Acne Vulgaris: Medical and Procedural Interventions

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Presented by Michael H. Gold, MD
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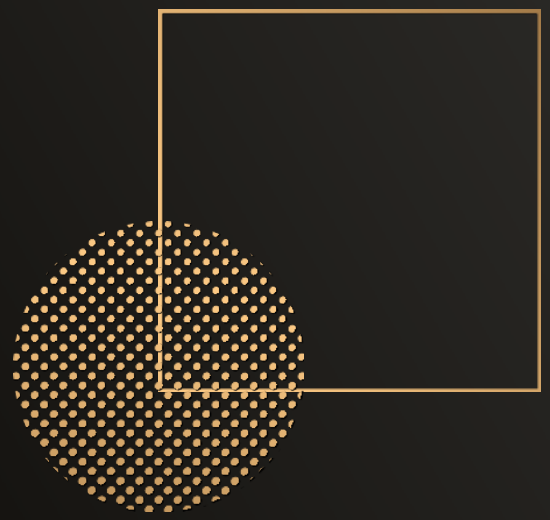
Academic Appointments



01. Assistant Clinical Professor

- Department of Medicine, Division of Dermatology, Nashville, TN USA
- Vanderbilt University School of Medicine: 2006-2014
- Vanderbilt University School of Nursing: 2006-2020

02. Adjunct Assistant Professor

- Meharry Medical College: 2013 – Present
- School of Medicine, Nashville, TN

03. Visiting Professor of Dermatology

- Huashan Hospital, Fudan University (Shanghai Medical University), Shanghai, China
- The First Hospital of China Medical University, Shenyang, China:
- Guangdong Provincial People's Hospital, Guangzhou, Zhejiang

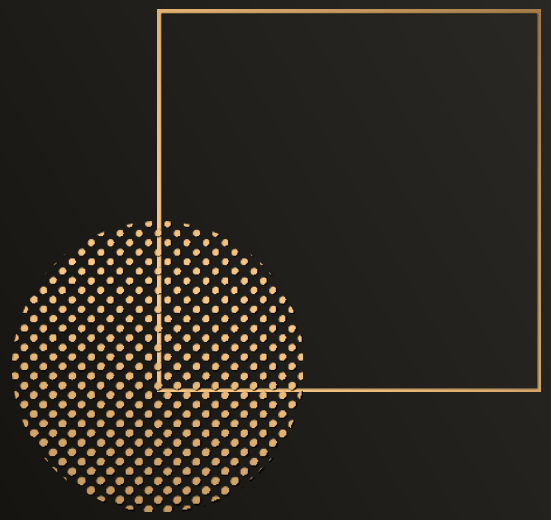
04. Visiting Professor of Plastic Surgery

- First People's Hospital of Foshan University, Guangdong, China
- The First Affiliated Hospital of Zhejiang University, Hangzhou, Zhejiang
- Rongjun Hospital, Jiaxing, China
- The People's Hospital of Hunan Province, Changsha, China

05.

- Editor-in-Chief – Journal of Cosmetic Dermatology – Wiley: 2016-Present
- Editor-in-Chief- Dermatological Reviews – Wiley: 2019 - Present

Conflict of Interest



01. Consultant to many pharmaceutical, cosmeceutical, laser and energy-based device companies

02. Consultant, performs research and speaks on behalf of numerous pharmaceutical and medical device companies

03. For the benefit of this presentation, consultant, Investigator, Speaker for almost every company in this space

Acne Vulgaris Treatments with Lasers & EBD’s in 2025

The growing demand for a different acne approach

$4.3B

US acne treatment market[1]

~50M

Americans affected by acne annually[2]

46%

Nearly half of acne patients are unsatisfied with their current treatment[3]

$13B

That acne treatment market value is estimated to grow to $13.1B by 2030[4]

1. Fortune Business Insights. **2.** American Academy of Dermatology. Skin conditions by the numbers. Available from https://www.aad.org/media/stats-numbers. Accessed Sep. 2, 2022.**3.** Hayran Y, et al. Factors affecting adherence and patient satisfaction with treatment: a cross-sectional study of 500 patients with acne vulgaris. *J Dermatol Treat.* 2021;32(1):64-69. **4.** PR

The Psychosocial Consequences of Acne

Depression[1,2]

LOW SELF-ESTEEM[1,2]

Anxiety[1,2]

SOCIAL PHOBIA[3]

Social isolation[1,2]

Negative psychosocial impact does not correlate with acne severity, and **even mild disease can impact negatively** on work, social interactions, and mood[1]

Female patients, particularly those >20 years of age, appear to be **more vulnerable** to appearance-related distress related to acne[1]

Acne imposes **significant psychological burden** on patients[1-4]

1. Layton AM et al. *Br J Dermatol.* 2021;184(2):219-225. 2.Cortes H et al. Int J Dermatol. 2022;61(7):783-791. 3. Halvorsen JA et al. *J Invest Dermatol.* 2011;131:363-370. 4. Samuels DV et al. J *Am Acad Dermatol.* 2020;83:532-541.

Patients and physicians need a more effective, predictable, and cost-effective, cost-efficient approach to addressing acne for the modern patient

Addressing The Complete Acne Patient Journey

ACTIVE ACNE

POST-ACNE ERYTHEMA SCARRING

POST-ACNE ATROPHIC SCARRING

GENERAL TEXTURAL CONCERNS

Devices for Acne
Expert Review of Dermatology 2006

Novel treatment options for severe inflammatory acne vulgaris

Michael H Gold

Acne vulgaris is one of the most common dermatological disorders encountered in everyday practice. Treatment options for this often psychologically scarring disease are numerous and, for many individuals, provide relief from the disorder. However, factors such as antibiotic resistance and, slow onset of action from many topical therapies has led researchers to seek out alternative therapies, especially for those suffering from moderate to severe inflammatory acne vulgaris.

Expert Rev. Dermatol. 1(1), 13–23 (2006)

Energy- Based Devices in Treatment of Acne Vulgaris
Dermatol Surg 2016;42:573-585

REVIEW ARTICLE

Energy-Based Devices in Treatment of Acne Vulgaris

MARC Z. HANDLER, MD,* BRADLEY S. BLOOM, MD,† AND DAVID J. GOLDBERG, MD*†‡

BACKGROUND Acne vulgaris is a chronic dermatologic complaint with a multifactorial cause. Traditionally, antibiotics and retinoids have been used to manage the condition; patient compliance has been an ongoing issue. A variety of energy-based devices have been reported to be effective in the treatment of acne vulgaris.

OBJECTIVE To review and summarize the current literature specific to treatment of acne vulgaris with energy-based devices.

METHODS A review of the current literature of energy-based devices used for the treatment of acne vulgaris.

RESULTS AND CONCLUSIONS Although limited randomized controlled trials for the treatment of acne have been performed, significant clinical improvement of acne vulgaris, especially of inflammatory lesions, has been demonstrated with a variety of energy-based devices. Newer approaches may lead to even better results.

The authors have indicated no significant interest with commercial supporters.

Acne Vulgaris

- Laser/Light technology
  - Lasers/light sources to reduce the *P. acnes* population
    - Blue Light Sources - Blu-U
    - Red Light Sources – RhodoLED XL Lamp
    - Intense Pulsed Light Devices– Quantum/Vasculight/Lumenis One/M22/Stellar M22, Ellipse, BBL/Joule, Harmony XL, Lumecca and others
    - Vascular Lasers –Cynergy, V-Beam Perfecta, AdvaTX
    - Short-Pulsed 650 usec 1064 nm – Aerolase Neo

Acne Vulgaris

- Phototherapy and PDT with blue light is beneficial in the treatment of acne vulgaris
  - Process works through the photo-excitation of the *C. acnes*’ porphyrins after exposure of appropriate wavelength of light
    - Leads to the formation of singlet oxygen within the bacteria
  - Ultimate destruction of the P. acnes bacteria
  - Acne lesion will resolve leaving alone surrounding tissue and structures

Studies With Low-Level LED and Laser Light in Acne Vulgaris
Dermatol Surg 2016;42:573-585

TABLE 4. Studies With Low-Level LED and Laser Light in Acne Vulgaris

Author of Trial	*Type of Study*	*Device*	*Number of Patients in Study*	*Duration or No. Treatment*	*% Reduction in Inf or NI*
Liu and colleagues[13]	OL	Blue-red LED	50	9 ± 3.34 treatments	>90 in 44% of subjects
Kwon and colleagues[31]	DBRCT	Blue-red LED	35	2.5 minute bid for 4 weeks	77 (Inf); 54 (NI)
Goldberg and Russell[29]	OL	Blue-red LED + microdermabrasion	24	2 treatments per week for a total of 8 sessions	81 (Inf)
Lee and colleagues[32]	OL	Blue-red LED	24	2 per week for 4 weeks	77.8 (Inf); 34.3 (NI)
Gold and colleagues[33]	SBRCT	Blue LED	30	Twice daily for 2 days	77 (Inf)
Akaraphanth and colleagues[34]	OL	Blue LED	20	Once per week for 4 weeks	56.7 (Inf)
Wheeland and Koreck[35]	OL	Blue LED	31	Twice daily for 8 weeks	60 (Inf)
Gold and colleagues[36]	OL	Blue-violet LED	17	Twice per week for 4 weeks	36.4% complete clearance
Na and Suh[37]	SBRCT split face	Red LED	28	Twice daily for 8 weeks	66 (Inf); 59 (NI)
Aziz-Jalali and colleagues[38]	SBRCT split face	Red LLLT+ 2% topical clindamycin	28	Twice per week for 12 sessions	26 (Inf)

DBRCT, double-blinded randomized controlled trial; Inf, inflammatory lesions; NI, noninflammatory lesions; OL, open label; SBRCT, single-blinded randomized controlled trial.

Acne Vulgaris

- Previous studies with blue light
  - Gold 2003 AAD poster presentation
    - 43% improvement in inflammatory acne lesions with ClearLight PhotoClear ing device for mild to moderate acne vulgaris
    - 40 patients evaluated with 2x/week therapy for 4 weeks
    - *All patients included in the results – responders and non-responders*

Acne Vulgaris

- Blu-U device FDA cleared for inflammatory acne
  - Used originally for ALA-PDT therapy
  - Works for mild to moderate inflammatory acne vulgaris as well
  - 2004 AAD Poster Presentation; J Drugs Dermatol 2004– Gold, Goldman, Rao
    - Blu-U more effective in inflammatory acne lesions than 1% clindamycin solution
    - Safety and efficacy proved

Blue Light/Acne
Gold/Goldman

A MULTICENTER CLINICAL EVALUATION OF THE TREATMENT OF MILD TO MODERATE INFLAMMATORY ACNE VULGARIS OF THE FACE WITH VISIBLE BLUE LIGHT IN COMPARISON TO TOPICAL 1% CLINDAMYCIN ANTIBIOTIC SOLUTION

Michael H. Gold MD,[a] Jaggi Rao MD,[d] Mitchel P. Goldman MD,[b] Tancy M. Bridges NP,[c] Virginia L. Bradshaw NP,[c] Molly M. Boring NP,[c] April N. Guidet RN[c]

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d. Dermatology/Cosmetic Laser Associates of LaJolla and LaJolla Spa MD, La Jolla, CA

Abstract

Background: Blue light sources have been shown to be effective in the treatment of mild to moderate inflammatory acne vulgaris lesions.

Objective: We evaluated the safety and efficacy of a new blue light source in the treatment of mild to moderate inflammatory acne vulgaris in comparison to topical 1% clindamycin solution.

Results: Blue light therapy reduced inflammatory acne vulgaris lesions by an average of 34%, as compared to 14% for topical 1% clindamycin solution.

Conclusions: The blue light source presented in this report is a safe and effective rreatment option available to our patients wirh mild to moderate inflammatory acne lesions.

- IPL Technology

Acne Vulgaris

- Laser/Light technology
  - Intense Pulsed Light (IPL) technology for acne-many systems exist
    - Quantum, VascuLight, Lumenis One, M22, Stellar M22
    - Other systems – Harmony, BBL, Isolaz, Elos Plus, Lumecca
    - ClearTouch, SkinStation
      - Ross V (2002 ASLMS) – 50% inflammatory acne lesion improvement
      - Elman M, Lebzelter J. Light therapy in the treatment of acne vulgaris. Dermatol Surg 2004 ; 30: 130-146.
        - 85% > 50% improvement; 15-20% non-responders

Studies With IPL in Acne Vulgaris
Dermatol Surg 2016;42:573-585

TABLE 3. Studies With IPL in Acne Vulgaris

Author of Trial	*Type of Study*	*Device*	*Number of Patients in Study*	*Duration of Treatment*	*% Reduction in Lesions, Inf or NI*
Liu and colleagues[13]	OL	IPL	50	6 ± 2.15 treatments	>90 (Inf)
Shamban and colleagues[4]	Retrospective	IPL + pneumatic	56	4 treatments	90 (Inf)
Berger (unpublished)	OL	IPL + pneumatic	15	1 treatment every other week × 2 sessions	75 (Inf)
Gold and Biron[14]	OL	IPL + pneumatic	11	4 treatments	78.8 (Inf)
Wanitphakdeedecha and colleagues[15]	OL	IPL + pneumatic	18	4 treatments	65 (Inf)
Elman and Lask[16]	OL	IPL	19	8 treatments	85 (Inf); 87 (NI)
Yeung and colleagues[17]	OL	IPL	30	4 treatments per week at 3-week intervals for 12 weeks	22 (Inf); 44 (NI)
Baugh and Kucaba[18]	OL	IPL	25	2 treatments per week for 2 weeks	20 (Inf)
Sadick[19]	OL	IPL	8	3 treatments spread over 12 weeks	32 (Inf)
Myers and colleagues[12]	OL	IPL	7	1 treatment every 3 weeks	70 (Inf)

Inf, inflammatory lesions; NI, noninflammatory lesions; OL, open label.

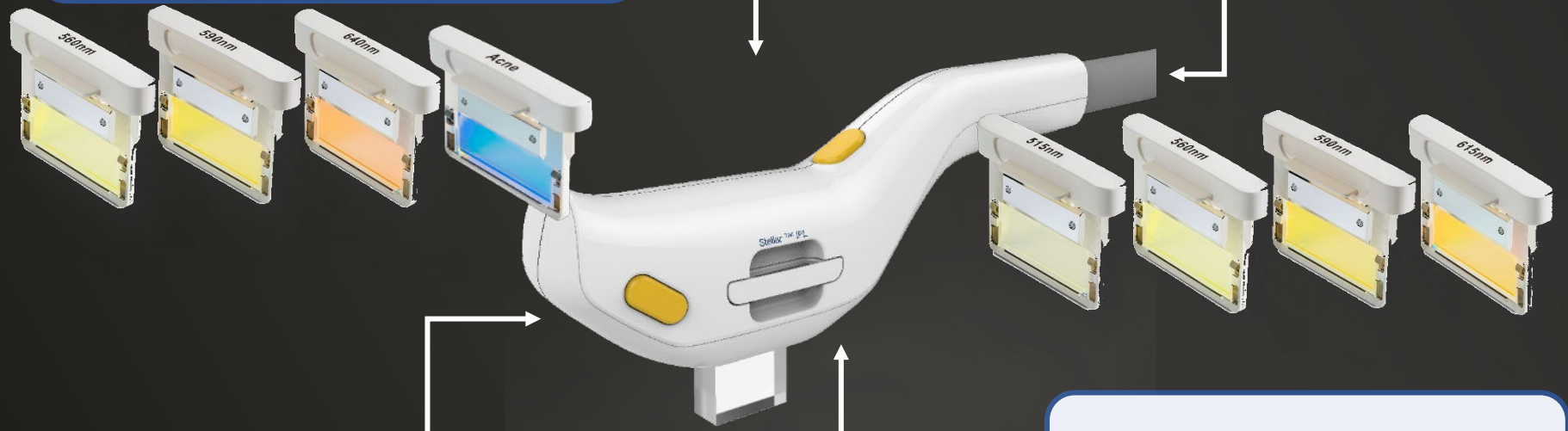
4 Different Treatment Groups

ST – Skin Treatments

- Aesthetic and cosmetic applications requiring selective photothermolysis
- Mild to moderate inflammatory Acne

PL – Pigmented Lesions

Benign epidermal lesions



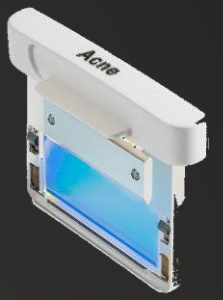
HR – Hair Removal

Permanent hair reduction

VL – Vascular Lesion

Benign cutaneous vascular lesions

Dedicated ACNE notch filter*



Propionibacterium acnes produce endogenous porphyrins as part of their normal metabolism

The notch filter 400-600 & 800-1200nm is ideal for inflammatory acne:

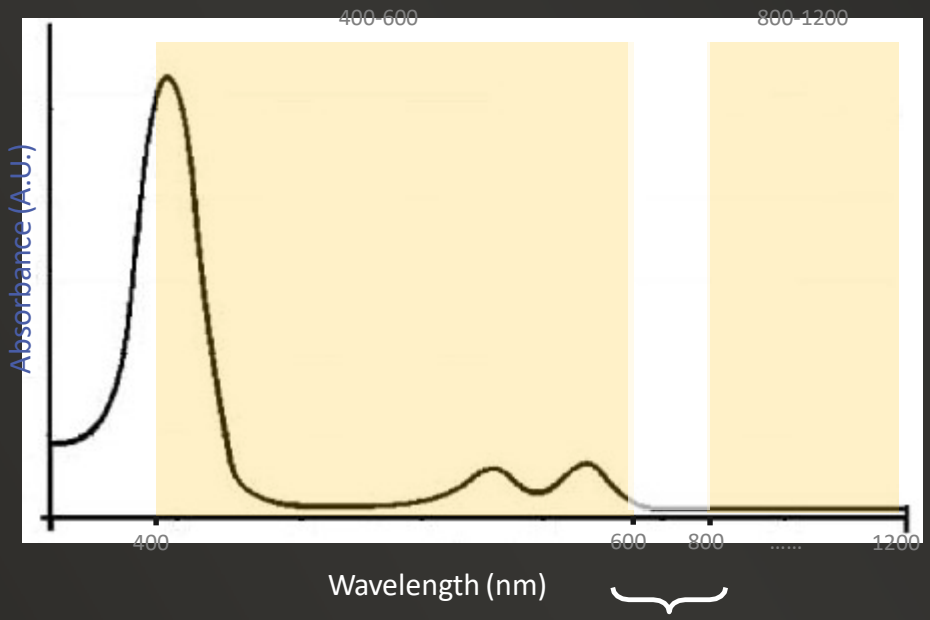
When exposed at 400-600nm (with a peak at the Soret band around 400-420nm)

- Porphyrins are excited to release Singlet Oxygen which eradicate P. Acnes
- Superficial inflammation is reduced

When exposed at 800-1200nm

- Light penetrates deeper to reach the sebaceous glands
- The “shrinkage” of the sebaceous glands reduces the anaerobic environment necessary for the bacteria to proliferate

Porphyrin absorption spectrum
(not drawn to scale)

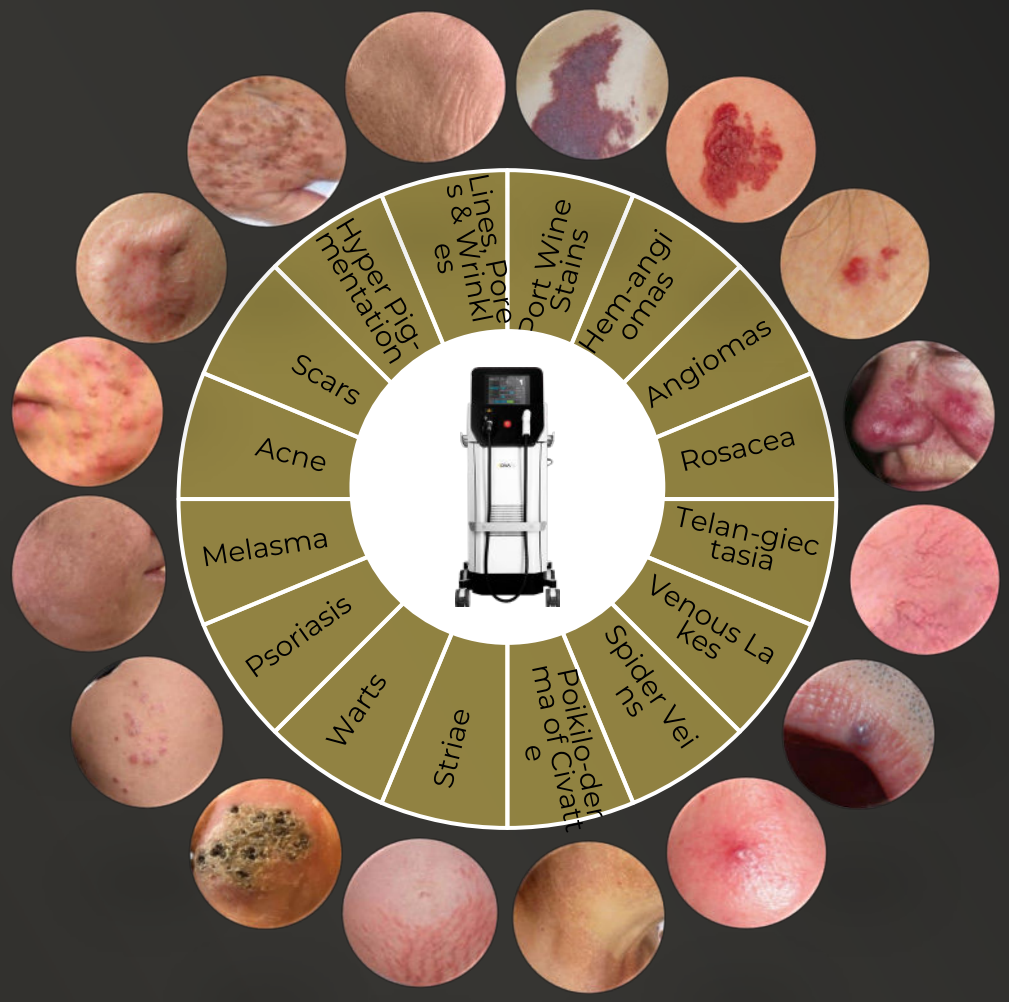


**** Optional***

- Vascular Lasers

589/1319 nm – a Foundational Technology in Dermatology & Aesthetics

- The laser system was launched commercially in 2018
- It is CE/FDA approved as medical equipment suited for the treatment of 25 different skin conditions
- Its unique, patented laser technology makes it highly versatile, clinically efficacious, and very safe to use



589/1319 nm

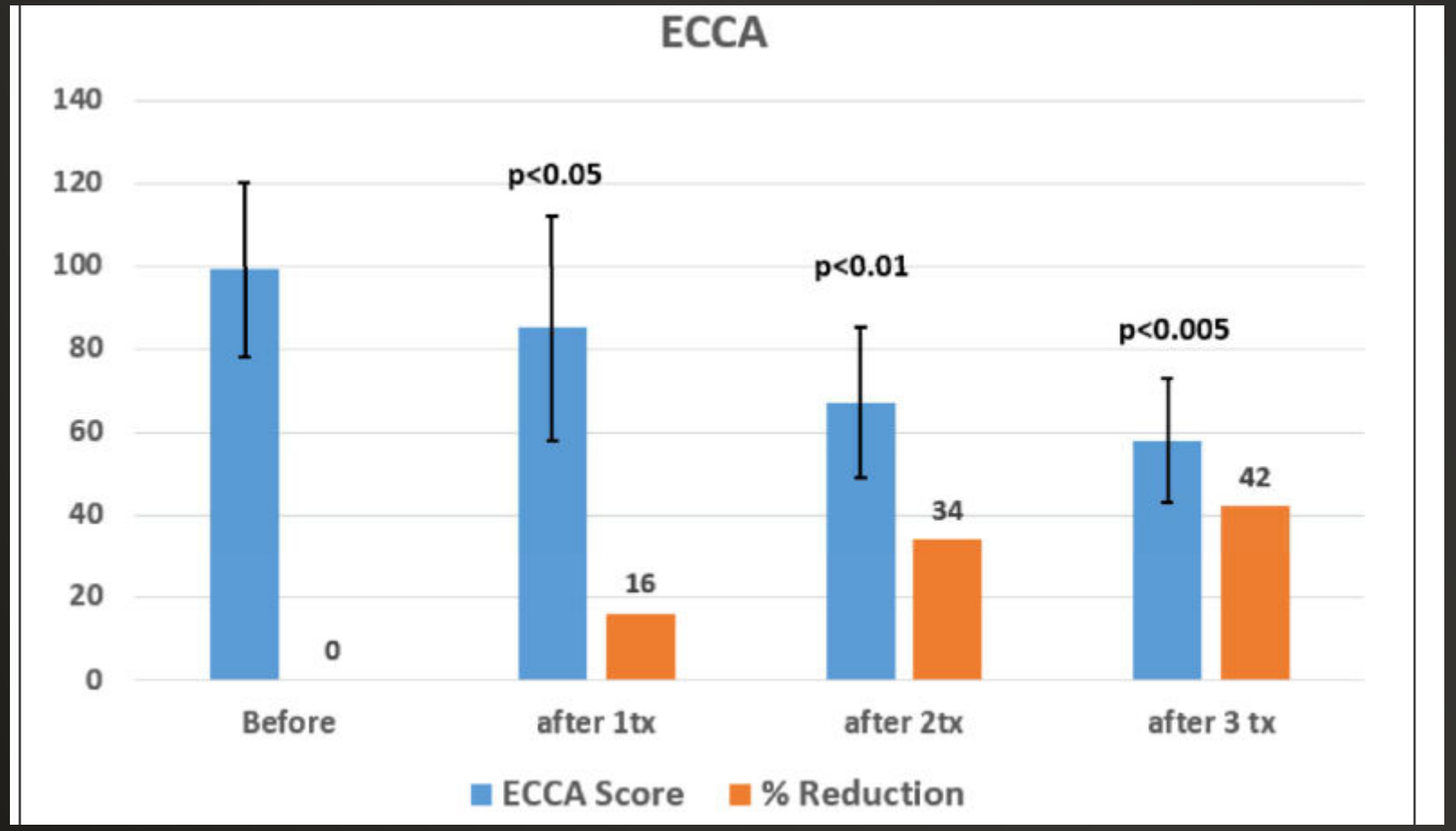
- Solid-state 589/1319nm
  - ND Yag Diode Crystals
    - No Consumables

- Scanner Hand piece
  - Single spot or fractional
  - 1mm spot size
  - Multi-pattern up to 10x10mm
  - Both wavelengths delivered with the same hand piece

Background and Objectives for TCRC Study

- Facial acne scarring is a prevalent disease
  - Physical and psychosocial sequelae
- Innovative solid state, dual-wavelength laser investigated
  - 589/1319 nm
  - No consumables
  - No dye kits

ECCA Scale


ECCA
140
120
100
80
60
40
20
0
p<0.05
p<0.01
p<0.005
0
16
34
42
Before
after 1tx
after 2tx
after 3 tx
ECCA Score
% Reduction

Treatment of Acne Scaring with a Novel Dual-Wavelength Laser
J Cosmetic Dermatol. 2019;18:1290-1293

ORIGINAL CONTRIBUTION

JCD Journal of Cosmetic Dermatology | WILEY

Treatment of acne scarring with a novel dual-wavelength laser

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Funding information
Advalight, San Diego, CA, USA

Abstract

Background: Facial acne scarring is a prevalent disease with both physical and psychosocial sequelae.

Aims: This study aims to evaluate an innovative solid state dual wavelength 1,319 and 589 nm laser, which does not require consumable dye, for the treatment of acne scars.

Patients/methods: A total of 12 patients (11 female, 1 man - Fitzpatrick skin phototypes II & III) with acne scar for more than one year, were treated with 1,319 nm and subsequently by 589 nm, all having four-sessions, one every other week. A full face was covered in approximately 30 minutes. Acne scars were scored by one physician evaluator using the ECCA grading scale before, 2 weeks after each treatment and 1 month and 6 months after the 4th treatment. Safety was measured by recording subject discomfort scores and adverse effects.

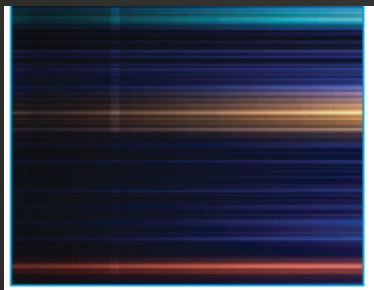
Results: 12 subjects were enrolled into the study, 10 completed all 4 treatments and 2 were lost to follow up. Fluence used was 28 J/cm² ± 2.4 J/cm² at 1,319 nm and 16 ± 2.9 J/cm² at 589 nm. At baseline, mean ECCA score was 98 ± 23. This score was reduced to 88 ± 30 ($p<0.02$), after one session, to 68 ± 21 ($p<0.01$) after 2 sessions, to 58 ± 17 ($p<0.01$) after 3 sessions to reach 58 ± 15 ($p<0.01$) 1 month after the 4th and finally 66 ± 11 ($p<0.01$) at 6 month follow up. This observation corresponds respectively to 14%, 33 %, 42 %, 40% and 30% reduction of the ECCA score. Only one patient (ECCA score: 120) did not improve after 3 sessions. Slight to moderate erythema was sometimes observed without dryness or bruising. No or minimal burning or stinging was reported. No crust was observed.

Conclusion: Improvement in scarring was noted in almost all patients with minimal discomfort and minimal downtime. Combining both minimal side effects with effective acne scar reduction, this laser appears to be highly effective. Long-term evaluation remains necessary to confirm the efficacy of this new laser.

KEYWORDS
acne, ECCA, near-infrared laser, scarring, yellow laser

Treatment of Moderate-to-Severe Facial Acne Vulgaris with Solid-State Fractional 589-1,319-nm Laser

J Clin Aesthet Dermatol. 2019;12(3):28–31



Treatment of Moderate-to-severe Facial Acne Vulgaris with Solid-state Fractional 589/1,319-nm Laser

by ALISON KANG, MD; ALEXIS LYONS, MD; JENNIFER HERRMANN, MD; and RONALD MOY, MD

Drs. Kang and Herrmann are with the Division of Dermatology, Harbor-UCLA Medical Center in Torrance, California. Drs. Lyons, Herrmann, and Moy are with Moy-Fincher-Chipps Facial Plastics and Dermatology in Beverly Hills, California. Dr. Moy is with the Department of Dermatology, Keck School of Medicine at the University of Southern California in Los Angeles, California.

J Clin Aesthet Dermatol. 2019;12(3):28–31

ABSTRACT

Objective: The objectives of this study were to evaluate the efficacy, safety and patient satisfaction of a unique combination of wavelengths 589nm and 1,319nm for the treatment of facial acne vulgaris. **Design:** This was a small, randomized, prospective, split-face, single-blinded study of patients with moderate-to-severe acne vulgaris. **Setting:** The study took place at a single outpatient center study in Torrance, California. **Participants:** Nine patients underwent four treatment sessions at 2- to 3-week intervals. Each patient received one pass with the 1,319nm laser followed by one pass with the 589nm laser only to the randomized treatment side of the face. **Measurements:** A blinded, board-certified dermatologist reviewed photographs and counted acne lesions on treated and nontreated sides. **Results:** Of the nine patients, eight were Fitzpatrick Skin Type IV. At the final visit, inflammatory acne lesions were reduced by 2.5 (-23.1%) on the treatment side and increased by 1.1 (+11.1%) on the control side. No patients experienced bruising, edema, hyperpigmentation or scarring. At the conclusion of the study, 77.8 percent of the patients reported overall satisfaction. **Conclusion:** This unique combination of lasers appears to be safe in patients with Fitzpatrick Skin Type IV, and might be useful in treating moderate-to-severe acne vulgaris.

KEYWORDS: Acne, acne vulgaris, active acne, acne scarring, laser

Acne vulgaris is the most common skin condition in the United States, affecting up to 50 million Americans each year.[1] Although most prevalent during the teenage years, acne often persists into adulthood and is more common in women than men.[2] Acne affects all skin colors and can cause negative self-image, lower self-esteem, and feelings of isolation, anxiety, and depression.[3] Scarring is a common complication of acne and has been reported in up to 95 percent of patients with acne.[4]

Standard medical treatments for acne include topical medications such as benzoyl peroxide, antibiotics, retinoids, and salicylic acid, as well as oral medications such as antibiotics, contraceptive pills, spironolactone, and isotretinoin.[5–7] Treatments are individualized depending on acne severity, type, and etiology. Recently, there has been increasing recognition of laser- and light-based therapies for the treatment of active acne and resultant scarring.[8,9] Lasers studied include the 1,540-nm erbium:glass laser, 1,550-nm fractionated erbium:glass laser, pulsed-dye

To date, few studies have investigated laser combinations, including PDL combined with either a 1,064-nm Nd:YAG or a 1,450-nm diode laser.[11–13] The device investigated in this study is a unique, solid-state laser with both 589-nm and 1,319-nm wavelengths. The 589-nm wavelength targets the superficial cutaneous microvasculature and might reduce acne-associated erythema,[14–16] while the 1,319-nm wavelength is absorbed primarily by water, generating thermal energy nonspecifically, leading to dermal collagen remodelling.[21] Studies evaluating the 1,320-nm wavelength have demonstrated histologic improvement in epidermal and dermal thickening as well as acne scar improvement.[17–24] In addition, the 1,319-nm wavelength might also target the sebaceous gland directly, leading to reduced sebum production.[25]

The primary objective of this study was to evaluate the efficacy of a unique combination of the 589-nm and 1,319-nm wavelengths for the treatment of facial acne vulgaris. The secondary objectives of this study were to assess the safety

Use of a Novel 589-nm Solid-State Laser for Treatment of Facial Erythema
J Cosmet Dermatol. 2018;17:770–774.

ORIGINAL CONTRIBUTION

WILEY JCD Journal of Cosmetic Dermatology

Use of a novel 589-nm solid-state laser for treatment of facial erythema

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Correspondence: Diana K. Cohen, MD, MS, Skin Laser & Surgical Specialists of NY and NJ, Hackensack, NJ (cohen.dianak@gmail.com).

Funding information
Advalight

Summary

Objective: To evaluate the efficacy and safety associated with use of a 589-nm solid-state laser for treatment of facial erythema.

Methods: A prospective, IRB-approved study was conducted. Participants who were interested in treatment for facial erythema were recruited. They received four monthly treatments with the 589-nm laser. Erythema of the right and left face was graded on a scale of 0-4, 4 being most severe, by both investigators and participants prior to each treatment and at follow-up. Safety was assessed by any reported side effects.

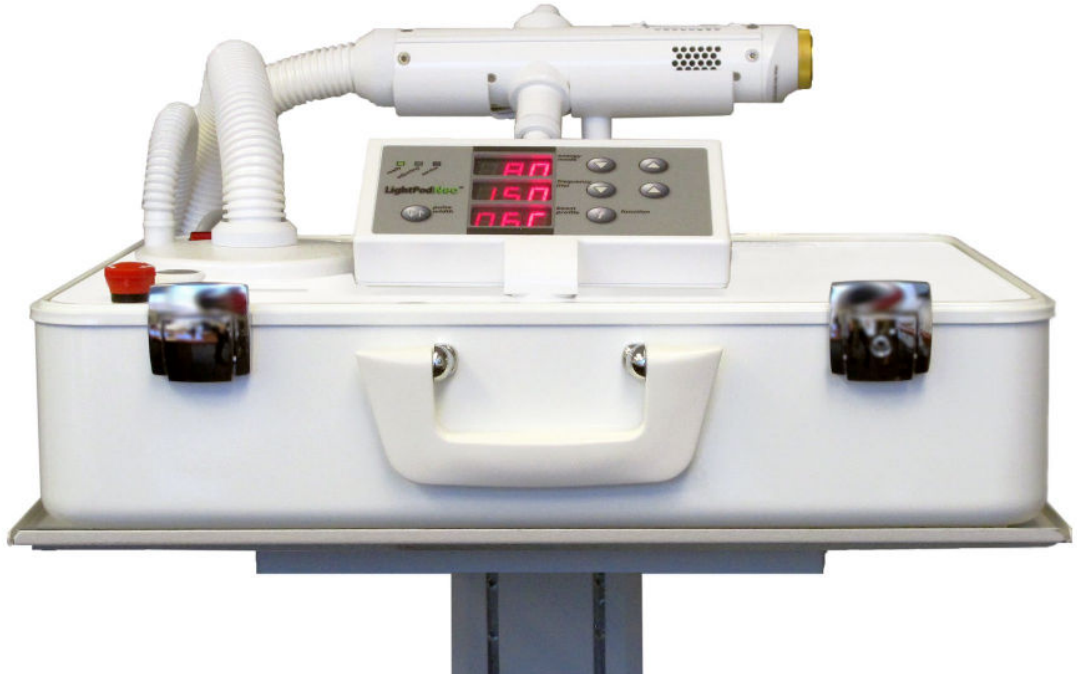
Results: Twenty-four participants enrolled in the study, 16 women (67%) and 8 men (33%), with an average age of 51.1 years. Investigator grades showed a statistically significant improvement in erythema of 31% for both the right and left face. Participant grades showed a statistically significant improvement in erythema of 23.2% for the right face and 22.8% for the left face. Side effects were limited to transient erythema posttreatment.

Conclusion: A 589-nm solid-state laser achieved a modest improvement in facial erythema when evaluating results 1 month after four monthly treatments. No major safety issues were reported.

KEYWORDS
erythema, vascular laser

- Short-Pulsed 1064 nm Laser

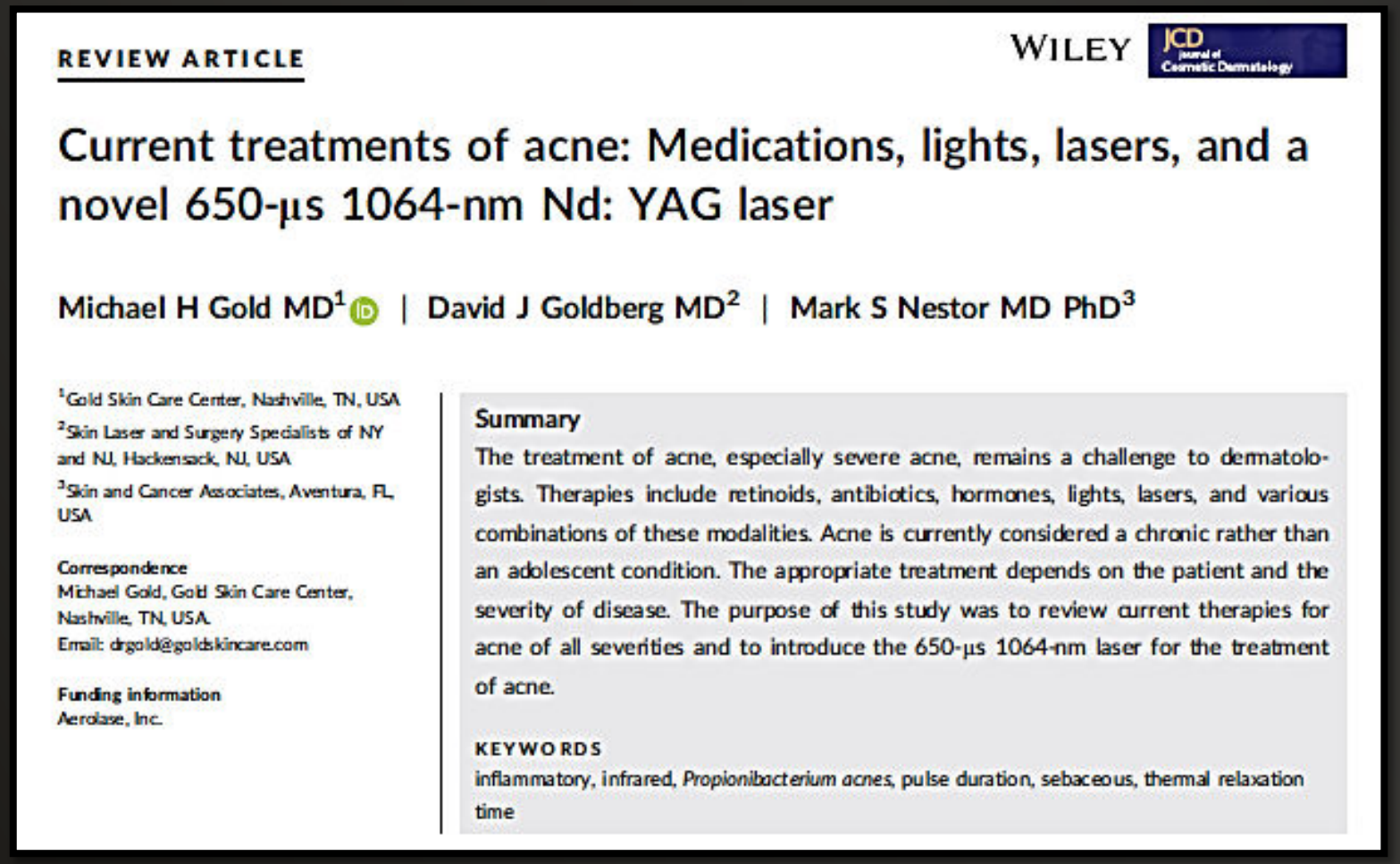
650 Microsecond Technology®



• Short-Pulsed 1064 nm Laser

- 650-microsecond technology for up to 255 J/cm2 in a single pulse duration
- More than 50 FDA cleared medical aesthetic indications
- Ability to perform anesthetic, gel & skin contact free treatment on all skin types
- Eliminates pain, burns or adverse effects of the previous generation of lasers
- No costly service contracts

Current treatments of acne: Medications, lights, lasers, and a novel 650-μs 1064-nm Nd: YAG laser
J Cosmet Dermatol 2017:1-16



REVIEW ARTICLE

WILEY JCD Journal of Cosmetic Dermatology

Current treatments of acne: Medications, lights, lasers, and a novel 650-μs 1064-nm Nd: YAG laser

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Funding information
Aerolase, Inc.

Summary

The treatment of acne, especially severe acne, remains a challenge to dermatologists. Therapies include retinoids, antibiotics, hormones, lights, lasers, and various combinations of these modalities. Acne is currently considered a chronic rather than an adolescent condition. The appropriate treatment depends on the patient and the severity of disease. The purpose of this study was to review current therapies for acne of all severities and to introduce the 650-μs 1064-nm laser for the treatment of acne.

KEYWORDS
inflammatory, infrared, *Propionibacterium acnes*, pulse duration, sebaceous, thermal relaxation time

Received: 15 April 2020 | Revised: 1 May 2020 | Accepted: 6 May 2020
DOI: 10.1111/jocd.13480

ORIGINAL CONTRIBUTION

JCD Journal of Cosmetic Dermatology WILEY

650 usec 1064nm Nd:YAG laser treatment of acne: A double-blind randomized control study

Katarina Kesty MD, MBA | David J. Goldberg MD, JD

Skin Laser and Surgery Specialists of NY & NJ, Hackensack, NJ, USA

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Funding information
Skin Laser and Surgery Specialists of NY & NJ received funding from Aerolase for this study.

Abstract

Background: A variety of energy-based devices have been used to treat acne. However, all studies have been subjective and have not involved double-blind and randomized controlled studies.

Aims: We undertook a randomized controlled study evaluating the use of a 650 usec 1064 nm Nd:YAG laser compared with a sham in the treatment of acne.

Patients/Methods: A total of 20 subjects with moderate-to-severe acne were randomized to receive either 650 usec 1064nm Nd:YAG laser or sham treatment. All subjects received 3 treatments, two weeks apart, plus an additional session undertaken 4 weeks after the 3rd treatment. Subjects were evaluated for investigator global improvement, improvement in inflammatory lesions, improvement in comedonal lesions, total porphyrin score, and total sebum score.

Results: The laser-treated group showed an Investigator's Global Assessment Scale (IGA) improvement of 26% compared with 7% for the sham group (a 271% improvement over sham treatment group). The treatment group also showed a decrease in the number of inflammatory lesions of 42% compared with 26% in the sham group (a 62% improvement over sham). The laser-treated cohort also experienced a reduction in total number of comedones similar to that seen with inflammatory lesions and a decrease in total porphyrin score. There was also an 18% reduction in sebum production in the treated group, compared with 9% in the sham group (a 100% improvement).

Conclusion: This is the first study that has compared laser treatment of acne compared with a sham treatment. A 650 usec 1064nm Nd:YAG laser can effectively treat acne.

KEYWORDS
acne, laser, Nd:YAG

1 | INTRODUCTION

Acne vulgaris is one of the most common conditions treated by dermatologists.[1] The pathogenesis of acne is multifactorial. Epidermal hyperproliferation and excess sebum production result in blockage of the pilosebaceous units. This is followed by increased proliferation and activity of commensal skin bacteria *Propionibacterium acnes*, resulting in subsequent inflammation.[2,3] Moderate acne is traditionally treated with topical cleansers, retinoids, and antibiotics. Moderate-to-severe acne may sometimes require additional treatment with systemic antibiotics or retinoids.[4] Treatments can often be irritating, unsatisfactory, and the chronic exacerbations and remissions throughout adolescence and adulthood can have a major impact on patient quality of life.[5,6] Devices and lasers are often employed as an adjunctive treatment for acne and acne scarring. Common treatments include chemical peels, nonablative radiofrequency,

A randomized, double-blind, controlled study to determine the efficacy and tolerance of a 650 microsecond YAG laser therapy in the treatment of moderate to severe acne vulgaris

David J. Goldberg, MD, JD & Katarina Kesty, MD, MBA

The first study of its kind to be completed:

- 271% improvement in acne vs. sham
- 42% reduction in inflammatory lesions
- 18% reduction in sebum production

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Treatment of Moderate to Severe Acne and Scars With a 650-Microsecond 1064-nm Laser and Isotretinoin

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ABSTRACT

Background: Laser procedures for acne and acne scars have traditionally been postponed for at least 6 to 8 months after the end of systemic isotretinoin therapy. Lower dosages with more modern laser devices having unique energy parameters of high power in microsecond pulse durations have made it possible to administer laser therapy during or shortly after completion of isotretinoin therapy, thus reducing the risk of side effects of isotretinoin.

Methods: Patients with moderate to severe facial acne (n=46) and atrophic scars enrolled in a 6-month study. Genetic analysis of patients revealed the presence of polymorphisms of genes Col1A2, MMP3, ESR1, MMP1, and MMP7, which can lead to scar formation. Patients underwent low-dosage isotretinoin therapy (0.2-0.3 mg/kg/day) in combination with facial laser treatment using a 650-microsecond, 1064-nm Nd:YAG laser. Acne severity was graded using the Investigators Global Assessment (IGA) scale and quality of life was evaluated by the Dermatology Life Quality Index (DLQI).

Results: IGA parameters decreased from 1.8 ± 0.2 (mean ± SD) initially to 0.5 ± 0.4 at the end of the study, a 72.3% reduction which was significant ($P<0.01$). The DLQI index decreased from 10.1 ± 1.3 initially to 2.8 ± 1.2, a 72.3%, a significant reduction ($P<0.01$). Inflammatory elements resolved without scarring. Laser treatment was well tolerated and improvement in pre-existing scars was noticeable.

Conclusions: The 650-microsecond, 1064-nm laser in combination with low-dose isotretinoin is safe and effective in patients with acne complicated by atrophic scars and genetically prone to post-acne scarring.

J Drugs Dermatol. 2020;19(6):646-651. doi:10.36849/JDD.2020.5108

INTRODUCTION

Tradition holds that laser procedures to treat acne vulgaris should be postponed at least 6 to 8 months after the end of systemic therapy with isotretinoin. This is based on data suggesting that dermabrasion or laser therapy during isotretinoin treatment may induce keloid formation or delay the repair of skin integuments (ie, skin scar tissue).[1-7] The validity of this practice has recently been questioned.[8-12] In their consensus recommendations, Spring and colleagues[10] reported insufficient evidence that physicians should delay manual dermabrasion, cutaneous surgery, superficial chemical peels, laser hair removal, and fractional ablative and nonablative laser procedures in patients receiving or recently completing therapy with isotretinoin. The authors did not, however, recommend mechanical dermabrasion and fully ablative laser therapy while patients underwent systemic isotretinoin treatment.

Two months later the American Society of Dermatologic Surgery reported its consensus recommendations regarding the safety of lasers, dermabrasion, chemical peels, energy devices, and skin surgery during and after isotretinoin use.[11] The Task Force concluded that evidence was lacking that physicians should delay procedures with chemical peels and nonablative lasers (ie, hair removal lasers and lights, vascular lasers, fractional devices) in patients currently or recently exposed to isotretinoin, and that superficial and focal dermabrasion, when performed by a well-trained professional, may also be safe.

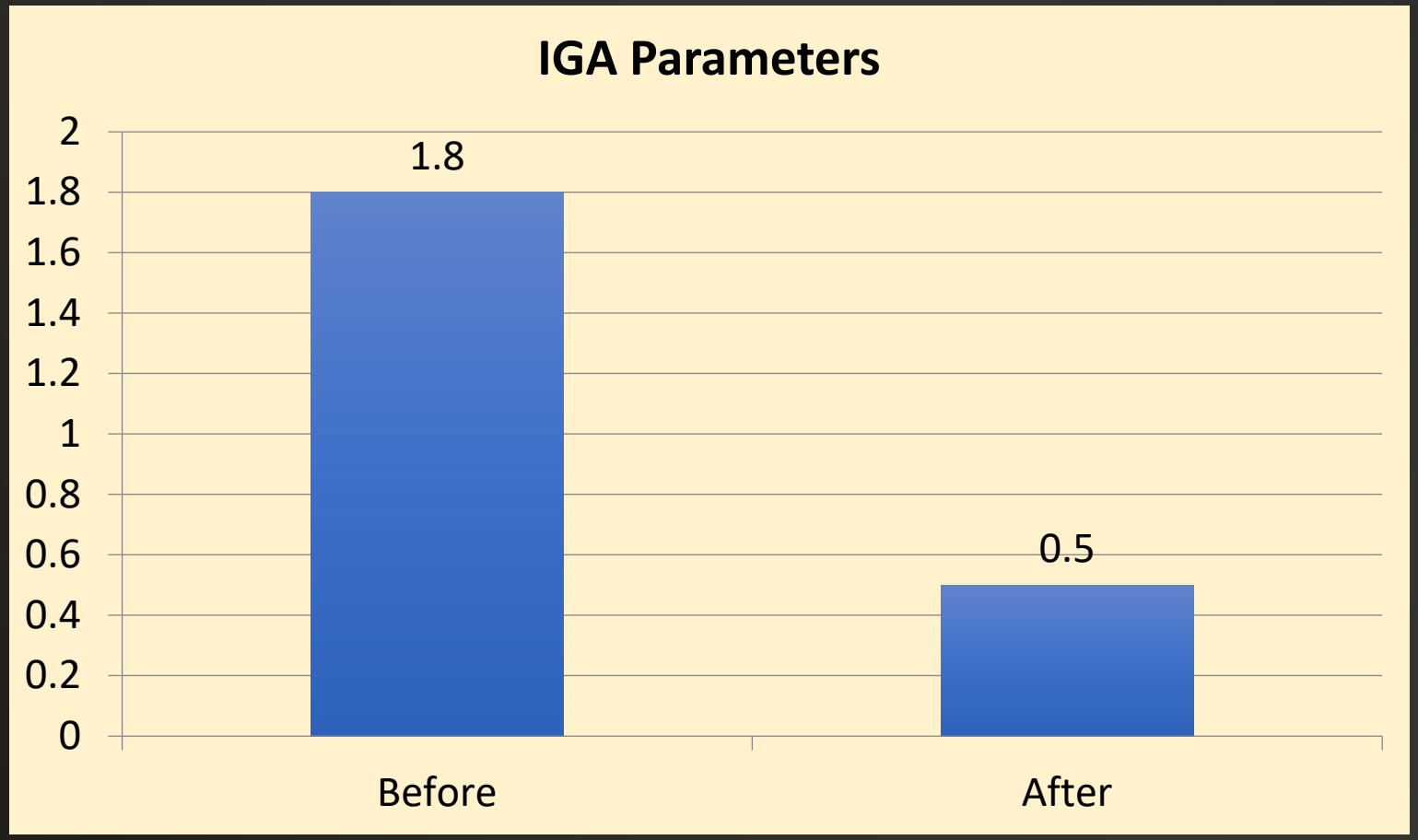
Mysore and colleagues,[12] after reviewing published studies, reported that evidence for avoiding a variety of procedures (fractional CO2 resurfacing, fractional Nd:YAG laser, fractional infrared lasers, laser hair removal, microdermabrasion using

Treatment of Moderate to Severe Acne and Scars with a 650-microsecond 1064nm Laser and Isotretinoin

Published by Michael H. Gold, MD

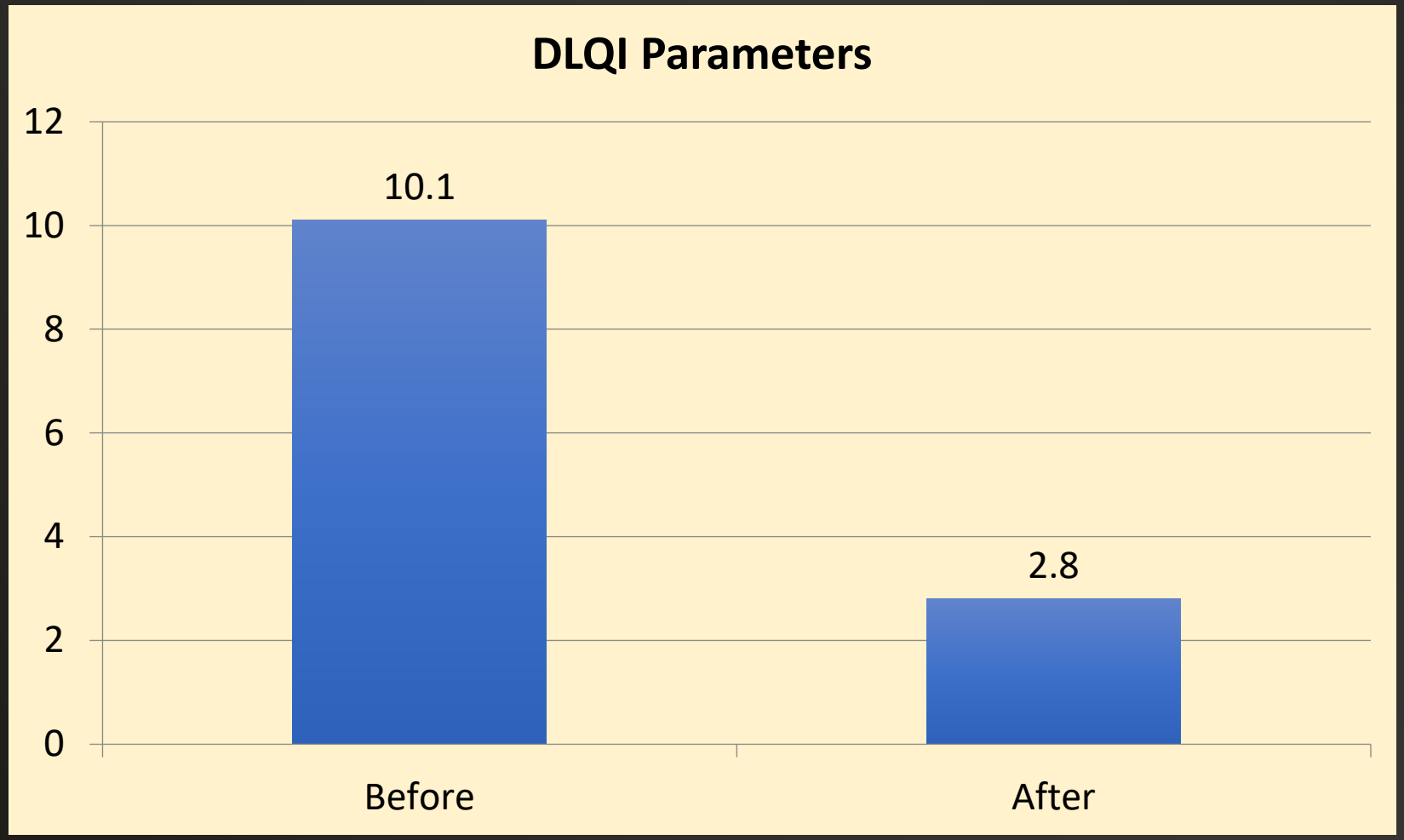
TREATMENT OF MODERATE TO SEVERE ACNE AND POST ACNE SCARS WITH 650 MICROSECOND 1064nm LASER COMBINED WITH LOW DOSE ISOTRETINOIN

Results: IGA Parameters



Decreased by 72.2% and reached 0.5± 0.4 ($p < 0.01$) points

Results: DLQI Parameters



Decreased to 2.8± 1.2points (p <0.01)

Results

- During the study, it was noted that the resolution of inflammatory elements occurred without scarring
- Increased sensitivity of the skin to laser radiation and the deterioration of the repair process of the skin was not observed
- Tolerability was high

- Acne Devices Targeting Sebaceous Glands

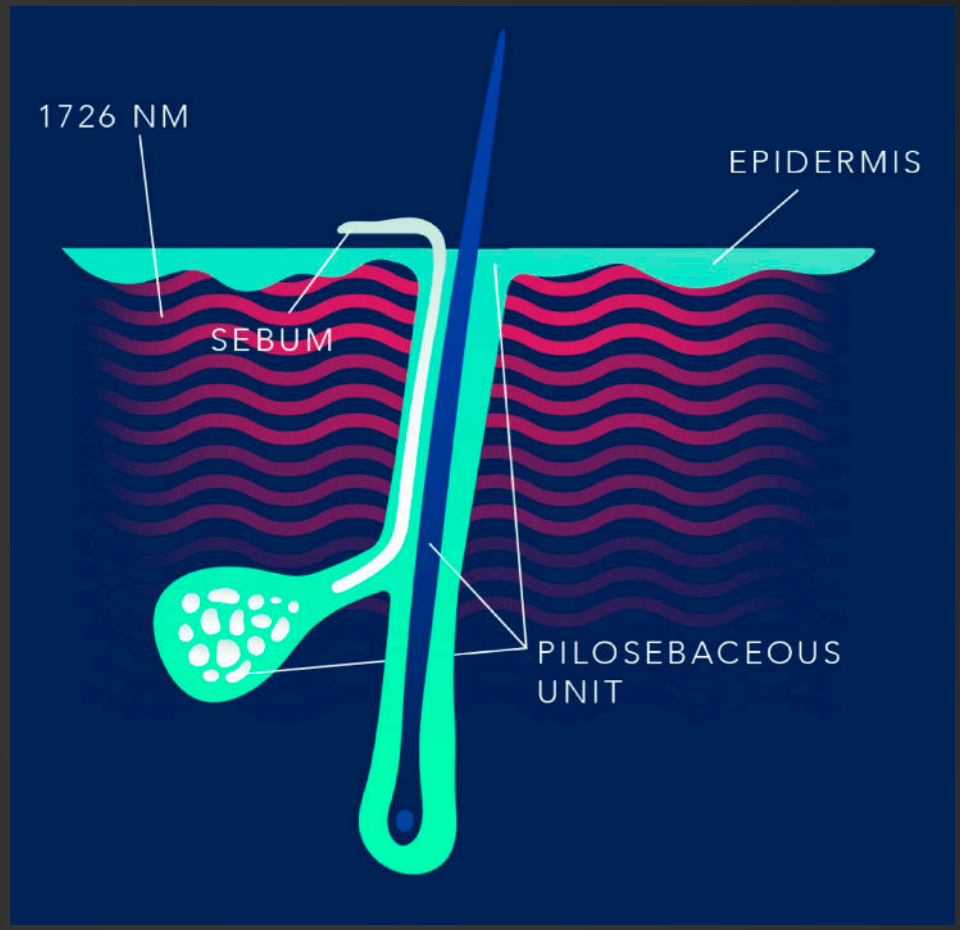
• Acne Devices Targeting Sebaceous Glands

- Two new devices developed for targeted sebaceous gland activity at 1726 nm
- AvaClear – FDA Approved March, 2022
- Accure – CE Cleared May, 2022

Mechanism of Action

Target acne at the source

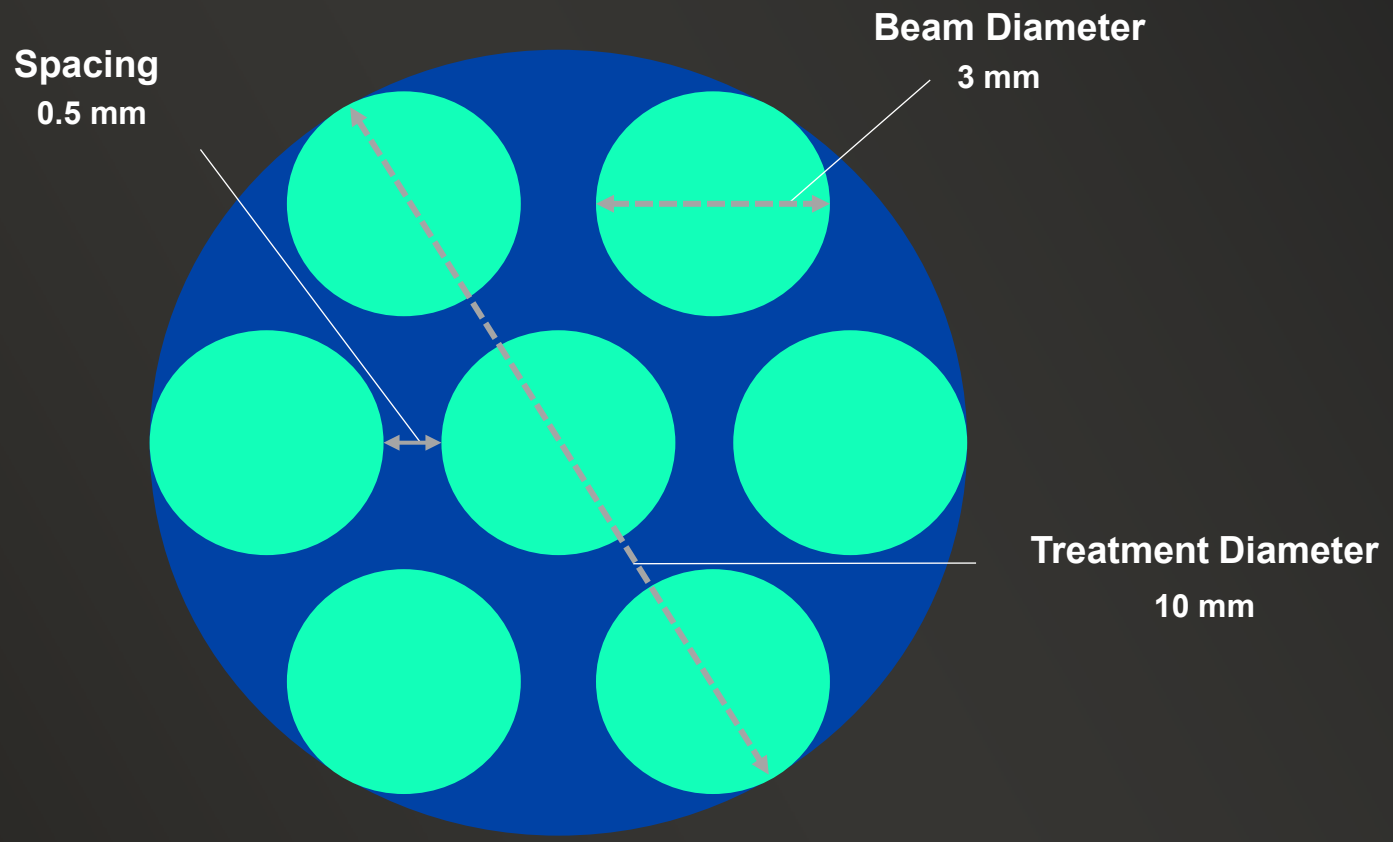
- Overproduction of sebum by the sebaceous glands is one of the leading causes of acne[1]
- At 1726 nm sebum absorbs 2x more energy compared to H_2O[2]
- AviClear uses this wavelength to selectively target and damage sebocytes
- Sebaceous glands shrink and sebum production decreases



[1]O'Neill AM, Gallo RL. Host-microbiome interactions and recent progress into understanding the biology of acne vulgaris. Microbiome. 2018;6:177
[2] Sakamoto FH, et al. Selective photothermolysis to target sebaceous glands: theoretical estimation of parameters and preliminary results using a free electron laser. Lasers Surg Med. 2012;44(2):175-183

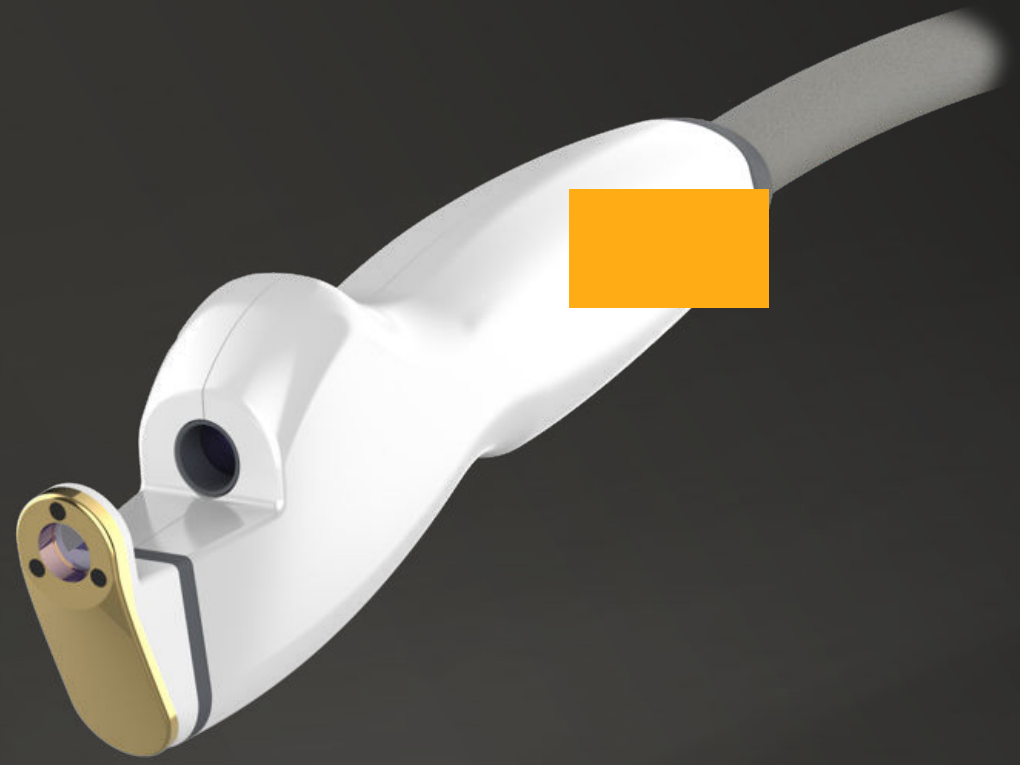
Unique imprint designed for acne

- 7 Individual 3 mm laser spots delivered in a 10 mm treatment area
- Exceptionally fast scanning pattern that takes into account thermal relaxation times of sebaceous glands
- Algorithm delivers a treatment imprint at roughly 0.3 Hz and a 1.5 mm depth of penetration



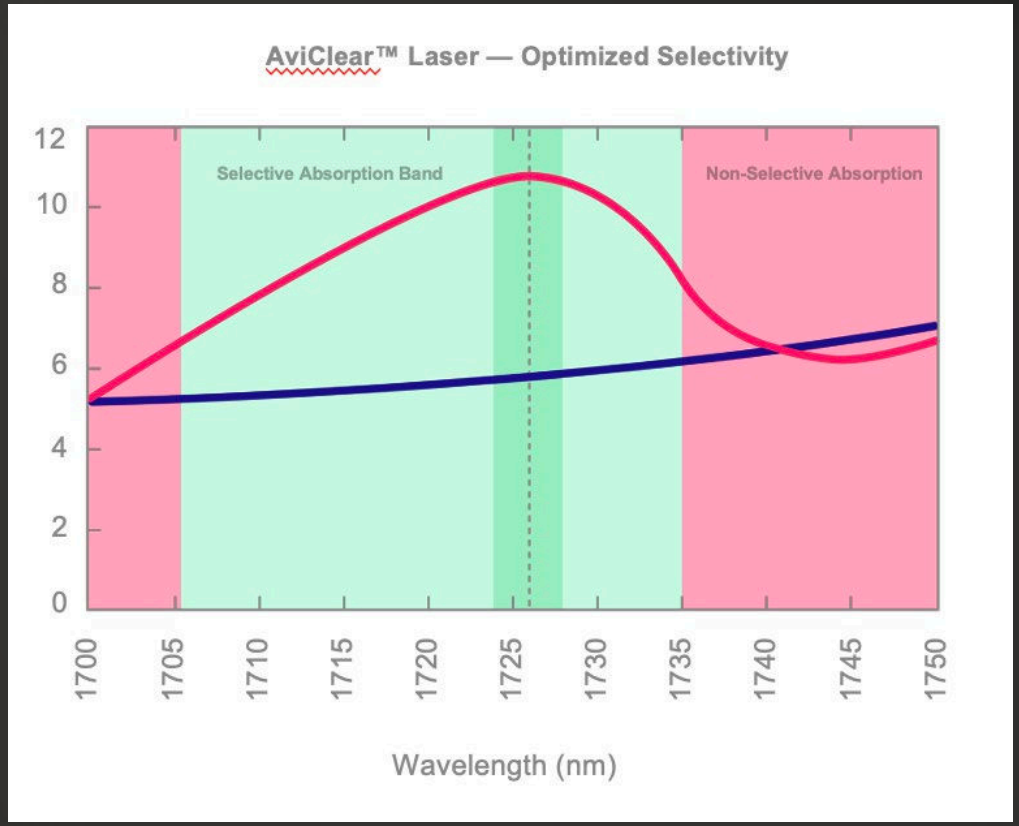
Advanced Cooling

Handpiece designed with exclusive sapphire skin cooling and smart sensors to maximize patient comfort and safety – This is required for patient comfort and compliance



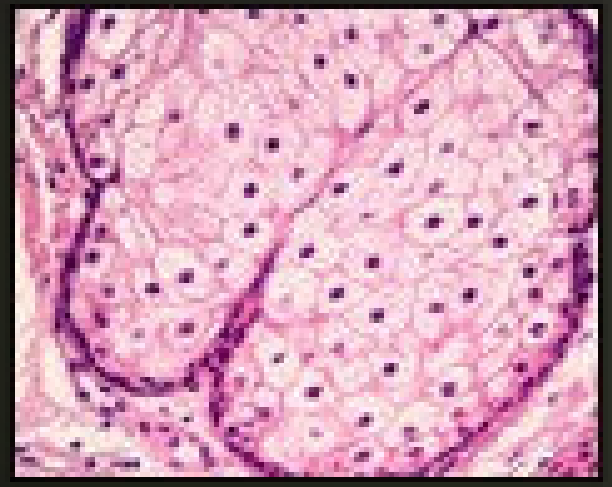
• Selective Absorption of 1726 nm

- The 1726 nm wavelength is clinically proven to absorb 2x more energy in sebum compared to H2O1
- The 1726 nm wavelength to selectively target and damage sebocytes to suppress sebum production

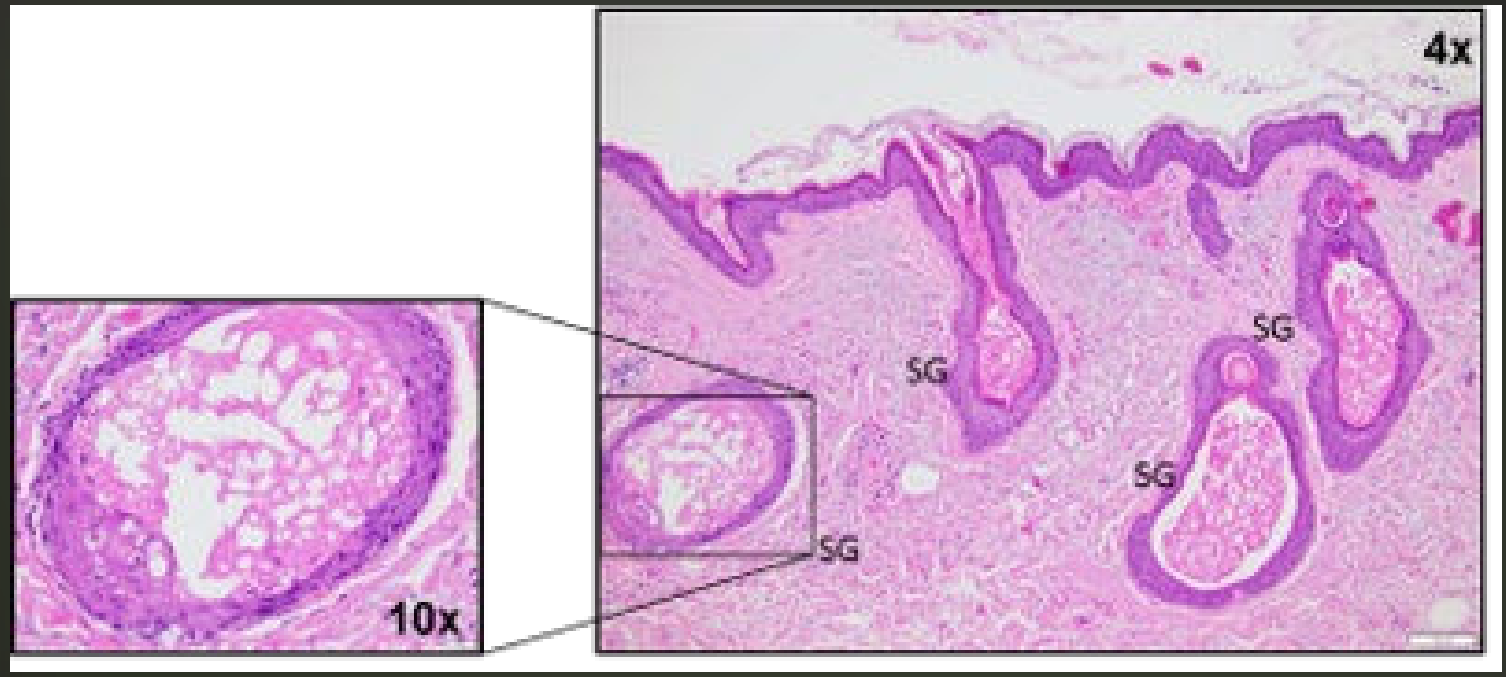


1. O'Neill AM, Gallo RL. Host-microbiome interactions and recent progress into understanding the biology of acne vulgaris. *Microbiome.* 2018;6:177. **2.** Sakamoto FH, et al. Selective photothermolysis to target sebaceous glands: theoretical estimation of parameters and preliminary results using a free electron laser. *Lasers Surg Med.* 2012;44(2):175-183

• Histological Evidence[2]



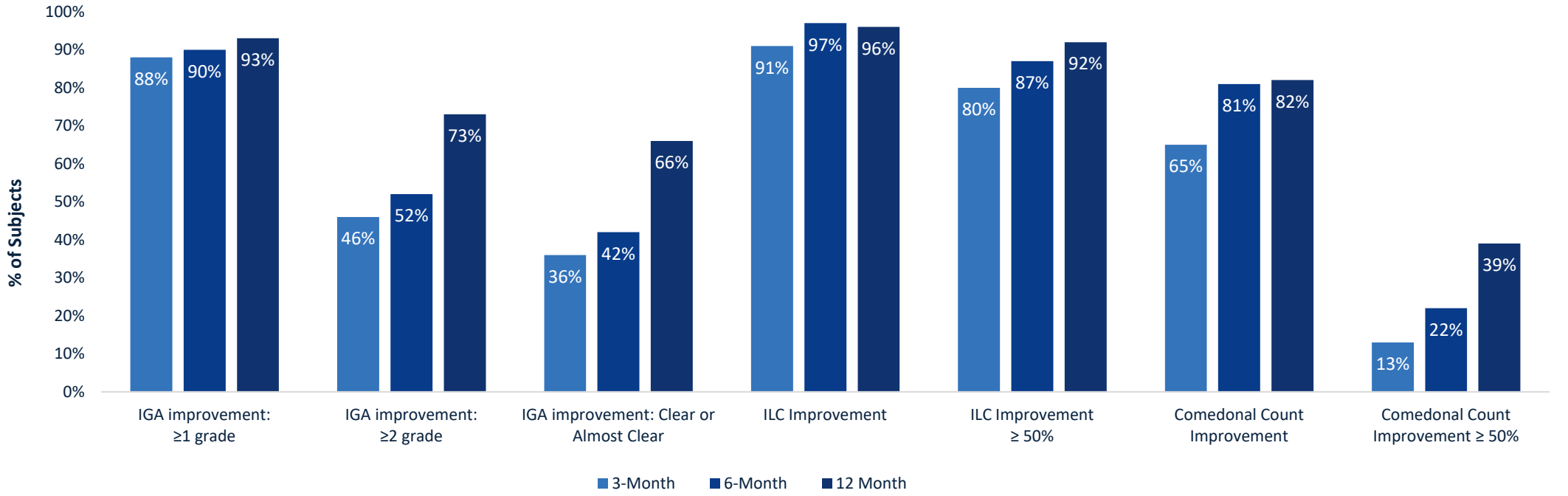
- Healthy sebaceous gland with nucleated sebocytes



- 5 days post-treatment
- Destroys nucleated sebocytes
- Epidermis remains intact

Procedure Efficacy: 3-, 6-, and 12-Month Data[1,3]

Acne Improvement Over Time

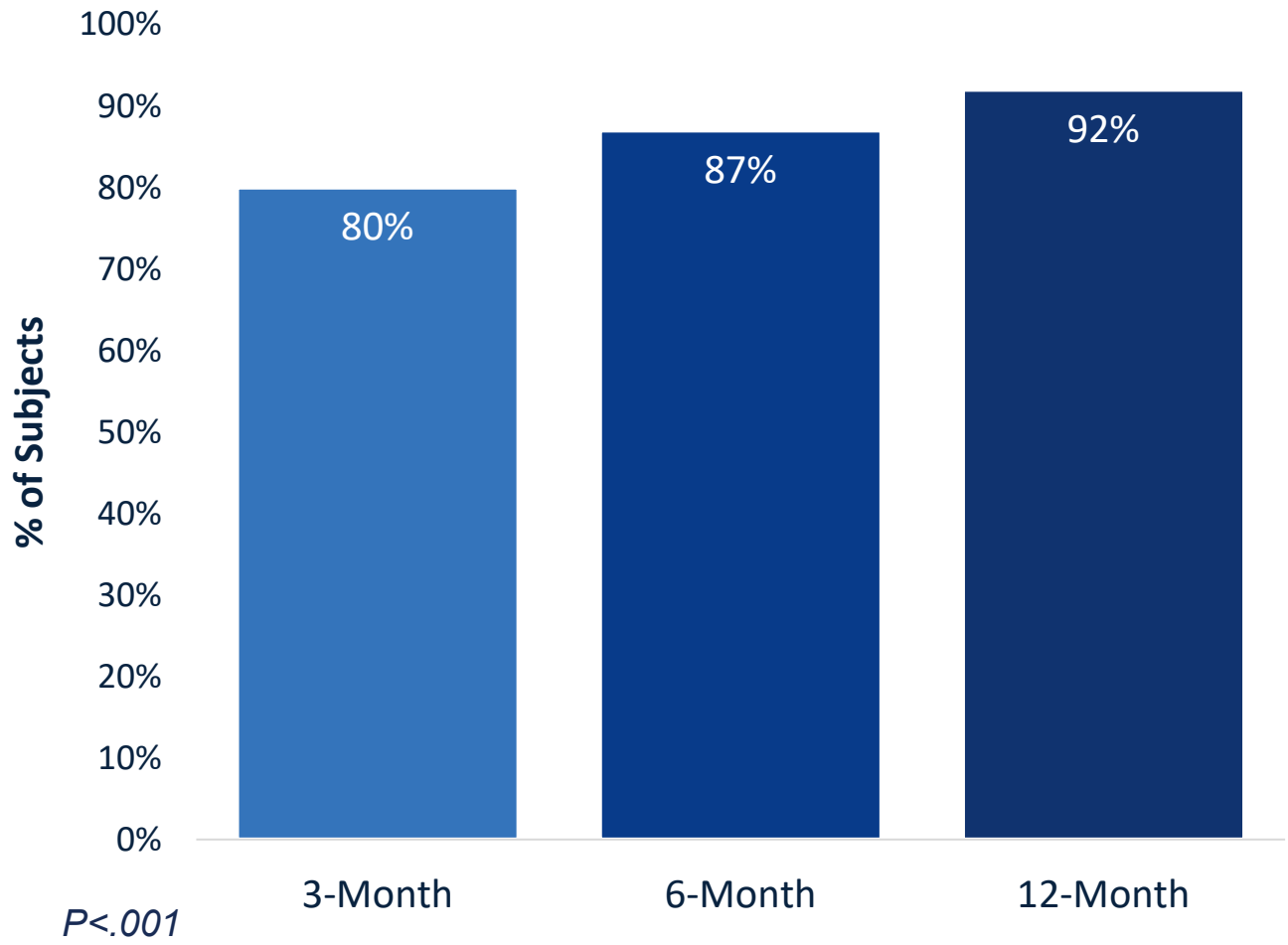


*Follow-up timepoints are post three 1726nm treatments

Clinical Results:

Inflammatory Acne Lesion Count Reduction[1,3]

≥ 50% ILC Improvement



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Clinical Results:

Acne Lesion Count Reduction[1,3]

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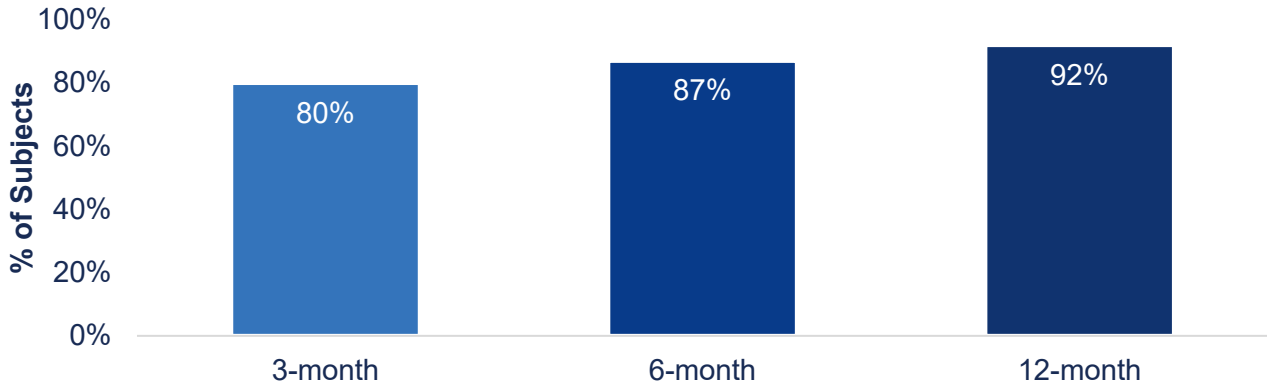
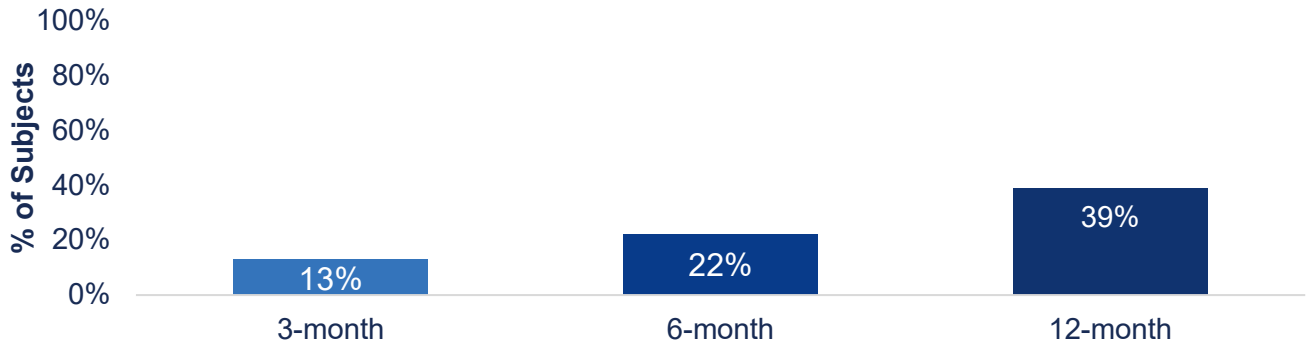


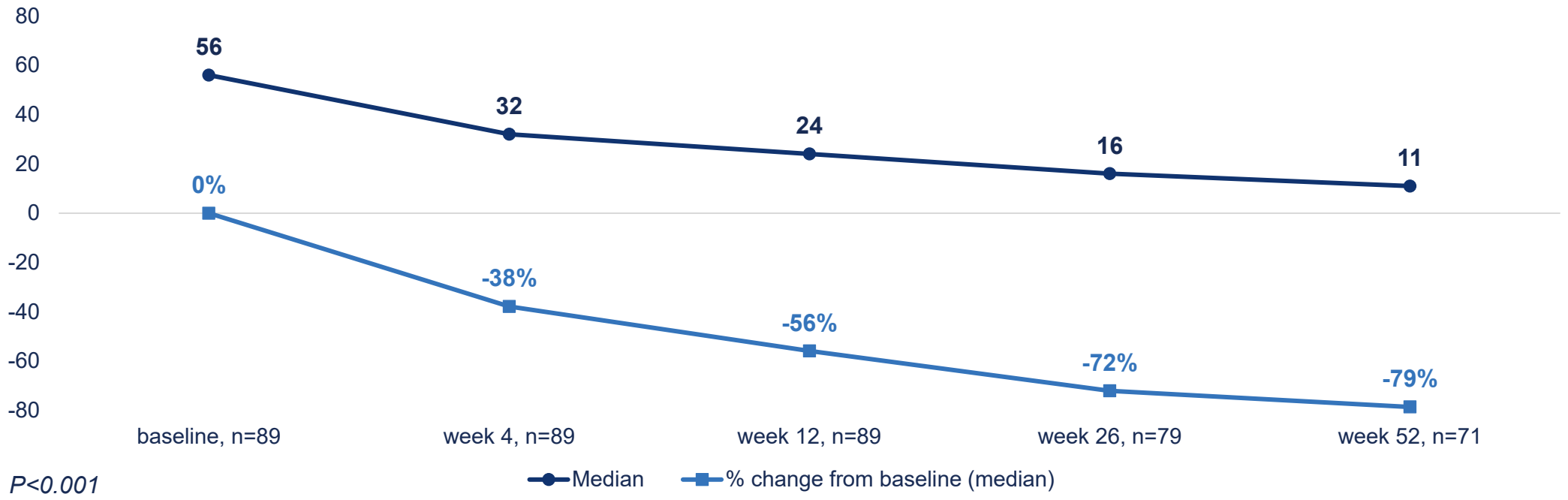
≥ 50% Comedonal Count Improvement



*Follow-up timepoints are post three 1726nm treatments

Median Inflammatory Acne Lesion Counts & Percent Reduction[3]

Absolute median ILC and percent change from baseline (PP cohort)

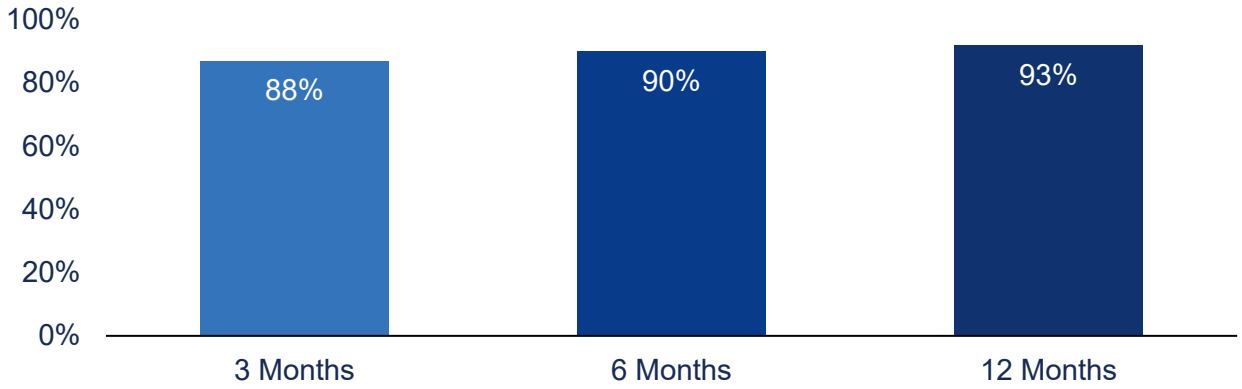


*Follow-up timepoints are post three 1726nm treatments

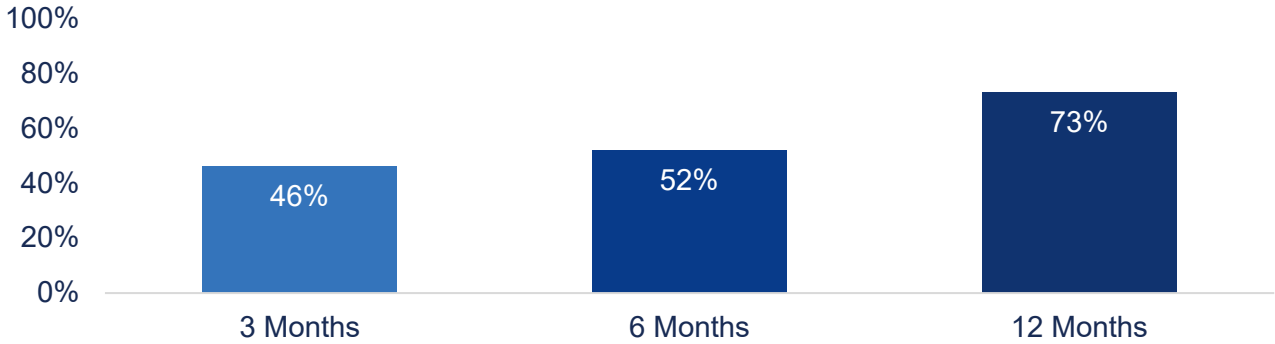
Clinical Results:

IGA Improvement at 3, 6 and12-Months[1,3]

IGA Improvement +1



IGA Improvement +2



*Follow-up timepoints are post three 1726nm treatments

Selective Photothermolysis with a Novel nm Laser Beam…
J Cosmet Dermatol. 2023;22:486–496

Selective photothermolysis with a novel 1726 nm laser beam: A safe and effective solution for acne vulgaris

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Email: amer@cutera.com

Funding information
Cutera Inc.

Abstract

Background: Selective photothermolysis on sebaceous glands is an effective method for treating acne vulgaris (AV); however, safety, efficacy, and discomfort hinder its utilization in clinical settings.

Aims: The primary objective is to evaluate the safety and efficacy of a novel 1726 nm laser with contact cooling to treat AV.

Methods: Seventeen patients aged 18 to 36 were enrolled and treated in this IRB-approved, single-center, open-label study. Patients received up to three facial laser sessions up to seven weeks apart. Follow-up visits happened ten days post-session and at the 4 and 12 weeks following the final session. The investigator assessed the severity of device-related adverse events (AEs). Investigator Global Assessment (IGA) and inflammatory lesion counts (ILC) were used as metrics to evaluate acne resolution and skin condition enhancement. Patients' perspectives on satisfaction and comfort using this technology were assessed using Subject Experience Questionnaires (SEQ).

Results: Safety assessment showed mild and transient AEs. All subjects tolerated anesthetics-free treatments well, with a mean treatment discomfort score of 4.9 ± 1.5. Compared to baseline, a statistically significant reduction in ILC ($p = 0.003$) of 52% to 56% is achieved four to twelve weeks following treatment. Long-term follow-ups showed progressive improvement 24 months post-treatment with a 97% reduction in ILC. SEQs revealed high subject satisfaction (71%) with psychosocial improvement three months post-treatment.

Conclusion: The novel 1726 nm laser appears safe and effective for treating mild-to-severe acne. Acne resolution is apparent within the first month and progresses beyond the study duration.

Novel 1726 nm Laser Demonstrates Durable Therapeutic Outcomes and Tolerability for Moderate-to-severe Acne Across Skin Types
J Am Acad Dermatol. 2023 Oct;89(4):703-710

Novel 1726 nm laser demonstrates durable therapeutic outcomes and tolerability for moderate-to-severe acne across skin types

Macrene Alexiades, MD, PhD,[a,b,c] Amogh Kothare, MS,[d] David Goldberg, MD,[e,f] and Jeffrey S. Dover, MD[b,g,h]

Background: Traditional acne management with topical therapy, systemic antibiotics, hormonal agents, or oral isotretinoin requires compliance and may produce significant side effects. However, alternative treatments with lasers had failed to demonstrate durable clearance.

Objective: To assess the tolerability and therapeutic outcomes of a novel 1726 nm laser treatment of moderate-to-severe acne across skin types.

Methods: A prospective, open-label, single-arm, Investigational Device Exemption-approved, institutional review board-approved study of 104 subjects with moderate-to-severe facial acne and Fitzpatrick Skin Types ranging from II-to-VI was conducted. Subjects received 3 laser treatments at 3 (-1/+2)-week intervals.

Results: Following final treatment, ≥50% reduction in active acne inflammatory lesions was 32.6% at 4-weeks follow-up, increasing further to 79.8% and 87.3% at 12 and 26-weeks, respectively. The percentage of subjects clear or almost clear increased from 0% at baseline to 9%, 36.0%, and 41.8% at 4-, 12-, and 26-weeks follow-up. No serious adverse events were observed related to device or protocol; treatments were well tolerated, requiring no anesthetic. Therapeutic outcomes and discomfort were similar across all skin types.

Limitations: Lack of control group.

Conclusions: The study findings demonstrate the novel 1726 nm laser is well tolerated with durable progressive posttreatment improvement to at least 26 weeks for moderate-to-severe acne across skin types. (J Am Acad Dermatol 2023;89:703-10.)

Key words: acne; acne guidelines; acne management; acne scarring; acne severity; acne skin types; acne treatment alternatives; acne vulgaris; antibiotic therapy; hormone therapy; isotretinoin; laser; light therapies; sebaceous glands; selective photothermolysis.

Safety[1]

Treatment was safe for all skin types

No incidences of treatment related hypo- or hyperpigmentation

Erythema and edema typically resolved within several hours to a day, but some instances lasted several days

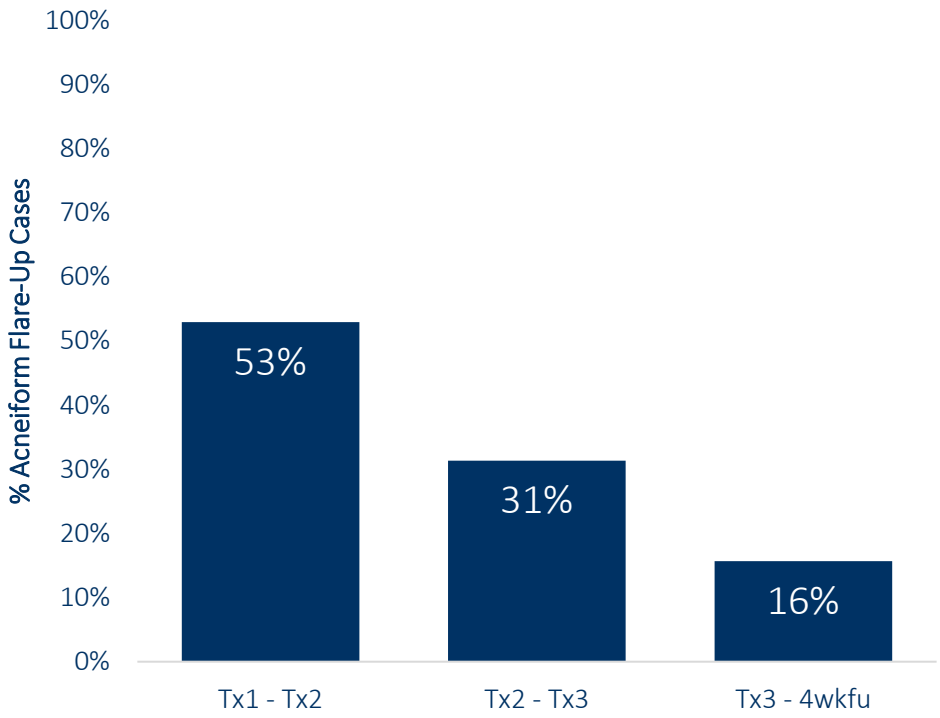
Vast majority of **side effects were mild** with no serious or unexpected adverse events reported

Transient side effects	Incidence (%)
Erythema	100%
Edema	98%
Acneiform flare-up	42%
Dryness	18%
Itchiness	2%

Acneiform Flare-Up[3]

Transient acneiform flare-ups were a mild one-time event for most subjects with a little over half of the flare-ups occurring within a few weeks post treatment 1.

A strong majority of acneiform flare-ups typically resolved within **6-weeks of treatment.**



Patient Comfort[1,3]

Built-in technology that helps maintain patient comfort and spare the epidermis during treatment.

- Subjects tolerated treatment well without the need for topical anesthetic
- Average VAS score during treatment was 5.2 out of 10
- No subjects dropped out or ended treatments prematurely due to discomfort

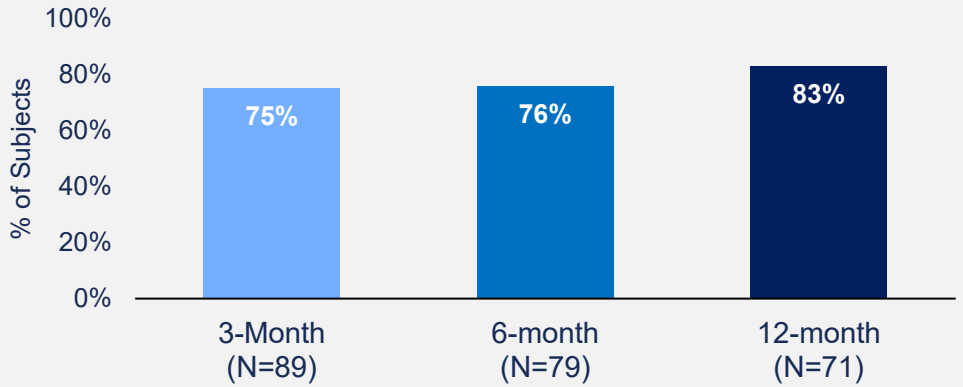
0-10 VAS Numeric Pain Scale

Patient Satisfaction[1]

Subject Reported Visual Improvement

Over 80% of subjects saw visual improvement in their skin at 6- and 12- months post three 1726nm treatments

Satisfaction with Results



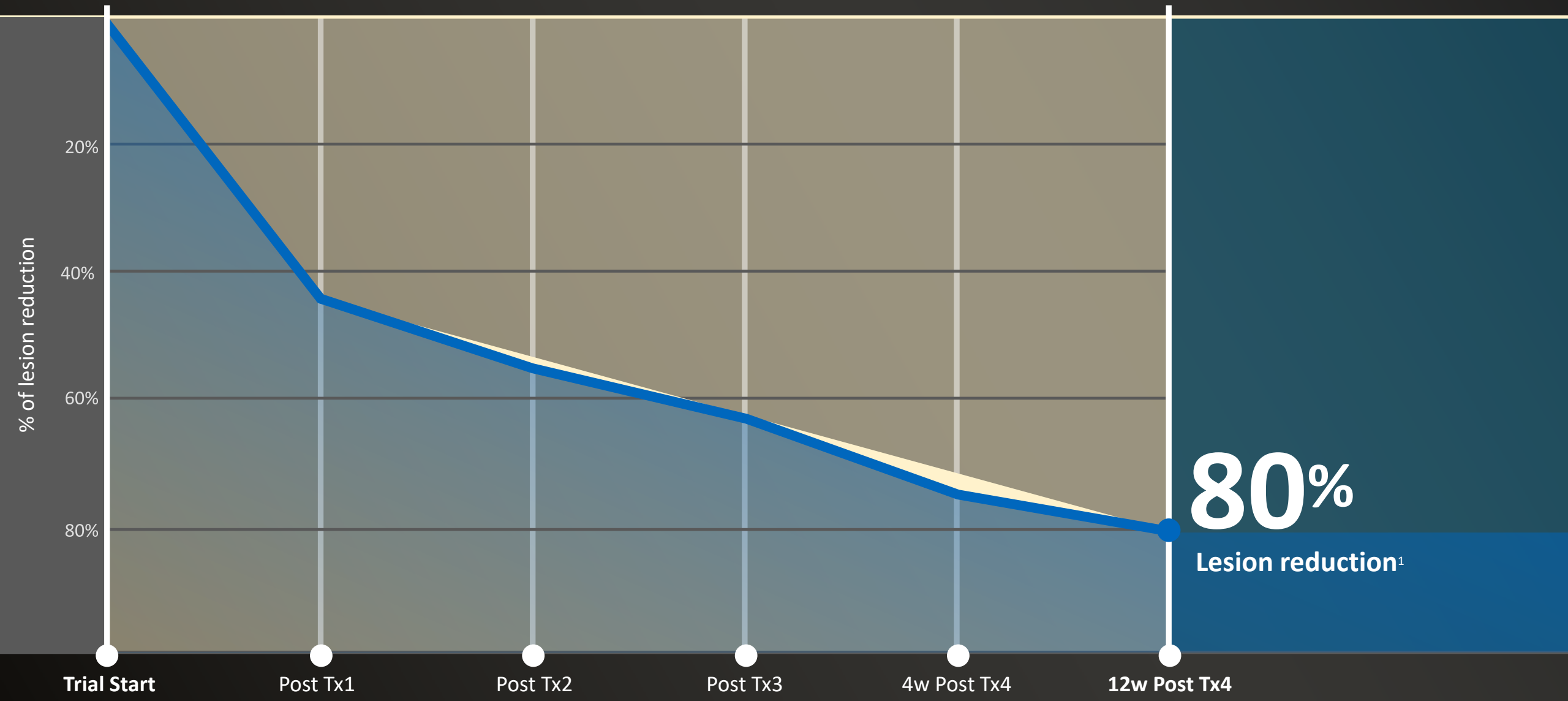
- Satisfaction, defined as being “satisfied” or “very satisfied” with improvement after 3 treatments, was maintained through 1 year after last 1726nm treatment.
- The large number of subjects completing the study with no additional acne therapies utilized during the 1-year follow-up period post last 1726nm treatment further emphasizes the positive subject perspective of the results.

The System

- 40W 1726nm Raman fiber laser
- Real-time temperature monitoring with continuous clinical feedback
- We have correlated a target surface temperature to a dermal and sebaceous gland temperature which produces a delayed clinical end point and precise and selective sebaceous gland damage
- Our current software is closed-loop: the device controls that laser power based on temperature feedback. We have a temperature cut-off where the device will stop pulsing if a specified high temperature is reached.

Acne Lesion Reduction

Percent Inflammatory Acne Lesion Reduction on treated side of hemiface — Face Acne Trial



1. "Tanghetti, E., Geronemus, R., Bloom, B., Anderson, R.R., Ross, E.V., Sakamoto, F.W. Safety And Efficacy Data In A Pilot Study Of The Treatment Of Acne With A Fiber Laser. 40th ASLMS Annual Conference; 2020

Summary

- This 1726nm laser is effective at improving acne vulgaris
  - Improved inflammatory lesion counts
  - High responder rate with what appears to be a durable response

- High level of safety without serious adverse events
  - Real-time temperature monitoring with continuous clinical feedback and temperature cut-off
  - Integrated highly-controlled skin cooling system
  - Over 15,000 trigger pulls safely performed

- Current large-scale clinical trials are underway and almost completed

Acne Treatment with Lasers

- Acne therapy with lasers and EBDs can make your acne patients better – and faster than with conventional therapy

- Use the tools we have to make your patients better each and every day