Utilizing the GentleMax Pro®, a Dual Wavelength Laser for a Variety of Skin Treatments – White Paper

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INTRODUCTION:

Medical lasers have been evolving since Theodore Maiman introduced the first ruby laser in 1960[1]. Beyond tissue coagulation and ablation, the largest contribution advancing the understanding of tissue interaction came when Anderson and Parrish published their study of selective photothermolysis in Science in 1983[2]. The theory taught that lasers can target selective chromophores in tissue when taking into consideration the laser wavelength, the pulse duration, and the thermal relaxation time of the target which is dependent on its size and dimension. The end goal of laser therapy is to affect the target in some desired way while sparing nearby surrounding tissues. Desired laser tissue effects can include as examples denaturation, coagulation, apoptosis and necrosis.

Since Maiman, there have been many advances in laser technology including the introduction of new wavelengths, increased laser fluences, longer and shorter pulse durations and the evolution of increasing spot sizes. One example of this evolution is the GentleMax Pro, a laser system designed and manufactured by Candela Corporation.

This paper will discuss a wide variety of applications of the GentleMax Pro, a dual wavelength platform emitting 755nm laser energy from an alexandrite laser and 1064nm laser energy from a Nd:YAG laser. Both wavelengths have reasonably good transmission in skin, with 1064 nm being less sensitive to melanin and more sensitive to oxyhemoglobin compared to 755 nm (Figure 1).

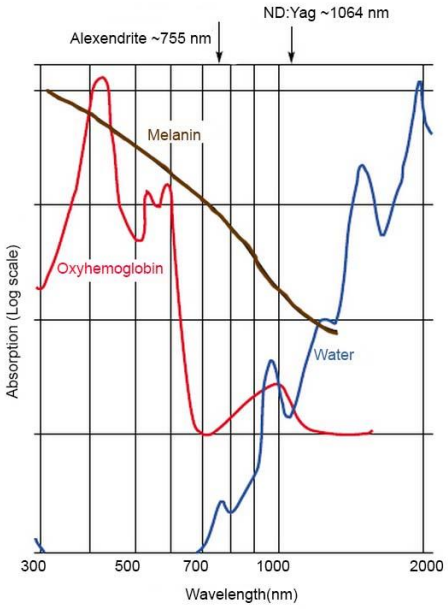

Figure 1

These wavelengths have been well studied for the removal of unwanted hair. They have also been used to treat both vascular and pigmented lesions. In addition, the Nd:YAG laser has been utilized to rejuvenate aging skin[3], to treat hyperhidrosis[4], and onychomycosis[5]. Melanin is the primary target for hair and pigmented lesion applications while hemoglobin is the primary target for vascular applications.

The GentleMAX Pro™ incorporates a Dynamic Cooling Device™ (DCD) that applies bursts of cooling cryogen in adjustable spray durations before and after the laser pulse. The DCD assists with the protection of the epidermis which reduces the risk of scarring and pigmentation changes such as post-inflammatory hyperpigmentation (PIH).

HAIR REMOVAL TREATMENTS:

The desire for hair removal has been around for thousands of years and date back as far as the Egyptians who were reported to have used depilatory creams. The 1800's introduced the razor

and galvanic electrology, and lasers were first described as a method to remove hair in 1963 by Leon Goldman[6] but this technique did not reach commercial +use until the 1990's.

In order to understand how lasers are used to remove hair, we must first discuss anatomy and biology of the hair follicle and the cycle of hair growth[7]. The important structures are the dermal papilla, hair shaft, the blood vessels and the bulge area. Cells from both the dermal papilla area and the bulge area may generate hairs, thus in order to destroy the hair, both areas must be damaged. The theory of selective photothermolysis predicts that laser light in the wavelengths from 690 nm to 1064 nm can be preferentially absorbed by the pigment in the hair shaft and by pigmented cells in the dermal papilla to damage or destroy the hair[8]. (See Figure 1) The longer millisecond pulse durations used in hair removal will allow the pigment in the hair shaft and dermal papilla to dissipate the heat so that the laser energy is able to destroy the desired target which is the hair follicle.

Understanding the cycle of hair growth is also an important factor in laser hair removal. The four cycles of hair growth are anagen, catagen, telogen and exogen. Anagen is the active growth phase of the hair. In this phase, melanin synthesis and growth of the hair shaft begins and towards the end of this phase there is the highest amount of melanin in the hair follicle and the deepest penetration of the hair into the skin. The catagen phase is the resting phase where growth of the hair and melanin production stops. In the telogen phase, the hair begins to lose its attachment to the dermal papilla and shrinks in size. At the end of the telogen phase, the hair eventually falls out of the hair follicle, and the follicle enters the exogen phase. The hairless follicle remains dormant until the start of a new anagen growth phase. The hair is most susceptible to laser light energy during the early to mid anagen phase where the hair follicle has generated a good amount of melanin but before the hair follicle has a chance to extend deep into the dermis[9,10].

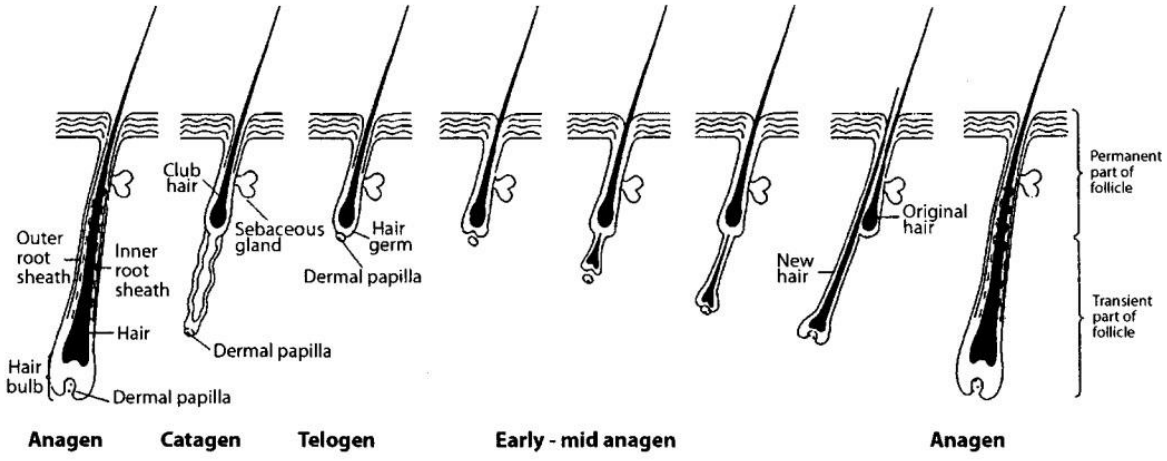

Figure 2

Selection of Wavelength

The selection of wavelength of the laser is determined based on skin type. Optimizing contrast between pigment in the epidermis and pigment in the hair shaft and dermal papilla is crucial when choosing the appropriate wavelength. While early generation lasers for hair removal were generally contraindicated for individuals with Fitzpatrick skin phototypes IV-VI. Advances in the past decade have given rise to a range of devices that can be safely used to treat ethnic skin[11]. Longer wavelength lasers such as 1064 nm Nd:YAG are less absorbed by epidermal melanin,

penetrate deeper into the dermis and are therefore ideal for darker skin types [12,13,14]. Lighter skin types with dark coarse or thinner brown hair can be effectively treated by the 755 nm Alexandrite laser which has a higher absorption by melanin[15,16]. Both lasers can be used with DCD™ (Dynamic Cooling Device), a cooling spray designed to allow the laser pulse to pass through the epidermis without heating the melanocytes in the epidermis. Therefore, epidermal damage is minimized while patient comfort is increased.

Pulse Duration:

An important factor for ensuring the safety and efficacy of laser hair removal is the pulse duration. It must be long enough for the melanin in the epidermis to dissipate the heat, but short enough to hold sufficient temperature in the hair follicle in order to destroy the follicle. The thermal relaxation time for the epidermis is about 10 ms while for the hair bulb it is about 20 – 40 ms[17]. Therefore, when treating thick course hair or darker skin, longer pulse durations around 20 to 40 ms are recommended.

Spot Size and Repetition Rate

The last factor influencing efficacy of laser hair removal is the size of the laser delivery spot. The larger the spot size, the deeper the laser light will penetrate into the skin[18]. The spot size coupled with the repetition rate of the laser determines the speed of the procedure; the larger spot sizes and higher repetition rates allow for a larger area to be treated quicker.

Recommended Hair Removal Treatment Settings:

- **High Contrast (Dark Hair, Light Skin):**
  The GentleMax Pro™ 755 nm wavelength can be used with minimal risk of damage to the epidermis when treating coarse and fine hair in Fitzpatrick Skin types I – III. This wavelength may be used in Fitzpatrick Skin type IV with care. No patient with an active tan should be treated with this wavelength of laser light. The spot size is determined by the area of treatment. The 8 mm spot is often used on the ears. The 10 -12 mm spots are used on the upper lip. The 15 mm spot is used on the arms, cheeks and under the arms. The larger spot sizes, 18 – 24 mm, are used on the legs and the back. The Dynamic Cooling Device™ (DCD) should be set at 40 – 50 ms pulse with a 30 – 40 ms delay. The fluences for each specific treatment are determined by the location of the treatment and skin type.
- **Low Contrast (Dark Hair, Dark Skin):**
  For lower contrast patients (dark hair and darker skin), the choice would be the GentleMax Pro™ 1064 nm Nd:YAG. The long wavelength bypasses the epidermal melanin and delivers a higher bulb-epidermal temperature ratio. This provides effective, yet safe treatment options for all Fitzpatrick Skin types, especially types V and VI. At this long wavelength, larger spot size and longer pulse duration increases clinical effectiveness by increasing depth of penetration and heat diffusion. The fluence and DCD settings are determined by the location of the treatment.

Hair Removal Conclusions:

The GentleMax Pro™ has many features that make it the “Gold Standard” of hair removal. The dual wavelength laser, the Dynamic Cooling Device™ (DCD), the large range of spot sizes from 1.5 mm up to 24 mm in diameter and the pulse duration that may be set in a range from 0.25 ms up to 100 ms. In addition to the advantageous features listed, the speed of the laser is 2 Hz for most applications.

VASCULAR LESION TREATMENT:

Historically, the argon laser was first used to selectively treat vascular lesions. The 488 nm and 514 nm wavelengths were well absorbed by oxyhemoglobin. The problem was that the argon laser emitted light continuously opposed to delivering short individual pulses making it difficult to confine laser heating to the target blood vessels. This led to superficial bulk heating increasing the risk of damage in the epidermal layer as well as scarring. In essence the small therapeutic safety window made it difficult to use even by the most experienced users. For these reasons, pulsed dye lasers were developed to treat vascular abnormalities. The earlier lasers emitted short 450 µsec pulses at a wavelength of 577 nm. However, the light did not penetrate deep enough into the skin to treat pathologic conditions plus the short pulses were too energetic causing significant purpura. Lengthening the wavelength to 585 nm improved the efficacy and safety margin, but it was still highly absorbed by hemoglobin limiting its use for deeper lesions and lesions with larger vessels. The introduction of 595 nm further improved the laser operation and was helpful in reducing purpura and allowing deeper dermal penetration. The introduction of longer pulse durations also helped improved the efficacy and safety margin and allowed treatments of vascular lesions without significant purpura.

All these issues were finally perfected with the introduction of the Vbeam Perfecta 595 nm pulsed dye laser. The Vbeam Perfecta introduced a laser macropulse made of up to 8 subpulses to allow effective but gentle laser treatments. Theoretical models have shown more cumulative thermal damage from 8 subpulses compared to a single pulse having the same energy and pulse duration as the macropulse (Figure 3).

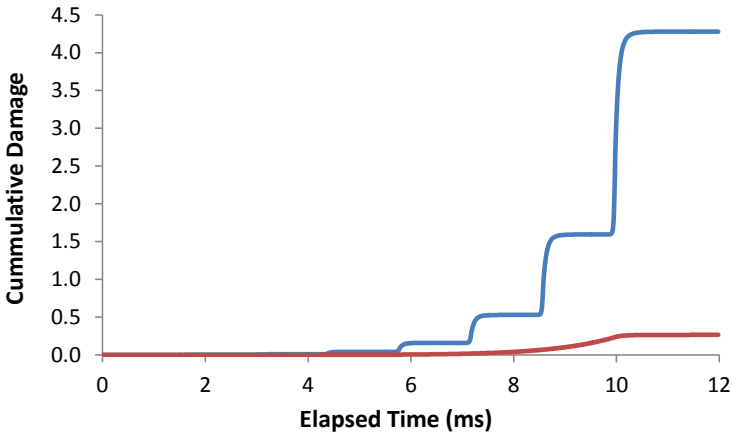

Figure 3

The Vbeam Perfecta having a large therapeutic safety margin is the laser of choice for treating most vascular lesions, especially red lesions.

The 755 nm alexandrite and 1064 nm Nd:YAG lasers can also be used to treat thicker and deeper lesions. While using the dual wavelengths of 755 nm and 1064 nm GentleMax Pro for hair removal, it was noted that both wavelengths are also useful in treating vascular conditions. Both of these wavelengths penetrate deeper into the skin and are able to treat many vascular conditions. In addition, the GentleMax Pro like the Vbeam Perfecta delivers energy in subpulses to allow even more effective treatments.

At 755 nm, higher photon absorption by hemoglobin occurred in juxtaposition of the 1064-nm

lasers making it better suited for the treatment of thick PWS (Port Wine Stains). On the other hand, Nd:YAG lasers can have even deeper penetration (4-6 mm) and have been used for years for the treatment of leg veins. One benefit of the 1064-nm wavelength is the inherently lower absorption coefficient for melanin, which makes it the primary wavelength for treating leg veins, as there is less concern for coincident epidermal damage and it can be used more safely with Fitzpatrick IV – VI skin type patients. Nevertheless, epidermal pigment must be protected in darkly pigmented individuals with the DCD cryogen spray[19].

Recommended Vascular Lesions Treatment Settings:

- **Resistant Port-Wine Stains (PWS):** Port-wine stains, or now more correctly termed capillary malformations, are present at birth and continue to grow as the patient ages. Later in life, it is common for these vessels to develop vascular nodules that cause thickening of the port-wine stain lesion.
  Standard of care treatment has long been the pulsed dye laser for PWS and it is recommended to start treatments as early as possible, ideally as infants. Unfortunately, with time, some port-wine stains appear to no longer respond to pulsed dye laser treatments.
  Several studies have shown that although the therapeutic safety margin of long-pulsed 755 nm Alexandrite laser is lower than PDL, when taking precautions canbe very effective in treating these resistant port-wine stains20.
  The GentleMax Pro™, using the 755 nm Alexandrite laser light is very useful in treating resistant port-wine stains. The recommended settings for this particular treatment are the 8 mm spot, 3 to 5 ms pulse duration, 30 to 45 J/cm^2, DCD 50/30. Multiple treatments will be needed spaced approximately one month apart.

- **Leg Veins:**
  Sclerotherapy is still considered the benchmark for removal of leg veins. There are several possible side effects with this which include bruising, clotting and telangiectatic matting. The latter side effect is when isolated veins are replaced with a group of fine veins in the area of the injection. This occurs in about 15 - 20 percent of sclerotherapy cases[21].
  Many different lasers have been used to treat leg veins. Leg veins have been treated with the 595 nm pulsed dye laser[22]; particularly superficial telangiectatic vessels less than 1mm. Due to longer penetration into skin, the 755 nm long-pulsed Alexandrite laser[23] and 1064 nm Nd:YAG laser[24] have been used to treat leg veins greater than 1mm.
  My personal preference in laser is the 1064 nm long-pulsed Nd:YAG of the GentleMax Pro™ family. The 1 to 1.5 mm bluish veins are best treated with the following settings: 1064 nm, 3 mm spot, 30 ms pulse duration, 130 to 180 J/cm2, DCD at 50/30. If the veins are bright red and less than 1.0 mm, I recommend using the 1.5 mm spot, 400 J/cm2, 30 ms pulse duration, with the DCD at 50/30. Single pulses are used and the endpoint for this treatment is the immediate disappearance of the vessel.

- **Telangiectasia and Rosacea:**
  Rosacea is a common condition with a variety of presentations. These include an erythemato-telangiectatic type with redness, flushing and isolated facial telangiectasia. The second common presentation is the papulopustular type that presents with an acne form eruption. The third common presentation is the phymatous type that shows thickening and nodularity of the nose and face. There is an ocular type of rosacea that presents with inflammation of the eye.

There are different medical treatments to help manage rosacea, but when there is a telangiectatic presentation; lasers have proven to be extremely helpful. The 1064 nm Nd:YAG wavelength has been most useful in treating facial telangiectasia. For bluish vessels greater than 1 mm in diameter, I recommend the 3 mm spot, 30 ms pulse duration, 130 J/cm2 and the DCD at 40/30. The treatment, which pulses the laser along the vessels, starts at the smallest end and moves in the direction of the larger end. If the vessels are smaller (especially if they are red), my preference is the 1.5 mm spot, 30 ms, 400 J/cm2, DCD 40/30. For diffuse redness, I use the "painting" technique with the 8 mm spot, 0.3 msec pulse duration, 8 J/cm2, 10 HZ and the DCD system turned off. The painting technique involves holding the handpiece about one centimeter over the skin and rapidly moving over the treatment area. A back and forth motion is used, taking care not to stop in any one spot. The endpoint is the patient saying the area is becoming hot.

PIGMENTED LESION TREATMENT:

Pigmented lesions have been divided into epidermal and dermal lesions. The epidermal lesions include lentigines, freckles and Café au Lait spots. Dermal lesions include Nevus of Ota, Nevus of Ito and Nevus of Hori. Dermal lesions are treated using Q-switched laser technology while epidermal lesions have been treated by the 532 nm KTP and Q-switched lasers. The 755 nm long-pulsed Alexandrite laser has also showcased its usefulness in treating epidermal pigmented lesions.

Recommended Pigmented Lesion Treatment Settings:

- **Lentigines:**
  The GentleMax Pro™ using the 755nm alexandrite wavelength has been very effective in treating lentigines[25]. The DCD is turned off so the cooling does not protect the surface pigment. The parameters are the 8mm spot, 3ms pulse duration 24 J/cm^2 with the DCD off. If a patient is very sensitive to the laser, you may use the 10mm spot set at 16 – 18 J/cm^2. Single passes are used and most lesions respond after one treatment.

- **Cafe Au Lait Spots:**
  The GentleMax Pro™ using the 755nm alexandrite wavelength has been reported to be effective in treating Café au Lait spots with similar parameters as with lentigines.

TREATMENT OF THE AGING SKIN:

The "Gold Standard" for treating aging skin has been laser resurfacing which uses the carbon dioxide (CO_2) laser[26]. Although this may have been the most effective laser for sun damage and wrinkle reduction, many side effects have been noted which includes infection, persistent erythema and persistent hypopigmentation, and scarring[27,28]. These side effects have limited the use of this modality; this has introduced the search for less aggressive approaches of this type of treatment. Other modalities have been attempted for facial rejuvenation and the reduction of wrinkles; for finer lines and wrinkles, the Nd:YAG laser had been used with success.

Recommended Aging Skin Treatment Settings:

- Long pulse 1064 nm Nd:YAG wavelength has been shown to be effective in treating sun damaged skin. The GentleMAX Pro™ may be used in two modes for non-ablative

resurfacing. The first uses the technique described by Dr. Mark Taylor, using a 10 mm spot, 50 ms pulse duration, 50 J/cm^2, DCD system off[29]. This has since been modified to using the 18 mm spot, 18 J/cm^2, 50 ms pulse duration, DCD system off. The skin is to be warmed to 40 to 452 degrees centigrade.

A second technique with the 1064 nm Nd:YAG wavelength is called the "painting" technique. The parameters include using an 8 mm spot, 0.3 ms pulse duration, 8 J/cm^2 and the DCD system off. The laser is fired at 10 Hz repetition rate with the applicator tip one centimeter off the surface. The applicator is moved rapidly and the skin temperature slowly reaches approximately 40 degrees centigrade. This is not only an effective treatment for skin rejuvenation, but an efficacious treatment for diffused rosacea.

TREATMENT OF ONYCHOMYCOSIS

Several oral therapies are available to treat onychomycosis. Terbinafine is the most efficacious and considered first-line treatment. However, Terbinafine is contraindicated in certain patient populations, including patients with liver disease. Average cure rate of only 65.6% after 3 months of therapy with Terbinafine[30],[31]. There is a need for efficacious therapy that does not cause systemic side effects and lacks multiple drug interactions.

The GentleMax Pro can be used to temporarily increase clear nail in patients with nail fungus. Nd:YAG 1064-nm laser can penetrate as deep as the lower nail plate and has been shown to temporarily improve appearance of clear nail without significant complications and is especially suitable for older patients with low immunity or liver and renal dysfunction[32].

Recommended Onychomycosis Treatment Settings:

- Using the the 5mm podiatry spot size with the 1064, nm, the treatment should start at low settings, increasing slowly per patient's tolerance.

  Pulse duration of 0.3 ms, with 2-3 hz repetion rate. Fluence of 14-18 J/cm2 for skin types 1-IV, and 12-16 J/cm2 for skin types V-VI. 1-5 treatments are recommended. Minimum total of pulses 1000+ per foot, 600+ for the Hallux and 100+ for other toes. DCD should be turned off , anaesthesia or nerve blocks are not recommended as patient feedback is required and proper technique should be practiced. **Pulses should be adjacent with a slight overlap but not stacked.** End point is number of pulses and not temperature reached.

TREATMENT OF HYPERHIDROSIS:

The GentleMax Pro has also been found to be useful for treating axillary hyperhidrosis. When operated at hair removal setting at 1064 nm, it was found that some patients reported reduced sweating following treatments[33] This observation led to a study that specifically enrolled subjects diagnosed with clinical hyperhidrosis. All subjects enrolled reported a noticeable reduction in sweating that was confirmed with a modified starch iodine test. Selective deep heating of melanin at the hair follicle bulb by 1064 nm light leads to damage to the base of the eccrine gland particularly those in close proximity to the hair follicle.

SUMMARY:

The GentleMax Pro™ with the combination of two wavelengths, 755 nm Alexandrite and 1064 nm Nd:YAG is the gold standard laser for hair removal procedures for all skin types. On top of this, it has the capability of treating multiple other conditions. While the 755nm Alexandrite laser is highly absorbed by melanin, it is able to treat pigment as well as unwanted hair on Fitzpatrick Skin types

I-IV. The 1064nm Nd:YAG laser is less absorbed by melanin and can be effective for hair removal on all skin types, especially darker skin[34]. The Nd:YAG is absorbed by hemoglobin making it possible to treat facial and leg veins with less risk of PIH by using longer pulses[31]. In addition, it has been documented (Taylor et al) that the laser can treat fine lines and wrinkles[35]. The large range of pulses, widths and spot sizes the GentleMAX Pro™ offer enable fast, safe and effective hair removal in all skin colors. This is also effective in the treatment of vascular conditions such as port wine stains resistant to PDL, leg veins, benign epidermal pigmented lesions as well as the treatment of aging skin.

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