Welcome to the 6th edition of the Medical Bulletin for Omnilux users. This issue focuses on the excellent work by Professor Park and Dr Lee from the National Medical Center in Korea. Their work on combination therapy for the treatment of acne further supports our established protocol. However their work on skin rejuvenation, including the findings from polymerase chain reaction (PCR) method and immunohistochemistry (ICH), is quite outstanding. This work not only answers, in a definitive manner, many questions on the mechanisms of Omnilux LED therapy, but also raises others! I look forward to its publication in early 2007. Until then, may I wish you all a successful conclusion to 2006 and a prosperous New Year.

IMCAS: Join us for Breakfast in Paris

January 2007 will once again see Omnilux exhibiting at IMCAS (10th-13th January), with a breakfast workshop organized for Friday 12th January at 8.30am, Symposium 9, Room 3. The workshop, entitled Omnilux- Fact Not Fiction, will see Drs David Goldberg, Mark Taylor, Benjamin Ascher and Glen Calderhead present the latest Omnilux clinical data and also allow participants to discuss their own clinical experiences in a workshop forum.

To register your interest contact Michelle.Flaherty@Omnilux.co.uk

AAD Preview:

PTI will be exhibiting Omnilux at the Academy of Dermatology meeting, February 2nd-6th, 2007 Washington, DC.

Omnilux will showcase on booth number 2855 and will also be supported by talks within the main programme and poster sessions. Dr David Goldberg will be presenting our most recent data from South Korea from Drs Park and Lee.

Omnilux will be appearing at the following major shows in early 2007.

***IMCAS* - January 11th-13th 2007**

Paris, France, Palais des Congres, Booth E21

***AACS* - January 25th-28th 2007**

AZ Biltmore Resort and Spa, Phoenix,AZ

***AAD* - February 2nd-6th**

Washington DC, Booth 2855

***South Beach Symposium* - February 14th-18th**

Loews Miami Beach Hotel, Miami Beach FL

Hawaii Dermatology Seminar - March 3rd-9th

Grand Wailea Resort, HI

***EADV* - May 16th-20th 2007**

Vienna, Austria, Booth Y17

Webinars prove a Success

Photo Therapeutics, Inc (PTI), the US arm of Photo Therapeutics Ltd, have now held 3 successful webinars, attended by over 100 dermatologists. The webinars were presented by eminent dermatologists and cosmetic doctors in the US and featured their individual experiences of the product.

"Omnilux fact not fiction." Dr David Goldberg

"Omnilux in practice." Dr Mark Taylor

"Non invasive light based treatments" Dr Joe Niamtu

Recordings of these webinars are now available on the new secure download section of our website.

You will also be able to use the site to gain instant download access to large files, such as presentations and images, that we would normally have to send to you by CD. To access the site log on to www.phototherapeutics.com/secureAreaRegister.asp

Click the webcast link under Current news and follow the on-screen instructions.

Publication of Korean Studies imminent

Blue and red light combination LED phototherapy for acne vulgaris in patients with skin phototype IV

Accepted for publication, Lasers in Surgery and Medicine

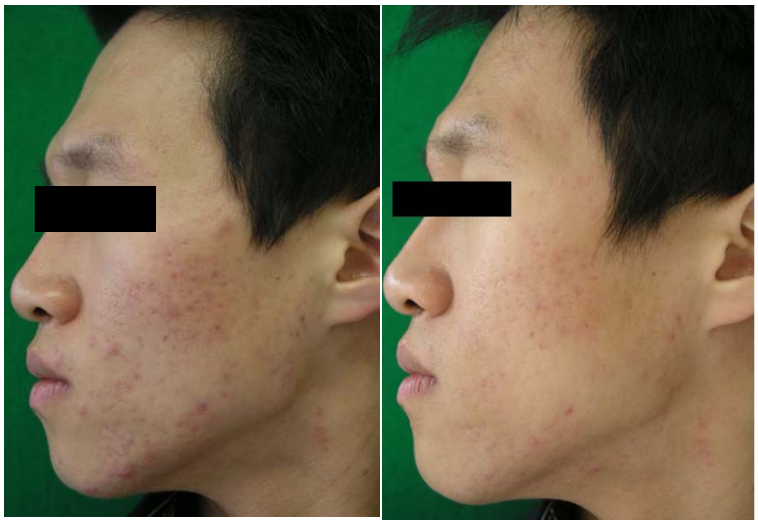
Seung Yoon Lee, MD, Chung Eui You, MD, Mi Youn Park, MD, PhD.

Available online

http://www3.interscience.wiley.com

The study involved 24 patients treated with the standard Omnilux acne protocol for 4 weeks. Clinical assessments were conducted before treatment, after the 2nd, 4th, and 6th treatment sessions, and at 2, 4, and 8 weeks after the final treatment, by grading and lesion counting. In addition, objective instrumental assays of various aspects of the skin condition (moisture, sebum levels, melanin content) were carried out before and after treatment at each treatment session. The result showed mean percentage improvements in non-inflammatory and inflammatory acne lesions of 34.28% and 77.93%, respectively. Highly inflamed lesions such as nodules or cysts also responded to this therapy, with significant reductions in both papules and pustules (p=<0.0001).

Significantly 'brightened skin tone' and improved skin texture were was spontaneously reported by 14 of the 24 patients. Interestingly, objective instrumental measurements with a Mexameter indicated that the mean melanin levels significantly decreased in all subjects after the eighth treatment, compared to those measured before the first treatment.



Baseline and 8 weeks post therapy

Blue and red light combination LED phototherapy for acne vulgaris in patients with skin phototype IV…continued

Further work by Drs Park and Lee (awaiting publication) demonstrated that revive (633 nm) alone had the effect of normalising melanin levels. This demonstrates the importance of using a combination of blue and red LED therapy for acne in skin type IV to minimse any risk of hyperpigmentation and to lighten the skin.

The authors concluded that this combination LED therapy was safe and effective for mild to moderately severe acne vulgaris, particularly for inflammatory-stage lesions, and would offer an extra tool to dermatologists dealing with antibiotic-resistent refractory acne.

Combined visible light and infrared light-emitting diode (LED) therapy enhances wound healing after laser ablative resurfacing of photodamaged facial skin. Trelles MA et al. Medical Laser Application 21 (2006) 165-175.

LED therapy accelerates healing post resurfacing.

Laser ablative resurfacing is still the most effective method for the rejuvenation of severely photoaged and photodamaged facial skin, but the long healing time coupled with other troublesome sequelae mean a long patient downtime. Phototherapy with light-emitting diodes (LEDs) has recently been attracting attention in accelerating wound healing. The current study was designed to assess the beneficial effects of LED phototherapy on wound healing and post operative sequelae following laser ablative resurfacing. The study had both a prospective and retrospective arm.

The prospective study population consisted of 28 female patients who underwent ablative ER:YAG/CO2 laser resurfacing (4 full face, 8 periocular, 16 perioral), followed by hemifacial LED therapy with 830 nm followed by 633 nm LED, 20 min/session (55 J/cm2 and 126 J/cm2 respectively). The contralateral side of the face was covered with an opaque material to prevent exposure to the LED energy. A similar number of age- and treatment-matched patients previously treated with exactly the same laser resurfacing parameters and postoperative wound care, but without LED therapy, formed the retrospective arm. Tissue healing time and postoperative sequelae were compared for the treated and untreated sides in the prospective group and for the untreated retrospective group. The healing time in the LED – treated side was around 50% faster, and sequelae significantly less, compared with the untreated side, but interestingly these factors were slightly better in the untreated side of the prospective subjects compared with the retrospective untreated controls. The systemic effect, well-reported in the laser therapy and other light therapy literature, may well have been responsible for this. This phenomenon involves the spread of light-activated photoproducts from the irradiated to unirradiated areas of the body carried via blood and lymphatic circulation.

At a 6-month follow-up in the prospective group, no significant difference in wrinkle improvement was seen between the treated and untreated side, but the skin appeared younger-looking on the LED – treated side compared with the untreated side. Combined LED therapy significantly improved healing time and treatment sequelae in laser ablative resurfaced photoaged facial skin, enabling combination LED patients to return to their social or work commitments in less than one-half of the time of LED-untreated patients. It further appears that this combined LED therapy approach may also help to sustain the good results through a maintenance therapy program.

LED phototherapy for skin rejuvenation: Optimisation of treatment protocols

Seung Yoon Lee, MD, Chung Eui You, MD, Mi Youn Park, MD, PhD.

Submitted to Journal of Photochemistry and Photobiology

The study, which involved 76 subjects, was a randomised, controlled, double-blinded clinical study to determine the clinical efficacy, and investigate histologic and ultrastructural changes, enzymatic alterations and the changes in key cytokines after Omnilux therapy. Subjects were divided into four groups. Each group received either:

a) Sham light (Omnilux on a low power setting) (Control group).

b) Omnilux plus: 830 nm, 66 J/cm^2, 55 mW/cm^2 (Infrared [IR] only group).

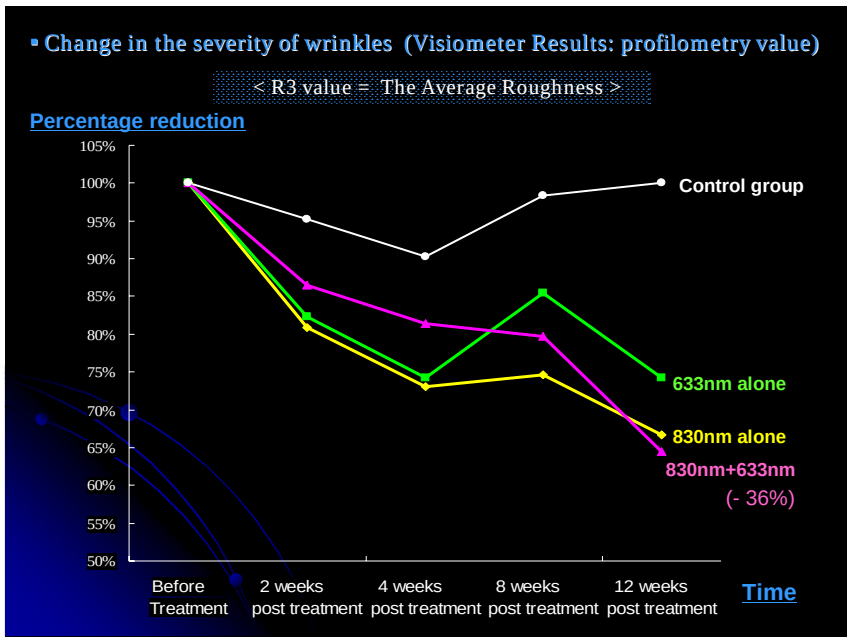
c) Omnilux revive: 633 nm, 126 J/cm^2, 105 mW/cm^2. (red light only group)

d) Omnilux plus: 830 nm, 66 J/cm^2, 55 mW/cm^2, in combination with Omnilux revive, 633 nm, 126 J/cm^2, 105 mW/cm^2 (Combination LED group)

In every subject only one side of the face was irradiated (even in the control group), the contralateral side being shielded by an opaque mask. The study thus enabled intra-subject as well as intra-group assessment. Each subject received a specific treatment programme that consisted of two light therapy treatments a week for 4 weeks. Each group received their designated wavelength(s) delivered under a precise time regime in order to stimulate the cell lines involved in all phases of the wound healing process.

Assessments were carried out at baseline and 2, 4, 8 and 12 weeks after the final therapy session, and included subjective patient response, objective blinded clinician review of the clinical photography, and objective profilometry. Additionally, punch biopsies were taken 2 weeks post therapy from treated areas. Samples were subjected to a number of assessments, including routine histological and transmission electron microscopy (TEM), PCR and immunohistochemical staining.

The severity of wrinkles was “remarkably reduced” in the 830 and 633 nm combination group. Elasticity also improved in this group. Mexameter results indicated that there was a significant drop in melanin levels ($p<0.0001$) in the 633 nm arm only. Finally, subject satisfaction level was much higher in all of the treatment groups (most notably in the 830/633 nm combination) than in the control group.

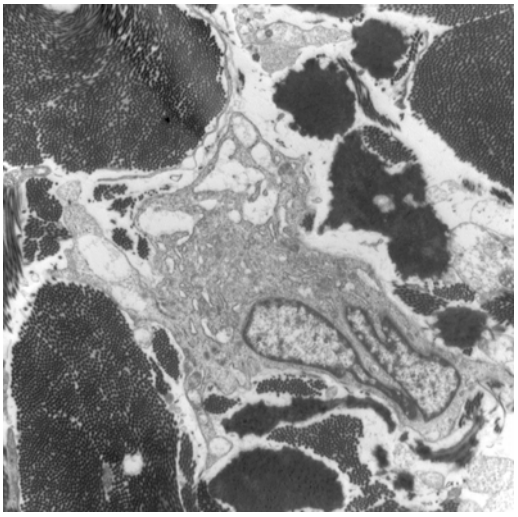


Both routine and transmission electron microscopy results showed very clearly that there was excellent collagen synthesis with a very strong, dense and well-organised layer of collagen running under and parallel to the dermoepidermal junction (the so-called grenz zone), and attached to it, but

also a good improvement in elastin fibres. Interestingly, improved collagen density in all the treatment groups extended down into the deeper dermal reticular layer and was not restricted to the superficial dermis, as has often been the case with other photothermally-based nonablative skin rejuvenation modalities.

The TEM findings demonstrated numerous active fibroblasts compared with controls. The fibroblasts appeared highly active and were surrounded by thick collagen bundles in the treatment groups, which may indicate the production of large amounts of collagen and elastin fibers.

At a subcellular level, TEM indicated enlarged rough endoplasmic reticula and Golgi complexes, and many active mitochondria in the irradiated fibroblasts. This finding supports earlier data from Takezaki and Omi. Takezaki I et al; 'Ultrastructural Observations Of Human Skin Following Irradiation With Visible Red Light-Emitting Diodes (LEDs): A Preliminary *In Vivo* Report' - Laser Therapy 14.4: 153 – 160.



Transmission electron microscopy demonstrates numerous active fibroblasts. Fibroblasts appear highly active and surrounded by thick collagen bundles.

PCR indicated significant increase in cytokines (chemical messengers), which are essential in amplifying the inflammatory response. Increases in Interleukin (IL) -1b, IL-6 and tumour necrosis factor (TNF) –alpha, support Takezaki and Omi's second paper, (Takezaki S, Omi T, Sato S, Kawana S; Light-emitting diode phototherapy at 630 +/- 3 nm increases local levels of skin-homing T-cells in human subjects. J Nippon Med Sch, 2006; 73: 75-81), which additionally demonstrated fibroplastic changes in fibroblasts and the dramatically elevated levels of both Th-1 and particularly Th-2 T-cells.

Drs Park and Lee also demonstrated a marked increase in growth factors and key cellular proteins that indicate increased cellular communication. Of particular interest was the increase in Connexin-43, a subunit of connexon a protein that forms a gap junction, a channel that permits ions and small molecules to move between adjacent cells. The connexins are important to intracellular communication. Increases in this protein indicate high levels of intracellular communication. This supports the proposal by Calderhead and other workers that Omnilux LED phototherapy has a cascade effect, leading to stimulation of many cells from a single point source.

Dr Park and Dr Lee concluded that the clinical results and evidence of tissue assays showed that Omnilux LED therapy was effective in improving the visible signs of photoaged skin both clinically and histologically. Omnilux LED therapy was a safe, easy-to-perform, and side effect-free treatment that can be used conveniently in dermatology clinics.

Before and twelve weeks after commencing the study (830 & 633nm combination)

Call for abstracts

Anyone wishing to submit an article to be included in the bulletin, please contact our medical affairs team. We are interested to hear from anyone who has had experience in the use of Omnilux for the treatment of cellulite and also hair restoration. We sincerely hope that you will add value to this publication throughout next year with your experiences and comments.

Please contact steve.baker@omnilux.co.uk