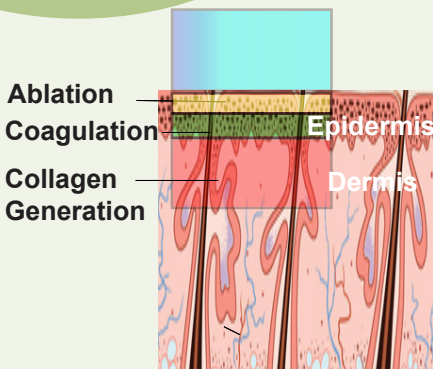




Cutera® Pearl™ Clinical Roundtable

While there are many ablative and semi-ablative devices in the market, including the variety of fractionated technologies, none to date have had the ability to maximize patient outcome with minimal downtime. The fractionated devices showed early promise over some of the more traditional CO₂ and Erbium resurfacing options, but have fallen short of meeting the criteria of today's patient who desires excellent outcomes without the wound care typically affiliated with aggressive treatments. As a market leader, Cutera developed a revolutionary new technology called Pearl with YSGG, utilizing for the first time in aesthetic light-based medicine, the 2790 nm wavelength. This paper contains excerpts taken from a roundtable discussion of three of Cutera's Pearl research physicians; plastic surgeon Dr. Richard Green, and dermatologists, Dr. Amy Taub and Dr. Victor Ross.



Moderator:

To begin, Dr. Ross, can you give us a brief overview of the Pearl?

Dr. Victor Ross:

The Pearl was created to offer a minimally-invasive approach to address wrinkles and skin tone changes without the need for seven or eight treatments. The idea was to have a fairly robust response in one treatment with only three to four days recovery maximizing the ratio of cosmetic benefit versus patient downtime.

The procedure begins with the separation of a precise amount of tissue known as ablation. Rather than remove this tissue completely, exposing the undamaged skin below, this fine layer of coagulated skin which remains is used to form a natural, biological dressing. Finally, the residual heat which is conducted down to the dermis, provides an impetus for new collagen deposition. With this process, we are able to create this very good result with minimal downtime in only one or two treatments.

The result of the Pearl procedure is a global freshening of the skin. From hairline to jawline, patients feel like there is an overall improvement in their appearance because the procedure achieves two goals. You achieve some improvement in pigmentation and you have a nice, glowing increase in the skin albedo or skin brightness. You also improve some of the fine-toning texture.

There are several benefits for both the patient and the practitioner. For the patient, the entire epidermis is treated while depositing a small amount of heat into the dermis. The treatment is quick and easy. The patient literally comes in, has a topical anesthetic, and goes on their way after the procedure. With four days of social downtime, a patient can come in on a Thursday and be back to work on Monday.

For the practitioner, the benefit is predictable and repeatable results without wound care or any kind of intricate sedation. Additionally, there are no recurring costs or disposables. The treatment time is less than 20 minutes. In our study, our average treatment time was about 12.5 minutes.

The contents of this paper were taken from the transcripts of the Pearl Clinical Roundtable web seminar held on June 26, 2007. A recording of this web seminar can be found on the Cutera VIP web site at www.cutera.com.

Patient Benefits

- Treat the entire epidermis while depositing heat into the dermis
- Well-tolerated procedure and recovery
- No more than 4 days of social downtime recovery
- No weeping or oozing
- One to two treatments for desired endpoint

Practitioner Benefits

- Predictable, repeatable results
- No wound care, sedation
- Solid-state technology
- No recurring costs or disposables
- Fast treatment time
- Technology compatible with Xeo platform



Clinical Results

“The Pearl procedure also provides quick results which is something that our patients always want. Patients come back in a week and they're excited because they see a change. All of my Pearl patients have been receiving unsolicited comments about their skin.”

Amy Forman Taub, M.D.

Moderator:

What kinds of results are you seeing with the patients you've treated with Pearl?

Dr. Amy Taub:

Pearl is a big patient-pleaser. It is a simple technique that ablates the epidermis, yet leaves behind a wound that doesn't ooze or need complex skin care. The patient's skin looks really bright and fresh. What has been a pleasant surprise is the good response with superficial wrinkles.

The Pearl procedure also provides quick results which is something that our patients always want. Patients come back in a week and they're excited because they see a change. All of my Pearl patients have been receiving unsolicited comments about their skin. People who didn't even know they had had a procedure are saying, "Your skin looks really good. What have you done?" This is very encouraging for patients to know other people have noticed in a positive way.

Dr. Rick Green:

The results we are seeing with Pearl show significant reduction of superficial photodamage and mild to moderate wrinkles. The patients have universally really liked it. Everyday I'm receiving notes and cards telling me, "Everyone's commenting on how great my skin looks!"

Dr. Amy Taub:

This is a patient that we treated. It's before and one week after this patient's first treatment. I've been excited about how Pearl takes away some fine wrinkles. If you look under her eye, that's a pretty great result after one treatment.

“The results we are seeing with Pearl show significant reduction of superficial photodamage and mild to moderate wrinkles. The patients have universally really liked it.”

Richard Green, M.D.



Before



One week after 1st tx

Photos courtesy of Amy Taub M.D.

3.0 J/cm²
full face
20% overlap

Dr. Victor Ross:

This is one of our patients. This is the pre-picture to your left, and the next photo is one day after the first treatment.



Before



One day after 1st tx



28 days after 2nd tx

Although the patient is red and pink, she is not so unpresentable she couldn't do some things in public. She might not be ready to work the next day, but certainly she can do many typical activities and not look too bad. The photo on the right is four weeks after the second treatment and eight weeks after the first. There is a fairly significant reduction in pigment here. But also, there is some nice improvement in fine lines.

Below is the same patient from a different view; left pre and right, post-28 days after the second treatment. Again, notice the improvement in the fine lines and pigment.



Before



28 days after 2nd tx

Photos courtesy of Victor Ross M.D.



Patient Selection

Moderator:

Can you elaborate on the types of patients you are treating?

Dr. Rick Green:

We've treated several patients in their 30's. However, most of our patients have been in their late 40's, early 50's. We've had five or six patients in their 70's who have had previous laser resurfacings or previous facelifts. Across the spectrum, they've been really satisfied with this treatment and very satisfied with the moderate social downtime.

Dr. Victor Ross:

I would agree. That is the same range of patients we are treating. The mean age of our patients is about 52, but our youngest patient was 32. Our oldest patient was an older gentleman, approximately 72. The critical thing is managing expectations. It is not going to be like a super deep peel with dramatic, one-time improvement of deeper wrinkles. It is a procedure to finesse some of the milder wrinkles that are present. I think the other critical thing is improving the pigmentation. There's a really nice effect four days after treatment right after the peel is finished.

“Across the spectrum they've been really satisfied with this treatment and very satisfied with the moderate social downtime.”

Richard Green, M.D.

Treatment Protocol

Moderator:

Before you perform the Pearl treatment, how do you prep the patient?

Dr. Victor Ross:

We talk to the patient about the risks and benefits and we take photographs. Then, we clean the face and apply numbing cream. We leave the cream on anywhere from 18 minutes to an hour depending on what we feel the patient's pain tolerance is going to be and also how aggressive a peel we're going to perform, whether it's 1.5 joules per cm^2 up to 3.5 joules per cm^2 . We typically take an acetone-impregnated gauze and thoroughly wipe off the cream before beginning the treatment.

Moderator:

What are your typical Pearl treatment parameters?

Dr. Rick Green:

A typical treatment is 2.8 to 3 J/cm^2 . Around the mouth, we've been trying up to 3.2 J/cm^2 . My experience has been that the actual redness time, whether it's three days or four days, doesn't seem to vary a lot if you treat at 2.5 J/cm^2 versus 3 J/cm^2 . We apply as high a fluence as patients can tolerate because they have all healed up nicely and social downtime has consistently been three to four days.

Moderator:

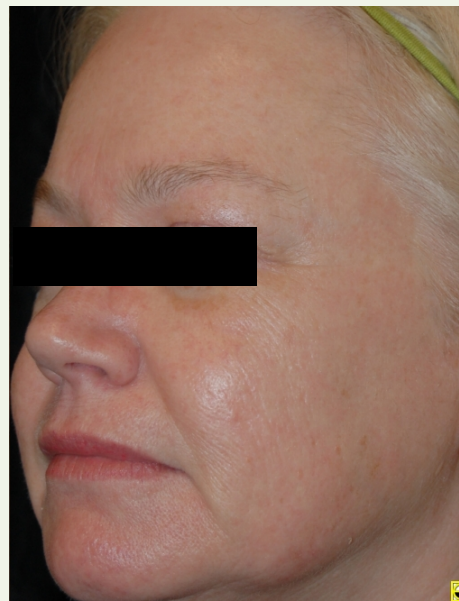
What does post-op care consist of?

Dr. Victor Ross:

Post-op care is very straight forward. We place Aquaphor fast-healing ointment on right after the procedure to soothe the skin. The patient continues to apply a light coat of Aquaphor for 2-3 days.



Before



One month after 2nd tx

Photos courtesy of Richard Green M.D.

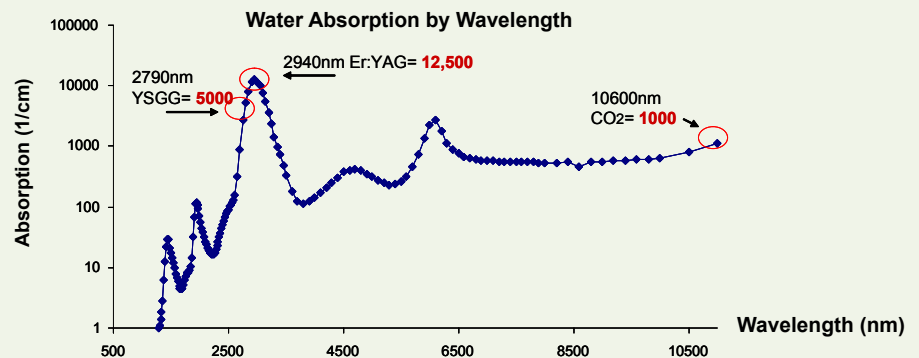
Mechanism of Action

Moderator:

What is unique about the 2790 nm YSGG wavelength?

Dr. Victor Ross:

If you look at the full spectrum of wavelengths that we typically use in resurfacing, Erbium YAG has a 2940 nm wavelength which is the water absorption peak, and CO₂ has a wavelength of 10,600 nm which is not nearly as well absorbed by water, but strongly absorbed by the skin. The Pearl wavelength of 2790 nm is just off the water absorption peak. It has a hybrid status between the heating tendencies of CO₂ and the explosive vaporization event you experience with the Erbium YAG laser. Using the *Goldilocks and the Three Bears* analogy, this procedure is not too hot and not too cool, but just right.



Moderator:

We talked about ablating part of the epidermis and then coagulating another portion to create the protective dressing. Can you talk about the advantage of the protective dressing?

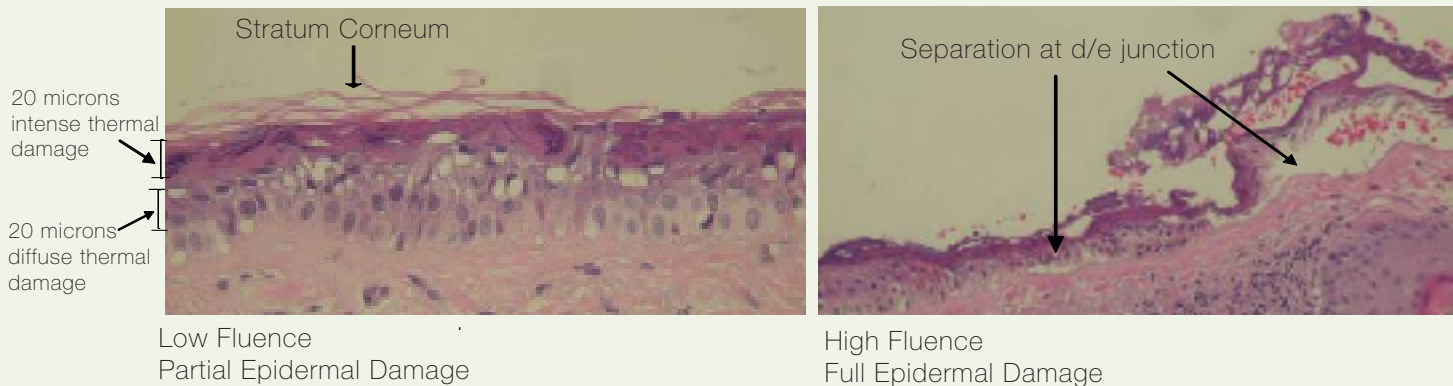
Dr. Victor Ross:

With the retention of denatured epidermis, you help to seal in the moisture. You don't have as much water loss from the surface. That's been shown in multiple studies. Transepidermal water loss is going to be decreased to a high degree if you allow this dressing to stay on the skin. This aids healing. You have less inflammation.

Can you walk us through these histology slides and describe what is happening following the Pearl treatment?

Dr. Victor Ross:

The images below show the gamut from low fluence to high fluence. In the left photo, you can see some necrosis here in the epidermis. This is a typical result with low fluence using 1.5 to 2 joules per cm^2 . What you see here is not a lot of ablation at all. In fact, the stratum corneum is still there. In this case, there is a fine zone of thermal damage about 20 microns thick, a real hardcore thermal damage. Additionally, you see a little bit of diffuse thermal damage in a less intense zone about another 20 microns.



When you go to the higher fluences, you see there is full transepidermal thermal damage all the way from the stratum corneum down to the dermal-epidermal junction. There is actually some dissolution and separation at the dermal-epidermal junction which is fairly typical for a deeper injury. There is a little bit of tint change on the H and E stain which is pretty consistent with some heating here.

Competitive Technologies

Moderator:

How would you compare the Pearl to fractionated technologies?

Dr. Amy Taub:

Although there is more obvious discoloration of the face immediately after Pearl, Fraxel still has 3 days of noticeable redness and sometimes swelling. With Pearl you only need 1-2 treatments whereas with Fraxel we usually do 3-5, so the total number of days with some downtime is greater for the Fraxel. In addition, Pearl treatments are less painful for the patient than Fraxel.

In my practice, I use Pearl and Fraxel for different things. I don't really do a lot of Fraxel for your standard photo rejuvenation patient because I don't think the results warrant the extra cost to the patient. If somebody came in with photodamage and fine wrinkles, I would choose Pearl, whereas for deeper rhytides or scarring I would use Fraxel.



Competitive Technologies Cont.

Moderator:

How does Pearl compare to other ablative devices?

Dr. Victor Ross:

The problem with the CO₂ laser, historically, even with low settings, has been the pain. Even with settings of 2 to 3 J/cm², it's hard to manage just with topical anesthetic. With the standard Erbium YAG laser, there's less pain, but it's very difficult to not ablate the skin removing the very dressing you're trying to retain. Wound care becomes very important with both of these technologies.

The Pearl allows you to have a little bit of retained debris but not a lot of pain. You can get the same long-term endpoint with a CO₂ laser, a Pearl, or Erbium YAG if you're clever with the settings. The question is, what's going to happen between the time of treatment and that three or four week window?

Moderator:

How does the Pearl compare to the Rhytec Portrait?

Dr. Victor Ross:

The difficulty with the Portrait is that it is hard to see where you've been with lower settings. There's very little change at the surface at all except for some mild redness. The nice thing about the Pearl is you do have a little bit of frosty whitening at the surface, a little bit of ablation. You can see a little bit better where you've treated. You can get very nice results with the Portrait, but with the lower range of settings, it takes practice to lay down the pulses contiguously and have a nice, even peel.

Pearl in Your Practice

Moderator:

How does the Pearl fit into your practice?

Dr. Rick Green:

I have a mix of cosmetic and surgical patients all day long. My challenge is giving enough face time to cosmetic patients so they feel well taken care of and that they've gotten value for their money. It takes me about 10 minutes to do the face because I don't have to do any of the pre-treatment. The aesthetician does that. I do the procedure, smile and walk out. Yet the patient is there for maybe 50 minutes to an hour and they feel well taken care of. Even though I'm in this very mixed practice environment, it's worked out very nicely.

Pearl is also drawing new patients into my practice. For somebody that's never done anything to their skin before, it gets them curious about other possibilities.



Conclusion

Moderator:

Closing remarks?

Dr. Victor Ross:

The nice thing about the Pearl is this freshening that you don't get with the IPL or your more traditional Fraxel procedures. What makes this stand apart from other technologies is at three or four days, the patients really have a fresh baby-bottom feel to their skin. That's what you have to emphasize in counseling the patients. That's where they really realize the benefit and the dollar value for this procedure.

Dr. Amy Taub:

I agree with that. If you position this for people with mild to moderate photodamage and wrinkles, you are talking about a procedure which has relevance to a large patient population. The patients we have done have been thrilled with it. The benefits of quick results, 3-4 days of downtime with intact skin and minimal discomfort means this procedure is going to open the door again for ablative procedures. It is going to be a very popular procedure.

Dr. Rick Green:

When we started offering Pearl in our clinic, we treated 2 or 3 patients per week. Through word of mouth, we are now treating 10-15 per week. Pearl has been very gratifying for us as providers because, not only does it treat many popular indications, but it also delivers high patient satisfaction and immediate results.

"The nice thing about the Pearl is this freshening that you don't get even with the IPL or your more traditional Fraxel procedures. What makes this stand apart from other technologies is at three or four days, the patients really have a fresh baby-bottom feel to their skin."

Victor Ross, M.D.



Richard Green, M.D.



Amy Forman Taub, M.D.



E. Victor Ross, M.D.

Physician Bios

Dr. Richard Green is a board-certified plastic surgeon in Vancouver, Washington. He graduated magna cum laude from Notre Dame in 1985 and from the University of Illinois Medical School in Chicago in 1989. Dr. Green trained in general surgery and plastic surgery at Loyola University in Illinois. He is a Fellow of the American College of Surgeons and a member of the American Society of Plastic Surgeons. Dr. Green is in private practice at Salmon Creek Plastic Surgery which offers a full range of cosmetic plastic surgery procedures. Dr. Green is also the medical director of the Interlude Medical Spa.

Dr. Amy Forman Taub is a board-certified dermatologist who's been in private practice since 1989. In 2003, she founded Advanced Dermatology and Skinfo, Specialty Skincare Boutique in Lincolnshire, Illinois. Dr. Taub graduated from Northwestern University Medical School in 1985 and completed her internal medicine internship and dermatology residency at Northwestern Memorial. Dr. Taub is currently a clinical assistant professor at Northwestern University Medical School. Dr. Taub is experienced with a wide variety of lasers including fractional and erbium resurfacing devices.

Dr. Ross is a board-certified dermatologist and currently the director of the Laser and Cosmetic Dermatology Unit at Scripps Clinic in San Diego. He is also on the teaching staff at the University of California, San Diego. Dr. Ross is the president of the American Society of Laser Medicine and Surgery also known as ASLMS. He completed his dermatology residency at the National Naval Medical Center and performed a two-year fellowship in photomedicine at the prestigious Wellman Laboratories and Massachusetts General Hospital Dermatology Laser Center. He was honored in 2001 as the Navy recipient of the Chairman Joint Chief of Staff Award for Excellence in Military Medicine. Dr. Ross is the Lead Clinical Investigator for the Pearl.