90	58	97	66
	YES	0	3	0	1	0	4
Total	NO	29	39	207	165	236	204
	YES	0	4	0	50	**0**	**54**

Drill vs. laser: $p < 0.001$

		STUDY 1		**STUDY 2**		**TOTAL**	
Discoloration		DRILL	LASER	DRILL	LASER	DRILL	LASER
Baylor	NO	3	4	46	46	49	50
	YES	5	14	2	23	7	37
UCSF	NO	11	7	69	82	80	89
	YES	3	7	0	5	3	12
UOP	NO	5	9	90	42	95	51
	YES	2	2	0	17	2	19
Total	NO	19	20	205	170	224	190
	YES	10	23	2	45	**12**	**68**

Drill vs. laser: $p < 0.001$

TABLE 5: Post-treatment enamel evaluation.

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