



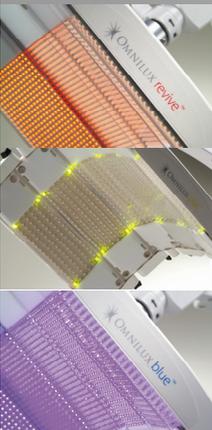
Welcome to our new medical bulletin! This is the first edition of a specially prepared publication that focuses on current Omnilux trial data and news from the medical field. In early 2005 we launched Omnilux plus™ (830nm). Already FDA approved, this addition to the Omnilux group of treatment heads offers clinicians further proof of our commitment to developing an established pipeline of product and expanding the treatment modalities that Omnilux encompasses.

The medical bulletin gives us the opportunity to share with you our experiences with Omnilux and we sincerely hope that you will add value to this publication over the forthcoming year with your experiences and comments.

Laurence Reilly, Director of Medical Affairs



FDA APPROVALS RECEIVED



Phototherapeutics Ltd (PTL) has received FDA approval for the 830nm, Omnilux plus™ head (FDA 510K number K043317) for "the relief of minor muscle and joint pain". This approval has important significance as it forms the basis for ongoing submissions expanding the range of indications for Omnilux plus™, both on its own and in combination with other treatment heads from the Omnilux family.

The second successful submission is also a milestone for PTL in that it relates to a combination treatment. Omnilux revive and Omnilux blue used together for the treatment of mild to moderate acne vulgaris. The approval recognises that this combination treatment protocol achieved reductions in lesion counts of more than 80% over a significant period post treatment. (FDA number KO43329)

OMNILUX PLUS

Wound healing
The use of 830nm LEDs in accelerating healing of post-operative wounds.

Exciting preliminary clinical results on the use of Omnilux Plus™ in postoperative acceleration of wound healing have been reported in procedures such as breast augmentation, blepharoplasty and minor surgery. These observations clearly indicate the need for high quality scientific investigation to explain and quantify these enhanced effects.

Psoriasis
The use of Omilux plus™ in the treatment of severe plaque psoriasis.

Agents used as monotherapy in moderate to severe plaque psoriasis may often exhibit cumulative toxicity effects and poor efficacy.

Effects of many of the topical agents used (e.g. staining of clothing and surroundings) are undesirable to patients.

Phototherapy in psoriasis has long been used in the form of UVB and PUVA. The use of ALA-PDT using red light (633nm) has reported some success but the issue of pain negates the benefits of this treatment modality. Omnilux Plus™ offers a unique patient-friendly treatment in stable moderate to severe plaque psoriasis.

A large population double blind randomised trial is currently underway to investigate the effects of Omnilux 830 nm LED treatment used in conjunction with topical retinoid versus light alone and topical alone groups. Initial results are encouraging and will be reported in the next issue of medical bulletin
 (Continued on page 2)



Pain Management

A preliminary report on the use of an 830nm LED light source in the management of pain.

Encouraging preliminary results have been seen in the treatment of musculoskeletal pain using Omnilux plus.TM The open trial at the University of Ulster Sports Rehabilitation Clinic – a facility staffed by research-trained sports physiotherapists and funded by the Sports Institute for Northern Ireland was completed over a period of 5 months.

Omnilux PlusTM was employed in range of musculoskeletal injuries, which would otherwise have been considered for treatment with laser therapy using a multisource or 'cluster' array. Over the trial period, a total of 200 treatments were performed using Omnilux plus.TM Patients presenting with tendinopathies, muscle tears and injuries, low back pain and joint pain were treated for 5 or 10 minutes, 54 or 108J/cm² respectively. In all cases, treatment was performed as part of a comprehensive package of physiotherapy and rehabilitation.

Monitoring outcome measures such as return to full activity, return to a pain free gait and return to athletic competition impressive results were observed using only 1 to 5 Omnilux plusTM light treatments. Of all the pathologies treated, significant pain reduction was observed in hip, degenerative knee and sacroiliac pain. In terms of tendinopathies, Achilles tendinopathy and Achilles rupture responded especially well. In the muscle pain category - rectus femoris strains and mechanical lower back pain yielded the most impressive results.

The physiotherapists treating with the Omnilux system indicated the popularity of the unit due to its ease of use and 'hands free' operation. The potential of Omnilux PlusTM to treat more deep-seated and intractable lesions and conditions was noted as a point for further study.

Facial Rejuvenation

Inveresk study submitted for publication:

The study entitled "A Study to determine the efficacy of Combination light therapy (633nm and 830nm) in facial skin rejuvenation" has been submitted for publication to the Journal of Cosmetic and Laser Surgery.

The profilometry study was designed to assess potential skin surface roughness changes related to regular dosing over a 5-week period of filtered light at 633nm and 830nm. Casts of the skin surface and photographic data were taken at baseline and predetermined time points (Days 7 and 14 and weeks 6, 9 and 12). Thirty one subjects (7 male, 24 female. Mean age 46.2, range, 35-57 years old) displaying wrinkles or crowsfeet in the periorbital and nasolabial area completed the trial. No significant adverse events were reported and the treatment was well tolerated. Cast analysis noted a significant difference in Sq ($p < 0.001$) at weeks 9 and 12 compared to baseline and Sa ($p < 0.001$) at week 12. Sq reduced by more than 13% at week 9 and 27% at week 12.

Subject responses were excellent with 83% reporting softening of fine lines and wrinkles even at 12 weeks. Sixty-five and seventy-five percent reported improvement in softness and smoothness at 12 weeks respectively. Dr. Russell, the principle investigator, was encouraged by these findings.

"Matching wavelengths with specific cellular targets and taking the photocharacteristics of epidermal and dermal components into consideration has produced a significantly better result than we previously have seen with a single wavelength. This leads to patients seeing more visible results and, ultimately, to greater patient satisfaction.

This study further supports the widely accepted theory that effective light therapy must be predicated upon the correct wavelength, intensity and dose for the desired structural change. The single platform technology of Omnilux lends itself well to this type of treatment protocol. The ability to interchange treatment heads and deliver the proper light at the proper time is really the linchpin of any effective light therapy."



12 weeks after Omnilux combination phototherapy with Omnilux plus and Omnilux revive.

COMBINATION OMNILUX PHOTOTHERAPY

Studies Reveal Omnilux LED Phototherapy Enhances Botox and Fillers

By Steve Zucker

The results of a new study reveal that combining Omnilux LED phototherapy with Botox and fillers provides a new level of aesthetic treatment. The study shows that the combination of Omnilux LED phototherapy and Botox and fillers provides a new level of aesthetic treatment. The study shows that the combination of Omnilux LED phototherapy and Botox and fillers provides a new level of aesthetic treatment.

The Omnilux system (Omnilux Revive, Omnilux Plus, Omnilux Revive) provides an effective and safe treatment for a wide range of aesthetic concerns. The Omnilux system (Omnilux Revive, Omnilux Plus, Omnilux Revive) provides an effective and safe treatment for a wide range of aesthetic concerns.

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Combination Omnilux Phototherapy sheds new light on aesthetic treatments.

Using their knowledge of light therapy **Dr Denis Branson, Fayetteville, New York, Dr Mark Taylor, Salt Lake City, Utah, Dr Mario Trelles, Cambrils, Spain and Dr Fabian Baez, Sydney, Australia**, propose that using a combination of Omnilux revive (633nm) and Omnilux

Typical protocols

- ⇒ For laser therapy patients can commence Omnilux treatments using Omnilux plus™ up to 2 weeks before laser ablation to condition the skin and stimulate the cells responsible for tissue regeneration.
- ⇒ Post laser ablation Omnilux plus™ is used for around 2-3 days post treatment followed by a course of at least 3 Omnilux revive treatments spaced around 3 days apart. To increase speed of tissue contraction two further treatments of Omnilux plus™ is suggested around 21 days post therapy.
- ⇒ For Botox and fillers use Omnilux revive immediately after injecting and then either 2-3 times weekly or once weekly dependent upon the desired outcome.
- ⇒ For Botox and Fillers patients commence Omnilux revive treatments immediately after injections and then once weekly for 4-5 weeks.

plus™ (830nm) or Omnilux revive alone can drastically reduce erythema, swelling, bruising and general downtime their patients experience after laser therapy, IPL treatments, Botox and surgery.

Using a combination of wavelengths delivered at specific time points pre- and post- elective therapy, both Dr Taylor and Dr Branson have seen a significant reduction in patient downtime. Dr Trelles and Dr Baez have noted a significant reduction in bruising around the injection sites for Botox and fillers and have also seen a marked improvement in longevity of the treatment.

Benefits of Omnilux combination therapy after laser resurfacing, IPLs, Botox and surgery!

- ◆ **Less pain, bruising, swelling and erythema**
- ◆ **Faster re-epitheliasation**
- ◆ **Better patient follow-up and care**
- ◆ **Less patient downtime, greater acceptance**



"Our patients are healing amazingly quickly. I've noted using this protocol that erythema is dissipating at 3 weeks post treatment"

Dr Mark Taylor Salt Lake City, Utah.

OMNILUX IN THE PRESS

As this bulletin goes to print, Omnilux is one step further to publication in peer-reviewed journals.

- Lanigan et al (2004) - 633 nm skin rejuvenation - Lasers in Medical Science (Springer) - published in April 2005
- Tremblay (2004) - 415 nm in Inflammatory acne - Journal of Cosmetic and Laser surgery - submitted-peer review
- Morton et al (2003) - 415 nm mild to mod acne - Journal of Dermatological treatment - submitted-peer review
- Russell (2004) - 633 & 830 nm in Skin Rejuvenation - Journal of Cosmetic and Laser Therapy - to be submitted 05/05
- Russell (2004) - 415 & 633 nm mild to severe acne - to be submitted 05/05
- Omi et al (2005) - British Journal of Plastic Surgery – The photobiological effects of red LED therapy in human tissue in vivo. Submitted 8th April 2005
- Omi et al (2005) - Journal of Cosmetic and Laser Surgery – Red LED therapy enhances fibroblast metabolism: A morphological in vivo study. Submitted 8th April 2005
- Kubota et al (2005) - Journal Cosmetic Dermatology - Combined LED phototherapy in the Japanese skin type - submitted -18th April 2005
- Calderhead G (2005) - Journal Cosmetic Dermatology - The photobiological basis of combined LED therapy. Planned submission May 2005
- Trelles M (2005) - Journal of Laser therapy – Combined LED therapy augments full face resurfacing and non ablative skin rejuvenation. Planned submission May 2005

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