**Quicklase Dual, Dr Mervyn Druian**

## Abstract

Recently a great deal of excitement, skepticism, and controversy has erupted in reaction to the creation and subsequent release of the first dual wavelength laser in the worldwide history of dentistry.

I have reviewed the United States Food and Drug Administration submission by QuickLase. I have reviewed the scientific contributions made in defense of that submission. I have evaluated the system in surgery and I have weighed the clinical relevance of any of it to the practitioner, the patient, and the health care system at large.

This article is a review and summary of that journey and will stand as a testament to the fact that the dual wavelength laser is a technology that has been imported from the future and that the QuickLase Dual Dental Surgical Laser is simply the finest surgical instrument available in dentistry.

Tissue reaction to laser energy at various wavelengths is a very broad subject with great potential, it certainly beyond the scope of this review to describe its entirety. A review of wavelength effect on ablation and coagulation is adequate for the gross surgical surgical functionality for this discussion and to illuminate the advantages and disadvantages of the technology at hand.

Pursuant to that end, ablation is defined, for the sake of this discussion, as tissue removal by way of intercellular generation of steam and subsequent explosive bursting/destruction of the cell by the pressure of the steam.

Coagulation is defined, for the sake of this review, as the thickening of blood whether by biological-chemical means enhancement (ie increased platelet aggregation) or mechanical enhancement (ie removal water from the blood increasing viscosity).

Figure 1 contains a graphical representation of the electromagnetic spectrum relevant to our discussion (A), a triangular image that represents the scope and intensity of the coagulation effect of the various wavelength (B), a triangular image that represents the scope and intensity of the ablation effect of the various wavelength (C), and a scale which defines the wavelength measurement in nanometers and the laser medium responsible for generating that particular wavelength (D).

As one can see, the shorter wavelengths have a greater effect on coagulation. This is because the shorter wavelengths affect coagulation factors in the blood, directly. As one can see the longer wavelengths have a greater effect on tissue removal or ablation. This is because the longer wavelengths are absorbed by water. The vibrational, translational, and rotational frequencies of water most closely match these longer wavelengths with causes the water to immediately absorb the energy and, thereby, increase the vibrational, translational, and rotational movement. This increase in movement transforms to water from a liquid state to a

gaseous state (steam) nearly instantaneously. The immediate increase in cellular pressure caused by the generation of steam ruptures the cell explosively and we have ablation.

Please refer to Figure 1. These tissue effects of the wavelengths have been known for decades. Carbon Dioxide lasers are produce some of the fastest and most complete ablation known.

The 514 nanometer wavelength generated by argon lasers and the 532 nanometer wavelength generated by frequency doubled Nd:YAG lasers produce some of the fastest and most complete photocoagulation witnessed.

The Nd:YAG laser at 1064 nanometer is also a very rapid ablator. Because the Nd:YAG produces 1046 nanometer ablation wavelength and because the a frequency doubling crystal can change the 1064 nanometer to 532 nanometers, an excellent ablator, the interest in simultaneous dual wavelength surgery was focused on the use of these Nd:YAG lasers and frequency doubling crystals. Much intellectual, academic discussion and pursuit went into this combination. The combination remains of value and anticipated. The problem associated with this combination is one of price. Such a laser currently would cost tens of thousands of Euros.

As one re-examines figure 1 it is noted that two relatively inexpensive and relatively easy to package alternatives exist; the diode lasers 810 nanometer and 980 nanometer. The laser companies have argued that one is better than the other. Of course they always argue the one they are selling is the superior wavelength, in fact, one company even introduced a third wavelength at 950 nanometers claiming that this wavelength was the ‘perfect’ choice as it has properties of both 810 nanometer and 980 nanometer.

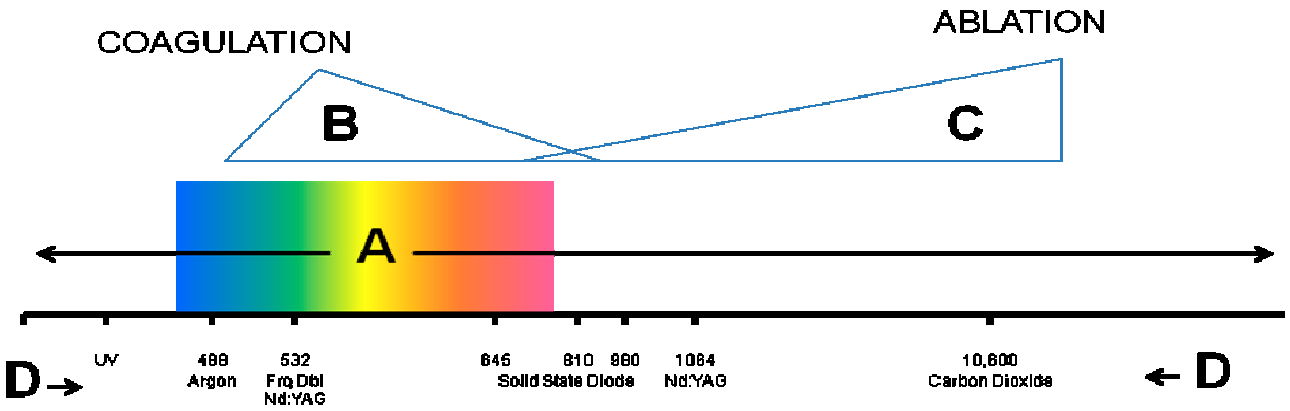
The fact of the matter is that there is only 170 nanometers of wavelength separating the wavelengths at the extreme point and all three of these wavelengths (810, 950 and 980) all have the ability to coagulate and ablate, therefore, these superiority arguments have always been viewed as marketing hype by clinicians and academicians alike.

When the QuickLase Dual was invented, patent filed, and then submitted to US FDA for approval, academicians and clinicians alike, again, viewed the combination of the two wavelengths as straight marketing hype. In fact, the US FDA agreed with the skeptics and refused to grant clearance until further research documenting the benefit could be produced.

The US FDA, in a letter to the company dated November 2, 2007 the FDA stated “In your submission you explain that this device can combine the use of the 810nm wavelength and the 980nm wavelength. …. There is no predicate that uses two wavelengths simultaneously for this indication, pleas provide… histological data”. In short, the US FDA refused to grant clearance until histological data could be presented to corroborate the claims of efficacy and safety for the indications. The company conducted the study preparing and looking at hundreds of tissue samples. The study was submitted to the US FDA on December 3, 2007. Upon review of the data the US FDA immediately granted clearance on December 18, 2007 (K072995). A copy of the study is included.

## Figure 1

### SURGICAL FUNCTIONALITY OF WAVELENGTH




While an in depth examination of the study is encouraged, the results can be fully explained by reviewing Figure 2. The vertical axis represents diameter in millimeters. The horizontal axis represents the mixture of wavelengths starting on the left with 0% 810nm and 100% 980 to the far right of the graph with 100% 810nm and 0% 980nm. The top line of the graph is the coagulation zone. The middle line is the necrotic zone. The bottom line is the ablationzone.

The trend on all three lines is predictable given our understanding of ablation-coagulation and the effect of wavelength on each. That is to say, refer to the bottom line of figure 2, one would expect that the ablation of pure 980 nanometers would be slightly more effective than the ablation effects of pure 810nanometer.

However, given the very close proximity of the wavelengths one would not have predicted that the ablation effects of pure 980nm would be on the order of 100% better than pure 810nm. Likewise, refer to the top line of Figure 2, one would have predicted a, perhaps, a minor difference in coagulation effect between the two wavelengths but one would have never anticipated that there would be a difference on the order of 60%.

The most astounding finding is that when the wavelengths are mixed, refer to the middle portion of all three lines, that the effects are greatly magnified: a mixture of the two wavelengths provide superior coagulation and ablation effects as compared to the pure wavelengths alone. Such a finding is unprecedented. Of course many time we see such dramatic differences in published data in vitro and then much to our disappointment we find that the findings do not transpose to in vivo and have little clinical relevance. With the QuickLase Dual this is not the case.

# Histological Evaluation 810nm Vs 980nm Wavelength Laser Radiation on Pig Liver Tissue

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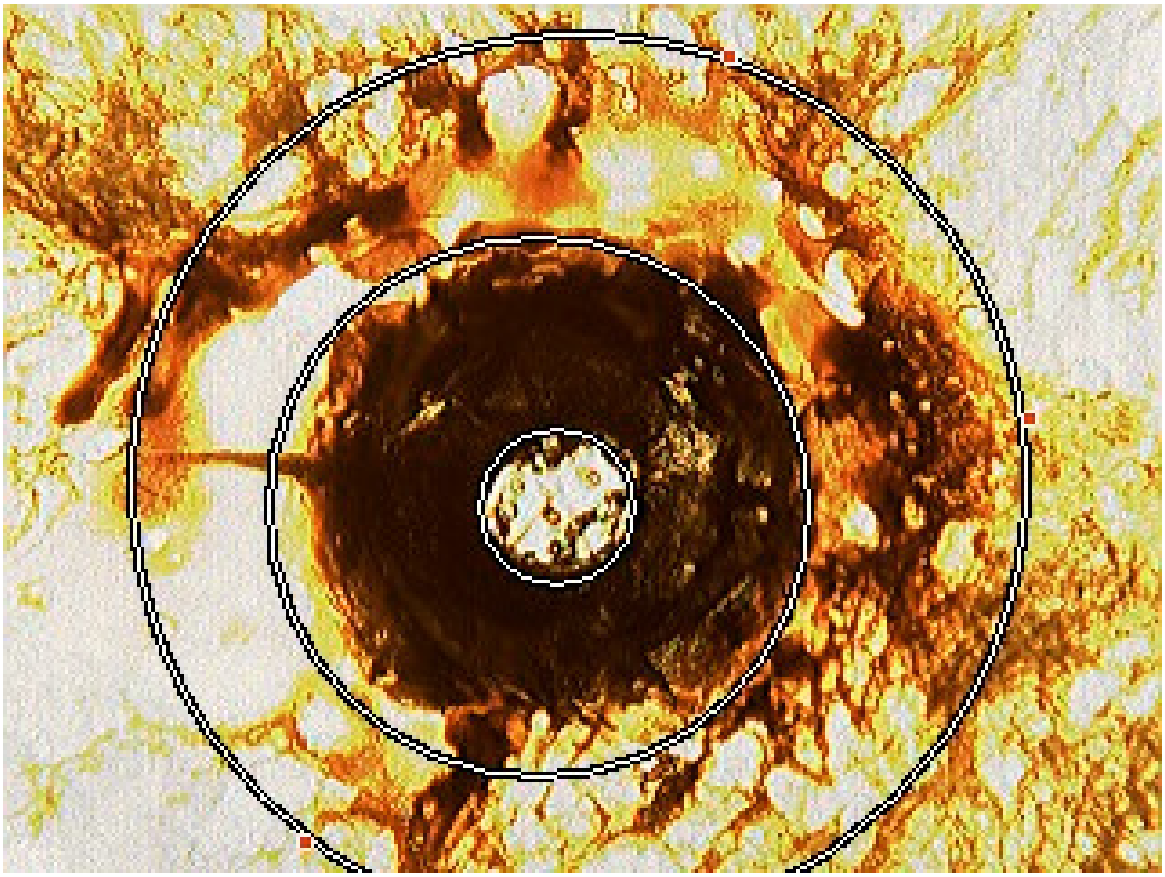
**Abstract**

This study addresses the current dental laser surgical industries' arguments that one of the other of two predominate wavelengths in the industry is 'better' than the other; those wavelengths being the 808-810nm and 980nm wavelengths that are produced by the so called solid state "diode lasers" because the laser energy is actually produced by a laser diode. While there is clearly a major difference between earlier dental surgical laser, namely the Argon Ion Laser and the Nd:YAG (also the Carbon Dioxide Laser). The major performance differences in the earlier laser was clearly because of the different tissue elements which reacted/absorbed the wavelengths produced by the lasers. The Argon Ion Laser producing visible blue (457-488nm) and visible green (501-514nm) was rapidly and readily absorbed by the red hemoglobin in blood. This made the Argon Ion Laser a very good coagulation device, but in a relative sense, a poor tissue remover (alabation). The Nd:YAG producing invisible infrared laser energy (1064nm) was not well absorbed by blood relative to the Argon Ion Laser but was very rapidly absorbed by water which made it and excellent tissue removal surgical laser. The recent marketing claims made by the relative manufactures lend the argument to the fact that 810nm is closer to Argon Ion Laser and would be a better coagulator than tissue remover and that the 980nm wavelength is very closer to Nd:YAG and is therefore a better tissue remover. The difference between 514nm (best coagulation wavelength of the Argon Ion Laser) and 1064nm produced by the Nd:YAG is 550nm, a large difference. The difference in between 810nm and 980nm is a relatively small 170nm. This study examines the clinical significance of this difference. The results of this study demonstrate that the 810nm wavelength nearly doubles the coagulation performance of the 980nm wavelength in pig liver. The results of the study further show that the 980 wavelength is produces more than double the ablation performance and involves less tissue overall in pig liver. This study demonstrates that by combining the two wavelengths coagulation and ablation performance can be adjusted and even increased beyond the performance of a single wavelength in pig liver. Conclusion: there is a clinical difference in the performance in pig liver. There may be major clinical advantages in mixing the wavelengths in surgery and oral tissue treatment.

**Introduction**

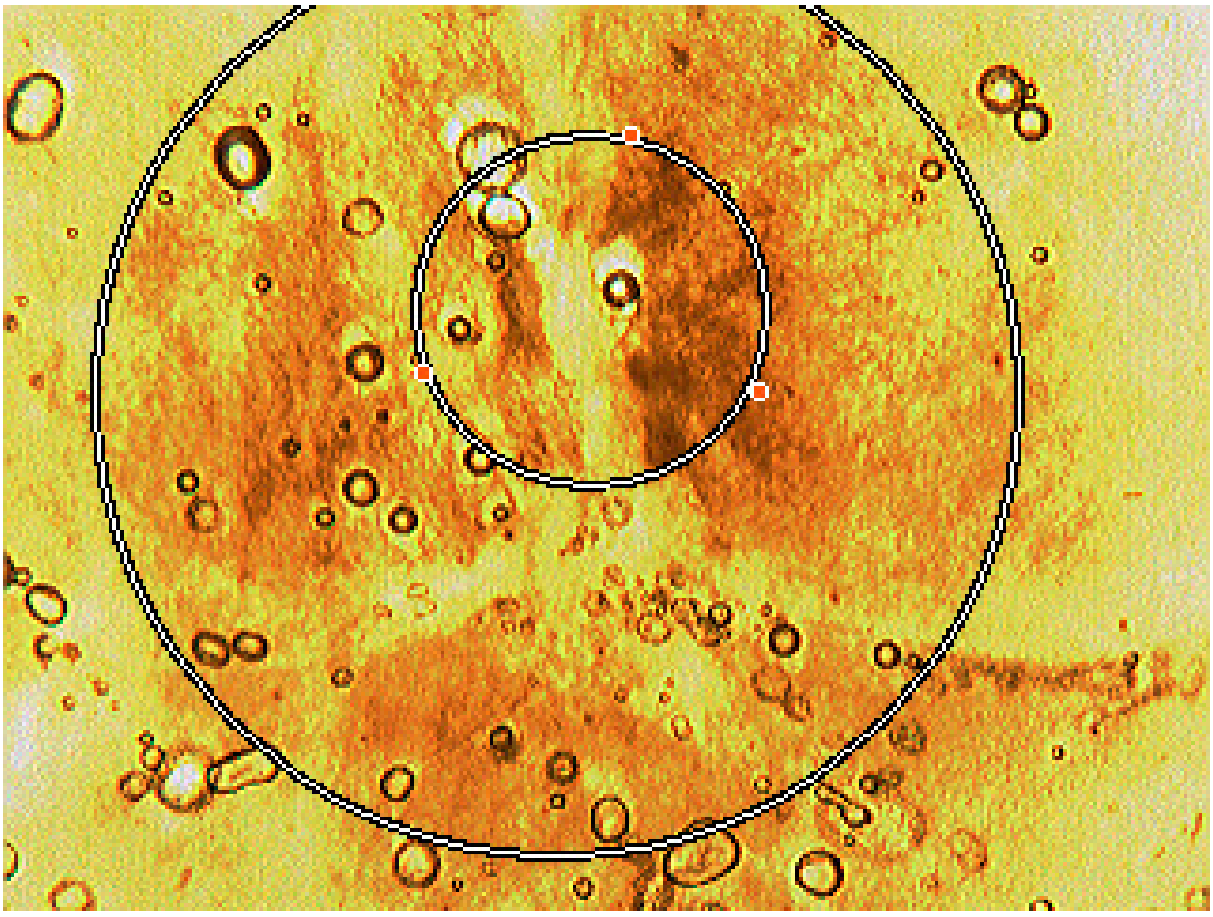
The ablation, necrotic zone and coagulation zone of the 810nm and 980nm laser, individually, are well defined and well understood. However, the TidalWave Dental Diode Laser will supply both wavelengths simultaneously. Furthermore, the TidalWave Dental Laser will mix user defined amounts of each wavelength. Therefore, this study is designed to determine the effects on the ablation zone, necrotic zone, and coagulation zone of pig liver tissue of mixtures of the two wavelengths.

The study intent is to evaluate the effects of a varying mixtures of 810nm and 980nm laser radiation on pig liver. The parameters of interest are the area of ablation, the fringe of necrotic tissue surrounding the area of ablation, and the area of coagulation surrounding the necrotic fringe (refer to photograph below):



The photograph is of a thin section of pig liver that has been exposed to laser radiation. It is presented here to illustrate the regions, zones, fringes, discussed above. For the sake of this study the following definitions of those regions, zones, fringes, areas, etc.

apply. The center circle is the ablation zone. This is the area where the tissue has be ablated (or vaporized), the tissue is all but gone. The area between the center circle and the middle circle represents the zone, fringe, or region that is comprised of charred, dead, or necrotic tissue that was not ablated or vaporized by the laser. The area between the middle circle and the outer circle represents that area in which the tissue is not necrotic but the blood in the tissue has coagulated, this is considered the coagulation region, zone, fringe, area, etc. How each of these regions, zones, fringes, areas, etc. change as the mixture of wavelengths change is the object of this study. Because the depth of cut of laser energy delivered through a cleaved fiber (no clear focal point as with lens focused lasers) varies not only in power applied but also hugely varies in the distance the fiber is held from the tissue and the angle the fiber is held to the tissue, objective, statistically significant data is all but impossible to obtain. By way of example, the section above was positioned .5mm from the fiber delivery tip.



Identical sections (refer photograph above) exposed to the same radiation for the same amount of time at a position 1.5mm from the fiber show only minor to moderate coagulation; no ablation and no necrotic tissue. The center circle shows moderate coagulation zone while the area between the center circle and the outer circle

represents minor coagulation. As one can clearly see the removal of oral soft tissue by a dentist with a cleaved fiber delivery system is very technique sensitive. The purpose of this study is to not to evaluate various techniques or fiber distances for depth of cut but is to study the three tissue effects of different mixtures of the two wavelengths as discussed above.

**Design**

The object of the study is to evaluate the effect that different mixtures of 980nm and 810 nm wavelength energy have on three surgical characteristics of treated tissue, namely: ablation, necrosis, and coagulation. The study is therefore designed to eliminate all other variables.

All tissue comes from the same pig liver.

The thickness of the tissue sections are maintained +/- 15%

The distance between the end of the fiber and the surface of the tissue in held constant.

The total output power his held constant

The exposure time is held constant

4 sections of pig liver are exposed to the same wavelength mixture and the average values of the three diameters from the 4 sections is used for the data point.

**Experimental**

Two fresh pig livers are obtained from Tooele Valley Meats, Grantsville, Utah. Tooele Valley Meats were given the instruction to slice the livers as thin as possible. Tooele Valley Meat then partially froze the liver, sliced both livers, individually, wrapped the livers individually and hard froze both livers. Upon receipt and evaluation of the livers the liver were sectioned too thick for practical histological work. One of the livers was chosen and sectioned into approximately 3cm X 3cm X 10cm block running with Tooele Valley Meat slices cross sectioned on the 3cm X 3cm face, The liver was section into the block while hard frozen on a 12” band saw manufactured by Rigid. A medium coarse wood band saw blade was used for the sectioning of the blocks. The blocks were then wrapped and returned immediately to the freezer and were kept in a hard frozen state.

Immediately prior to laser exposure a hard frozen liver block was removed from the freezer, four standard 25mm X 75mm X 1.15mm thick microscope slides were placed

on the counter next to the cutting board containing the hard frozen live block. Four thin sections of hard frozen pig liver were taken from the frozen block using a manual dermatome. The sections were less than .5mm thick and approximately 1cm square. The freshly taken, still frozen sections were then placed on the microscope slide using tweezers. The section was then immediately covered with a brand new standard 18mm X 18mm $ .17mm thick microscope slide cover glass. The freshly prepared set of four slides were then moved to the laser testing area and allowed to stand for 5 minutes directly on a counter top to attain room temperature.

The freshly warmed slide was then placed in a custom made fixture to which the laser delivery fiber was permanently mounted. The fixture was designed to take the slide with the cover glass toward the laser delivery fiber. The fixture is made to maintain a distance of 0.5mm between the end of the laser delivery fiber and the inside surface of the microscope slide cover glass. The fixture was also designed to apply even amounts of pressure squeezing the microscope slide and microscope slide cover glass together. With this adjustable even pressure we were able to maintain a tissue thickness between the microscope slide and microscope slide cover glass of 0.25mm +/- 10%.

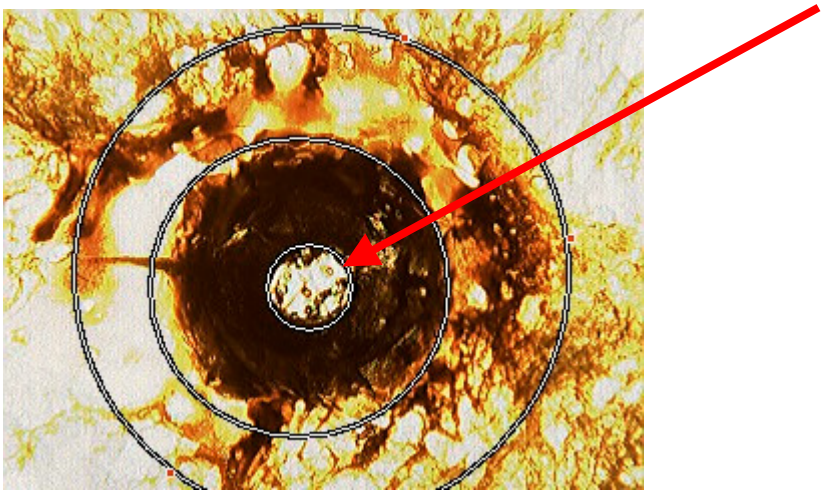
All measurements were made using a Model 799 Digital Veneer Caliper manufactured by Starrett and purchased, freshly calibrated, in June 2007.

The slide is then exposed to the laser radiation for 15 seconds and removed from the fixture. Once all 4 freshly prepared slides have been exposed to the laser radiation the slides are moved as a labeled set to the biological microscope workstation.

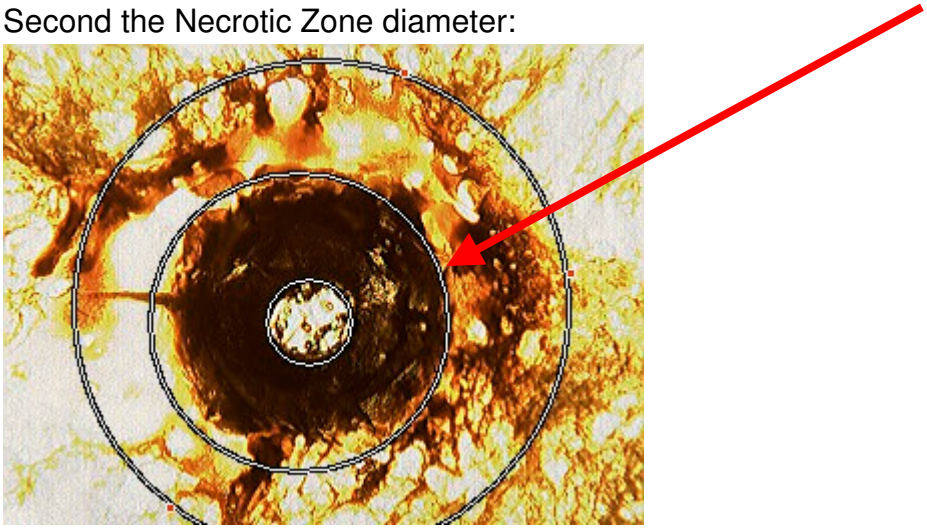
The microscope is a standard trinocular biological microscope manufactured in China, manufacturer is not listed on the microscope, Model # XSZ-105E, S/N 046865. The objective lens used is an Olympus brand MPlan 5X. The eqypieces are Olympus prand 10X wide field, the left eye piece contains a pointer the right eye piece contains a 100 division reticle which is scale calibrated with this set of optics at .025mm per division. The third eye piece is fitted with a Moticam 1000, 1.3 megapixel live resolution digital microscope camera manufactured by Motic company. Images are captured on a Satellite model laptop computer manufactured by Toshiba, with a Windows XP operating system. Software used to capture the images is produced by the camera manufacture Motic and is Motic Images PLUS, Version 2.0.

Technicians then take and record three diameter measurements on each of the four freshly prepared and exposed slides:

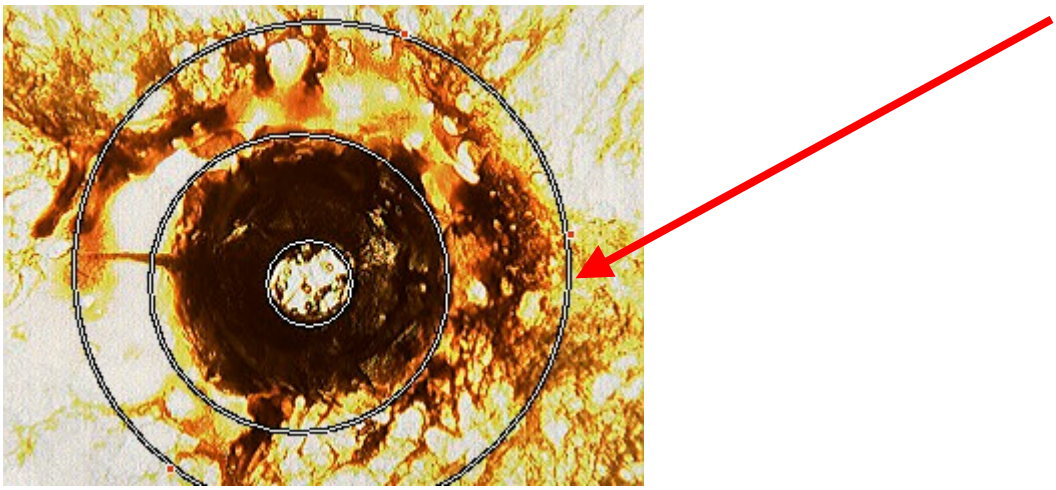
First the Ablation Zone diameter:



Second the Necrotic Zone diameter:



Third the Coagulation Zone diameter:



The slides were then immediately submerged in 90% denatured ethanol and allowed to soak for 48 hours before they were discarded. On 6 occasions technicians noted grossly aberrant specimens. In all 6 cases the aberrations were diagnosed as being caused by fixture issues. In these cases all four slides for that exposure were discarded and four more slides were prepared at that exposure level after the fixture issue was identified and corrected.

The four measurements were for each category were then averaged and the results entered into the raw data spreadsheet.

Initial pre-study experimentation with the same pig liver and same equipment determined the ideal thickness of the section to be 0.25mm. The ideal distance of the section from the end of the fiber optic delivery system to be 0.5mm. The ideal power level was determined to be 3.0 watts. The ideal exposure time was determined to be 15 seconds.

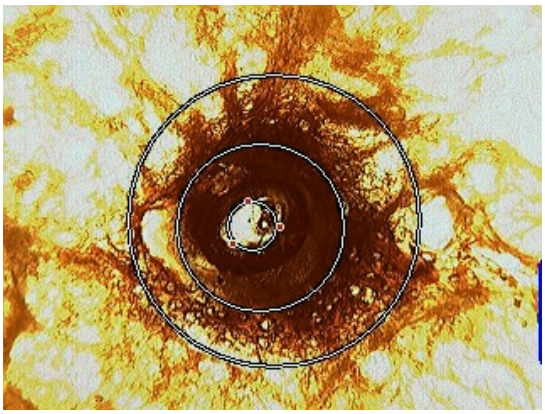
A TwinWave Diode Dental Laser S/N TWPT0003 was adjusted and calibrated by Electrical Engineer to perform the study in 50 individual settings where slide set 1 was 100% (3 watts) 980nm and slide set 50 was 100% (3 watts) 810nm. Each setting from 1 to 50 adjusted the 980nm down .06 watts (2%) and adjusted the 810nm energy up .06 watts (2%). In total 4 freshly prepared slides were made and exposed to each of the 50 individual settings totaling 200 slides and exposures (refer to Attachment A for tabular representation of the settings and average raw results).

The TwinWave Diode Dental Laser power output was monitored before every series of four slides to insure proper energy was supplied. The power output was measured with an Orion/TH digital laser power meter manufactured by Ophir, S/N 500594, Calibrated in Feb. 2007 and a L30A-SH-V1 head manufactured by Ophir, S/N 501265, Calibrated

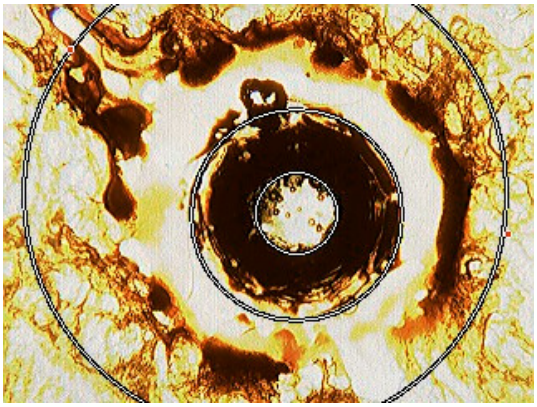
in Feb. 07. Both the head and laser meter are not scheduled for recalibration until 8/2008.

**Results**

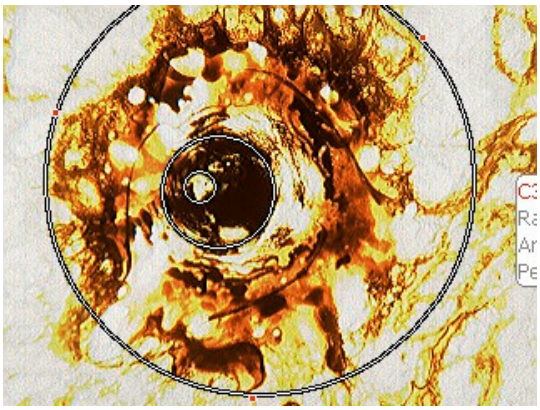
Refer to the two photographs below:



**Specimen 0C**



**Specimen 25B**



**Specimen 50D**

The photographs above were captured in the course of the experiment. The photograph on the top left was labeled Specimen 0C was exposed to 100% (3 watts) of 980nm for 15 seconds. The photograph on the top right labeled Specimen 25B is of a section of pig liver that was exposed to 50% (1.5 Watts) of 980nm and 50% (1.5Watts) of 810nm laser energy for 15 seconds. The photograph on the bottom is a section of pig liver that was labeled Specimen 50D and was exposed to 100% (3 watts) of 810nm for 15 seconds. The recorded diameter values for the three specimens on each of the three zones are:

| Measured Parameter | 0C, 100% 980nm | 25B, 50%-50% | 50D, 100% 810nm |
|---|---|---|---|
| Ablation Diameter | 0.425mm | 0.488mm | 0.200mm |
| Necrotic Diameter | 0.800mm | 1.375mm | 0.600mm |
| Coagulation Diameter | 1.250mm | 2.488mm | 2.200mm |

Please refer to Attachment A for full results.

**Discussion**

The marketing wing of the laser dental business has recently engaged in debates and positioning that one of either of the two predominate surgical wavelengths available in dentistry is 'better' for removal/treatment of oral soft tissue. One company (Biolase Technology Inc.) has released a laser that introduces yet a third wavelength into the argument with the claim that its 940nm wavelength was the perfect merging of the two predominate wavelengths. Even more recently, however, the same model laser has been released by the same company in 810nm wavelength with the paraphrased claims that it is available for the more traditional dentist. Of course, in many instances, marketing claims which may even attain statistical significance has little to no clinical relevance.

The scientific argument between the two wavelengths (980nm and 810nm) is that the difference lies in the tissue elements which absorb or react to the specific wavelengths of the well documented early laser surgical devices, namely the Argon Ion Laser and the Carbon Dioxide Lasers (considered Predicate Devices by FDA, i.e. all dental surgical laser ultimately claim substantial equivalency to these two wavelengths), and more recently the Nd:YAG lasers. B The Argon Ion Laser produces visible blue (457-588nm) and visible green (501-514nm) laser radiation. These wavelengths, particularly the visible green and 514nm preferentially, are well and rapidly absorbed by hemoglobin in blood because of its red color. This absorption causes the blood to heat up and coagulate, heated further it vaporizes (ablates) the surround tissue. This makes the Argon Ion Laser a very good coagulator but a relatively poor tissue remover. The Nd:YAG and Carbon Dioxide Laser produce invisible infrared energy at 1064nm and 10,600nm respectively. These wavelengths are readily and rapidly absorbed by water and translated into rotational and vibrational energy. This translation of energy causes the liquid water in tissue to immediately change to steam. This change literally blows the cells apart causing the tissue removal (ablation). Because of the efficiency of this translation and the concentration prevalence's of water in tissue, the Nd:YAG and Carbon Dioxide Lasers are very good ablators but relatively poor at coagulation. A brief discussion on the performances difference between the Nd:YAG and Carbon Dioxide

Lasers is warranted. The Carbon Dioxide wavelength is/was less expensive to produce than the Nd:YAG and its performance as an ablator is superior to that of the Nd:YAG. The Carbon Dioxide laser, is in fact the best ablator of all laser discussed in this study, however, the 10,600 nm wavelength will not transmit through a glass fiber, it is therefore difficult to get the energy from the laser tube to the tissue. With the introduction of the very inexpensive diode laser that can ablate and be transmitted through a glass fiber both the Carbon Dioxide laser (and Nd:YAG because of its relative expense) have fallen out of favor in the dental community.

The difference in wavelengths between the best coagulation wavelength of the Argon Ion Laser, which is 514nm and the ablation wavelength of the Nd:YAG (1064nm) is a large 550 nanometers, while the difference between 810nm and 980 nanometers is a relatively small 170nm. This study address the clinical significance of that small difference and the any benefits of mixing the wavelengths.

Astonishingly this study demonstrates a substantial difference in performance despite such a small difference in wavelengths. The results demonstrate a large difference in coagulation affects, ablation affects, and tissue involvement affects between the two wavelengths. As theorized in the industry the 810nm wave is a better wavelength for coagulation. This study demonstrates that the 810nm wavelength was near twice as effective at coagulation in pig liver. This study also demonstrates a substantial difference in ablation performance with the 980nm wavelength being more than twice as effective at ablation of pig liver. The 980nm performance also involves about half of the tissue as well. In short, 810nm involves a larger area of tissue providing more coagulation and less outright destruction, 980nm involves far less tissue but the tissue that is involved is mostly ablated with less surrounding coagulation. The results of this study provide additional verification of the theorized clinical performance difference in these two wavelengths.

Most astonishingly the study demonstrates that by combining the two wavelengths in different percentages the user can actually control or dial in the amount of ablation Vs coagulation and adjust the tissue involvement as well. The greatest ablation, coagulation, and tissue involvement mixture is a 50%-50%. The further the user goes to 100% 810nm from that 50-50 point the less ablation and a little less coagulation produced. The closer the user goes to 100% 980nm from the 50-50 point, less ablation is witness but far less coagulation and tissue involvement is apparent, in pig liver. Please refer to Attachment B for graphic representation of this data and discussion.

**Conclusions**

810nm wavelength energy provides better coagulation and would be preferred in larger area surgeries involving more vascularized tissue.

980nm wavelength energy provides better ablation and narrower tissue area involvement and would be preferred in areas were the tissue is less vascularized and/or in areas where narrower tissue involvement is indicated.

Mixing the two wavelengths provide definite advantages and general recommendations can be advanced to practitioners on the preferred mixture of the two wavelengths based on tissue types and dependent procedures.