

Post-Market Case Series of the Syntech IPL, Er:YAG, Long Pulse and Q-Switched Nd: YAG Handpiece of the Apollo V+ for Multiple Indications: Results for 7 Subjects

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Summary Provided by Syntech Co., Ltd.

Introduction

Over the past decade, there have been striking advances in dermatology to treat a wide range of skin-related abnormalities with energy delivery devices including laser and light-source devices.

IPL, or intense pulsed light, devices were developed in the early 1990s and made a significant impact in the treatment of cutaneous abnormalities allowing a variety of skin abnormalities to be treated effectively using an intense, pulsed, broad-spectrum, non-coherent flash lamp. Consequently, with the growing indications for this type of treatment and increased clinical experience, new technologies began to develop to meet market demands.¹

Patients demand low-risk procedures with minimal downtime and thus, the market for new, light-based devices is growing.¹

According to 2013 statistics released by the American Society for Dermatologic Surgery, the top cosmetic treatment for 2013 was laser/light/energy-based procedures. The numbers were up 34 percent over 2012 with 2.25 million procedures.²

Efforts can be assigned to three primary approaches — refinement of existing technologies (lasers and non-ablative lasers); refinement of tried-and-true techniques (chemical peeling); and innovative use of new technologies (photo rejuvenation).³

With these exciting technological advances, the breakthrough of multi-technology systems encompassing the ability to treat numerous clinical applications have become the gold standard, offering both the clinician and the patient wide-ranging therapeutic choices with a single compact yet powerful system. This breakthrough reduces the need for dedicated application systems and their associated floor space and high maintenance costs⁴ while producing high levels of efficacy, safety and patient satisfaction.⁵

System Description

The Apollo V+ System (Beijing Syntech Laser Co., Ltd., Beijing, China), is a complete, multi-function light-based platform, with an enhanced cooling system, incorporating laser and Intense Pulsed Light (IPL) systems. Apollo V+ provides a wide range of applications for a variety of clinical indications eliminating the need for a stand-alone application system and providing greater cosmetic benefits to the consumer. Apollo V+ is equipped with multiple handpieces and treatment filters that can be easily interchanged for a variety of applications in dermatology, cosmetic surgery and other surgical applications. The System offers contact cooling from 0-5 degrees and additionally the Long Pulse Nd:YAG and IPL sources offer handpieces that contain an actively cooled output lens.



Figure 1: The Apollo V+ multi-function light based platform

Case Series Evaluation

Procedures

A post-market case series evaluation of the Apollo V+ was conducted in seven (7) patients to demonstrate the clinical and technical performance of the following eight (8) applications of the System (Table 1): IPL for treatment of rosacea, facial telangiectasia, and hair reduction, Q-Switched Nd: YAG for treatment of unwanted tattoos and pigmented lesions, Er: YAG treatment for wrinkles and photo damage, and Long Pulse Nd: YAG for treatment of hair reduction. All seven (7)

After the treatment was performed, the treating investigator was asked to record any clinical observations (i.e., the severity of anticipated treatment response/side effects of the treatment with regard to any erythema, scaling and dryness, edema or blistering, etc.) as well as any adverse/unanticipated events (whether treatment related or not). If an expected side effect noted above (erythema, edema, etc.) was severe in nature and/or lasted more than 30 days, it was considered an adverse event.

Indications	IPL Intense Pulse Light	Er: YAG Erbium	Long Pulse Nd: YAG	Q-Switched Nd: YAG
Tattoo removal				Subject #1
Pigmented lesions	Subject #3			Subject #2
Facial Telangiectasia	Subject #2			
Rosacea	Subject #4			
Wrinkles		Subject #5		
Hair reduction	Subject #7		Subject #6	

Table 1 Apollo V+ Evaluation: Laser handpiece and corresponding indications

subjects provided informed consent to participate and have photographs taken in this post-market evaluation.

The study was open to subjects aged 18 years or older (with the exception of the Er: YAG wrinkles arm of the study that was open to subjects aged 30 or older) who desired treatment for one of the aforementioned aesthetic conditions and met study inclusion/exclusion criteria.

Subjects were prepared for laser treatment in accordance with acceptable medical practice.

Subjects were given verbal and written post-treatment skin care instructions. Standard, digitalized, high-resolution photographs were taken of the treatment area at baseline and again after the third laser treatment/final follow-up visits. The photographs were taken by a professional clinical photographer

Subject discomfort (stinging/burning sensations, etc.) during the laser procedure was recorded using the following four-point scale:

0 = None

1 = Mild

2 = Moderate

3 = Severe

The investigator noted the estimated or average total time for each treatment in minutes.

Success of the treatment was based on clinical improvement after treatment using baseline and follow-up photographs assessed separately by the subject and the study investigator. A quartile rating scale (shown on next page) was used.

1=<25% = Mild Improvement

2=25-50% = Moderate Improvement

3=51-75% = Good Improvement

4=76%-100% = Excellent Improvement

Results

Tattoo Removal

Subject #1 {JAE}: 26 year-old Asian female with Fitzpatrick Skin Type IV and an unwanted tattoo on her inside wrist. Subject underwent three (3) treatments with the Q-Switched Nd:YAG handpiece of the Apollo V+ System for 10 minutes each session, using a 1064nm wavelength, output of 200-800mJ, 4mm spot and pulse rate of 5Hz. In the laser sessions, subject discomfort ratings remained at a score of 1 (mild) or less. Mild erythema was noted after the procedure. Both investigator and subject assessments taken after the third treatment revealed Excellent Improvement (76-100%). No adverse events were reported.

Pigmented Lesions

Subject #2 {EAB}: 55-year-old, Caucasian, female with Fitzpatrick Skin Type II and solar lentigo on the left cheek. Subject underwent two (2) recommended treatments with the Q-Switched Nd:YAG handpiece of the Apollo V+ System for approximately 10 minutes each session using a 532nm wavelength and a 4mm spot size. The first treatment was performed at 600mJ with a pulse rate of 5Hz and was increased to 800mJ with pulse rate of 5Hz for the second treatment. In both laser sessions, subject discomfort ratings remained at a score of 1 (mild). Both investigator and subject assessments taken after the two (2) treatments revealed Excellent Improvement (76-100%) of the solar lentigo.

Subject #3{CR}: 57-year-old, Hispanic, female with Fitzpatrick Skin Type IV with mottled pigmentation underwent four (4) treatments with the IPL handpiece of the Apollo V+ System for 20 minutes each session, with 5degrees cooling at 20-24J/cm². In the laser session, the subject discomfort rating remained at a score of 1 (mild). Subject experienced mild erythema and mild follicular edema after each treatment. Good Improvement (51-75%) was noted by both investigator and subject assessments taken after the fourth treatment). No adverse events were reported.

Facial Telangiectasia

Subject #2 {EAB}: Subject #2 (55-year-old, Caucasian, female with Fitzpatrick Skin Type II) also underwent three (3) recommended treatments with the IPL handpiece of the Apollo V+ System for facial telangiectasia on the cheeks. Treatment lasted approximately 10 minutes each session, with 5degrees cooling at 15-18 J/cm² using the Vascular Rejuvenation (VR) tip. In the laser sessions, subject discomfort ratings remained at a score of 1 (mild) to moderate (2). Vascular blanching and frosting were noted. Both investigator and subject assessments taken after the three (3) treatments revealed Good Improvement (51-75%) of the facial telangiectasia.

Rosacea

Subject #4 {PAL}: 45-year-old, Asian, female with Fitzpatrick Skin Type III and rosacea previously treated with Fraxel in 2008. Subject underwent three recommended treatments with the IPL handpiece for 30, 10 and 20 minutes each session, with treatment fluence of 16-20 J/cm² and 5degrees cooling. In the laser sessions, subject discomfort ratings remained at a score of 1 (mild) to moderate (2) with vascular blanching noted. At study end, investigator and patient rated Moderate Improvement (51-75%) in the rosacea.

Wrinkles

Subject #5 {KMB}: 59-year-old, Caucasian, female with Fitzpatrick Skin Type II with moderate wrinkles and photoaging and underwent a single (1) treatment with the 2940nm Er:YAG handpiece of the Apollo V+ System for approximately 60 minutes using energy of 1600mj, pulse width of 3ms, and spot size of 9mm, for the face. In the laser sessions, subject discomfort ratings remained at a score of 2 (moderate) or less. Subject experienced moderate erythema and redness after the treatment which lasted approximately one week. Both investigator and subject assessments revealed Excellent Improvement (76-100%) in the appearance of wrinkles and photo aging from Baseline.

Hair Reduction

Subject #6 {MUL}: 26-year-old, Asian, female with Fitzpatrick Skin Type IV with unwanted hair under armpits underwent four (4) treatments with the 1064nm Long Pulse Nd:YAG handpiece of the Apollo V+ for 10-15 minutes each session, at 7-18J, pulse width of 10ms, and 8mm spot. In the laser sessions, subject discomfort ratings remained at a score of 1 (mild) or less. Subject experienced mild erythema and perifollicular edema. Both investigator and subject assessments taken after the fourth treatment revealed Excellent Improvement (76-100%). No adverse events were reported.

Subject #7 {RC}: 28-year-old, Hispanic, female with Fitzpatrick Skin Type IV with unwanted hair under armpits underwent four (4) treatments with the IPL handpiece of the Apollo V+ System for 5-10 minutes each session, with 5 degrees cooling at 25-30J/cm². In the laser session, the subject discomfort rating remained at a score of 1 (mild). Subject experienced mild erythema and mild follicular edema after each treatment. Excellent Improvement (76-100%) was noted by both investigator and subject assessments taken after the fourth treatment). No adverse events were reported.



Tattoo Removal

Subject #1 {JAE}: 26 year-old Asian female with Fitzpatrick Skin Type IV before and after three (3) treatments with the Q-Switched Nd:YAG handpiece of the Apollo V+ System for an unwanted tattoo.



Pigmented Lesions

Subject #3 {CR}: 57-year-old, Hispanic, female with Fitzpatrick Skin Type IV before and after four (4) treatments with the IPL modality of Apollo V+ System for mottled pigmentation and solar lentigines.



Solar Lentigo

Subject #2 {EAB}: 55-year-old, Caucasian, female with Fitzpatrick Skin Type II before and after three (3) treatments with the Q-Switched Nd: YAG handpiece of the Apollo V+ System for solar lentigo on the left cheek.



Facial Telangiectasia

Same subject; Before and after three (3) recommended treatments with the IPL handpiece of the Apollo V+ System for facial telangiectasia on the cheeks



Rosacea

Subject #4 {PAL}: 45-year-old, Asian, female with Fitzpatrick Skin Type III before and after three recommended treatments with the Apollo IPL V+ handpiece.



Wrinkles

Subject #5 {KMB}: 59-year-old, Caucasian, female with Fitzpatrick Skin Type II and moderate wrinkles and photoaging before and after a single (1) treatment with the 2940nm Er: YAG handpiece of the Apollo V+ System.



Same subject; Full face



Hair Reduction

Subject #6{MUL}: 26-year-old, Asian, female with Fitzpatrick Skin Type IV before and after four (4) treatments with the 1320nm Long Pulse Nd: YAG handpiece of the Apollo V+ for unwanted armpit hair



Hair Reduction

Subject #7{RC}: 57-year-old, Hispanic, female with Fitzpatrick Skin Type IV before and after four (4) treatments with the IPL handpiece of the Apollo V+ System for unwanted armpit hair.

References

- 1 Orenstein MD, A. and Lepselter PhD., J. Modular Light-Based System with Advanced Fluorescence Technology (AFTTM) for the Treatment of Cosmetic and Aesthetic Skin Irregularities. [WWW page] www.orionlasers.com. 2004.
- 2 American Society for Dermatologic Surgery. [Feb 2014]. ASDS survey: Skin cancer, cosmetic procedures jump 22 percent in 2013 [WWW page] <http://www.prnewswire.com/news-releases/asds-survey-skincancer-cosmetic-procedures-jump-22-percent-in-2013-244666121.html>
- 3 Hassan KM, Benedetto AV. Facial skin rejuvenation: ablative laser resurfacing, chemical peels, or photodynamic therapy? Facts and controversies. Clin Dermatol. 2013 Nov-Dec;31(6):737-40. doi: 10.1016/j.clindermatol.2013.05.011.
- 4 Orenstein MD, A. and Lepselter PhD., J. Modular Laser and Pulsed-Light System for Treatment of Cutaneous Abnormalities. [WWW page] www.almalasers.com. 2004.
- 5 Zamir, B MD. Lumenis One-An Expandable Technology Platform for Comprehensive Aesthetic Treatments http://www.aesthetic.lumenis.com/pdf/L1_White_Paper.pdf. 2004.