Preliminary Clinical Outcomes Using Quadra Q4™ Intense Flash Lamp Technology and the Relevance of Constant Spectral Output with Large Spot Size on Tissue

Marc Clement PhD¹, Michael Kiernan PhD², Dr. G. D. Ross Martin M.B., Ch.B³, Godfrey Town⁴.
¹University of Wales Swansea, Wales, UK ²Cyden Ltd, Wales, UK ³Laser Clinician in Private Practice, ⁴Independent RPA2000 Certificated LPA

Abstract: The recent rapid growth in demand for non-invasive cosmetic light-based treatments has led to a boom in the sale of medical devices that treat a range of skin conditions. Medical and cosmetic conditions being treated include unwanted facial and body hair, age-related sun-damaged skin, changes in pigmentation, vascular blemishes as well as early signs of ageing such as lines and wrinkles. The often onerous safety regulations governing the sale and use of Class 4 lasers has contributed to the popularity of similarly powerful non-laser intense pulsed light (“IPL”) sources, particularly in the salon and spa sector. This paper aims to be a practical science-based review of key issues that impact directly on efficacy and safety of the treatment procedure. The paper documents preliminary case studies showing single procedure success in the treatment of hair and pigmented lesions with an innovative approach to white light therapy. In addition long-term hair reduction is reported using low fluences and repeat treatment protocols. All outcomes reported have been achieved using a constant spectrum Quadra Q4 Intense Flash Lamp device without the need for parallel skin cooling.

1. Introduction

Hair removal with IPL

Hair removal using laser systems was initially introduced into the market in the mid-90’s.¹² These systems, as is the case with all laser technology were monochromatic, in other words emitted one pure wavelength or color of light. In the new millennium, white light emitting IPL (intense pulsed light) technology emerged as a powerful competitor and challenged the dominance of the laser in the marketplace.

The recent success of IPL as a tool for long-term hair removal (“permanent hair reduction”) has largely been based upon the use of high-energy exposure. Such intense flashes of white light are transmitted through the upper layer of skin, the epidermis and absorbed in the hair shaft. The melanin present in the hair shaft absorbs the optical energy. The process leads to damage of the hair follicle and results in suppression of hair growth. Melanin absorbs energy relatively efficiently across a wide range of optical wavelengths and this fact has made white light systems the current technology of choice.

Some authors have suggested that the longer wavelengths that are absorbed in blood and tissue water may also play a role in the hair removal process. It is claimed that these wavelengths cumulatively damage hair follicle support structures such as the blood supply to the hair bulb. The relatively large spot sizes used together with the wide range of wavelengths may also go some way to provide depth of light penetration to the underlying follicle.

However, current approaches to long-term hair removal remain relatively unsophisticated and it is generally accepted that technology and science will lead to further developments, which will improve efficacy and reduce further incidents of unwanted side effects.

Selective Photothermolysis

R. Anderson et al. first proposed the concept of selective photothermolysis in 1981.³ The phrase describes an optical process; light incident on tissue is preferentially absorbed by a target component in the tissue and largely ignored by other tissue structures. The light energy absorbed in the target (the chromophore) is then converted into heat. The heat in turn is controlled to induce the desired therapeutic effect.

The primary relevant chromophores in the skin are:

Melanin: the epidermis pigment (also found in hair) and;
Hemoglobin: the red pigment in blood and other tissue.

Figure 1 illustrates the absorption curves for both melanin and oxyhaemoglobin.

The absorption curve for melanin is relatively featureless and the absorption coefficient simply decreases as the optical wavelength moves from the ultraviolet through the visible to the infrared. The absorption curve for the oxyhemoglobin in blood on the other hand contains a number of peaks. These can be used to induce a range of positive therapeutic outcomes. Of particular interest is the oxyhemoglobin absorption peak at 578nm. This allows the use of yellow light to induce selective thermothermolysis in blood vessels. The yellow wavelengths pass through the upper layers of skin since absorption in the melanin is modest. The wavelength is then heavily absorbed in the oxyhemoglobin of the blood where it is converted to heat. By careful control of optical parameters, a range of therapeutic outcomes can be achieved; for example fine thread veins and small superficial vessels may be eliminated, usually over several treatments.

On the other hand, melanin is a chromophore that can be targeted by a range of wavelengths. If the desired target is the hair shaft then longer wavelengths such as red (circa 700nm) are optimal since their penetration into tissue is greater. If on the other hand issues of epidermal pigment such as age spots are the problem, then it is better to use green wavelengths (circa 550nm) to remove the lesion. White light systems deliver a broad range of wavelengths and can therefore be used to treat a number of skin conditions.

Photo-rejuvenation

Photo-rejuvenation, as the word suggests, is the use of light to renew skin. Skin rejuvenation can take place in both the epidermis and dermis. Shorter wavelengths are highly absorbed in the melanin and problems of pigment can be addressed. This epidermal “Photorejuvenation” can include improving skin dischromia and multiple treatments with high-power IPL devices can reduce epidermal melanin in photo-damaged skin and some cosmetic benefit has been reported after multiple treatments.4-6

Dermal rejuvenation takes place deeper in the skin. The concept was first postulated in 20007,8 when the FDA approved a laser system for the ‘improvement in the appearance of wrinkles’. Bjerring et al suggested that the mechanism responsible for skin rejuvenation was that of an ‘optically induced wound healing cascade’. Yellow light is preferentially absorbed in the blood chromophore (oxyhemoglobin) and deposits a controlled amount of energy in the skin’s microvasculature. This interaction then leads to the initiation of the natural wound healing response of the skin. Mediators released into the dermis stimulate collagen production from fibroblasts resulting in photo-rejuvenation. Early work undertaken with laser systems has been replicated to a degree with white light systems where the yellow portion of the emitted spectrum is absorbed in the blood and initiates the wound-healing cascade.

2. The Science of Quadra Q4™ vs IPL

Spectral Control

In contrast to monochromatic laser sources, IPLs provide an intense broad-band output which generally covers both the superficial melanin absorption area (green) and the hemoglobin absorption area (yellow) but it also extends into the red region which provides deeper penetration into tissue. The interaction of these multiple wavelengths with the skin is sufficiently selective to treat vascular lesions with yellow light around 578 nm (the absorption peak of hemoglobin) and superficial pigmented lesions with green light around 500 nm where melanin
absorption is highest. The red output (circa 700nm) gives less scatter and deeper penetration and the melanin absorption curve ensures good absorption in even deep lying hair follicles.

Despite these advantages there is much opportunity to improve the efficacy of white light systems. It is particularly important to consider how the optical output energy is distributed across the broad output spectrum. This energy “sharing” within the wavelengths is further complicated by the fact that in traditional IPL systems it is a dynamic process. Energy distribution across the wavelengths at the start, middle and end of the pulse may not be the same. The energy distribution varies during the period of the pulse resulting in ‘spectral jitter’.

Conventional high power IPL white light systems use free-discharge technology i.e. electrical energy is released from a capacitor bank into the Xenon lamp. Such technology allows current in the discharge to build up from a low level reach a peak and then fall away again. This results in a plasma discharge in the Xenon that runs cold, heats up and then cools again. The variable high-density current discharge produces a spectral output, which shifts towards the blue end of the visible electromagnetic spectrum as the discharge current density rises and back towards the red end as the energy pulse tails-off. (Figure 2). This effect of spectral jitter during the pulse means that the spectral output not only varies during the pulse but also differs significantly from one energy setting to another. This can mean that much of the pulse output is at wavelengths that are not useful for targeting chromophores in question and much of the potentially useful energy is wasted.

The Quadra Q4 system uses partial discharge technology which in simple terms means that a large value capacitor is fully charged but only partially discharged during every pulse. Using a sophisticated computer-control system and low power Xenon lamp, a constant current discharge can be achieved (“top-hat” profile). This means that the current in the Xenon is constant throughout the pulse. The wavelengths emitted are therefore constant throughout the pulse and spectral jitter is eliminated. This means that at any instant during the pulse the wavelength sharing will be the same. This control of the spectral output leads to greater efficiency and efficacy of treatment.

Spatial Control

Almost all conventional intense pulsed light (IPL) devices use a single linear high-power Xenon flashlamp configuration. This leads to an elongated rectangular treatment “footprint” on tissue. The plasma in all flashlamp discharges has a concentration towards the centre of the lamp tube. This invariably results in a “hot spot” near the lamp center which is can be only partly mitigated by the optical system delivering the light energy to the tissue.

The Quadra Q4 system uses multiple low-power Xenon lamps, enclosed in an optical system designed to ensure that the energy distribution on tissue is spatially uniform. Traditional single flashlamp systems typically results in a ‘long and thin’ footprint on tissue.

![Figure 2: Temporal Output of Traditional IPL and Quadra Q4](image)

**Figure 2: Temporal Output of Traditional IPL and Quadra Q4**

![Figure 3: Treatment Footprint (a) Traditional IPL and (b) Quadra Q4](image)

**Figure 3: Treatment Footprint (a) Traditional IPL and (b) Quadra Q4**

Such configurations lead to significant scatter of light away from the treatment area as the light is transmitted through the skin. Again energy is wasted, efficiency lost and efficacy reduced.
Figure 4: Effect of Beam Width on Penetration Depth

Figure 4 demonstrates that the larger beam width is also far more effective in achieving depth of penetration than the same energy (per cm\(^2\)) delivered in a small spot size. As a result, the Quadra Q4 system once again uses less energy to achieve greater treatment efficacy.

The design philosophy adopted for Quadra Q4 allows the spot shape to be changed to one of a more beneficial area-to-edge ratio as illustrated in Figure 3b. Such a pulse shape reduces optical losses from the treated volume increasing efficiency and efficacy. This beneficial area-to-edge ratio means less need for overlapping pulses and less troublesome regrowth of hair along the margins of treatment spots.

The design also allows a larger spot size area of 9.0 cm\(^2\) that ensures efficient delivery of photons into tissue by minimizing scattering through perimeter losses.

Figure 5 shows a thermal image of skin following application of the Quadra Q4 system at 8J/cm\(^2\) with a 20msec pulse. As can clearly be seen, the heat distribution in the skin is uniform across the entire treatment area. In addition, the individual hairs can be clearly identified as discrete points of elevated temperature.

3. Case Studies

Hair Removal

Figure 6 shows a typical treatment outcome following treatment with the Quadra Q4 (PLATINUM SERIES, DermaMed USA, Lenni, PA. FDA 510(k) No. K040156). Both the control and treatment areas were shaved prior to application of the Quadra Q4. Following treatment, peri-follicular erythema appeared after approximately 20 minutes and resolved after 4-5 hours. In the days following treatment, the hair in the control area resumed normal growth.

An analysis of the hair regrowth in both the treated and control areas was performed. Figure 7 shows the results of this analysis. As can be seen, the hair in the control area regrew approximately as predicted by typical hair growth rates and was 75% of the length of mature hair after 45 days. The treated area showed no hair growth for a period of 40 days following a single Quadra Q4 treatment.
Figure 7: Hair Growth Analysis Following Quadra Q4 Treatment

Figure 8 shows the forearm of a male treated with the Quadra Q4 with a corresponding adjacent control site. Prior to treatment, both areas were shaved and immediately following Quadra Q4 application, slight peri-follicular erythema was seen which faded after 4-6 hours.

Figure 8: Forearm 45 Days Following Quadra Q4 Treatment

Hair Density Analysis

By using close-up photography, the hair density pre and post treatment was determined.

Figure 9a: Typical Pre-Treatment Hair Density

Figure 9b: Same Area 45 Days Post-Treatment

Figures 9a and 9b show a typical measurement of hair density. Care was taken to ensure correct alignment of the pre- and post-treatment 1cm² counting grids.

Twelve Caucasian male subjects, phototypes I/II, with multiple treatment sites, primarily forearms and lower legs, were enrolled. Prior to treatment, the area was coarsely shaved followed by close-up photography to enable accurate hair counts. The area was then close shaved to ensure minimal excess surface hair.

The area was treated with adjacent pulses of 30msec duration (single pulse) with an average energy density of 11J/cm². The average follow-up period was 45 days.

Immediately following treatment, slight redness was observed around the hair follicles, in many cases intensifying over subsequent hours. However, this had resolved 24hrs post-treatment. No incidents or blistering were reported.

Data analysis on the treated areas showed that the hair density had dropped from an average of 48 per cm² pre treatment to 19 per cm² 45 days post, equating to a 60.4% reduction in hair density.

Efficacy in Asian Skin

(Data courtesy of Dr T. Omi, Queens Medical Centre, Yokohama, Japan)

It has been reported that Asian skin (Phototypes III / IV), while appearing light in color, often reacts differently to Caucasian skin. In order to determine the efficacy of the Quadra Q4 system, a pilot study was undertaken in Japan to ensure clinical benefit and safety.

Fifteen subjects, 10 female and 5 male, with multiple treatment sites were enrolled in the study. Adjacent treatment and control areas of 5cm by 5cm were identified and the average hair density in each region recorded. Prior to application of the Quadra Q4 both areas were shaved.
Treatments were performed with pulse durations between 25 and 50 msec at an average energy density of 11.8 J/cm².

Immediately following treatment, mild diffuse redness was observed which faded after ~1 hr. Pain, while a subjective measurement, was rated as tolerable with only a slight stinging sensation which faded within minutes.

At both the 30 and 90 day review point, the hair density in each of the control and treatment sites was recorded.

Figure 10 shows the recorded hair density at pre treatment and both review points.

Figure 10: Hair Density Analysis in Asian Skin Pre and Post Treatment

Table 1 shows the results of the statistical analysis of the hair density counts pre- and post-treatment. Non parametric statistical analysis techniques were used (Wilcoxon Signed Rank Test) due to the relatively low numbers of data points. Significance was taken at the standard 5% point.

<table>
<thead>
<tr>
<th>N</th>
<th>Treatment Median (Mean)</th>
<th>Control Median (Mean)</th>
<th>Difference</th>
<th>% Reduction From Baseline</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre</td>
<td>14</td>
<td>22.4 (19)</td>
<td>21.6 (19.7)</td>
<td>1.2 (0.7)</td>
<td>0.46</td>
</tr>
<tr>
<td>Post 30 Days</td>
<td>11</td>
<td>12.4 (13.2)</td>
<td>19.6 (19.6)</td>
<td>7.2 (6.4)</td>
<td>0.012</td>
</tr>
<tr>
<td>Post 90 Days</td>
<td>14</td>
<td>12.6 (12.9)</td>
<td>20.6 (18.9)</td>
<td>8 (6)</td>
<td>0.009</td>
</tr>
</tbody>
</table>

Table 1: Statistical Analysis Results

As can be seen from Table 1, at baseline there was no difference between the treatment and control areas. However at both the 30 and 90 day review points, there was a statistically significant reduction in the hair density.

The results of this pilot study show that the treatment is well tolerated in Asian skin with excellent clinical efficacy.

Pigmented Lesions

Figure 11 shows benign pigmented lesions before and after a single treatment with the Quadra Q4. Immediately post treatment, the lesions appeared darker with peri-lesional inflammation. Over the following 3-4 days, the lesions darkened and localised scabbing formed which resolved in <14 days.

Figure 11: Pigmented Lesions Treated with the Quadra Q4

4. Conclusions

The Quadra Q4 system is a significant advance over traditional IPL technology. The partial discharge technology developed permits output spectral control and eliminates spectral jitter. This allows the operator to be confident that wavelength outputs are consistent and constant throughout the pulse. This results in the ability to treat conditions at lower fluences increasing efficacy and reducing side effects.

Intense pulsed light with Quadra Q4 technology provides a constant output of suitable wavelengths and energy densities for repeated treatments to achieve permanent hair reduction as well as single-step treatment of most epidermal benign pigmented lesions. These results were achieved without unacceptable patient discomfort or side-effects.
References

(1) Clement, RM; Kiernan, M; Gault, D, Long Term Depilation. SPIE Medical Applications of Lasers in Dermatology, Cardiology, Ophthalmology and Dentistry. September 1995


About the Authors

Professor Marc Clement is Chair of Innovation at the University of Wales Swansea, UK and Non-Executive Chairman of Cyden Ltd. Professor Clement has spent the last 20 years developing light-based products for the dermatology market and is the author of a number of publications and patents in the field.

Dr Mike Kiernan is Clinical Research Director at Cyden Ltd., UK Dr Kiernan has worked in the dermatology field for 15 years and has been involved in the development of a number of light-based products for hair removal, skin rejuvenation and the treatment of acne.

Dr. G. D. Ross Martin is a laser clinician in private practice in Nottingham, UK. Dr. Martin has 15 years clinical experience with a wide range of lasers and intense pulsed light devices lecturing extensively on medical laser use both nationally and internationally.

Godfrey Town RPA2000 Certificated LPA is an independent Laser Protection Adviser and registered Clinical Technologist in Haywards Heath, UK.

Correspondence to:

DermaMed USA, Inc.
Email: info@DermaMedUSA.com