Lumenis One™ - An Expandable Technology Platform for Comprehensive Aesthetic Treatments

BOSMAT ZAMIR, M.D.
Haifa, Israel

Lumenis One™ is a modular medical device which is equipped with an Intense Pulsed Light (IPL™) treatment head, the Nd:YAG 1064 nm laser, and the LightSheer™ diode laser. The system allows treatment of a wide range of aesthetic conditions. This report contains preliminary clinical results achieved using Lumenis One, along with a brief summary of the system's technological and operational features.

Of the treated areas that reached one month post-treatment at the time of this analysis, 83% had improved by 50-100% in comparison to their baseline status. High safety and patient satisfaction levels were also reported.

INTRODUCTION

Lumenis One is a multi-technology, multi-application IPL and laser system, manufactured by Lumenis Ltd. A versatile, upgradeable platform, it comprises three technologies used for numerous clinical applications (see Table 1). The three technologies are Intense Pulsed Light (IPL), the Nd:YAG 1064 nm laser, and the LightSheer diode laser.

Intense Pulsed Light (IPL), Lumenis' propriety technology, is the gold standard for skin treatments using Photorejuvenation. Four years following initial IPL treatment, Weiss *et al* reported ~80% improvement in the appearance of superficial vascular and benign pigmented lesions on the face, neck, and chest, as well as textural improvement of the skin in these areas.[1] Additional positive reports of facial and non-facial treatments in various skin types, including darker skin, have also been published, along with emerging scientific-based proof for the evident clinical outcome.[2-5]

The Nd:YAG laser represents the gold standard technology for non-invasive treatment of deeper vascular lesions and leg veins. The results obtained via use of Nd:YAG lasers are complete and long-lasting, often eliminating the need for painful and risky invasive intervention.[6-7]

The LightSheer diode laser is the world's most accepted technology for photoepilation. Numerous articles and physicians have reported that LightSheer is an effective and safe modality for permanent hair reduction and for the treatment of pseudofolliculitis barbae in all skin types and nearly every hair color and diameter.[8-9]

Applications	IPL	Nd:YAG	LightSheer
IPL Skin Treatments Using Photorejuvenation	X		
Pigmented Lesions	X		X
Vascular Lesions	X	X	X
Leg Veins		X	
Facial Wrinkles		X	
Hair Removal	X		X
Scars, Striae, Warts	X		

Table 1. Lumenis One's FDA-cleared technologies and corresponding applications

SYSTEM DESCRIPTION

Lumenis One is equipped with an IPL treatment head and two laser treatment heads. The IPL source emits 3-100 ms pulses at a broad spectrum (515-1200 nm) with a fluence range of 10 to 40 J/cm^2. Pulses can be administered as a single, double or triple pulse string, with possible inter-pulse delays of 1-120 ms. The Nd:YAG laser operates at 1064 nm and a 10 to 225 J/cm^2 fluence range. This laser source also possesses the multiple synchronized pulsing option with pulse durations of 2-20 ms and pulse delays of 1-100 ms. The LightSheer diode laser emits continuous 800 nm light with extended pulse widths of 5-400 ms and fluence levels of 10-100 J/cm^2. The system can deliver high repetition rates of up to 1 Hz for the IPL and Nd:YAG sources and up to 2 Hz for the LightSheer.

The revolutionary state-of-the-art design of the Universal IPL™ treatment head eliminates the need to use different treatment heads for various applications. Instead, this treatment head comes equipped with seven ExpertFilters™ (515, 560, 590, 615, 640, 695 and 755 nm) that can be easily interchanged using the same treatment head. Two SapphireCool™ light guides, 15x35 mm and 8x15 mm, allow the user to change the spot size to suit various anatomical areas, for increased treatment convenience and patient/user comfort. Ease of use is enhanced by the ergonomic design of the Universal IPL treatment head, including its multiple gripping positions and three operating buttons.

Notably, the IPL modality of Lumenis One incorporates a genuine breakthrough in the form of Optimal Pulse Technology (OPT). The essence of OPT is the system's ability to control the pulse shape and to deliver homogenous "squared-off" pulses, resulting in more even distribution of the energy within each individual pulse and between sub-pulses. This novel pulse shape control mechanism enables use of lower fluence levels and can result in safer, more effective, and more reproducible treatments.

Considerable improvements have also been introduced with the Multi-Spot™ 1064 nm Nd:YAG treatment head, beginning with its exceptionally light-weight and compact design. The treatment head is also very simple to operate, and these aspects of its e rgonomic design contribute to reduced user fatigue. The dimensions of the three light guides (2x4 mm, 6 mm, and 9 mm) enable safe and precise treatments. The 2x4 mm light guide was specifically designed for quick and effective treatment of small and superficial telangiectases and veins (0.5-1.5 mm depth and diameter) since its rectangular shape is suited to the geometry of blood vessels when placed longitudinally to them. The 6 mm spot is suitable for the treatment of deeper leg veins and vascular lesions.

The LightSheer™ diode laser, with a 9x9 mm spot size, enables successful treatment of both light and dark skin types, thanks to its wide range of pulse widths (5-400 ms) and fluence levels (10-100 J/cm^2). The extended pulse width/fluence enables safer and more effective treatment in darker skin types.

The treatment heads have continuous contact cooling which enhances both patient comfort and safety. The chilled light guides are made of sapphire, instead of quartz, contributing to better cooling conduction and greater durability. Notably, all treatment heads have built-in calibration via a power meter in each treatment head cradle, a significant safety feature.

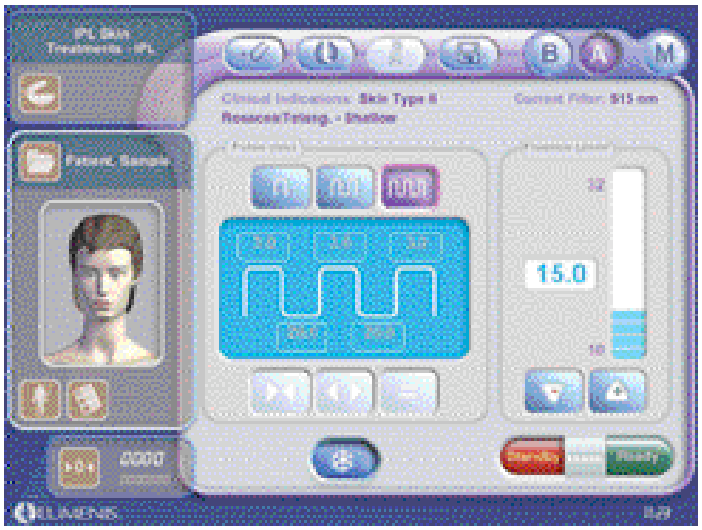

Figure 1. Lumenis One user interface

Lumenis One offers additional user-oriented features, such as a touchscreen monitor and an intuitive user interface with "body maps" for ease of use (see Figure 1). The system allows users to take advantage of the experience that has been gained over the years with these three light and laser technologies, as exhibited in the pre-programmed treatment parameters that are available for most applications, and are presented in two modes: the

Basic Mode for new users and ancillary staff and the Advanced Mode for more expert users. Most importantly, all treatment-related information is stored in a downloadable Patient Database, which is searchable via multiple queries, thus providing easy access to patient records and precise treatment information. The system is password-protected and has additional safety features, such as treatment head, spot size and filter recognition.

CLINICAL EVALUATION

PROCEDURES

A clinical evaluation of Lumenis One is currently being conducted at several centers worldwide in order to demonstrate the clinical and technical performance of the new system. The following is an interim report of the results at one of the participating centers, focusing on the following applications: IPL skin treatments using Photorejuvenation, IPL treatment of benign pigmented lesions, IPL treatment of vascular lesions, Nd:YAG treatment of deeper vascular lesions and leg veins, and IPL hair removal. The LightSheer diode laser treatment head was not included in this evaluation since there are no clinical implications to any changes made to this component.

A total of 167 individuals, mostly females (82%), received treatment for the aforementioned clinical applications. Patients ranged in age from 18 to 68 years (average age 40.12±13.70). The skin type distribution, generally representative of the center's geographical location, was 25% type II, 48% type III, 20% type IV, and 7% type V. Notably, patients could receive treatment in more than one anatomical area and/or for more than one application, leading to a total of 360 treated areas.

Patients received up to five treatments (up to four for vascular lesions) at 5±1 week intervals and were also invited for a follow-up visit one month after the last treatment. IPL treatments were performed with the 15x35 mm or 8x15 mm light guides; the 6 mm spot size was utilized in the Nd:YAG treatments.

After cleaning the area to be treated, a thin layer (1-2 mm) of cold coupling gel was applied to the skin. In a few cases, topical anesthesia (L.M.X.4, previously known as Ela-Max 4%, Ferndale Laboratories, Inc., Ferndale, Michigan, USA), was applied to the treated area for 30 minutes prior to this step. The sapphire chilled light guide was placed so it gently touched the skin while immersed in the cold gel. When treating superficial vascular lesions, light guide chilling was not utilized and room temperature gel was used.

In choosing the treatment parameters, the users utilized the system's recommended presets for each application and indication, individually matching a specific preset to the patient's skin type and lesion's baseline condition. The skin and lesion response immediately following treatment was monitored, along with possible changes in the lesion's condition during the treatment course. This sometimes led to a modification of the treatment parameters at subsequent visits (e.g., increasing the fluence as lesion becomes lighter).

Prior to each treatment and at the follow-up visit, photographs of the treated areas were taken and evaluations were performed. In all applications, excluding hair removal, the investigator rated the improvement level on a 5-point improvement scale: No change, 0-25%, 25-50%, 50-75%, and 75-100% improvement. In hair removal treatments, a sample hair count was performed in a 1.5x1.5 cm square template that was carefully placed in the same location at each visit (prior to treatment). Patients were asked to provide their level of satisfaction for each treated area at several time points (figures not shown), using a 5-point scale: Not satisfied, Somewhat satisfied, Satisfied, Very satisfied, and Extremely satisfied.

The data was analyzed, at the treated area level, using t-test or Wilcoxon test, as applicable. All statistical tests were two-sided, and 5% was regarded as the level of statistical significance for all tests of differences.

RESULTS

Three general comments apply to the results section:

1. Each specified evaluation time point actually reflects the effect of those treatments that preceded it; for example, the evaluations that appear under 'Tx 4' represent the influence achieved up until that time point.

2. The 'n' in the figures represents the number of treated areas at each time point; this value differs between the visits within each application since not all patients reached the same stage of the evaluation in this interim analysis.

3. In all of the presented clinical applications, response to treatment was typically limited to the expected and desired one. Any side effects were mild in nature (e.g., transient erythema), did not hinder the treatment schedule, and were all resolved or improved at the time of the interim analysis.

IPL Skin Treatments Using Photorejuvenation

Thirty six (36) patients with 49 treated areas were classified to this clinical application category. Full facial treatments were performed in 63% of the cases; neck, arms/hands and upper chest areas were also treated. The advantage of IPL skin treatments using Photorejuvenation is that they encompass a wide range of conditions, including rosacea, erythema of rosacea, telangiectases, poikiloderma, melasma, hyperpigmentation, and various sun/age spots. Indeed, this array of conditions was represented in the evaluation, sometimes a combination of conditions existing in the same patient or in the same treated area.

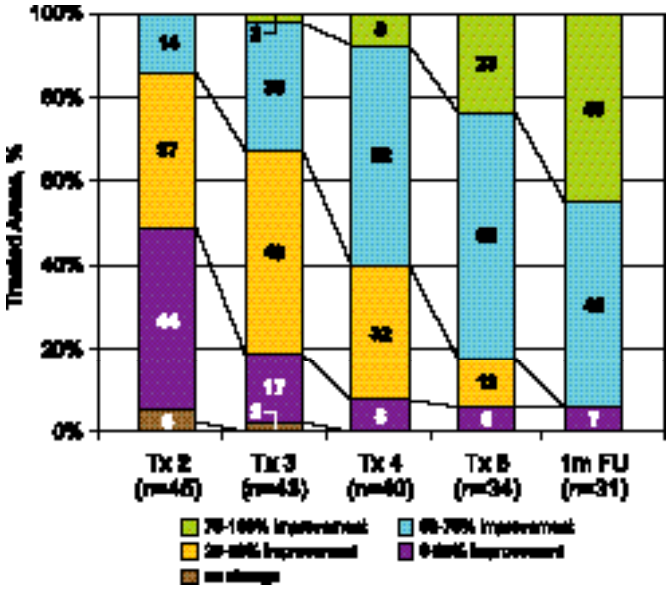

Figure 2. IPL skin treatments using Photorejuvenation – improvement level distribution per visit

Significant improvement was seen following two treatment sessions and continued to increase over the treatment course (see Figure 2). After three treatment sessions, all treated areas showed some level of improvement; after four treatments, 50-100% improvement was recorded for 83% of the treated areas. This improvement level was maintained and even enhanced, reaching 93% at the 1-month follow-up.

These results are also reflected in the satisfaction levels. In fact, after only two treatments, some satisfaction was reported for all treated areas, with a gradual increase of the satisfaction level to 86% 'Very satisfied' to 'Extremely satisfied' at the 1-month follow-up.

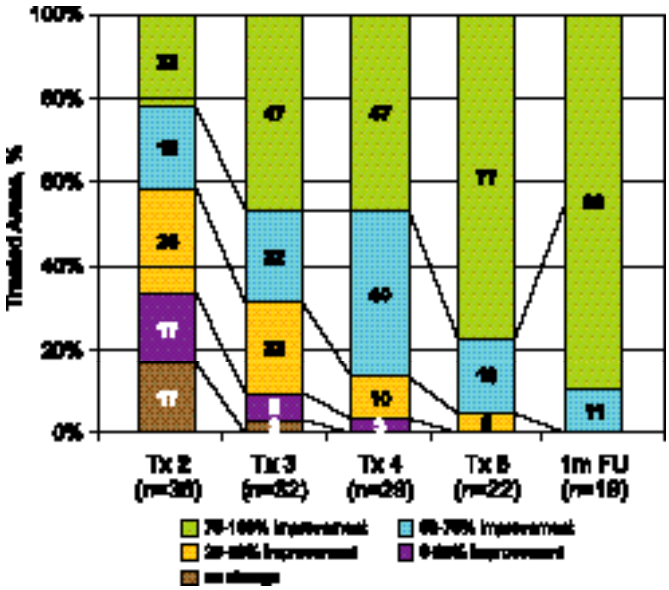

Figure 3. IPL treatment of pigmented lesions – improvement level distribution per visit

IPL Treatment of Pigmented Lesions

Thirty five (35) patients with 40 treated areas were enrolled to this category. The majority (78%) of the lesions were lentigines, 13% were cases of hyperpigmentation (post-inflammatory), and the rest were Café-au-lait spots, Becker's nevus and age spots. Seventy percent (70%) of the treated pigmented lesions were located on the face or arm/hand areas; the rest were distributed among different sub-areas of the torso and legs.

The recorded improvement levels for the treated pigmented lesions were statistically significant and very high. In fact, none of the areas remained unchanged following three treatments (see Figure 3). The percentage of pigmented lesions that reached 50-100% improvement after four and five treatment sessions was 95% and 100%, respectively. Moreover, five pigmented lesions (14%) cleared completely following only a single treatment session; an additional group of six treated areas (19%) reached complete clearance after two treatments.

In correlation to the investigator's improvement assessments, the patient satisfaction levels were also very high, with some level of satisfaction being recorded for all treated areas at the 4th treatment session. By the 1-month follow-up, the satisfaction level rose to 100% 'Very satisfied' to 'Extremely satisfied'.

IPL Treatment of Vascular Lesions

Thirty one (31) patients were treated for 35 cases of vascular lesions, including telangiectases (72%), cherry angiomas (14%), Port Wine Stains (11%) and leg veins (3%). The majority (74%) of these lesions appeared on the legs, and the rest were scattered among different body areas.

As seen for other applications, some vascular lesions (e.g., most cherry angiomas) responded immediately to treatment and disappeared after only 1-2 treatments. Starting from the 3rd treatment session, all lesions showed signs of positive response to treatment, resulting in overall significant improvement, which continued up to the 1-month follow-up, when 75% of the treated areas showed 50-100% improvement (see Figure 4). Ninety (90%) and eighty (80%) percent of the treated areas were rated as 'Very satisfied' to 'Extremely satisfied' at the 4th treatment visit and at the follow-up, respectively.

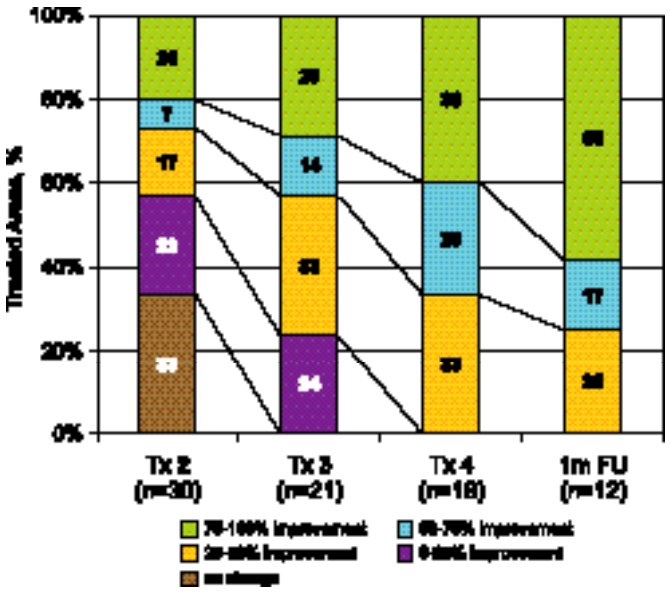

Figure 4. IPL treatment of vascular lesions – improvement level distribution per visit

Nd:YAG Treatment of Vascular Lesions

Forty (40) patients with 48 target vascular lesions were treated with the 6 mm spot size of the Nd:YAG treatment head. Most of these lesions (83%) were leg veins of various depths; the remaining were telangiectases or cherry angiomas, located on the face, chest, shoulder, or legs.

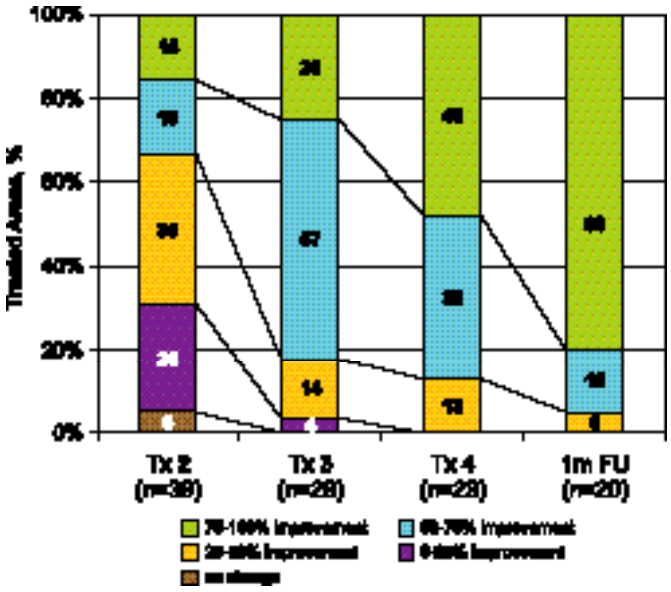

Figure 5. Nd:YAG treatment of vascular lesions – improvement level distribution per visit

The improvement level distribution for this application resembles the aforementioned results, with 13% of the lesions clearing completely after a single treatment session. All treated areas showed some improvement after two treatment sessions; 87% and 95% were classified to the 50-100% improvement rating after three and four treatment sessions, respectively (see Figure 5). The satisfaction level was high, with almost 90% of the areas receiving 'Very satisfied' to 'Extremely satisfied' marks after only three treatments; a similar pattern was reported at the follow-up as well.

IPL Hair Removal

Eighty one (81) patients received IPL hair removal treatments in a total of 188 treated areas (1- 4 areas per patient).

Significant hair clearance was obtained after one treatment, and was maintained all the way through to the follow-up visit. The median hair clearance was 54% after four treatment sessions, and continued to improve, reaching 66% after five (data not shown). Accordingly, some satisfaction was noted for 92% of the treated areas after a single treatment. The satisfaction level increased gradually over the evaluation course, and by the follow-up visit, satisfactory marks were recorded for all treated areas, with almost 80% of the areas assigned to 'Very satisfied' or 'Extremely satisfied'.

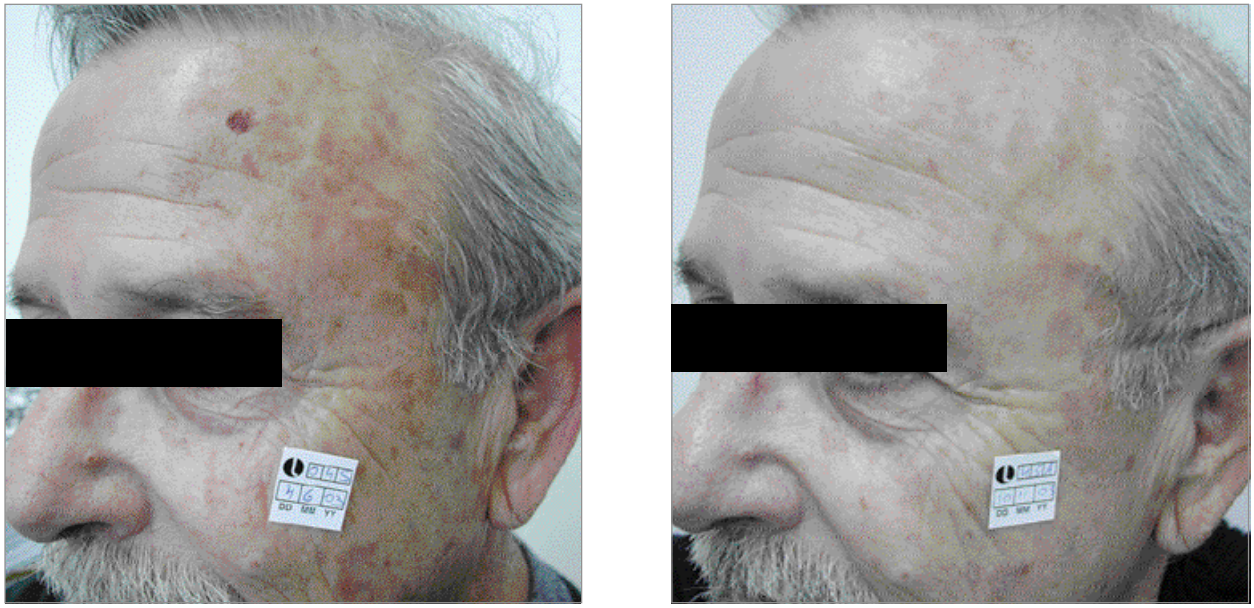

Figure 6. 57-year-old male, skin type IV, with senile lentigines, before (left) and after (right) five IPL treatments

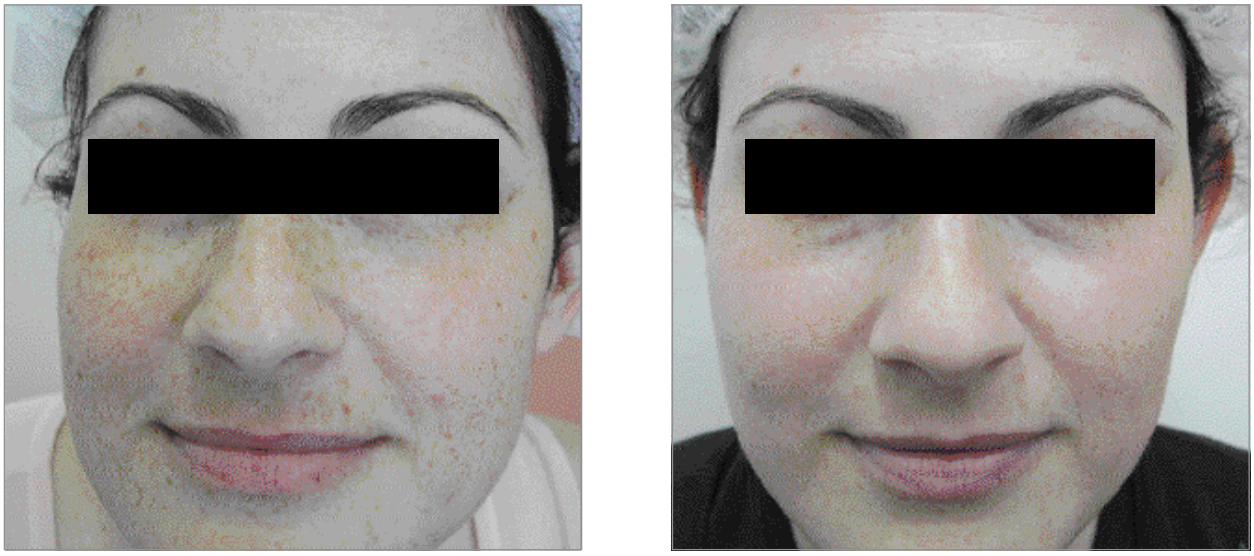

Figure 7. 31-year-old female, skin type II, with dense freckles, before (left) and after (right) five IPL treatments

SUMMARY

High levels of efficacy, safety and patient satisfaction are being obtained in the clinical evaluation of the Lumenis One system, as seen in this report. Notably, this interim analysis covers five different clinical applications, from IPL skin treatments using Photorejuvenation to 1064 nm Nd:YAG treatment of leg veins and deep vascular lesions. Over the entire range of these applications, 97% of the 140 treated areas that reached the 1-month follow-up showed improvement in comparison to their baseline condition. Eighty three percent (83%) of these areas were rated as having 50-100% improvement at this time point.

Additionally, many patients experienced full clearance of their treated lesions over the course of treatment, often prior to completion of the full treatment course. These clinical results are also reflected in the patient satisfaction levels, which at one month post-treatment were provided for 108 of the 140 treated areas. None of these areas received unsatisfactory marks, and 82% were rated to the top 'Very satisfied' or 'Extremely satisfied' categories.

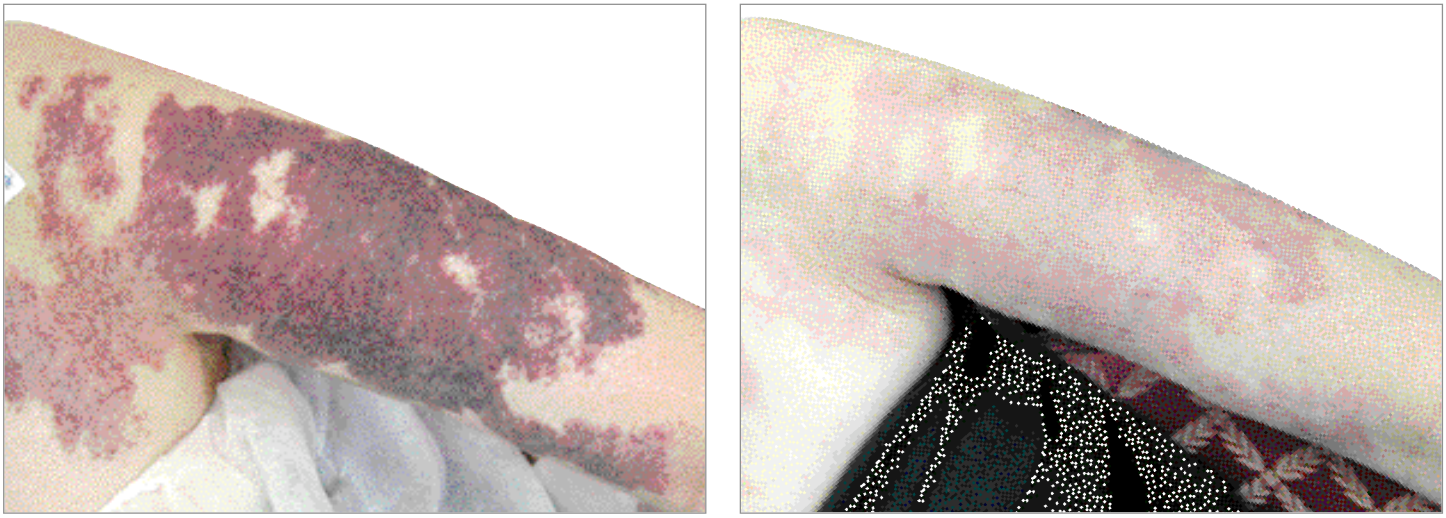

Figure 8. 58-year-old female, skin type III, with hypertrophic Port Wine Stain on shoulder and upper arm areas, before (left) and after (right) five IPL treatments

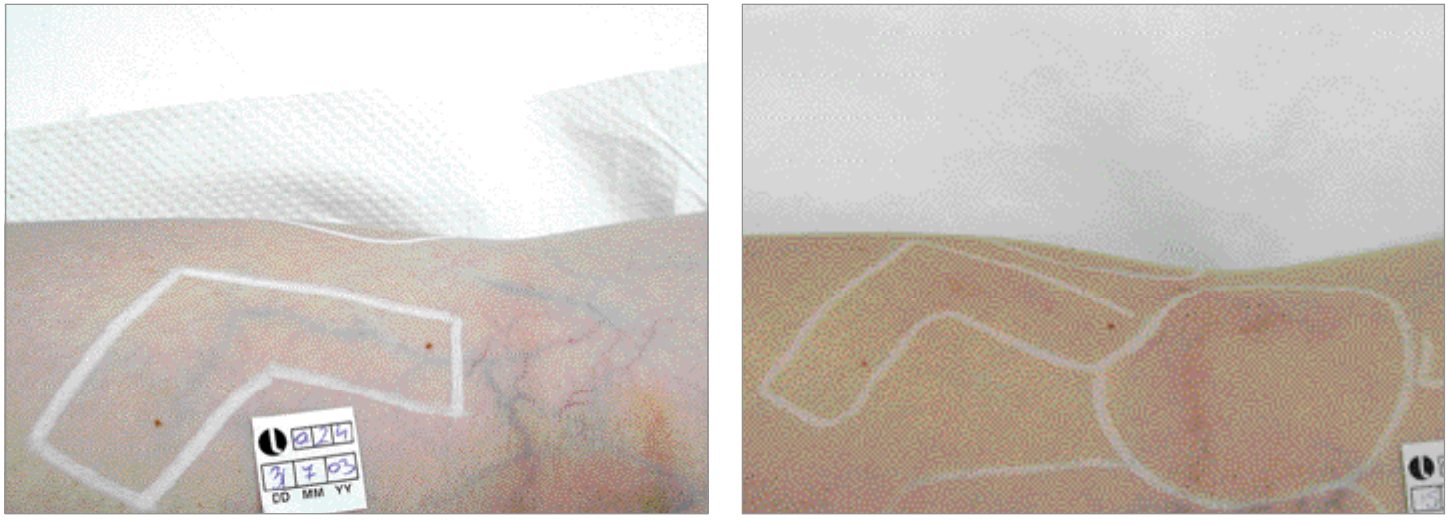

Figure 9. 27-year-old female, skin type II, with telangiectases and a reticular vein in posterior knee area, before (left) and after (right) two Nd:YAG 1064 nm treatments

Some fine-tuning of the system's parameter presets was implemented based on the evaluation results in order to increase the system's potential efficacy. Beyond these clinical implications of the evaluation results, feedback was received from users involved in this evaluation regarding various technological and operational features of Lumenis One. This includes the system's short learning curve, increased patient/user comfort, easy navigation vis-à-vis the interactive user interface, and high patient throughput.

In conclusion, technological improvements in Lumenis One have resulted in an advanced system with clear advantages over earlier systems in terms of clinical results, patient comfort, ease of use, and durability. Some of these advantages were discussed herein, for example, the introduction of novel technological innovations, such as Optimal Pulse Technology. Finally, one of the most important design features of the Lumenis One platform is its expandability, enabling the addition of new modalities and/or applications in the future.

REFERENCES

1. Weiss RA, Weiss MA, Beasley KL. Rejuvenation of photoaged skin: 5 years results with intense pulsed light of the face, neck, and chest. *Dermatol Surg* 2002;28(12):1115-9.
2. Bitter PH. Noninvasive rejuvenation of photodamaged skin using serial, full-face intense pulsed light treatments. *Dermatol Surg* 2000;26(9):835-42.
3. Adatto MA. Photorejuvenation of the forearms by treating hyperpigmented lesions with intense pulsed light source: a case report. *J Cosmet Laser Ther* 2003;5(2):117-9.
4. Negishi K, Tezuka Y, Kushikata N, Wakamatsu S. Photorejuvenation for Asian skin by intense pulsed light. *Dermatol Surg* 2001;27(7):627-31.
5. Hernandez-Perez E, Ibiett EV. Gross and microscopic findings in patients submitted to nonablative full-face resurfacing using intense pulsed light: a preliminary study. *Dermatol Surg* 2002;28(8):651-5.
6. Sadick NS. Long-term results with a multiple synchronized-pulse 1064 nm Nd:YAG laser for the treatment of leg venulectasias and reticular veins. *Dermatol Surg* 2001;27(4):365-9.
7. Wilder D. Pulsed 1064-nm Nd:YAG laser therapy for non-invasive treatment of a massive hemangioma: case report. *J Clin Laser Med Surg* 1999;17(6):245-7.
8. Lou WW, Quintana AT, Geronemus RG, Grossman MC. Prospective study of hair reduction by diode laser (800 nm) with long-term follow-up. *Dermatol Surg* 2000;26(5):428-32.
9. Adrian RM, Shay KP. 800 nanometer diode laser hair removal in African American patients: a clinical and histologic study. *J Cutan Laser Ther* 2000;2(4):183-90.

Lumenis, Inc.
2400 Condensa Street
Santa Clara, CA 95051
USA
Tel. +1.408.764.3000
877.586.3647
Fax. +1.408.764.3999
800.505.1133

Lumenis (HOLLAND) BV
Amstelveen, The Netherlands
Tel. +31.20.347.5060
Fax. +31.20.347.5099

Lumenis (GERMANY) GmbH
Dreieich-Dreieichenhain
Germany
Tel. +49.6071.922.0
Fax. +49.6071.922.400

Lumenis (FRANCE) SARL
Orsay, France
Tel. +33.1.69.33.1420
Fax. +33.1.60.19.5723

Lumenis (ITALY) Srl.
Rome, Italy
Tel. +39.06.90.75.230
Fax. +39.06.90.75.269

Lumenis (UK) Ltd.
London, UK
Tel. +44.20.8324.4200
Fax. +44.20.8324.4222

Lumenis (JAPAN) Co. Ltd.
Tokyo, Japan
Tel. +81.3.5789.8300
Fax. +81.3.5789.8310

Lumenis (HOLLAND) BV
Beijing Office
Beijing, China
Tel. +86.10.6510.2620
Fax. +86.10.6510.2621

Lumenis (HK) Ltd.
Kowloon, Hong Kong
Tel. +852.2174.2800
Fax. +852.2722.5151

PB6500380