Comparative Study between the Vectus™ Diode Laser System and LightSheer™ Duet for Long-Term Hair Reduction in the Axilla

Joe Lowery, Rich Cohen, Felicia Whitney, James Childs and Gregory Altshuler
Burlington, MA

OVERVIEW

The use of lasers for hair removal has been well established. The most commonly used devices include Intense Pulse Light (IPL), the alexandrite, Nd:YAG, and diode lasers[1], all of which have proven safe and effective for removing unwanted hair. Recently a new near-infrared diode laser system (Vectus™, Palomar Medical Technologies, Burlington, MA) has been introduced with features that provide fast, safe and effective hair removal. Unique design features of the Vectus™ system include an optimum wavelength for hair removal (800 nm), high peak power (3000 W), a uniform beam profile, a smooth pulse shape and photon recycling, all of which provide greater energy delivery to the hair follciles[2]. A clinical trial to validate the system's performance and design features was completed to demonstrate long-term efficacy.

MATERIALS & METHODS

This study was conducted under an IRB approved protocol, and all subjects provided signed, informed consent. Eight female adult subjects (Fitzpatrick Skin Type II and III) received treatment for unwanted hair in the axilla in a split-body fashion using the Vectus™ System on one side and the LightSheer™ Duet, (Lumenis, Yoakneum, Israel) on the other axilla. Large and Small Treatment Optics of both devices were tested in this study with four subjects randomly assigned to receive treatments with the large optics and the others receiving treatments with the small optics. The spot size of the Vectus™ Small and Large Optics were 12x12mm and 23x38mm, respectively; or about 74% and 14% larger than the 9x9mm and 22x35mm Small (ET) and Large (HS) tips of the LightSheer™ Duet. All subjects received three treatments at intervals of approximately four to six weeks, and were scheduled with follow-up 6 months after the laser treatment. High resolution photographs of the treatment areas were taken at each visit so that subsequent hair counts could be performed as a measure of percent hair reduction, the primary outcome measure of the study. Hair counts were performed in a blinded fashion by two trained investigators and the percent reduction in hair count was determined for each site relative to baseline. Specific treatment areas in each axilla approximately 25 cm^2 in area were identified using templates to aid in camera registration. Areas were cleaned and shaven prior to treatment and no anesthesia was administered. Maximum cooling was selected for both the large and small sapphire contact optics with exception of the LightSheer™ Duet Large HS Tip which has no cooling. Specifications of the Vectus™ are shown in Table 1.

	Vectus	
Wavelength	810 nm	
Optic	Large Tip	Small Tip
Spot Size	23 x 38 mm	12 x 12 mm
Fluence (max)	20 J/cm^2	100 J/cm^2
Pulsewidth	5 ms to 300 ms	
Repetition Rate	Up to 3 Hz	
Peak Power	2200 W	3000 W

Table One: Vectus Performance Specifications

With the Vectus™ system, fluence and pulsewidth were optimized for each individual patient and treatment area using a combination of the SkinTel™ Melanin Reader, the MaxPulse™ pulsewidth auto-selection feature, and the Hair Specific Fluence Selection system, all of which are integrated as standard components (Fig. 1). The melanin content of the skin in the treatment areas was measured using the SkinTel™ which converts the melanin content to a numeric value between 1 and 99, with 1 representing the lightest skin and 99 the darkest skin, or highest melanin content. The readings were automatically averaged and transmitted wirelessly to the Vectus™ base unit where additional characteristics describing the hair color, thickness and density were entered on the control screen, shown in Figure One.

The Vectus™ processes the entered information using a sophisticated algorithm to display a recommended starting fluence for the first test spot. As a final step, the MaxPulse™ feature was selected which, for a given fluence setting, automatically adjusted the pulsewidth to a value that will maximize the power, in Watts, of the delivered treatment pulse. For the Duet, the starting fluence for the first test spot was determined based upon the treatment guide recommendations for fluence and pulse width (Auto) for the individual's hair character and skin type. For both devices, after delivering the first test spot to the treatment area, the skin reaction and patient pain tolerance were evaluated, and the fluence incrementally increased to the highest level that was well-tolerated by the patient, or to the maximum fluence setting of the device. Treatments with the Vectus™ were performed with an average fluence of 10.6 J/cm^2 and 25.7 J/cm^2 with the Large and Small Tips, respectively, versus 11.6 J/cm^2 and 29.2 J/cm^2 for the Large and Small Tips, respectively, of the LightSheer™ Duet.

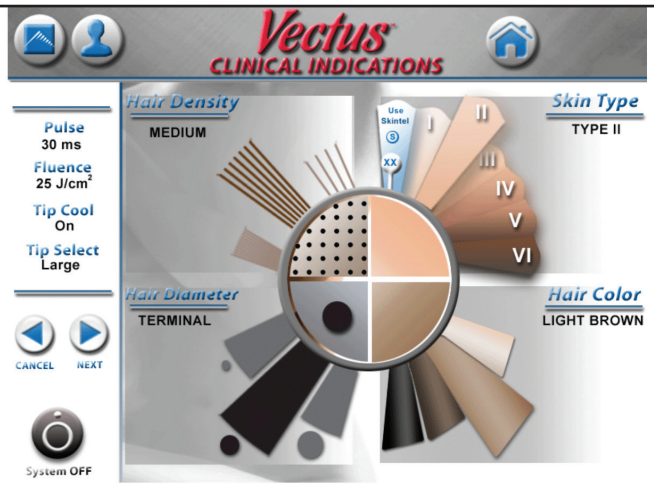


Figure 1: Hair Type Selection Screen for Vectus™

RESULTS

All subjects tolerated the treatments well with both devices, and hair reduction was observed in all areas. Clinical endpoints with the two devices, such as the appearance of perifollicular edema post-treatment were observed. However, treatment with the large area optics consistently had less perifollicular edema/erythema than the small area tip treatments.

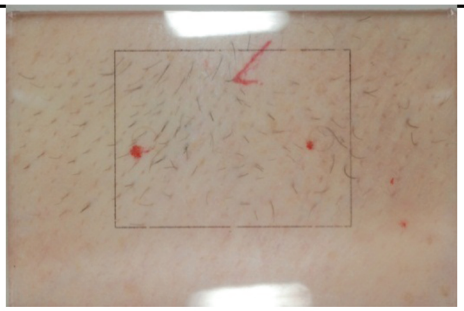
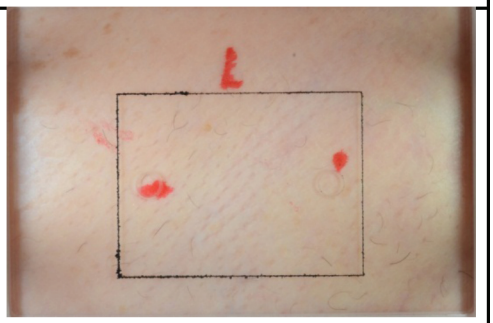
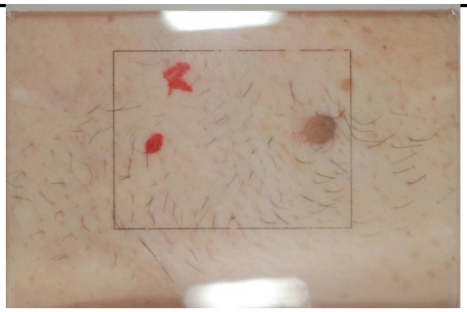
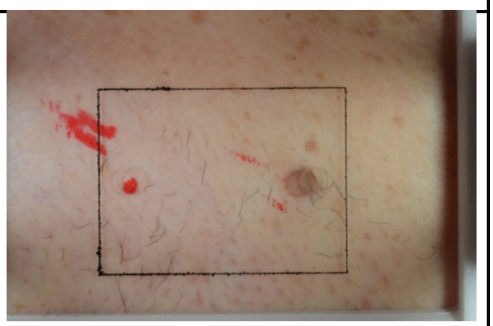
	Baseline	Six Month Follow-Up
Vectus Large Tip Hair Count Reduction 79.0%		
LightSheer Duet Large HS Tip Hair Count Reduction 45.5%		

Figure 3: 51 y/o Caucasian Female. Fitzpatrick Skin Type III. SkinTel Melanin Index 17. Vectus Large Tip treatments at 14.0 J/cm^2. LightSheer Duet Large HS Tip treatments at 12.0 J/cm^2 (device maximum).

The Vectus™ demonstrated 40% greater hair reduction at 6 months after 3 treatments than the LightSheer Duet with an average 64% hair reduction for Vectus compared to 46% for the Duet. The difference in hair reduction was statistically significant (18% ± 16%, p=0.01, n=8 paired T-test). All eight subjects had a higher percentage of hair reduction for Vectus (Fig 2). The baseline and 6 month follow-up hair count photos for subject LG3 are shown in Fig 3. The average hair reduction for the Vectus large and small optics was equivalent, 65% and 64%, respectively even though the average treatment fluence was 11 J/cm^2 compared to 26 J/cm^2 (Table 2). The large and small optics of the Duet similarly had equivalent hair reduction 48% and 44%, respectively, with 12 J/cm^2 and 29 J/cm^2 average treatment fluence. There was no difference in discomfort ratings between the devices.

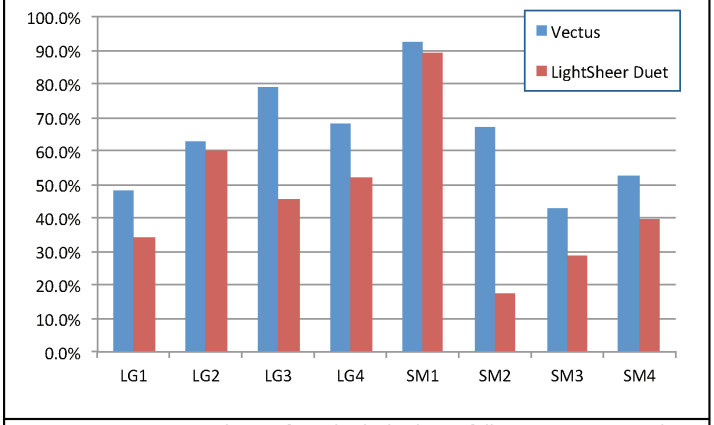


Figure 2: Percent Hair Reduction for Individual Subjects following treatment with Vectus and LightSheer Duet Large (LG) and Small (SM) Tips

	VECTUS		DUET	
	Large	Small	Large	Small
% Hair Reduction @6mo	65%	64%	48%	44%
Ave Fluence (J/cm²)	11	26	12	29

DISCUSSION

The split-body comparison of laser hair removal on the axilla is an effective means to evaluate differences between devices or settings. Both devices were tested using their max power setting modes that deliver the selected fluence in the shortest available pulse width. The 40% greater reduction observed with the Vectus compared to the LightSheer Duet was statistically significant. The 48% hair reduction for the LightSheer Duet large optic is similar to the 54 ± 24% reported 6 months after 3 treatments on the axilla in the Ibrahami study[3] and suggests that settings used in this study were appropriate. The higher efficacy observed with the Vectus™ is a consequence of the combination of a more uniform beam profile, better photon recycling[4] and compression with contact cooling providing more energy to the hair follicles without decreasing skin safety.

For fixed fluence, energy reaching a target at depth increases with the area of the device in part due to scatter and due to greater energy delivered into the skin. An additional increase is also realized with photon recycling that depends on internal design and also on the area of the device. Reflection from the internal surfaces of the device will send more captured light back into the skin. In turn, the percentage of light captured by the device is also increased with area. A portion of the light reflected back from the skin escapes beyond the edge of the device's optic within a distance that is independent of the optic size and is only determined by skin's optical properties. This reflected light is lost to recycling. The fraction of the total light that is collected by the optic and recycled back into the skin therefore increases with optic size.

The above considerations explain why similar efficacy is observed with the large and small optics despite over 50% less treatment fluences (11 vs 26 J/cm^2 for Vectus™ and 12 vs 29 J/cm^2 for LightSheer Duet, respectively). The decrease in a device's fluence can be compensated for by increase in area and photon recycling. Design differences between the two systems contribute to the observed performance differences: The special internal gold-mirror design provides the Vectus™ Large Tip with more efficient recycling leading to improvement in efficacy and a more uniform beam profile in both optics increases the effective spot sizes to nearly the actual window sizes. This leads to minimal overlapping requirements (about 10%) and faster, safer treatment. In addition, a contact device can compress the skin to decrease tissue scatter and bring the deep targets closer to the skin surface.

An interesting observation in both systems is that large optic treatments cause less perifollicular edema and erythema, but similar efficacy compared with the corresponding small optic treatments. Similar conclusions were presented in a histology study[5]. Note that injury to the tissue surrounding the superficial portion of the follicle, e.g., the infundibular epidermis and possibly the isthmus, manifests itself as perifollicular erythema and edema. The fluence in the superficial layer of the skin is apparently less for the large than for the small optic. In spite of this, the similar efficacy suggests that effective injury profiles are provided to the deeper targets by both tip sizes. Since the study design treated to tolerable fluences in both optics, it is not known if the small optic fluences would have been as effective at lower levels although such a result is not expected. As discussed above, this desirable feature may be explained as follows: A larger optic provides more energy to the deeper targets without adding as much energy

to the epidermis and superficial hair structures. However, increasing area increases the energy required from the device. Approximately 2.6 times more energy is required from the large versus small optic to compensate for approximately 6 times increase in area. The well-known rule that a 1 cm^2 beam area is optimum for heating a target located a few millimeters deep in human skin is applicable when trying to minimize the device's required energy output. Increasing the beam area, besides increasing area of treatment and speed, continues to add more energy to the target with less increase in energy to the epidermis.

The above considerations suggest that the current clinical end-points for laser-based hair reduction treatments may not be necessary with the new generation of very large optics.

SUMMARY

In a split-body direct comparison on laser hair removal the 65% hair reduction observed with Vectus™ was 40% greater than the 46% hair reduction observed with the Duet. The large and small optics were found to be equally effective even though the large optic used fluence settings that were over 50% lower and had reduced perifollicular skin reactions. The higher efficacy observed with the Vectus™ suggests that the combination of higher peak power, larger spot sizes, higher efficiency photon recycling and skin compression provides more effective energy to the hair follicles. At the same time, a uniform beam profile in combination with contact cooling and implementation of the Skintel Melanin reader with starting test dose range algorithm are safety features which helps protect the skin.

REFERENCES

1. Dierckx C. Hair Removal by Lasers and Intense Pulsed Light Sources. Dermatol Clin 20(1):135-146, 2002.

2. Childs J, et al. Optimization of a Laser Diode for Permanent Hair Reduction. Palomar Published Material.

3. Ibrahimi, O, Kilmer W. Long-term Clinical Evaluation of a 800-nm Long-Pulsed Diode Laser with a Large Spot Size and Vacuum-Assisted Suction for Hair Removal. Derm Surg 38: 912-917, 2012.

4. Yaroslavsky I, Altshuler G, Yaroslavsky A, Pankratov M, Stoll M, Manstein D, Anderson R. Photon Recycling as a Means of Increasing Efficacy and Safety of Flashlamp Systems. Lasers in Surg Med 2003 (Abstract).

5. Xia, Y, Moore, R, Cho, S, Ross, EV. Evaluation of the vacuum-assisted handpiece compared with the sapphire-cooled handpiece of the 800-nm diode laser system for the use of hair removal and reduction. J. Cosmet. And Laser Therapy, 2010; 12: 264-268.