



This is the first analytical report I have authored in several months. The simple reason for this “hiatus” is I found nothing compelling to write about. Reporting on truly innovative devices that are of real value define the analytical reports. The Editor in Chief of Aesthetic Trends has been respectful, and indeed has encouraged my position of not covering devices which are long on theory and short on scientific and clinical evidence. To be very direct, I refuse to be a part of the “hype” that so dominates this area of medicine.

As this industry continues to grow, so do the ill-founded claims of many of the products and devices that populate it. There are many simple ways to determine whether a product or device achieves the claims it makes without all the theoretical jargon, dubious testimonials, and less than ideal before and after photos. One of the methods is a well designed and reasonably large split anatomical study. Sadly, I see almost no studies of this kind in medical aesthetic device industry. Please do not misunderstand; there are many excellent devices and products which would be well served by better designed studies that are independently monitored and reviewed.

Most of us acknowledge and recognize the mechanisms and outstanding efficacies provided by BOTOX®. By contrast, the efficacies and safety of aesthetic devices are not as straightforward.

There are many devices on the market which make many claims. It has been over 10 years from the original theory selective photothermolysis, (R. Anderson, J. Parrish, 1993) and much has been learned from trial and error arising from this work. There are basic rules which govern how photons will affect tissue based on color, mass, depth, location etc. of the target. Other non-light devices such as radio frequency have entered the market and are governed by rules of impedance in tissue. Beyond the rules we still have scientific method to determine the efficacy of any device which lacks a strong clinical history.

I hope my reviews have been both informative and helpful. The devices I have covered are the very latest offerings from the top tier companies in the business. This reality alone reflects the predominantly positive reporting. Analytical reports in Aesthetic Trends are dedicated to unbiased reporting. I applaud Ms. Vandruff for implementing many of my suggested changes to the laser and light product charts. The goal is to provide the practitioners the information they need to make informed decisions. More information which will provide an even clearer understanding is in progress.

The many emails I receive reflect a need to obtain unbiased information. Physicians are not physicists. I advise the Physicians to understand what they intend to treat, what are their expectations, and what are the estimated percentages of skin types in their area. With these questions answered, I may answer your questions more accurately.

I will renew my telephone consultations for physicians only between 3:00 p.m. and 5:00 p.m. Eastern Time.

Analytical Report

Cynergy MultiPlex Technology

CYNOSURE INC.

By David M. Cauger, Contributing Editor

Cynosure Inc., (Westford, MA) has developed yet another long pulse multi-wavelength laser: Cynergy. What makes this laser a first in aesthetic medicine is it produces two wavelengths from the same handpiece at almost the same time. These wavelengths are 595nm (Pulse Dye) and 1064nm (Nd:YAG).

The Cynergy with MultiPlex, which is an added feature, utilizes the 595nm and the 1064 almost simultaneously creates a new approach from two “gold standard” wavelengths which have been used separately for many years. By combining the two wavelengths from one fiber at specific intervals, Cynergy is destined to become the new standard for treating specific vascular malformations such as port wine stains and may alter the way many other

vascular lesions are treated as well. I will explain the mechanisms and my reasoning later in this article.

The Cynergy is a marriage of Cynosure’s V-Star Pulse Dye and their Acclaim 7000 Nd:YAG without compromised specifications.

One cannot forget that the Acclaim 7000 Nd:YAG is also one of the few high powered Nd:YAGs on the market. What this means is that the Cynergy is also very effective for leg veins, and non-ablative

Utilizing the 595nm and the 1064 almost simultaneously creates a new approach from two “gold standard” wavelengths which have been used separately for many years.

collagen stimulation. However, the real story here is the synergistic effect of these two wavelengths working in tandem.

I visited Cynosure headquarters on September 6, 2005, where I was greeted by the Clinical Director, Evan Sherr. Mr. Sherr has a unique knowledge base in the industry, borne from a long history of clinical observations with the best investigators in the business. I enjoyed comparing notes with a fellow scientist who speaks frankly and is not influenced by a marketing department.

WHAT BENEFITS WOULD CYNERGY HAVE FOR ME?

Both pulse dye and long-pulse 1064nm-Nd:YAG lasers have been well studied for vascular applications, going back to 1983 for the dye laser.

The 595nm and the 1064nm provide specific benefits, bounded by clear limitations in regard to efficacy and safety. Those skilled in the art know this all too well. Very often the physician is forced to choose between safety and efficacy, and vast particulars on this subject are beyond the scope of this article. Physicians who use the long pulse dye and/or the

By using both wavelengths through one fiber some of the limitations of each laser may be reduced, or in some cases, eliminated.

Nd:YAG for vascular treatments are, or should be, aware of the limitations of each wavelength.

There is a common misconception in this growth industry that intense pulse light (IPL) is a safe and effective device for telangectasias. This is partially a falsehood. The long pulse dye laser is a superior device for telangectasias. While the IPL can be an effective and diverse device, it presents many opportunities for unwanted side effects when the physician treats darker skin types or attempts to treat larger telangectasias where IPL can produce unwanted side effects and is less than efficacious.

Over the years I have received a great deal of feedback from my many MD clients with regard to the use of the high-powered Nd:YAG for vascular treatments. A common consensus is the Nd:YAG is superior for veins 1-3mm, but is very painful and side effects from over treatment can easily occur. On the other hand, the Pulse Dye laser is superior for telangectatic veins < 600 microns in diameter but not deeper than about 1mm. The side effects are usually purpura which can last several days to several weeks. By using both wavelengths through one fiber some of the limitations of each laser may be reduced, or in some cases, eliminated.

This would apply to various classes of vascular disorders, while some would not benefit from intermittent use of both.

In this article I have chosen not to classify all the various and mixed vascular malformations as these are well known to those physicians who are candidates for this laser. Hemangiomas have been considered a separate classification for years, and the Dye laser is very capable of resolving most cases.

Nevertheless, the two lasers by themselves are state of the art. Cynosure's V-Star (595nm) has a six sub-pulse structure and a 40ms max pulse duration, and their Acclaim 7000 is one of a few high powered Nd:YAGs on the market. These two wavelengths can be used individually with great success. The Cynergy's color touchscreen interface makes it very simple to switch between both wavelengths, or set durations between the two wavelengths operating sequentially. It will be interesting to see how Candela responds since their V-Beam Pulse Dye laser has been a staple of their product line for many years.

If you desire to add hair removal and non-ablative collagen treatments to your practice, then the Cynergy

becomes an even more compelling laser.

Below are the established parameters for collagen stimulation.

ND:YAG COLLAGEN REMODELING PROTOCOLS

There are two popular protocols for collagen remodeling. Typically 3-5 treatments are recommended for optimal outcomes.

Protocol #1 – Set the laser at 50 msec, and 50 J/cm². Treat the area using a 10 mm spot size with a 10% overlap. Three passes are recommended. A topical anesthetic may be used prior to the procedure.

Protocol #2 – Set the fluence between 13-18 J/cm² and the pulse duration at 0.4 ms. Use the 5 mm handpiece at the maximum repetition rate. Defocusing the handpiece, treat the area using a feathering technique.

Area	Spot Size	Fluence (J/cm ²)	Pulse Duration	Hz
Face	10mm	50	50	Max rep rate



Post 3 Treatments

Photo Courtesy M. Gold, M.D.

I JUST WANT A BETTER WAY TO TREAT LEG VEINS

If you want a better way to treat leg veins and are not practicing sclerotherapy, I would suggest you start.

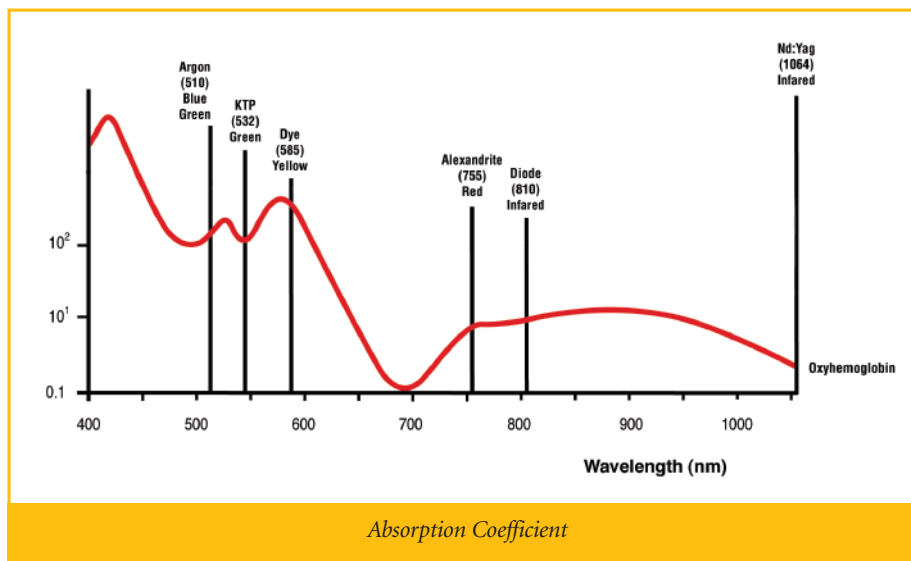
Sclerotherapy is the most common method of treating telangectasias of

the lower extremities and larger telangectasias of the general anatomy. It is also used for treating larger reticular veins. This therapy is both cost efficient and proven. However, greater numbers of patients are demanding laser treatments due to media coverage and the simple fact that many are needle phobic to one degree or another.

Some of the side effects of sclerotherapy include postsclerosis pigmentation and telangectatic matting. Hyperpigmentation usually resolves, where hypopigmentation can be a problem. Matting can be resolved with the dye laser. Sclerotherapy and the PDL are used by experienced physicians in treating leg telangectasias and reticular veins to achieve optimal clinical outcomes. Specific reticular veins will respond to the 1064nm wavelength of the Cynergy.

WHAT MAKES CYNERGY WITH MULTIPLEX A BREAKTHROUGH LASER?

The answer is very complex, but a simple explanation is that by "pre-



heating" the blood to approximately 70°C using the 595nm, a percentage of oxyhemoglobin is converted to Methemoglobin. Methemoglobin results when iron in oxyhemoglobin is reduced from the normal divalent state to a trivalent state; the resulting bluish pigment is methemoglobin.

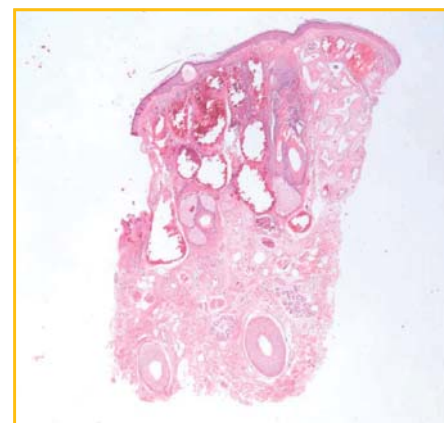
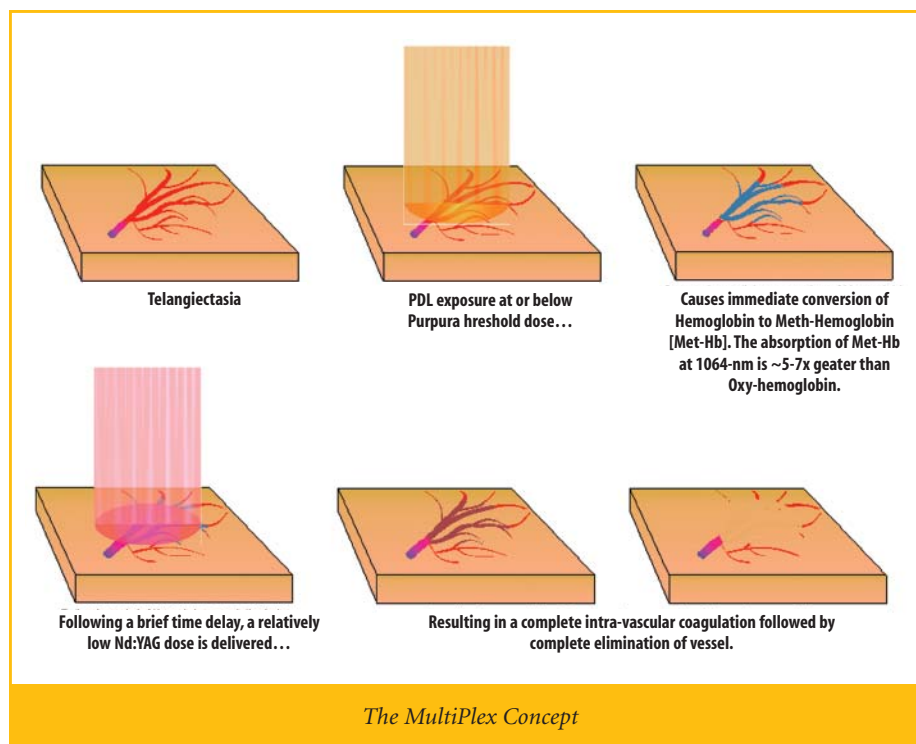
Methemoglobin has a 4-7 times greater absorption of the 1064nm

wavelength versus hemoglobin.

Therefore, approximately 1/2 of the typical fluence required by Nd:YAG is required to achieve the same clinical end-point versus using the Nd:YAG alone. This is very significant for specific lesions.

The ultimate objective in treating a vascular target is vessel coagulation with minimal side effects. With that being said, the PDL has difficulty with deeper vascular targets, and the Nd:YAG has difficulty in its lack of "affinity" for oxyhemoglobin.

When treating with the Nd:YAG,



Histology of a blebbed PWS showing complete coagulation to a depth > 4 mm without epidermal damage, treated with Cynergy with MultiPlex.

very high fluences must be used to compensate for this lack of absorption.

The effects of the high fluences and deep penetration of the 1064nm can be painful. However, the greater issue is that treatment in excess of standard parameters can lead to unwanted side effects such as hyperpigmentation, hypopigmentation, and other side effects.

When treating with the pulse dye laser the most common side effect is purpura. More current long pulse Dye Lasers (V-Star, Cynosure and V-Beam, Candela Corp.) use a series of sub-pulses to reduce purpura. The synergistic use of sub-purpuric doses of the Dye laser followed sequentially with the Nd:YAG may reduce this side effect even further in specific cases.

As of this writing Drs. Emil Tanghetti, Roy Geronomous, and David Golberg are the principal investigators. By the time this article is published, a substantial body of protocols is sure to be in place.

reimbursable under 17106 – 17108 cpt code up to approximately \$925.

While I was at Cynosure the emphasis was on deeper port wine stains. Visualize these dense and “twisted” low flow vessels exposed to the PDL which converts the oxyhemoglobin target to methemoglobin.

The converted methemoglobin now presents a target 4 – 7 times greater for the subsequent Nd:YAG wavelength. This would require approximately 1/2 the fluence than if the Nd:YAG were used alone for the deeper vessels. This is very significant with regard to both response and safety.

The role of flow rate of a vessel is important. For low flow vessels I would estimate a 250 – 500ms delay between the 595nm and the 1064nm. These would be most PWS and other vascular malformations. For medium flow vessels such as leg telangectasias, a shorter delay, on the order of 100ms delay may prove to be optimal. I

predict that the primary investigators will soon have near optimal parameters in place.

Some cases of PWS are beyond any available technologies

to achieve substantial results. However, for some specific adult recalcitrant PWS with blebs, this laser offers a new technology for those afflicted with these often disfiguring malformations.

Early results with Cynergy MultiPlex were presented by Emil Tanghetti, M.D., at the recent Controversies and Conversations meeting this past August in Colorado Springs. At this time, his small studies have shown 75-100% clearance of facial vessels in 75% of subjects in 2 treatments and improvement in PWS

cobblestoning, with vessel coagulation to depths in excess of 4mm.

Evan Sherr and I reviewed the scientific data as to flow rate and thermal loading (relaxation) time (TRT) of vessels. Despite the many theoretical mechanisms, we know the thermal conduction from any target chromophore has a value. The optimal clinical goal is coagulation with minimal side effects.

My “not so final analysis” is that while vessel flow rate, type of malformation, anatomical location, and several other factors would determine the many benefits of the Cynergy, it is clear that vessel depth remains a borderline mystery. For example, if the PDL were used with a 10mm spot on a vessel at 1mm in depth, it would seem some heating at the top geometry of the vessel would occur and some conversion to methemoglobin would result. How would this influence the subsequent Nd:YAG fluence?

All the mathematics and predicted tissue responses are simply insufficient to draw firm conclusions. What is interesting is that some larger telangectasias and smaller reticulars can be >1 mm in diameter but <500 microns in depth. In cases such as these the Cynergy would have to be a superior technology over the high powered Nd:YAG alone.

IS THIS LASER RIGHT FOR MY PRACTICE?

This is a very advanced laser from a very reputable and established company. However, I must say that at this writing, Dermatologists, Vascular

Studies have shown 75-100% clearance of facial vessels in 75% of subjects in 2 treatments and improvement in PWS cobblestoning, with vessel coagulation to depths in excess of 4mm.

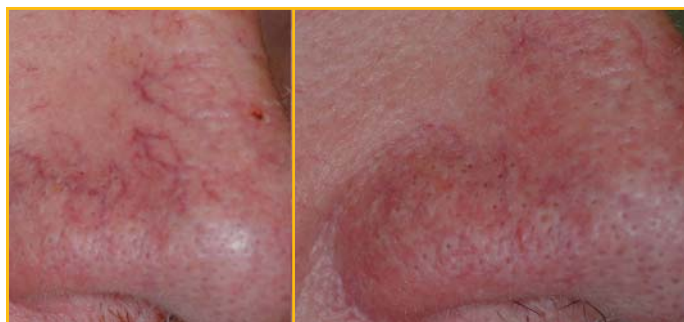
CYNERGY FOR PORT WINE STAINS AND TELANGECTASIAS

Since the effective depth of penetration of the Dye laser is approximately about 1-mm depth, vessels below this depth may not benefit with the concurrent use of the two wavelengths. However, many vessels treated are in the treatment region, and damage to collateral vessels can result in post treatment purpura. The benefits of the Cynergy with MultiPlex around these depths in low to medium flow areas present a clear benefit. This is especially true for many adult recalcitrant port wine stains with blebs (cobblestones). Please note that treatment of PWS are



Treatment with Cynergy MultiPlex Post 1 Treatment

Surgeons, Plastic Surgeons and other highly skilled surgeons who are accustomed to working with a pulse dye laser should consider the purchase of the Cynergy with the MultiPlex option. Those physicians who are in this category should strongly consider this laser.



Treatment with Cynergy MultiPlex Post 1 Treatment


For those physicians who regularly treat vascular lesions it is highly suggested to at least contact your colleagues or contact the manufacturer for some form of demonstration. The Cynergy can be a great benefit to your practice and you can add the MultiPlex at a later time. For those who do not own a long pulse dye laser and are still treating port wine stains with microsecond versions, maybe your "holding out" has been worth the wait.

I know first hand many physicians who have devised protocols they are comfortable with in treating vascular malformations and telangiectasias with the PDL. The techniques are endless. Average vessel size, depths, estimated flow rates, and anatomical location are just some factors influencing the parameter settings you may be comfortable with.

Comfort and familiarity aside, the PDL and Nd:YAG now are available through a single fiber with sequential pulses. These two well documented technologies which are available for use in tandem for improved clinical outcomes pose serious considerations with regard to standard of care. Granted, I fully realize that in the world of aesthetic medicine claims are not fully substantiated. However, in this case we have a very substantial body of evidence for the two wavelengths. The sequential use of

both in tandem does not rely on a "leap of faith."

I have been skeptical of many new devices for many reasons. Namely these reasons are lack of real scientific evidence and the fact that the manufacturers could prove the efficacies if they so desired by appropriate study designs. These studies simply are not commissioned and leads one with critical thinking skills to an obvious conclusion. In the case of Cynergy, we have none of this.

The Cynosure Cynergy is a true breakthrough vascular laser which has the ancillary benefit of being a collagen synthesis laser. Although all the parameters and protocols for various lesions have not been fully documented at the time of this writing, most will be by the time this article is published. At that time it is my studied opinion that Cynergy will become the vascular laser of choice in the industry. I recommend this laser for dermatologists, vascular surgeons and other accredited physicians. 

David M. Cauger is President of Boston Aesthetics, LLC, specializing in the development and implementation of strategies for increased cosmetic practice success. Contact Mr. Cauger via email at: cauger1@gis.net for light-based device questions free of charge. You may also contact Mr. Cauger by phone between 3-5:00 p.m. Eastern time at: 508.460.1128.

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Spider veins, portwine stains, age spots.
There's nothing unattractive about this market's potential.



Cynergy™ Vascular Workstation

By 2010, the number of annual procedures performed in the U.S. vascular lesion market will approach one million.* To make the most of this attractive business opportunity, you need a laser that treats the broadest range of skin abnormalities. For that, look no further than Cynosure's Cynergy workstation. With our revolutionary MultiPlex™ dual wavelength system, it's one machine that is equally effective treating scars, warts, hemangiomas, leg veins, age spots and more. And thanks to our comprehensive business and marketing support, your patients won't be the only ones who look good. Visit www.cynosure.com to learn more today.

*Source: Millennium Research Group, "U.S. Markets for Aesthetic Lasers 2006," May 2006
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