Optimization of a Laser Diode for Permanent Hair Reduction

James Childs, PhD, Richard Cohen, PhD, Mikhail Smirnov, PhD, Henry Zenzie, MS
Gregory B. Altshuler, PhD
Palomar Medical Technologies

INTRODUCTION

A Brief History of Laser Hair Removal

The first commercially successful laser for hair removal, a Ruby laser called Epilaser™, was launched by Palomar Medical Technologies, Inc. (PMTI) in 1997. The Epilaser™ system was developed in collaboration with Massachusetts General Hospital (MGH) following MGH's filing of a seminal patent application listing Drs. R. Anderson and M. Grossman and W. Farinelli as inventors (Anderson Patents) [1]. PMTI is exclusively licensed to the Anderson Patents and received the first FDA clearances for high power laser hair removal in 1997 and for permanent hair reduction in 1998. Supporting data was obtained from clinical trials at MGH under the direction of Drs. R. Anderson, M. Grossman and C. Dierickx. In addition to the Epilaser™ system, PMTI (working with its subsidiary Star Medical Technologies, Inc.) and MGH (under the direction of Drs. R. Anderson and C. Dierickx) developed and clinically tested the first diode-based laser for hair removal, the LightSheer® Pulsed Diode Array Laser. Through a series of acquisitions, the Lightsheer system is now owned by Lumenis and it continues to be a significant system in the hair removal market today. Lumenis' current version of the Lightsheer system, the Lightsheer Duet™, will be referred to as the "Lightsheer Laser" in this paper. The Lightsheer Laser as well as the professional light-based hair removal systems of all major manufacturers have been sublicensed under the Anderson Patents. PMTI has recently advanced diode laser hair reduction technology further with the introduction of the Vectus™ laser.

The Targets for Hair Removal & Treatment Paradigm

The Anderson/Parish Selective Photothermolysis paper (SP) [2] describes the application of optical and thermal principles for selective damage of pigmented and vascular lesions with laser light. Wavelengths should be selectively absorbed by pigment within a target near the skin surface and laser pulse widths should be short enough to localize thermal injury to the pigmented target. However, the conditions described in SP do not apply when treating a complex structure like a hair follicle. The degree of damage required, e.g. ablation/vaporization, coagulation or thermal stress, and details of the target's structure and depth impact device parameter selection. The targets for hair removal, for example, extend deeper than pigmented lesions and many vascular lesions. Furthermore, permanent hair reduction requires irreversible damage to structures responsible for hair growth, some of which are non-pigmented. The pigment used for laser hair removal is melanin which is contained in the hair shaft and hair matrix but is not contained within other structures of the hair follicle responsible for hair growth, namely the dermal papilla of the hair bulb and the stem cells located in the outer root sheath (ORS) in the "bulge" near the attachment of the erector-pili muscle to the follicle [3-4]. The Anderson Patents describe the need for thermal diffusion from melanin containing structures in the hair follicle to non-melanin bearing structures. Scientists from PMTI and MGH have also described the heating of a non-pigmented target that is remote to light-absorbing, pigmented objects in The Extended Theory of Selective Photothermolysis (ExSP, [5]). As the melanin in the hair shaft and matrix absorbs light and heats up, energy spreads from the shaft to the stem cells of the ORS at the bulge and from the hair matrix to the papilla by the process of thermal diffusion.

Devices that utilize short pulses of high powered light to vaporize the hair shaft or matrix are not only less safe for the skin, they are also less efficient. Vaporization leads to loss of the light-absorbing pigment before the pulse ends and to displacement of heated material. The remaining part of the laser pulse energy is therefore not absorbed at all and the energy of the displaced, vaporized material may be lost. There is less energy for heating the target cells and decreased efficiency of the treatment. Longer pulses of light energy below the threshold for hair shaft or matrix vaporization can deliver more energy to the target.

Efficacy vs Safety in Hair Removal

The optimization of hair removal parameters and device design is complex. Many inter-dependent factors must be considered, the most important of which is safety. Figure 1 shows a hair follicle in a stained section of porcine skin (Sinclair) after treatment with the Vectus Laser. There is complete coagulation of the hair follicle without hair shaft vaporization (the shaft is not visible in Fig. 1 as it was lost during processing) and the surrounding pigmented epidermis has been spared by contact cooling. This injury profile is ideal for selective hair follicle damage leading to permanent hair reduction.

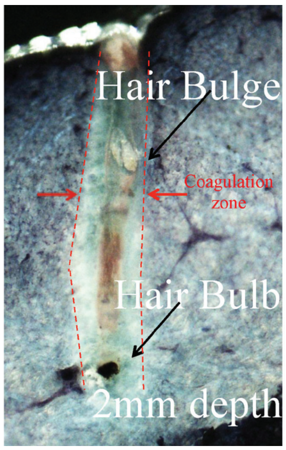


FIGURE 1 Image of a vertical section of porcine skin through one hair follicle stained with NBTC, a viability stain, after treatment ex vivo with the Vectus laser with Small Sapphire Optic (44 J/cm^2, 30 ms). Note perifollicular coagulation of the epidermis, in the area of the bulge (stem cell area) and at the bulb (hair matrix and papilla) with no injury to the surrounding epidermis because of contact cooling.

A pulse of laser energy applied to the surface of the skin is measured in fluence with units Joules/cm^2 (the energy per unit area). Subject to the restriction that vaporization of the hair shaft and matrix should be avoided, the higher the fluence of light delivered to the surface of the skin, the more the heating of the hair shaft and consequently, the more the diffusion of the heat to the target stem cells and papilla. Hence, more permanent hair reduction will occur per treatment. However, the epidermis also contains melanin so that the skin will heat up during the laser pulse. Skin safety therefore limits the possible treatment fluences. This is particularly relevant to the treatment of lighter colored hairs or darker skin types. In general terms, optimization of hair removal devices requires sufficient fluence to be delivered and absorbed by the follicle in appropriate pulse widths to cause the needed temperature rise of the follicle's cells without causing excessive skin temperatures.

VECTUS LASER SYSTEM

It is useful for practitioners to have two different spot sizes - one large and one small for treatment of a variety of anatomical sites. The Lightsheer Laser system provides two separate hand pieces each with a different spot size. The Vectus Laser, however, conveniently provides two interchangeable optics 23 x 38 mm^2 (8.74 cm^2) or a 12 x 12 mm^2 (1.44 cm^2) for the same hand piece that can be switched twice as fast as the Lightsheer Laser system.

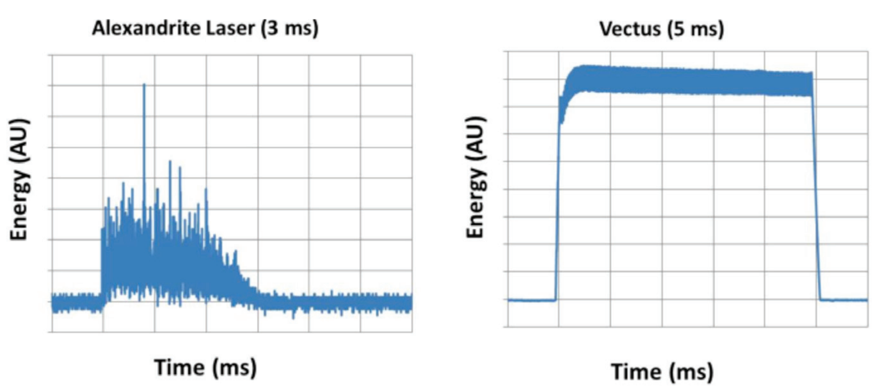
As detailed below, the Vectus Laser implements seven design features to optimize heating of the hair follicle and skin protection: laser wavelength, laser pulse widths and shape, output power, photon recycling, contact cooling and spatial beam profile.

Laser Wavelength, Pulse Widths and Pulse Shapes

Throughout the last 15 years, numerous clinical studies and in vitro studies have demonstrated the effectiveness of wavelengths around 800 nm for hair removal. This wavelength provides significant depth of penetration, an important feature for efficacy in hair removal, and also provides better safety compared with shorter wavelengths for Fitzpatrick skin types III - V. Wavelengths longer than 800nm are safer for darker skin types but are also less effective for hair removal for the same reason: there is less absorption of light energy by melanin. In addition, longer wavelengths are better absorbed by water and blood in the skin increasing the risk of skin injury or pain. In a practice that will provide hair removal on people of all skin types the best choice of wavelength is approximately 800 nm with pulse widths greater than 5 ms. The Vectus Laser is powered by a diode laser emitting at 800 nm in pulse widths from 5 ms to 300 ms and fluences from 1 to 100 J/cm^2.

The Vectus Laser delivers the output power in a smooth laser pulse whose profile in time resembles a "top hat", without the spikes seen in many competitor laser systems such as an Alexandrite laser (GentleLase, Candela, Fig. 2). These spikes can lead to excessive epidermal temperatures that cause discomfort and compromise safety [6, 7].

FIGURE 2
Output pulse profile of an Alexandrite laser (3 ms) is compared with that of the Vectus Laser (5 ms).



Output Power

The Lightsheer Laser hand piece utilizes 100 diode laser bars each capable of 20 W output power at 800 nm wavelength (considered state of the art at the time of its introduction). The laser bars are packaged and assembled into arrays and this process can lower the maximum output power of each bar depending on thermal characteristics. The Lightsheer Laser has an output power of 1600W. Recent advances in diode laser bar technology allow each bar to produce an order of magnitude higher power (150 - 200 W). In addition, PMTI has developed significant proprietary packaging technologies (patents pending) making it possible for the Vectus Laser to utilize a 24 diode laser bar array in a multi-bar module format with almost double the maximum total laser output power (3000W vs. 1600W).

Photon Recycling

The skin is actually a very reflective surface that can reflect up to 80% of the incident 800 nm wavelength light depending primarily on the skin's melanin concentration. The Vectus Laser hand piece incorporates a patented technology called "photon recycling" that minimizes the laser light losses due to light scattering or reflections from the surface and from lower layers of the skin. This technology is described in more detail by PMTI and MGH in "Photon Recycling: A New Method of Enhancing Hair Removal" [8]. The Vectus Laser uses contact of the hand piece's sapphire wave guide with the skin to capture the reflected light and the hand piece includes a system of mirrors to maximize photon recycling which is shown in Fig. 3. The left optic is without photon recycling mirrors and the right optic is with photon recycling mirrors. Blue rays indicate paths taken by photons that have interacted with the skin only once. In the left optic, upon reflection back from the skin, these photons are lost to absorption within the device. In the right optic, red rays are paths taken by those same photons that instead of being lost in the device are reflected back down into the skin by the mirrors. Photon recycling increases the fluence available to heat the desired targets in the skin. The gain factor for photon recycling is defined as the ratio of fluence available in the skin for heating the target with photon recycling to that without photon recycling. The gain depends on melanin concentration in the epidermis and is unity for darkest skin (no gain) but increases for lighter skin up to 1.5 – 2 times.

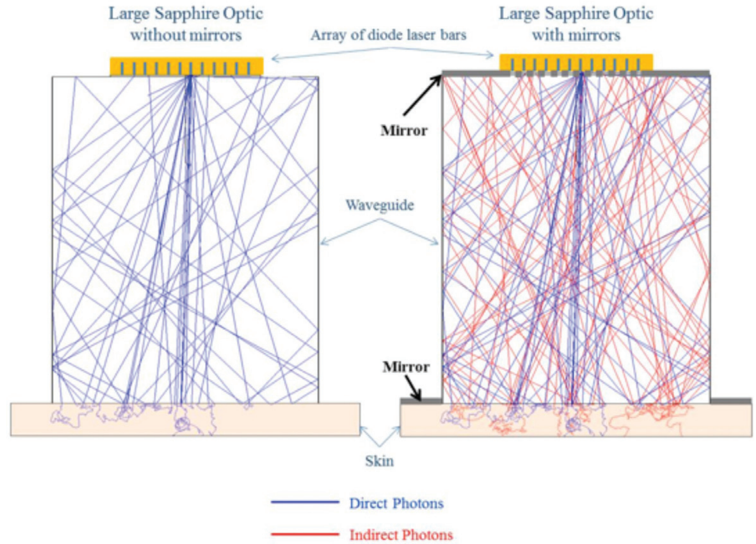


FIGURE 3 Cross-sectional view of Large Sapphire Optic waveguide on skin with results of a Monte Carlo ray trace model shows the benefit of the photon recycling mirrors. For the same incident fluence, there is a gain of 1.5 X in the number of photons at a target in the skin with the addition of the mirrors.

Contact Cooling

Light from any treatment device naturally scatters in the skin and can cause over-heating of the epidermis, papillary dermis and reticular dermis. Skin cooling is often therefore integrated with the treatment device and several methods have been used, the most common of which are contact with a chilled sapphire, cold air flow and cryogen spray. Regardless of method, cooling always begins at the skin surface and propagates downward by thermal diffusion. The time needed depends upon the temperature maintained at the skin surface and the required depth of cooling. For a given depth of cooling, lower temperature means a faster cooling time. Three methods for cooling are before (precooling), during (parallel cooling) and/or after (post-cooling) the laser pulse and appropriate use of each option can increase the safety margin and reduce negative side effects without compromising efficacy of the treatment. Only contact cooling devices can conveniently perform all three options without compromising laser energy delivery. For example, spray cooling might be terminated during the laser pulse to reduce laser light scattering off the droplets of the spray. Contact cooling is also used to provide compression to improve heat transfer from the skin to the device and to displace blood from the plexus to avoid heating hemoglobin. The contact method of skin protection by pre- and parallel cooling for hair removal is described in the Anderson Patents and in papers by researchers at Palomar and MGH [9-10]. The Vectus Laser provides superior contact cooling with a high capacity, compressor chiller and advanced hand piece design. The hand piece incorporates excellent heat transfer characteristics with a unique coolant flow pattern coupled to a large sapphire block with high thermal capacity. This design efficiently removes heat from the skin and maintains a constant low temperature of the contact optic throughout any treatment session. Many other contact cooling systems use a thin piece of sapphire at the tip of their hand pieces or use "slide-in" sapphire waveguides, but these are not optimal because they have a reduced rate of heat extraction.

Spatial Beam Profile

The spatial beam profile exhibits the uniformity of the light beam across the entire optic surface contacting the skin. Most laser systems and particularly many diode laser systems produce highly non-uniform beams of light that generate localized spots of intense laser power. Hot spots can be very evident both by increased pain and non-uniform effects on the skin including burns or striping. Figure 4a shows mild crusting and pigmentary changes at several focal spots on the axilla 24 hours post-treatment with the 9 mm x 9 mm Lightsheer Laser hand piece and Figure 4b shows significant crusting and epidermal injury on the anterior thigh 3 days post-treatment with the 36 mm x 20 mm Lightsheer Laser hand piece. Figure 5 compares the infrared images of the large and small area hand pieces of both the Vectus Laser and Lightsheer Laser. Note that the non-uniform profiles of the Lightsheer Laser small and large hand pieces exhibit hot spots whose dimensions coincide with those of the pigmentary changes in Fig. 4a (approximately 4.5 mm x 6.7 mm) and Fig. 4b, respectively. In contrast, the Vectus Laser provides a very uniform spatial beam profile. The benefits of the uniform spatial beam profile are manifested in less pain per equivalent output, better hair clearing because more laser energy can be safely launched into the skin and faster treatments because the need for overlapping of the hand piece is minimized. A non-uniform beam profile with fluence highest near the center of the output window causes the effective treatment area to be much smaller than the window area.

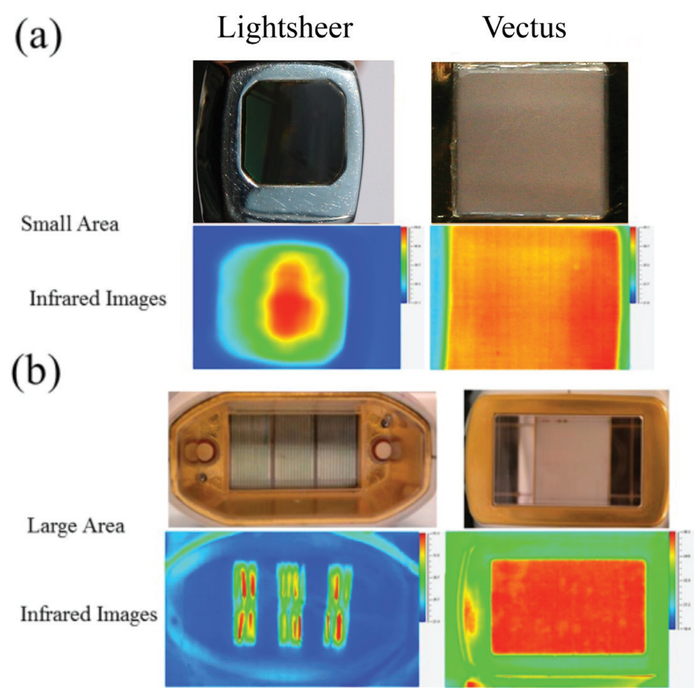


FIGURE 5 Digital pictures of the tips and beam profiles for Vectus Laser and Lightsheer Laser hand pieces. (a) Small area and (b) Large area.

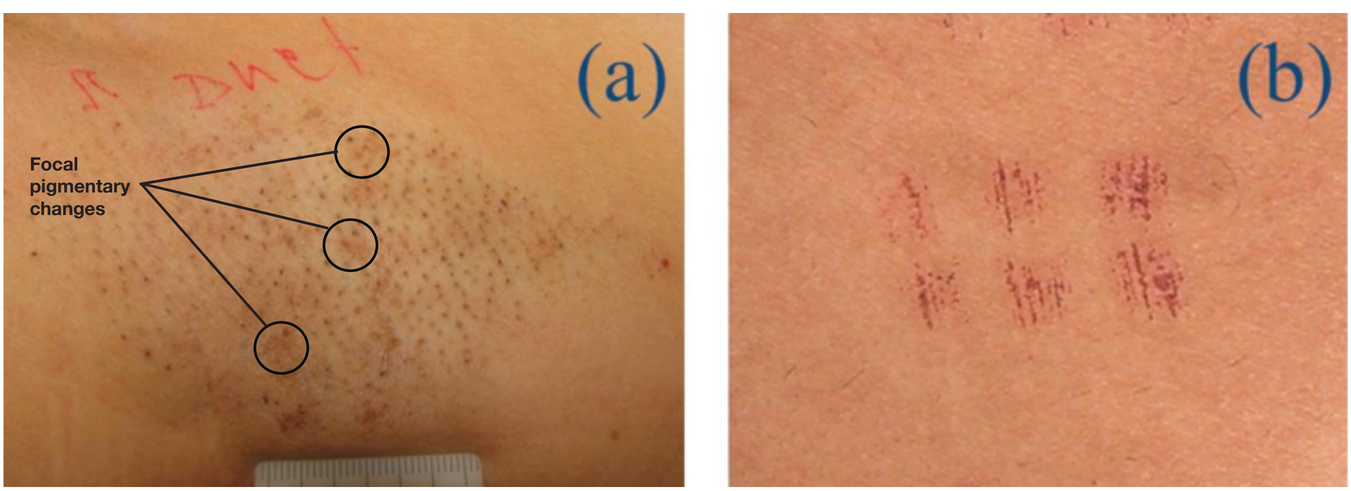


FIGURE 4 Effects of non-homogeneous beam profile on skin. (a) Axilla 24 hours post treatment with small Lightsheer hand piece at 33 J/cm^2, 17 ms. Note focal pigmentary changes. (b) Anterior right thigh 3 days post treatment with large Lightsheer hand piece at 12 J/cm^2.

IN VITRO COMPARISON OF TWO LASER DIODE SYSTEMS

The Vectus Laser and the Lightsheer Laser were compared in an ex vivo model with appropriate skin and hair characteristics. The treated samples underwent a histology analysis to evaluate and compare the extent of damage to the hair follicles.

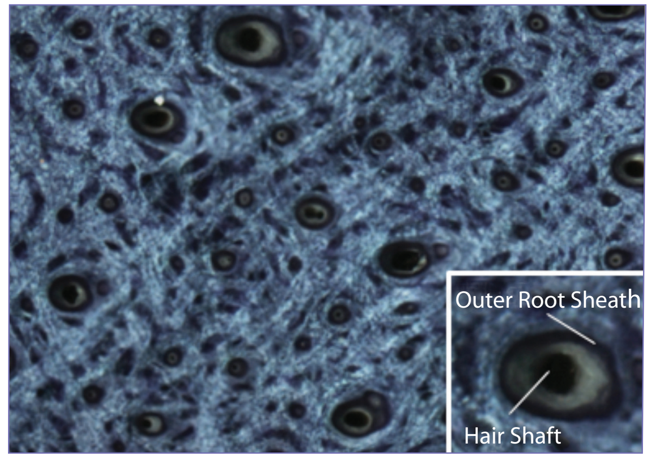
Material & Methods

Large and small hand pieces of each system were used to treat ex vivo porcine skin (Sinclair pig, Sinclair Bio Resources, LLC, Columbia, MO). The Sinclair pig was chosen for the study based on similarity with human hair and skin. Hair densities of the samples were 1.15 hairs/mm^2 with hair diameters ranging between 45 and 280 µm with a mean (standard deviation) equal to 77 µm (53 µm). The fluences and pulse widths for the large hand pieces were 12 J/cm^2, 60 ms for the Lightsheer Laser and 12 J/cm^2, 37 ms for the Vectus Laser. The small area hand piece parameters were 60 J/cm^2, 30 ms for the Lightsheer Laser and 60 J/cm^2, 40 ms for the Vectus Laser.

The skin was prepared and equilibrated in a water bath to 37 °C prior to treatment. After treatment, 12 mm biopsy punches were taken central to the device's footprint. Biopsy punches were also taken peripherally for the large area hand pieces to evaluate uniformity of treatment across the footprints. All biopsy punches were frozen and sectioned (140 µm thick) with a cryotome (Microm HM550) horizontally or vertically for NBTC viability staining. Horizontally sectioned samples were serially sectioned from the skin surface down and sections were placed in order into four wells, three sections per well, to later correlate results with skin depth. Each well represented a depth in the range 100 – 600 (300 µm), 600 – 1100 (800 µm), 1100 – 1600 (1300 µm) or 1600 – 2100 (1800 µm) microns.

The stained samples were imaged for hair counting on a B25 Olympus microscope equipped with a Nikon camera. Figure 6 compares a control section with a sample section treated by the Vectus Laser. Cells of the outer root sheath (ORS) stain blue when viable (see insert in the control image of Fig. 6) but do not stain blue when irreversibly damaged by heat. Note the loss of viability of cells (coagulation) in the outer root sheath of the follicles extending into the surrounding dermis in the Post Treatment image. Blinded investigators were trained to identify coagulation of hair follicles in the sections: If more than 50% of the outer root sheath of the follicle is unstained, it is considered coagulated. Percentages of coagulated hairs to total hairs in all sections at the depth of the bulge were assessed.

Control



Post Treatment

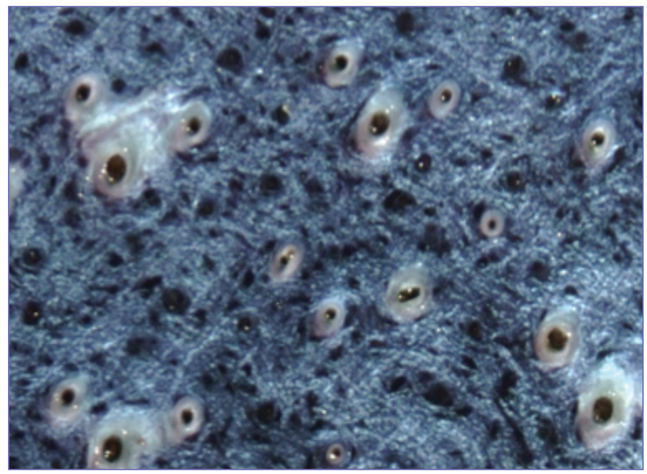
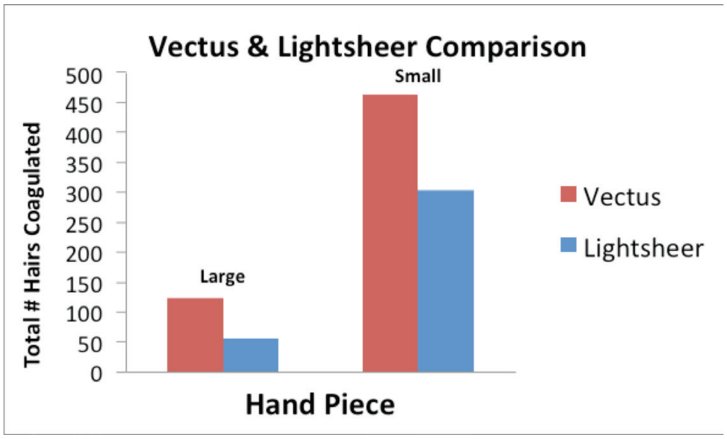


FIGURE 6 Control and treated horizontal sections after NBTC stain. The coagulated hairs have lost cell viability in the follicle's outer root sheath as demonstrated by the loss in blue stain around the hair shafts.

Summary Results

The Large Sapphire Optic of the Vectus Laser coagulated 56% more hairs than were coagulated by the Lightsheer Laser in all sections (25% versus 16%). There was no significant difference between percentage of coagulated hairs in the 12 mm central spot and the percentage of coagulated hairs in the peripheral regions of the Vectus Laser footprint (29+2% central and 33+1% peripheral, $p < 0.07$) whereas a significant difference was seen for the Lightsheer Laser (20+2% central and 15+1% peripheral, $p < 0.01$). The Vectus Laser therefore coagulated hairs more uniformly across the device's entire footprint. Greater uniformity requires less treatment overlap resulting in faster treatment time. An overall hair coagulation count at the depth of the hair bulge, approximately 1 mm [11], is compared for all devices in Fig. 7.



CONCLUSION

The Vectus Laser implements seven design features to optimize heating of the hair follicle, treatment speed and skin protection: an 800 nm laser wavelength, 5 ms – 300 ms pulse widths with smooth output shape, output power to 3 kW, photon recycling, contact cooling and a uniform spatial beam profile. Two different treatment spot sizes are provided in a single hand piece with two easily interchangeable sapphire optics. In an in vitro study, the Vectus Laser coagulated hair follicles more effectively over a larger area per pulse than the Lightsheer Laser when compared at similar treatment parameters.

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