# New Methods for Guidance of Light-Based Treatments Using Objective Melanin Measurements

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Background and Objective: Historically, clinicians have used visual assessment and Fitzpatrick Skin Type (FST) scale to determine appropriate treatment settings for intense pulsed-light (IPL) treatments. We investigated the potential of melanin index (MI) objective measurements to guide IPL treatment using a new melanin reader device (Skintel<sup>™</sup> Melanin Reader, Palomar Medical Technologies, Inc. Burlington, MA).

**Conclusions:** The new Skintel Melanin Reader generates reproducible measurements of melanin in the skin and was observed to provide a clearly defined correlation between MI and skin tolerance reactions. This correlation enabled the development of an MI-based treatment guide that provides starting test spot fluences for IPL treatments. MI-correlated fluences were tailored to the specific indication and objective MI measurement within the treatment site to provide more customized treatment guidance as compared to FST-based treatment guidance.

### Introduction

Based on the principles of selective photothermolysis, light energy delivered through lasers or intense pulsed-light (IPL) should be high enough to damage target tissue but low enough to avoid injury and excessive skin reactions in surrounding non-target tissue. Currently, visual assessment of skin in comparison to the Fitzpatrick Skin Type (FST) scale is the standard method used to guide selection of parameters for laser and IPL treatments, even though FST was originally intended to estimate dosimetry and response to ultraviolet light exposure. An individual's FST is based on eye color, hair color, and skin phototype and does not account for the current state of pigmentation, or melanin, in the skin. Given that melanin, hemoglobin, and water are the chromophores targeted in IPL phototherapy, we postulate that providing an objective measurement of melanin has the potential to provide the best guidance for selection of treatment parameters for most IPL treatments.

During IPL treatment, the amount of heat absorbed in the epidermis and dermal/epidermal junction is dominated by and proportional to the amount of melanin present. For example, IPL treatment of a pigmented lesion (higher melanin content) will result in increased heating of the lesion as compared to the surrounding skin (lower melanin content). With an appropriate clinical IPL setting, there is sufficient heating to induce controlled damage in targeted cells resulting in removal of the damaged tissue through the natural healing processes of sloughing and turnover. Ideally, the significantly lower energy that is absorbed in the surrounding (non-target) tissue will not result in prolonged skin reactions or injury due to the lesser amount of chromophore content of this tissue.

For this reason, we investigated the upper limit of fluence that can be tolerated in "uniform skin" using an objective measurement of the skin's melanin density or index, (MI). In this scenario, "uniform skin" is defined as the skin surrounding the targeted lesions that contains significantly lower levels of melanin and is relatively free of hair and pigmented or vascular lesions or other conditions. We postulate that correlating MI values to tolerable fluence levels in "uniform" skin will enable better treatment and site-specific guidance for IPL applications compared to current strategies based in part upon FST.

# Methods

*Study Design:* Using the Skintel Melanin Reader, MI values were collected from 65 subjects ranging in age from 18 to 82 years, with an average age of 35 and FST from I to VI. Test spots were performed on an area of the back with uniform skin tone that was free of hair, vascular and pigmented lesions and other conditions. Three MI readings were recorded from each of five locations (corners and center) of the test spot area and averaged to establish an overall MI value. Subjects received an ascending series of 6 mm diameter test spots at pulse width settings of 3

to 80 milliseconds (ms) for Palomar's intense pulsed light handpieces. Clinicians graded the severity of these skin reactions at 30 to 45 minutes and at 24 hours after test spot application. The results of these test spot matrices are shown in Figure 1.

Figure 1: Test Spot Matrix in a Subject with FST II. A) Observed skin reactions at 30-45 minutes and B) 24 hours following test spot application.



*Observation of skin reactions to test spots:* The "Maximum Tolerable Fluence" was defined as the highest fluence that yielded a skin reaction no greater than moderate erythema observed 24 hours after treatment. The skin reaction must also have completely resolved by the one week post-treatment observation.

*Device Description:* The Skintel Melanin Reader (Figure 2) is a portable instrument intended for objective measurement of melanin in human skin. It utilizes measurements of skin reflectance at multiple wavelengths that are subsequently processed to yield a value that is proportional to the average skin melanin content over the measurement area. The Skintel reader contains a threewavelength LED that emits at 640 nm, 700 nm, and 910 nm. Reflected and scattered light from the skin is collected by a waveguide which is detected by a silicon detector located adjacent to the LED. Based on the three measured signals, a MI value is calculated, which ranges from 0 (very light skin) to 99 (very dark skin). Figure 2: Recording MI Value of Forearm Skin with the Skintel Melanin Reader.



#### **Clinical Results**

As anticipated, a wide range in skin pigmentation was observed for a given FST (Figure 3). For example, individuals with a MI value of 14 to 19 could be classified under FST as a Skin Type II, III or IV. Figure 4 shows examples of the skin tone appearance of individuals with different ranges of MI values from light to dark. For all subjects, MI readings were higher on the forehead and lower on the cheeks.

Figure 3: Range of MI Values per Fitzpatrick Skin Type. Abbreviations. FST: Fitzpatrick Skin Type; MI: Melanin Index; std: standard deviation; Min: minimum; Max: maximum



	Melanin Index (MI)		
Fitzpatrick Skin Type (FST)	Mean ± std	Min - Max	
1-11	14 ± 3.2	8 – 19	
ш	17 ± 5.0	11 – 30	
IV	26 ± 7.3	14 – 39	
v	49 ± 11.8 29 - 7		
VI	76 ± 14.5	53 - 99	

Figure 4: Representative MI Values for a Range of Facial Skin Colors.



Results: Relationship between MI and skin tolerance to IPL treatment

The Maximum Tolerable Fluence for each individual was determined and plotted as a function of MI for each combination of handpiece and pulse width. The scatter plots shown in Figure 5 for MaxG<sup>™</sup> at 10 and 20 ms represent a subset of those generated for the handpieces. In each scatter plot, an individual's Maximum Tolerable Fluence was plotted (red squares) as a function of the individual's

MI. Individuals with the lowest fluence settings were selected (highlighted with blue diamonds) and used to generate a smooth curve (fitted, universal setting threshold curve depicted by black line with green triangles) such that the Maximum Tolerable Fluence settings for all subjects fit on or above the curve.



Figure 5: Scatter Plots for MaxG at 5 and 20 ms Pulse Widths Showing the Following:

- Each individual's maximum test spot fluence with acceptable side effects (skin reaction ≤ moderate erythema at 24hr and without lingering erythema at 1 week) plotted according to their MI.
- Selected individuals with the lowest fluence settings (high lighted with blue diamonds with solid white fill) were used to generate fitted threshold curve.
- ➤ The fitted threshold curve, black line with green triangles all individual's observed maximum test spot settings with accept able side effects fit on or above the curve.
- The Skintel<sup>™</sup> fluence value curve (blue line) was obtained by subtracting an additional safety margin.

Figure 6: Melanin Index (MI) Guidance of Palomar Icon™

		FST Treatment Guide Max G		
FST	MI	Vascular Lesions	PW (ms)	
I-II <20	Red facial vessels > 0.3 mm	10		
		20		
III 20-30	Ded facial as a star 0.0 mm	10		
	20-30	Red facial vessels > 0.3 mm	20	
IV	31-39	Red facial vessels > 0.3 mm	20	

IPL handpieces using the Skintel Melanin Reader. For the clinician, practical use of MI as guidance for treatment parameters not only involves selection of the appropriate handpiece and pulse width settings for the intended indication, but also assessment of the skin within the treatment area throughout which skin tone may vary. By performing MI readings in the region of skin with the darkest uniform (homogenous) skin color, and using this area to assess settings, this will ensure that the treatment will be appropriate throughout the entire treatment area. Because the Skintel reader averages the MI value over the entire optical window (6 x 12 mm), the measurement area should be as free as possible of potential chromophores, hair, pigmented lesions and tattoos. Inclusion of any of these items results in a higher MI value which would subsequently lead to lower, less effective guidance settings.

Once the MI value is obtained, the clinician should consult the Palomar Icon<sup>™</sup> Treatment Guide to select the handpiece-appropriate pulse width for the indication being treated. For example, for the MaxG, per Figure 6, either a 10 or 20 ms pulse width is recommended for treatment of red facial vessels measuring 0.3 mm or more in diameter. Once MI and pulse width have been entered into the Palomar Icon, the Skintel Value (J/cm<sup>2</sup>) is identified from an internal lookup table for the handpiece. This Skintel Value represents a starting fluence value for test spots. Use of test spots is essential for establishing appropriate treatment settings and should include assessment of skin reactions in both the target and non-target area. As with all recommendations, the clinician must also apply his/her best clinical judgment when selecting a starting test spot value. In addition to the recommended Skintel Value, consideration of the patient's FST, a visual assessment of the patient's skin, the patient's ethnicity, medical history, recent tanning and history of sun-exposure should also be factored in determining appropriate starting test spot fluences.

## Discussion

Successful light-based treatment of dermatologic indications entails appropriate damage and clearance of the intended target tissue with minimal impact to surrounding tissue. Results from extensive test spot testing were used to establish a relationship between melanin content measured using the Skintel reader and Palomar Icon's IPL handpiece parameters. The established relationship for each handpiece was then used to generate a lookup table of fluence values based upon MI values for each pulse width setting. These Skintel Values are now provided to the user as a starting fluence for guidance of test spots.

One of the major benefits of an MI-based treatment guide is that the MI value is specifically correlated to each IPL handpiece. Defining treatment parameters based on FST-guidance alone runs the risk of reduced efficacy or increased side effects due to the lack of consideration of the skin's melanin density. When using FST alone, treatment guidance needs to consider the darkest individual or most sensitive type of individual within that level of FST to ensure the safety of recommended settings. In reality, as our measurements have shown, the wide range of MI values highlights the challenge of finding a universally appropriate setting based on FST alone. In addition, treatment areas within the same person can vary in skin tone depending on the degree of lifelong and recent sun exposure. Using an objective MI-based form of guidance allows for the determination of starting test spot fluences that are specific to the individual and to the treatment area.

Other benefits of an MI-based guide are its objective form of measurement that will provide consistent measurements over time and across different users. For clinicians with less IPL experience, this method provides a faster learning curve enabling more consistent treatment outcomes. And importantly, this method enables clinicians to track sun exposure and tanning history in individuals between treatments to more objectively evaluate appropriateness of reusing prior treatment settings. Given these benefits, we predict that it will soon be considered best practice to incorporate an accurate reading of melanin reading into the evaluation and determination of treatment strategies.

There are several issues to consider regarding the use of an MI-based treatment strategy based upon skin tolerance reactions of "uniform" skin. One issue is that determining appropriate clinical treatment settings requires not just an assessment of skin tolerance around the target, but also an assessment of skin tolerance within the target lesion; these assessments require expert evaluation of clinical endpoints specific to the type of lesion being treated. A second factor to consider is that the Skintel reader measures average MI content over the entire optical window. Use of the MI measurement of the target as a basis for guidance would not be appropriate for vascular conditions since the primary target chromophore for these indications is hemoglobin, not melanin. For hair and pigmented lesions the sparsity and variation in concentration within the lesion would limit the ability to accurately measure melanin content. Another caveat is that certain conditions in the skin surrounding the target lesion (e.g. melasma, diffuse erythema, psoriasis, etc.) may potentially compromise the ability of the skin to tolerate treatment settings; in these instances, clinicians should proceed with caution before using Skintel Values as guidance for test spot settings. In light of these exceptions, when used appropriately, the Skintel reader can provide meaningful guidance for light-based treatments by narrowing the range of test spots and providing increased confidence in the selection of settings.

#### Summary

The relationship between Skintel Melanin Reader MI values and the Palomar Icon's IPL handpiece parameters was used to establish a new MI-based treatment strategy. This represents a major advancement over FST-based guidance. Objective MI-based guidance allows for customization of recommended treatment's starting test spot fluence that are specific to the individual's current skin condition in the treatment area and indication.

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