

Expanded Levulan Research Studies Continue to Produce Impressive Clinical Outcomes

By Bob Kronemyer, Associate Editor

Several recently published clinical studies highlighting treatment with topical 5-aminolevulinic acid (ALA) photodynamic therapy (PDT) using the Levulan Kerastick from DUSA Pharmaceuticals, Inc. (Wilmington, Mass.) have reported significant results in photorejuvenation treatments.

A prospective, randomized, controlled split-face study involving 20 patients is the first to show conclusively that Levulan plus intense pulsed light (IPL) achieves significantly better results compared to IPL alone. Each patient had three split-face sessions, three

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weeks apart. “Half the face was pretreated with Levulan, followed by IPL treatment,” said investigator Jeffrey Dover, M.D., FRCPC, a clinical associate professor of dermatology at Yale University School of Medicine. “The other half of the face was treated with IPL alone.” The incubation of Levulan was 30 to 60 minutes and the IPL device was the Quantum SR (Lumenis).

Following the three split-face sessions, two full-face treatments of IPL alone were also scheduled three weeks apart. One month after the final treatment, Dr. Dover and his patients assessed five variables: global photodamage, fine lines, mottled pigmentation, tactile roughness and sallowness. “Pretreatment with Levulan resulted in 80% improvement in global photodamage versus 50% with IPL alone,” Dr. Dover said. Mottled pigmentation and fine lines also improved greatly (95% vs. 65% and 55% vs. 20%, respectively). However, “there was no statistical difference in tactile roughness or sallowness,” Dr. Dover continued. Side effects were also minimal for both sides of the face.



Jeffrey Dover, M.D.,
FRCPC

“I think it is clear that adding Levulan to IPL photorejuvenation improves the final outcome,” Dr. Dover stated. “IPL photorejuvenation alone does not show significant improvement in fine wrinkles. Furthermore, if Levulan is used properly with caution to sun avoidance within 24 to 36 hours after treatment, it is extraordinarily well tolerated and has a high acceptance rate among patients.”

Mark Nestor, M.D., Ph.D., a clinical associate professor of dermatology at the University of Miami School of Medicine in Florida, retrospectively evaluated a small cohort of patients who each averaged about 5.7 facial skin cancers a year. “We looked at four or five patients a year. By using Levulan, the average number of skin cancers significantly decreased after one year to only



Mark Nestor, M.D., Ph.D.

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one per patient. But this is probably an overestimation because some of these cancers were located at the periphery of the treatment area, so these cancers may not have even been within the treatment area.”

Each patient underwent five PDT sessions at roughly two week intervals. The incubation period of Levulan was 30 to 60 minutes and the IPL source was the VascuLight (Lumenis). “It is gratifying to see this degree of improvement in facial skin cancers,” Dr. Nestor said. “Levulan continues to be a tremendous tool for a variety of conditions. My study is simply one more example of the potential long-term benefits of Levulan. We certainly are continuing to see a very significant benefit in acne and in cosmetic improvement.



Before Tx



After Levulan Tx

Photos courtesy of Martin Braun, M.D.

For acne, we now have patients who have remained clear for two years.”

Dr. Nestor’s typical acne patient protocol is three sessions with the pulsed dye laser (PhotoGenica V-Star from Cynosure) and an incubation period for Levulan between 30 and 60 minutes. “We have also had impressive results for acne on the back and neck,” Dr. Nestor noted. “Generally, these patients receive three PDT treatments, normally spaced two to four weeks apart. Again, I use the pulsed dye laser.”

Levulan was an important component of an extreme makeover contest sponsored by the *Vancouver Sun*, the largest daily newspaper in Vancouver, Canada. “The newspaper wanted to do the makeover without any surgery,” said Martin Braun, M.D., a cosmetic specialist from Vancouver, who performed the makeover on the two winners. “Both the man and the woman are in their late fifties. In my opinion, they are too old to benefit.” Regardless, treatment consisted of four modalities: ThermoCool TC System (Thermage), Levulan PDT, Botox (Allergan) and Restylane (Medicis Aesthetics). The woman underwent two sessions with the ThermoCool (two months apart); the man had just one session. Both patients also had three sessions of Levulan PDT with IPL (VascuLight SR), spaced one month apart. Botox and Restylane (Restylane Fine Lines, Restylane, Perlane) were also both injected twice (three months apart).

In total, the woman had nine treatment sessions between June and October, and the man had eight ses-

sions. “The before and after pictures look fabulous. In fact, they are the nicest ones I have ever seen,” Dr. Braun said. “There is quite an effacement of fine wrinkles, even in areas over the cheek where we didn’t do any Botox or Restylane. Photodamage is also lessened and the skin is much brighter. There is a nice, radiant glow. Of the four modalities, I believe the Levulan and Botox provided the most benefit.”

In an ideal world, Dr. Braun believes that individuals with Fitzpatrick skin type I – III should have a PDT treatment every year beginning at age 40 to 50.

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“This would pick up any potential cancers. It would also compensate for the 2% of collagen we lose in our dermis every year.”

For patients with moderate-to-severe acne, Levulan in combination with the SkinStation Clinical Phototherapy System (Radiancy) has shown encouraging results. “We were able to achieve over 70% clearance after four sessions at weekly intervals,” said Michael Gold, M.D., a dermatologist in private practice in Nashville, Tenn. “Incubation lasted from 30 to 60 minutes, but most patients were incubated for one hour.” The 12 patient study also maintained the high clearance rate through the three month follow-up. “The safety profile of the Levulan and the SkinStation was excellent,” Dr. Gold said.

One reason Dr. Gold prefers to use the SkinStation with Levulan for acne is that every skin type can be treated because of the low power. “With many of the other IPLs, you need to be very careful when treating darker skin types.” As for the future of Levulan, “the applications of highest interest and promise are acne, photodamage, ‘super-photorejuvenation,’ sebaceous gland hyperplasia and pustular/papular rosacea. A new successful treatment will be welcomed in most aesthetic practices.”



Martin Braun, M.D.



Michael Gold, M.D.