Optimized Patient Outcomes with the Novel Modality of VI Peel® & Botox®

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Objective

This study was conducted to improve standards of care in the cosmetic treatment of sun damage, fine lines, and wrinkles. VI Peels® and Botox® have been used cosmetically as monotherapies. This study aimed to confirm that the same-day combination created no additional side-effects while also improving outcomes.

Methods

The multi-generational study enrolled 30 patients with Fitzpatrick I-VI representation. The Roberts Skin Type Classification System was used to establish baseline patient information. Patients were treated with a VI Peel, followed by Botox. Objectively, photographic matching, Wrinkle Severity Scale, Uniformity of Pigment Scale, and Skin Tone Scales were used to evaluate skin improvement. Patient questionnaires were issued to assess satisfaction.

Results

Safety of the same-day combination was established with no adverse events reported. Improvements on the Wrinkle Severity Scale showed an average rating dropping from 1.46 to 0.59 representing a 60% improvement. Improvements on the Uniformity of Pigment Scale showed an average rating dropping from 2.27 to 0.92 representing a 59% improvement. Improvements on the Skin Tone Scale showed an average rating dropping from 2.35 to 0.71 representing a 70% improvement. Questionnaires correlated with objective findings with high satisfaction.

Conclusion

This study confirmed the safety of the same day combination. Efficacy of VI Peel & Botox same-day treatment was clinically proven by the improvements to Wrinkle Severity, Uniformity of Pigment, and Skin Tone via photographic matching. While perception studies indicated strong patient satisfaction with the combination.

Introduction

The medical aesthetics industry is a high-growth industry slated to reach 18 billion by 2027. This growth is primarily driven by minimally invasive and non-invasive cosmetic procedures according to All the Research 2020 Report [1].

The top 5 most performed minimally invasive therapies reported by the American Society of Plastic Surgeons includes Botulinum Toxin Type A, Soft Tissue Fillers, Chemical Peels, Laser Skin Resurfacing, and Intense Pulsed Light treatments comprising over 13 million patient visits in 2020 [2]. The diversity in the market continues to also evolve with not only a greater percentage of men receiving cosmetic treatments but also growth in familial aesthetics with grandparents, parents, and their adult children seeking both preventative and corrective care. As the aesthetic market continues to grow, advancements in optimal care have also evolved.

This study was conducted to improve standards of care in the cosmetic treatment of sun damage, fine lines, and wrinkles. VI Peels and Botox have been used cosmetically to improve patient concerns as monotherapies. This study aimed to confirm that the same-day treatment combination creates no additional side effects, and that patient results and satisfaction are heightened as a result.

Collagen degradation and wrinkling of the skin are caused by multiple intrinsic and extrinsic factors. Addressing wrinkling in the skin is often accomplished by reducing muscle contractions with the aid of neurotoxins as well as the use of chemical peels to improve skin elasticity, stimulate collagen regeneration and textural refinements.

Trials on chemical peels and botulinum toxin are vast, but research on the combination of the two therapies is minimal. One study published in 2006 by Marina Landau, MD, addressed the combination with the inclusion of both staggered and same day treatments [3]. The findings indicated safety of same day applications if only superficial and medium depth chemical peels were used in treatment.

Objective

This study utilizes mechanisms of action of both products to simultaneously address fine lines and wrinkles. VI Peels contain a synergistic blend of acids that produce keratolytic and keratocoagulant qualities focused on desquamation and cellular renewal. The VI Peel blend contains Phenol, Trichloroacetic Acid, Salicylic Acid, Retinoic Acid, and Ascorbic Acid. Botox containing Botulinum toxin type A is a purified substance, derived from a bacterium that blocks muscular nerve signals temporarily preventing muscular contraction and subsequent wrinkle formation.

The expected benefit of this investigational combination includes improvements to Standards of Care in relation to the treatment of the cosmetic patient by establishing safety of the combination treatment, improving patient outcomes by simultaneously addressing photodamage, fine lines, and wrinkles through dual mechanisms and an overall improvement to patient satisfaction.

Methods

Botox and VI Peel have been used successfully since 1989 and 2005 respectively with millions of visits annually for these treatments. Studying these therapies as a same-day treatment required defining the study population, delineating the treatment protocol, and producing clear outcome measurements.

Schedule of Events

The Schedule of Events listed in **Table 1** below identifies the interaction points and identified data collection, intervention, and timeline of events. With uncertainty due to COVID, the researchers compressed informed consenting and Day 1 visits into one visit. Subsequent visits allowed for +/- 3 day variance to allow for scheduling needs.

Table 1

Schedule of Events	Days From Baseline or Baseline Day 1	Baseline Day 1 Treatment	Day 7 +/- 3 Days Follow up	Day 30 +/- 3 Days End of Study
Informed Consent	X			
Inclusion / Exclusion Criteria		X		
Demographics		X		
Vital Signs		X		
Medication Review		X		
Facial Photos		X	X	X
Treatment VI Peel		X		
Treatment BoTox		X		
Collect AEs		X	X	X
Questionnaire		X	X	X

Study Population

The study enrolled 30 healthy subjects ranging in age from 30-70 years old. Four subjects were screen failed based on exclusion criteria. Of the 26 enrolled subjects 24 completed the study in its entirety and two were lost to follow up. Enrolled subjects encompassed both men and women of varying race, ethnicity, and skin concern. While enrolled subjects were required to avoid soft tissue filler, medium to deep chemical peel, ablative laser, radio frequency treatment, ultrasound device treatment, non-ablative laser treatment. The study duration upon completion of enrollment was 30 days.

Interventions

Visit 1 included a thorough investigator assessment via Case Report Form and included The Roberts Skin Type Classification System, Wrinkle Severity Scale, Uniformity of Pigment Scale and Skin Tone Scale.

Subjects then completed a questionnaire via Survey Monkey. Baseline photographs taken forward facing, 45 degrees (Left and Right) and 90 degrees (Left and Right). The subject's face was cleansed and degreased with acetone. The VI Peel was applied according to protocol with an average of 5-6 layers applied with 1-minute intervals. Botox was then immediately administered according to label protocol. Subjects were monitored for 15 minutes after treatment to assure safety including allergic reactions. Subjects were given a take-home post peel kit along with verbal and written aftercare instructions.

Visit 2 (7 days) included an investigator reassessment of skin and skin response, completed Case Report Form and completed 2nd set of photographs as stated above. Subject Perception Survey completed via Survey Monkey.

Visit 3 (30 days) followed the same flow as Visit 2.

Upon conclusion of the study, subjects were given cleansing maintenance kit of 4 VI Derm topical skin care products.

Data

Data was analyzed based on subject demographics, investigator assessments, photographic matching, and subject questionnaires. Clinical data points in the results section will measure the rate and occurrence of side effects and/or adverse events as well as improvements to skin conditions. Antimicrobial ingredients in the VI Peel proved to be a proper antibacterial cleanse prior to botulinum toxin injection eliminating the need for additional alcohol, Puracyn, or Hibiclense.

Investigator baseline assessment was determined via The Roberts Skin Type Classification System. The four elements of the classification system include Fitzpatrick Skin Type (measures phototype), Roberts Hyperpigmentation Scale (propensity for pigmentation), Glogau Scale (defines photodamage), and Roberts Scarring Scale (describes scar morphology) [4]. The four-part scale established baseline information on the study population as well as contributed to the demographic allocation of subjects.

Photographic Matching by Investigator includes Data points from Visits 1, 2, and 3 for Facial Wrinkle Severity Scale, Uniformity of Pigment Scale, and Skin Tone Scale. Photographs were taken with every visit encounter and included forward-facing, 45 degree left, 90 degree left, 45 degree right, and 90 degree right.

Wrinkle Severity Scale: Grade 0= No Wrinkles, Grade 1 = Mild Wrinkles, Grade 2 = Moderate Wrinkles Grade 3 = Severe Wrinkles.

Uniformity of Pigment: Grade 0 = Uniform, Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Moderate to Severe, Grade 4 = Severely Ununiform.

Skin Tone: Grade 0 = Clear and Radiant, Grade 1 = Mild Irregularities, Grade 2 = Moderate Irregularities, Grade 3 = Moderate to Severe Irregularities, Grade 4 = Severe Irregularities.

Subject Questionnaires were issued via Survey Monkey and included data points from Visits 1, 2, and 3. Surveys included personal ratings of skin health as well as general satisfaction levels with the intervention. Subjects were provided QR codes to complete surveys at the start of each encounter. If the subject was unable to utilize the QR code, a paper form of the survey was provided.

Results

Safety of the same-day combination of VI Peel & Botox was established. There were no reports of adverse events or significant adverse events. Side effects reported were in-line with the rate of occurrence of each intervention as a stand-alone treatment. The most commonly reported side effect noted with the same-day combination was dryness in the perioral area from the VI Peel and bruising on the lateral canthal lines from the injection of Botox. Dryness after chemical peels is a common side effect that self-resolves [5]. Bruising after injection from Botox is the most commonly reported side effect that self resolves [6]. All reported side-effects self-resolved within the 30-Day study duration.

Improvement to the following scales was established via use of investigator subject assessment and photographic matching. Both assessments were completed after establishing the subject baseline status on Day 7 and Day 30. **Table 2**

Table 2

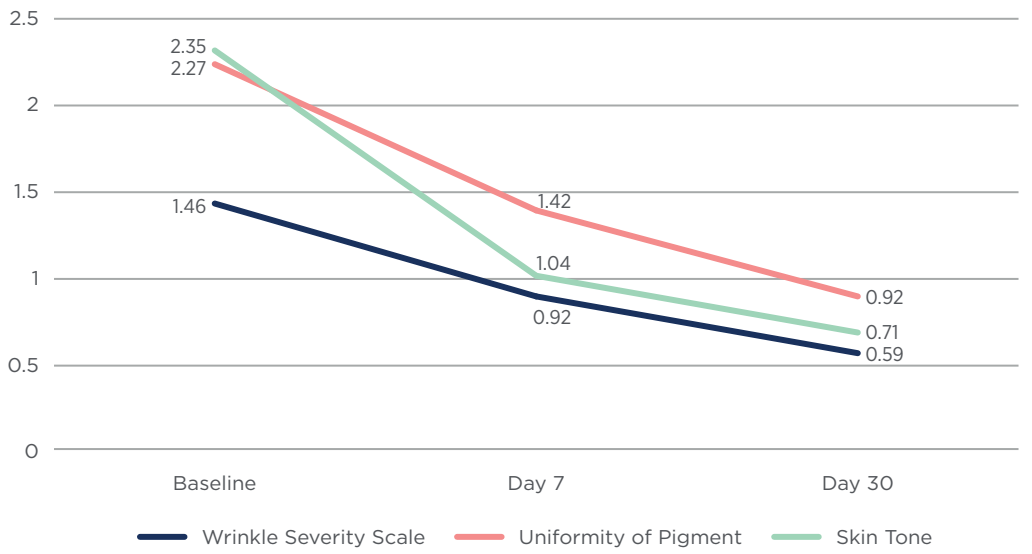


Image 1: 68-Year-Old Female Before (a), After 7 Days (b), and after 30 Days (c)

Image 1a

Image 1b

Image 1c

Image 2: 53-Year-Old Female Before (a), After 7 Days (b), and after 30 Days (c)

Image 2a

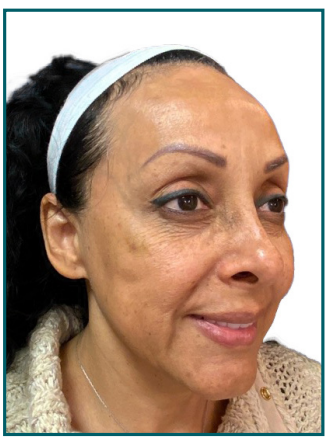


Image 2b

Image 2c

Image 3: 46-Year-Old Female Before (a), After 7 Days (b), and after 30 Days (c)

Image 3a

Image 3b

Image 3c

Image 4: 38-Year-Old Female Before (a), After 7 Days (b), and after 30 Days (c)

Image 4a

Image 4b

Image 4c

Wrinkle Severity

On average, the subject baseline was 1.46 on the Wrinkle Severity Scale indicating Mild to Moderate wrinkles. On Day 7, the average rating dropped to 0.92 indicating a 37% improvement and overall Mild Wrinkles. On Day 30, the average rating continued declining to 0.59 indicating an additional improvement of 36% and overall grading of No Wrinkles. Overall scale improvement averages showed improvement at 60% and scale improvement from 1.46 to 0.59 over 30 Days.

Uniformity of Pigment

On average, the subject baseline was 2.27 on the Uniformity of Pigment Scale indicating Moderate Pigment irregularities. On Day 7, the average rating dropped to 1.42 indicating a 37% improvement and overall Mild Pigment Irregularity was noted. On Day 30, the average rating continued declining to 0.92 indicating an additional improvement of 5% and overall grading of Uniform Pigment. Overall scale improvement averages showed improvement at 59% and scale improvements from 2.27 to 0.92 over 30 Days.

Skin Tone Scale

On average, the subject baseline was 2.35 on the Skin Tone Scale indicating Moderate to Severe Irregularities. On Day 7, the average rating dropped to 1.04 indicating a 56% improvement and an overall drop to Clear and Radiant. On Day 30, the average rating continued declining to 0.71 indicating an additional improvement of 32% and maintenance at the Clear and Radiant grade. Overall scale improvement averages showed improvement at 70% and scale improvements from 2.35 to 0.71 over 30 Days.

Subjective Data Population Analysis

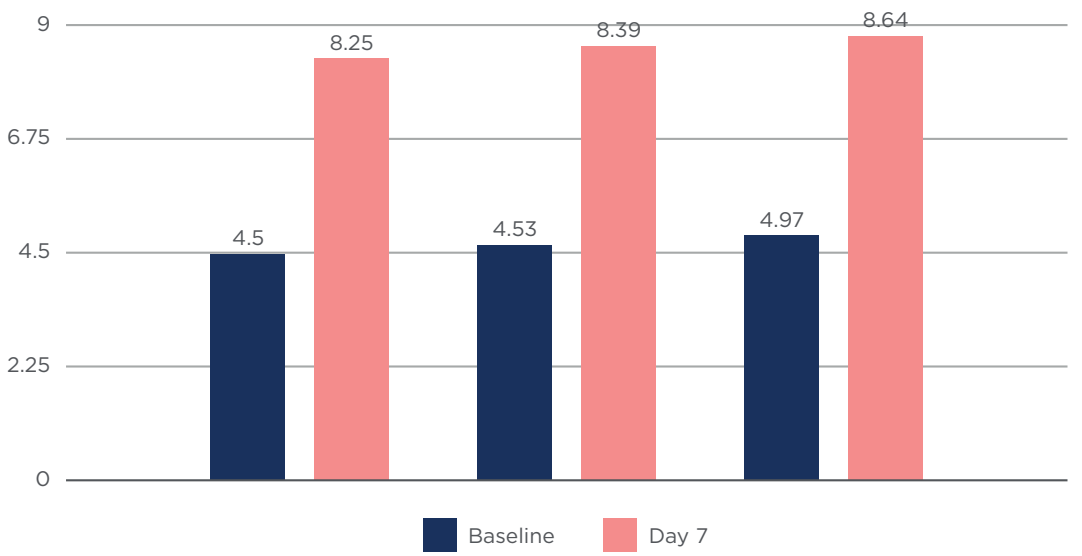
The study participants represented not only a 4-Decade span in age but also represented a broad range of races and ethnicities. Typically underrepresented in clinical studies, this study comprised of 69% Skin of Color and included men and women of varying ethnicities. 77% of respondents had never had a chemical peel, 58% of respondents had never had Botox before, and 100% had never had the VI Peel & Botox combination. Of the population 42% reported Dry Skin, 46% reported Combination Skin, 4% reported Normal Skin, 4% reported Oily Skin, and 4% reported Oily/Combination Skin.

Subjective Data & Perception Outcomes

Data obtained via subject surveys was analyzed both on individual survey responses and in comparison, with previous survey responses. Surveys were issued to subjects during their initial visit and on subsequent visits. Surveys focused on the subject's satisfaction with multiple aspects of their skin. A 10-point scale was used with 1 being least satisfied and 10 being most satisfied for number of sunspots, number of fine lines & wrinkles as well as smoothness of texture. **Table 3** provides results from subjects at baseline and Day 7 with consistent increases on all 3 metrics. Satisfaction rating on number of sunspots increased by 83%. Similar results were seen with satisfaction on number of wrinkles increasing by 85% and texture increasing by 74%.

Upon the final survey, 96% of respondents were likely to repeat the treatment and 100% of respondents felt their skin looked better after having the combination of VI Peel and Botox.

Table 3



Discussion

Upon conclusion of the study, several unique findings and applications of this combination emerged. The objectives of the study were met in that safety of the same-day combination was met along with significant improvements to photodamage, fine lines, and wrinkles but additional applications and findings grew with the analysis of the data.

Generational Diversity

According to ASPS, the 40-54-year-old bracket is the largest group receiving minimally-invasive procedures at 5.4 million [2]. By adding in the next younger (30-39-year-old) and the next older (55-69-year-old) age bracket, the number of minimally-invasive treatments in this group nearly doubles this total with another 5.0 million treatments. Regarding generational appeal, the study found significant improvements not only for those over fifty but also for those in their 30s and 40s. The future patients in aesthetics are the sons and daughters of the current generation. Providing a safe and effective treatment that offers generational appeal allows practitioners the ability to offer universally appropriate interventions for their growing patient base. The novel combination also reduces the "aging out" of viable cosmetic intervention offerings with a simple but impactful

Skin of Color

Remarkably, the study participants were predominantly Skin of Color with safety being of utmost concern. Patients of color carry a greater risk of hyperpigmentation from chemical peeling as well as many other aesthetic interventions. The results of the study clearly showed the safety of not only the VI Peel but also the same-day combination with Botox. This population of patients is growing within the United States and by 2050 over half of the population will be Skin of Color expanding safe treatment methodologies for this group [7]. Outside of clinical risk factors associated with this demographic, the study engaged and allowed for adequate representation of varying races and ethnicities which are often underrepresented even in direct-to-consumer communications [8-9].

Practice Efficiencies

Non-Invasive interventions comprise 53% of all cosmetic treatments provided in 2020 according to the latest report from Global Medical Aesthetics Markets [10]. As previously mentioned, botulinum toxin and chemical peels remain respectively the top first and third non-invasive treatments. The intervention of VI Peel & Botox occupied less than 30 minutes of clinician time and produced a clinically significant impact on patient outcomes. For the aesthetic patient, the combination falls under a minimal financial investment with a maximum service value. While for the practice, the combination addresses the aesthetic patient's needs with little impact on provider time thereby increasing provider access, efficiency, and a service that can now safely be delegated.

Conclusion

Achieving outcomes for the aesthetic patient interested in Anti-Aging and beautification begins with establishing safe care practices throughout aesthetics and dermatology. This study solidified the safety of the same day combination of VI Peel & Botox as there were no adverse events or significant adverse events and side effects were minimal and

consistent with incidence rates of the individual treatment as a stand-alone intervention. VI Peel prepped the skin and provided the antiseptic cleanse needed before the botulinum toxin injections. Although this study focused on Botox, the same protocol can be used with other FDA-approved botulinum toxins.

Additionally, this study engaged subjects ranging in race and ethnicity with over 69% of subjects identifying as Skin of Color and at a higher risk of developing Post-Inflammatory Hyperpigmentation of which there was no incidence.

With safety established, the outcome for the consumer is highly evidenced by the photographic matching of before and after on the Day 7 and again on Day 30. Further established clinically by the improvements in Wrinkle Severity at 60% overall improvement, Uniformity of Pigment at 59% improvement, and Skin Tone at 70% improvement. Addressing photodamage and wrinkles with the novel combination achieves outcomes for both primary and secondary conditions simultaneously. Of particular use for those in the Sunbelt states of California, Arizona, Texas, and Florida with inherent year-round sun exposure can lead to the development of photodamage and wrinkle formation.

The clinical significance of this combination will appeal multi-generationally to patients where anti-aging and skin health remain at the forefront of their buying habits. The perception studies indicated strong satisfaction with the combination with 100% of respondents agreeing that their skin looks better after the combination of VI Peel & Botox.

Introducing novel standardized treatments in the aesthetic space not only allows for safer more effective treatments but engages consumers with results that continue weeks beyond the initial intervention.

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