Aesthetic Lasers For Med Derm Issues

South Beach Symposium
Miami Beach, FL

February 9 -12, 2023

Presented by Michael H. Gold, MD
Gold Skin Care Center
Tennessee Clinical Research Center
Nashville, TN 37215

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

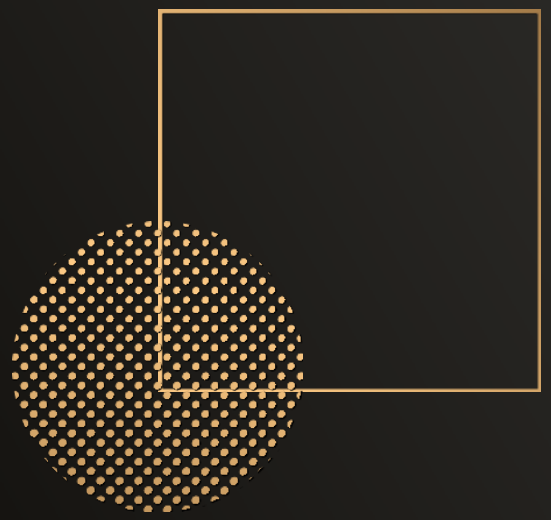
04. Visiting Professor of Plastic Surgery

- 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

Aesthetic Lasers For Med Derm Issues

Acne Vulgaris Treatment with Lasers and EBDs in 2023

The Psychosocial Consequences of Acne

Depression[1,2]

LOW SELF-ESTEEM[1,2]

Anxiety[1,2]

SOCIAL PHOBIA[3]

Social isolation[1,2]

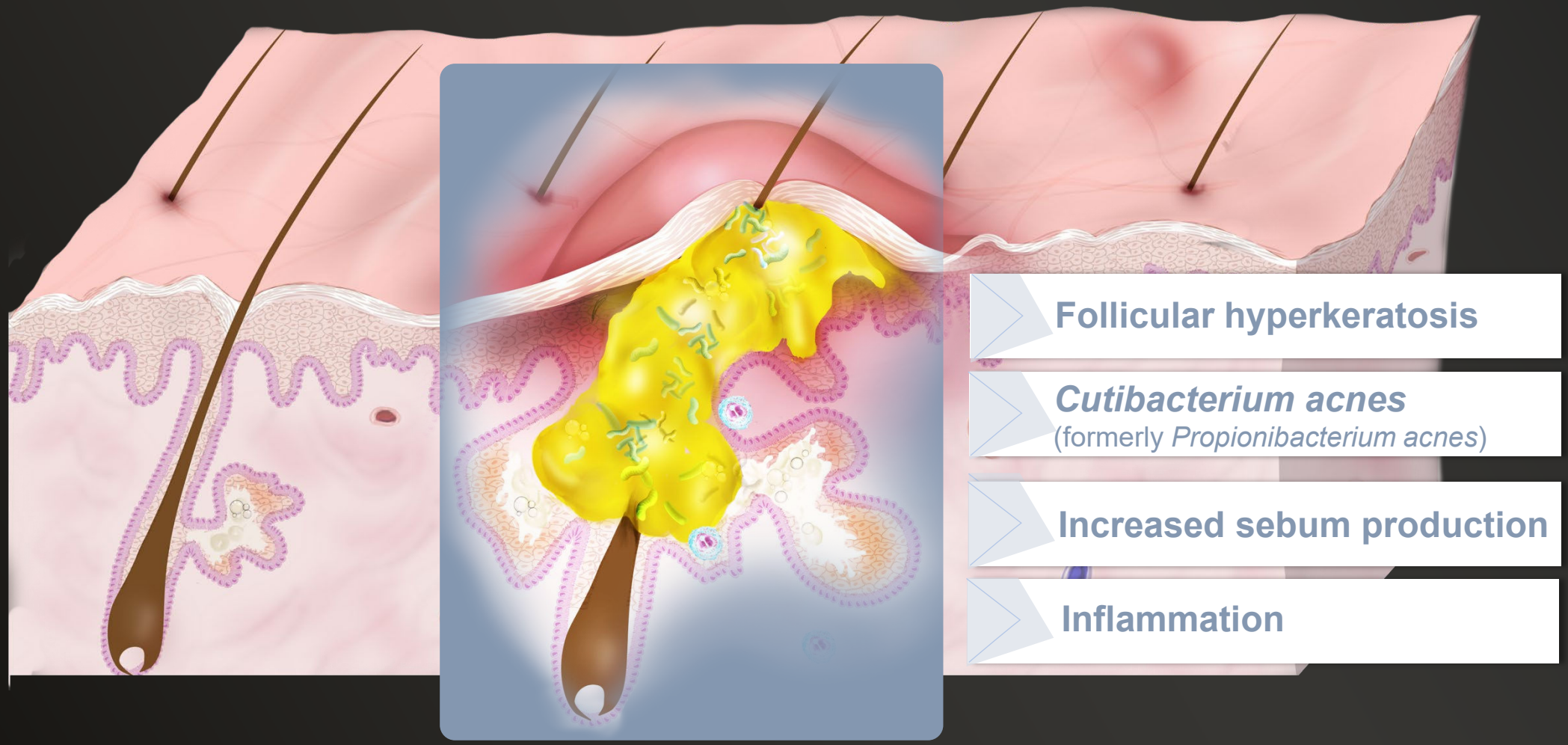
Negative psychosocial impact does not correlate with acne severity, and **even mild disease can impact negatively** on work, social interactions, and mood[1]

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.

Acne Treatments Target One or More of the Key Pathogenetic Factors



- Follicular hyperkeratosis
- ***Cutibacterium acnes*** (formerly *Propionibacterium acnes*)
- Increased sebum production
- Inflammation

1. Dagnelie MA et al. *Int J Dermatol*. 2022 May 6. doi: 10.1111/ijd.16220. Online ahead of print. 2 Siddiqui R et al. *Foli Microbiol*. 2022 Jun 16; doi: 10.1007/s12223-022-00982-5.

Conventional Acne Treatment Model

Diagnose Prescribe Wait & See

Limitations of Acne Treatments

Poor adherence due to

- Forgetfulness[1]
- Inconvenience[1]
- Side effects[1-3]
- Cost[1,3]

Frustration

~3 to 6 weeks
to achieve visible improvement[2]

Disappointment in the lack of "instant" results may lead patients to discontinue treatment early or opt for alternative treatments[2,3]

1. Snyder S et al. *Am J Clin Dermatol*. 2014;15(2):87-94. 2. Ip A et al. *Br J Dermatol*. 2020;183(2):349-356. 3. Ip A et al. *BMJ Open*. 2021;11:3041794.

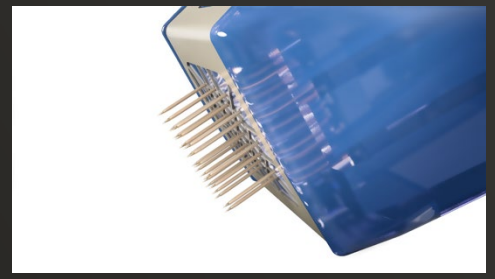
Patients and physicians need a more effective, predictable, and cost-effective, cost-efficient approach to addressing acne for the modern patient

Acne Vulgaris

- This presentation will cover lasers and IPLs that can be used for the treatment of acne vulgaris
- It is beyond the scope of this presentation to cover all the lasers and RF microneedling devices that can be used to treat acne scars
- Most devices that we use for acne scars can treat active acne through the generation of heat into the sebaceous gland and surrounding areas

The Designer Dermis: Dark Skin & Acne

- Deep fractional technology
- Penetration into the adipose tissue – 4000 microns
- Most uniform effect
- Little to no thermal damage to epidermis
- Disposable tips
- Supplements RFAL technology
  - Facial contraction
  - Cellulite treatment
  - Body skin laxity



The Fate of Active Acne and Acne Scars Following Treatment With Fractional Radiofrequency J Drugs Dermatol. 2019;18(12):1268:1272

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ORIGINAL ARTICLE JOURNAL OF DRUGS IN DERMATOLOGY

The Fate of Active Acne and Acne Scars Following Treatment With Fractional Radiofrequency

Bruce E. Katz MD
JUVA Skin & Laser Center, New York, NY

ABSTRACT

Introduction: Acne vulgaris (AV) is a common skin disorder that may result in long-lasting acne scars. Techniques such as delivering fractional radiofrequency (RF) energy through miniature pins or needles have been utilized to manage active acne and acne scars. Skin restoration through dermal remodeling, neo-collagenesis, neo-elastogenesis, and epidermal re-newal are typical results of such treatments.

Methods: 15 subjects suffering from acne received 3 sessions of facial treatments, 3-4 weeks apart, using a fractional RF device with 24 pins tip of 2500µm in length. The treatment's safety and efficacy were evaluated up to 6 months after the last treatment.

Results: Facial photos and classifications of active acne, acne scars, and overall skin appearance demonstrated improve-ments in follow-up visits compared to baseline. No significant or unexpected adverse events were detected.

Conclusion: The current study supports the safety and efficacy of the fractional RF treatment modality for acne condition.

J Drugs Dermatol. 2019;18(12):1268-1272.

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 (Dusa/Sun Pharma)
    - Red Light Sources
    - Intense Pulsed Light Devices– Quantum/Vasculight/Lumenis One/M22/Stellar M22 (Lumenis), Ellipse (DDD/Candela), elos Plus(Syneron), BBL/Joule (Sciton), Harmony XL (Alma), Lumecca (InMode), Isolaz (Solta)
    - Vascular Lasers –Cynergy (Cynosure), V-Beam Perfecta (Candela), N-Lyte (ICN), AdvaTX (Advantix)
    - 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

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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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c. Gold Skin Care Center, Tennessee Clinical Research Center, Nashville, TN
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 by Lumenis
    - Other systems – Harmony by Alma, BBL by Sciton, Isolaz by Solta, Elos Plus by Syneron, Lumecca (Invasix)
    - ClearTouch, SkinStation by Radiancy
      - 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.

Stellar M22™ Multi application Aesthetic platform

For over 20 skin conditions & hair removal using OPT® - (Optimal Pulse Technology)

The only true fractional non-ablative skin resurfacing laser with no disposables

Nd:YAG

For leg veins treatment using MSP™ (Multiple Sequential Pulsing

Q-Switched Nd:YAG

For dark tattoos removal and skin pigmentation

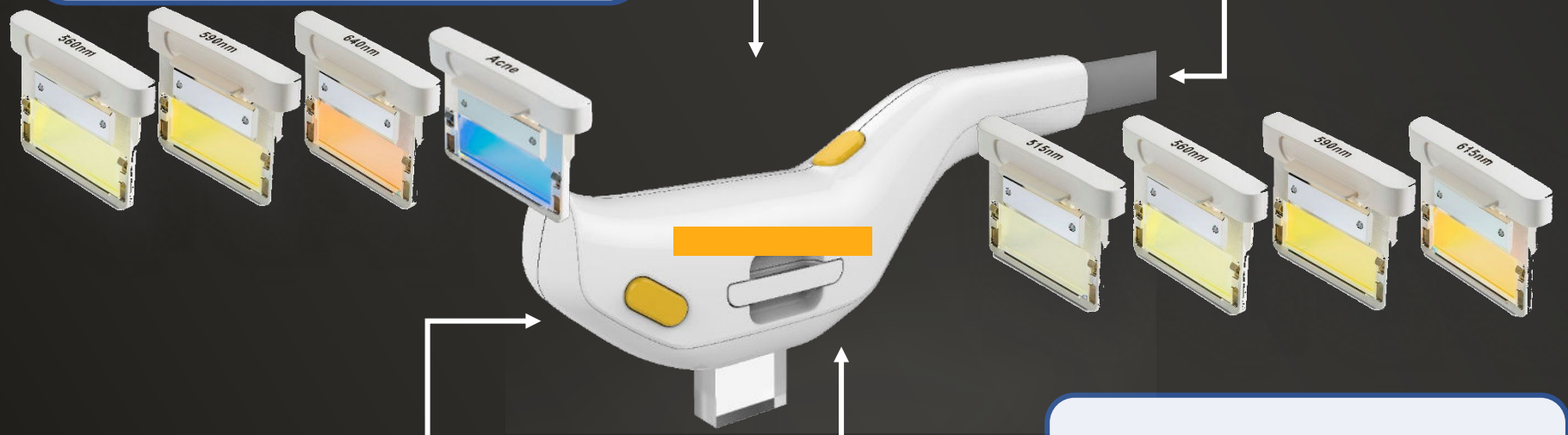
4 Different Treatment Groups

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:

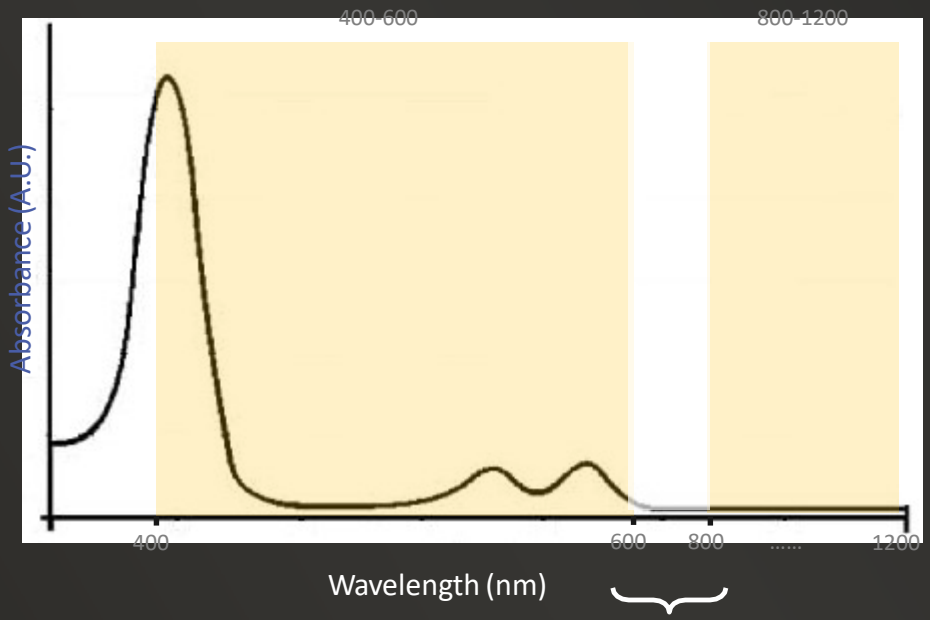
When exposed at 400-600nm (with a peak at the Soret band around 400-420nm)

- 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***

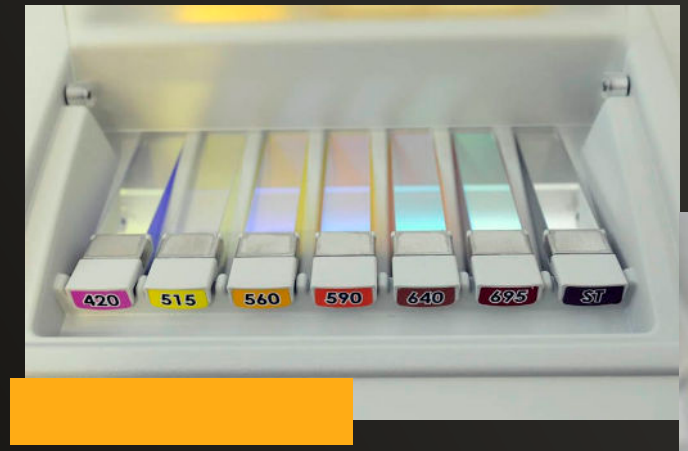
BBL is available in Several Options -- Old

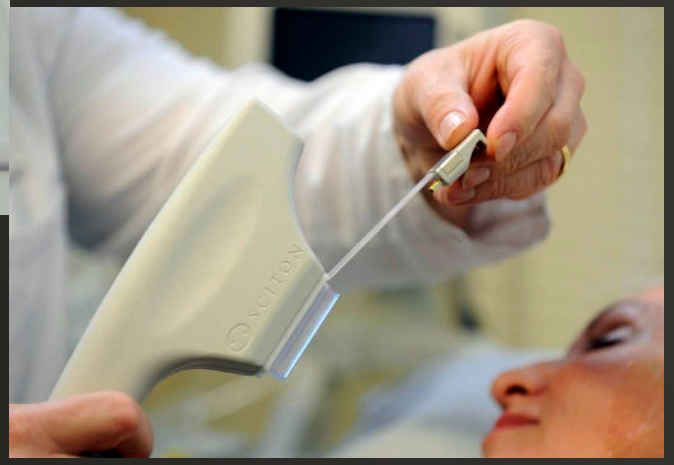
BBL module incorporated into [redacted]

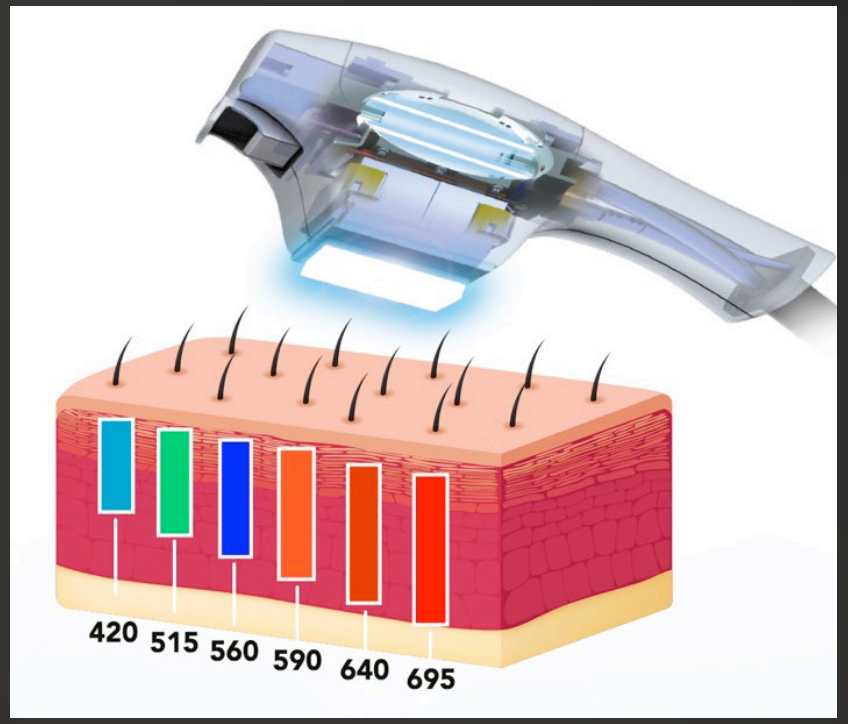
BBLs Stand alone System

BBL™ easy to change Smart Filters™

- BBL uses Smart Filters™ allowing for quick and easy adjustment of wavelengths on a single hand piece.
- This allows you to address multiple skin concerns without having to use or change multiple hand pieces.







How is BBL different from other IPLs?

BroadBand Light (BBL) is the most advanced and versatile broadband light system in its class.

What truly sets BBL apart?

- Advanced Intelligent Treatment Driven Interface
- Longer lamp lifetime with the DuraLamp Technology
- Snap on adaptors and Smart Filters for fast adjustments during treatment
- Precise and consistent treatments
  - Square Wave and True Pulse Width control
- Range of spot sizes, including large
- CoolComfort technology features:
  - Powerful cooling; 1-30 ˚C in 1 ˚C increments
  - Treat large areas with no lag

Patient Outcomes

Isolaz acne therapy harnesses the clinically proven, unique combination of vacuum extraction, broadband light and enhanced topical application

Treatment Outcomes

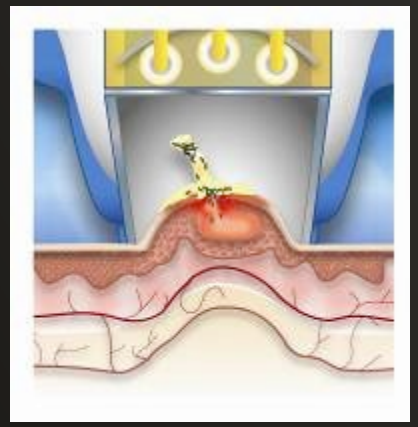
- Significant and lasting clearance of mild, moderat e and severe acne
- Effective acne solution for non-responders to oth er acne therapies
- Replenished, clearer skin and a more even compl exion

How It Works

Isolaz treatments cleanse, purify, and shrink pores while destroying acne causing bacteria for a clearer, more even complexion.

CLEANSE

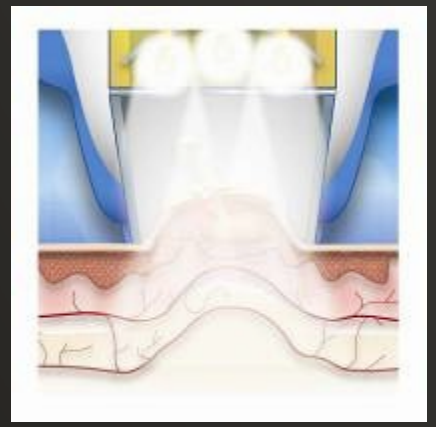
Isolaz Tip



Vacuum tip gently lifts acne impurities and extracts dirt, blackheads, and excess oil from your pores.

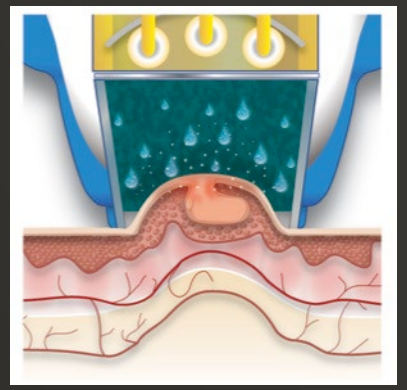
PURIFY

Isolaz Tip



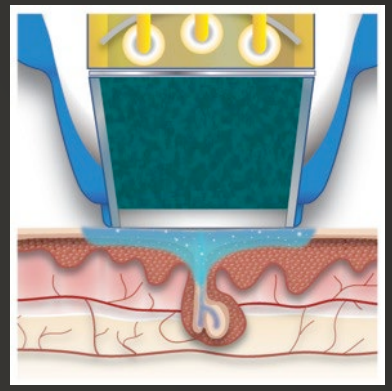
Broadband light is applied to help destroy acne causing bacteria and reduce sebum production.

REPLENISH



Skin care regimens get a kick-start by accessing the deeper layers of your skin.

RELEASE



Skin is released to normal position, and pores are left clean and purified for clearer, replenished skin.

Gold MH, Biron J. J Drugs Dermatol 2008; 7(2):139-145

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EFFICACY OF A NOVEL COMBINATION OF PNEUMATIC ENERGY AND BROADBAND LIGHT FOR THE TREATMENT OF ACNE

Michael H. Gold MD,[a] Julie Biron BS[b]

a. Medical Director, Gold Skin Care Center, Tennessee Clinical Research Center, Clinical Assistant Professor, Division of Dermatology, Department of Medicine, Vanderbilt University Medical School, Vanderbilt University Nursing School, Nashville, TN; Visiting Professor of Dermatology, Huashan Hospital, Fudan University, Shanghai, China

b. Director, Tennessee Clinical Research Center, Nashville, TN

Abstract

Introduction: A novel photopneumatic platform (Isolaz, Pleasanton, CA), combining vacuum pressure with a broadband light source device has been designed to attack multiple targets for the effective treatment of acne.

Objective: The objective of this study was to evaluate the safety and efficacy of photopneumatic technology for the treatment of mild to moderate acne vulgaris.

Methods: Eleven subjects (7 women) aged 15 to 54 years with skin types 1 to 4 presented with mild to moderate facial acne (defined as 15 or more facial inflammatory or noninflammatory lesions) were recruited to the study. All subjects underwent 4 photopneumatic treatments at 3-week intervals with follow-up visits at 1 and 3 months.

Results: Inflammatory lesion counts continued to decrease for at least 3 months after the final treatment. At 3 months, reductions in lesion counts were significant for both inflammatory ($P=.0137$) and noninflammatory ($P=.0383$) lesions. Mean scores between visits consistently dropped sharply from their immediate posttreatment values for pain, erythema, and edema. Nine subjects (82%) were moderately satisfied to very satisfied with treatment.

Conclusion: Results suggest that the photopneumatic device is a safe and effective modality for the treatment of mild to moderate inflammatory and comedonal acne vulgaris.

Clinical Study –
Gold and Biron – ASLMS 2008, AAD 2008

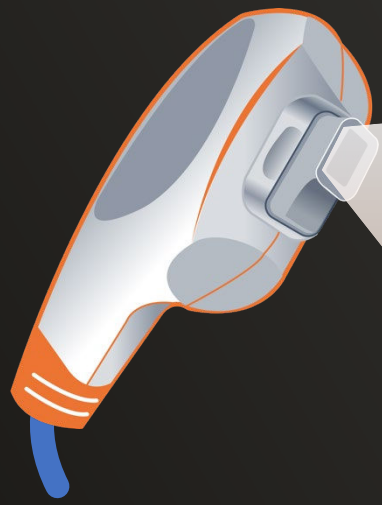
- Eleven Subjects, aged 15-54 years of age with mild to moderate acne vulgaris
- Four PPx treatments at 3 week intervals; follow-up at one and three months post last treatment
- Inflammatory acne lesion counts continued to decrease for at least the three months after the last treatment
- At 3 months:
  - Inflammatory lesion counts: 78% reduction (p=0.0137)
  - Non-inflammatory lesion counts: 57.8% reduction (p=0.0383)
  - Pain minimal with treatment
  - 82% moderate to very satisfied

Acne Therapy System

An addition to the armamentarium and management plan for the treatment of acne

Specifically designed for the indication of **mild to moderate acne**

Uses A Dual Mechanism of Action To Target Key Pathogenetic Factors



1 VACUUM

2 PULSED BROADBAND LIGHT

Photopneumatic technology that combines **VACUUM** with **PULSED BROADBAND LIGHT** delivered through a liquid-cooled handheld delivery system

Clears bacteria and follicular contents from pilosebaceous unit

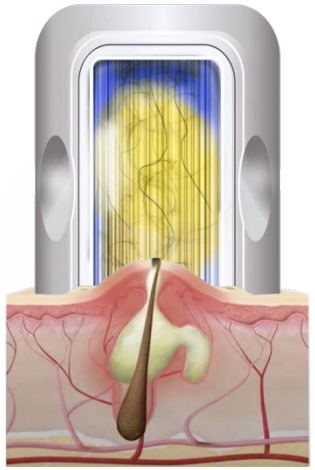
Destroys *C acnes*

Reduces sebum production

- 1. Dagnelie MA et al. *Int J Dermatol*. 2022 May 6. doi: 10.1111/ijd.16220. Online ahead of print. 2 Siddiqui R et al. *Foli Microbiol.* 2022 Jun 16; doi: 10.1007/s12223-022-00982-5.

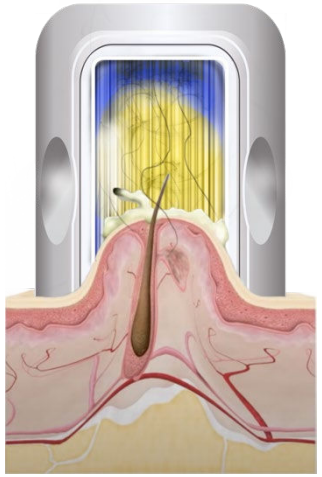
Treatment Timeline: Step By Step

Place



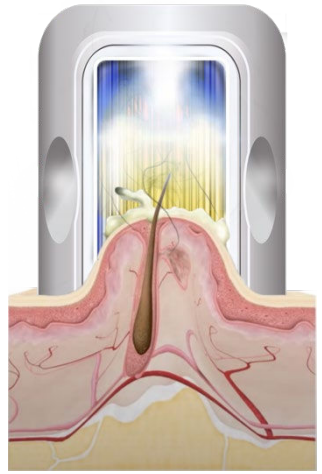
The handpiece makes full contact with treatment area

Extract



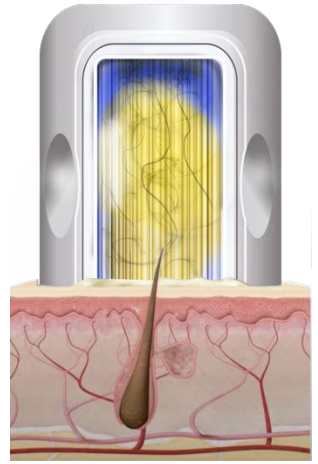
Pneumatics deep **cleans pores** by extracting sebaceous and follicular material

Treat



Along with targeting heating of the dermis, light activates porphyrins to **directly reduce *C acnes*** and sebum production

Complete



Obstruction in the pilosebaceous apparatus is removed and skin normalizes

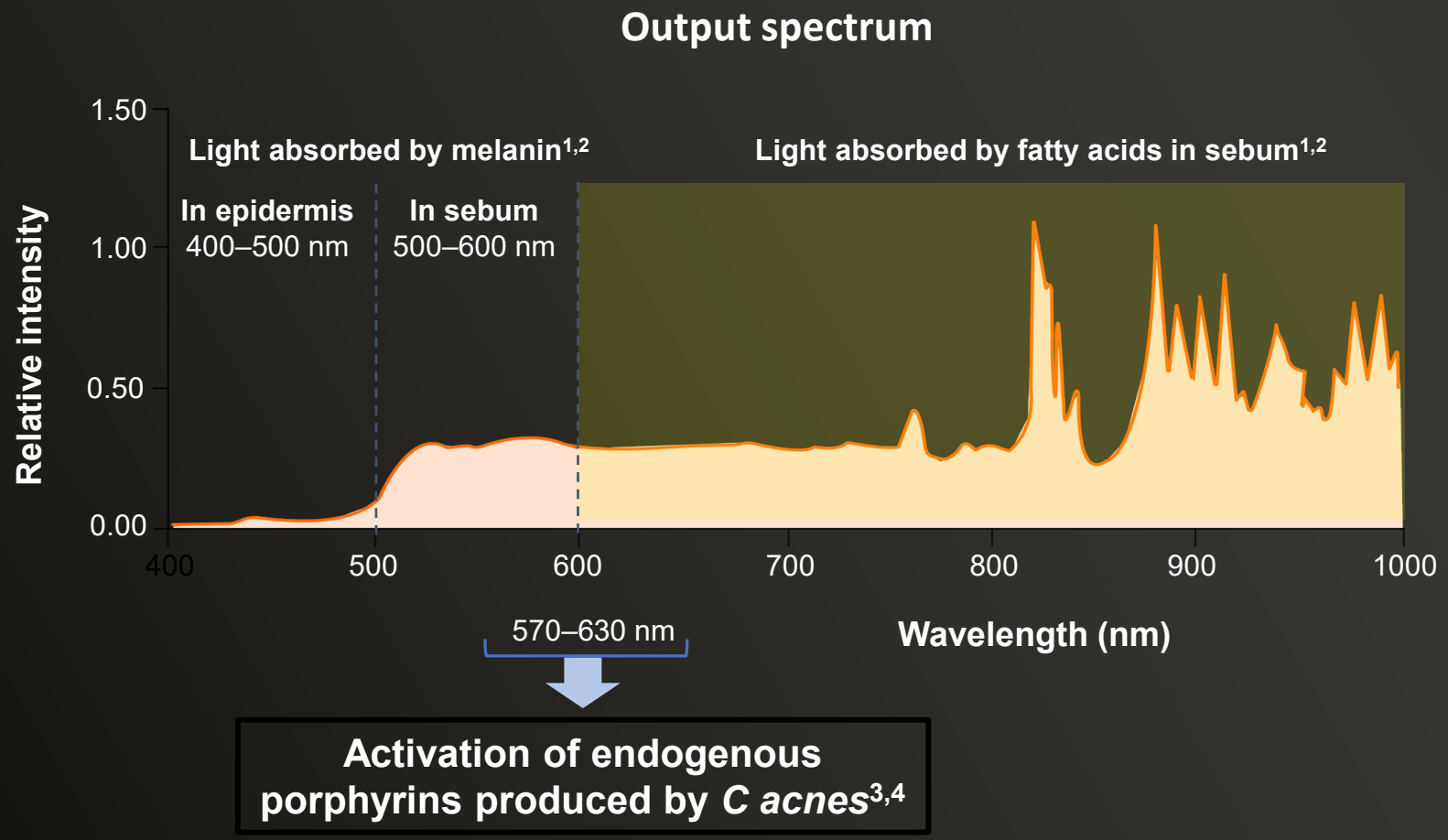
Benefits of Extraction

Extraction enabled by photo-pneumatic technology

- Safely removes occluding material from the infundibulum of the pilosebaceous unit
- Evacuates trapped sebum and necrotic cells
- Removes the breeding ground for *C acnes*
- Leads directly to a reduction in acne lesions
- Is quick with minimal discomfort

- Gold MH, Biron J. *J Drugs Dermatol.* 2008;7(7):639-642.

The Light Spectrum Extends From 500 nm to Over 1200 nm



By filtering the visible wavelengths light from the spectrum (400–500 nm), **absorption by melanin in the epidermis is minimized**, making the treatment safe for most skin types[2]

- 1. Cohen JL, Berlin AL. *The Dermatologist*. 2013;22-23. 2. Data on file. STRATA Skin Sciences. 3. Patwardhan SV et al. *Arch Dermatol Res*. 2017;309:159-167. 4. Omi T et al. *J Cosmet Laser Ther*. 2008;10(1):7_11.

Addresses the Limitations of Acne Therapies

Systemic and topical acne treatments

are often associated with **poor adherence** due to forgetfulness, inconvenience, and adverse effects[1-3]

typically require 3 to 6 weeks to achieve visible improvement[2]

can be associated with skin dryness, irritation, photosensitivity, and bleaching effects[2]

an in-office procedure, thus obviating the need for patient adherence

achieves visible symptom improvement as early as treatment 2[X]

is associated with mild erythema that typically resolves within 30 minutes

- 1. Snyder S et al. *Am J Clin Dermatol*. 2014;15(2):87-94. 2. Ip A et al. *Br J Dermatol*. 2020;183(2):349-356. 3. Ip A et al. *BMJ Open*. 2021;11:3041794. 3. D el Rosso JQ. *Cutis.* 2016;98:21-25. 4. Dréno B et al. *J Cosmet Dermatol.* 2020;19:2201-2211. 4. Hoai XLL et al. *JAAD Int*. 2021;2:109-115. 4. Del Rosso JQ et al. *J Clin Aesthet Dermatol*. 2015;8(1):31-37.

Treatment Process

Treatment regimen

- 4 to 6 in-office treatments, depending on acne severity
- 1 to 2 weeks apart

Procedure

~15 minutes per treatment

No pre-treatment with topical analgesics

Comfortable with no down time

Can be delegated (depending on state laws)

Time to improvement

- Visible improvement of acne lesions **as early as after second treatment**
- Visible improvement of skin texture, pore size, and perilesional erythema **after the first few treatments**

Identifying Patients for Treatment

- **Teenage and adult patients** with mild to moderate acne interested in additional treatment options
- **Interested in enhancing their acne regimen** by adding alternative treatment
- **Looking to "jumpstart"** their acne therapy
- **Potential hesitancy** to using systemic medications

Summary

Addresses multiple pathogenetic factors

- Clears bacteria and follicular contents from pilosebaceous unit[1]
- Directly reduces *C acnes* bacteria[1]
- Reduces sebum production[1]

Offers benefits for patients

- Enhance and expedite improvement from conventional acne treatment regimens, with visible symptom improvement seen as early as treatment 2[1]
- Comfortable, with no pre-medication required

Treatments easily delegated to appropriate office staff

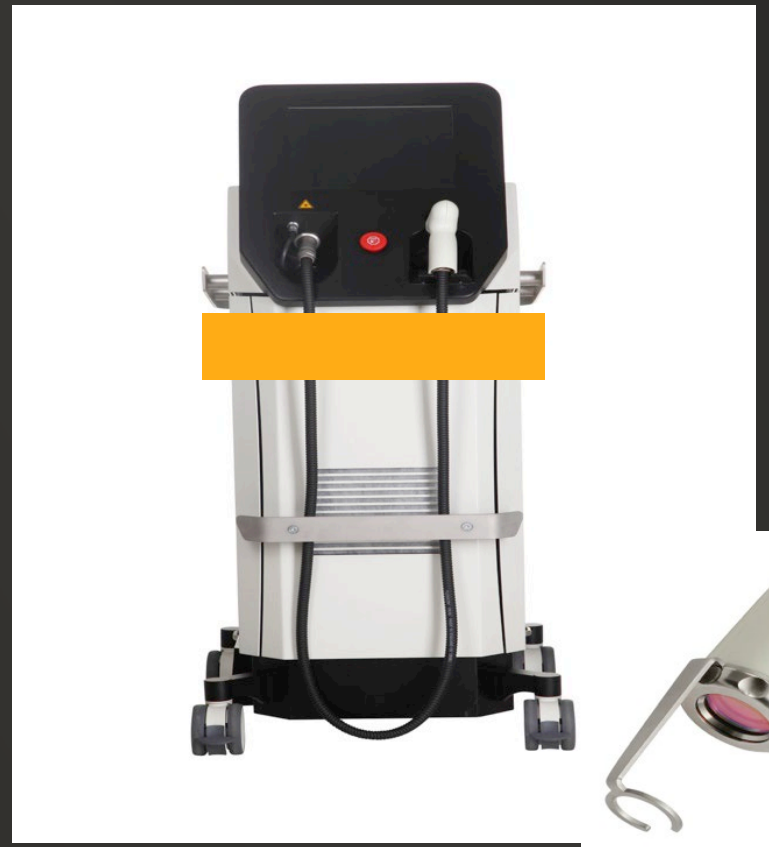
(state laws apply)

- Treatment sessions can be completed in 10–20 minutes
- Treatment providers found the device fast and easy to use

ADVATx

- 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



Treatments – 589nm

- Telangiectasia
- Spider veins, both facial and leg
- Rosacea
- Hemangiomas
- Port wine stains
- Venous lakes
- Red or hypertrophic scars
- Melasma
- Hyper pigmentation
- Skin rejuvenation

Treatments 1319nm

- Skin rejuvenation
- Reduction of acne scars
- Reduction in the appearance of pores
- Mild and moderate inflammatory acne vulgaris

Confidential and Proprietar

Delivery Mechanism

Scanner hand piece delivering either 589 or 1319nm

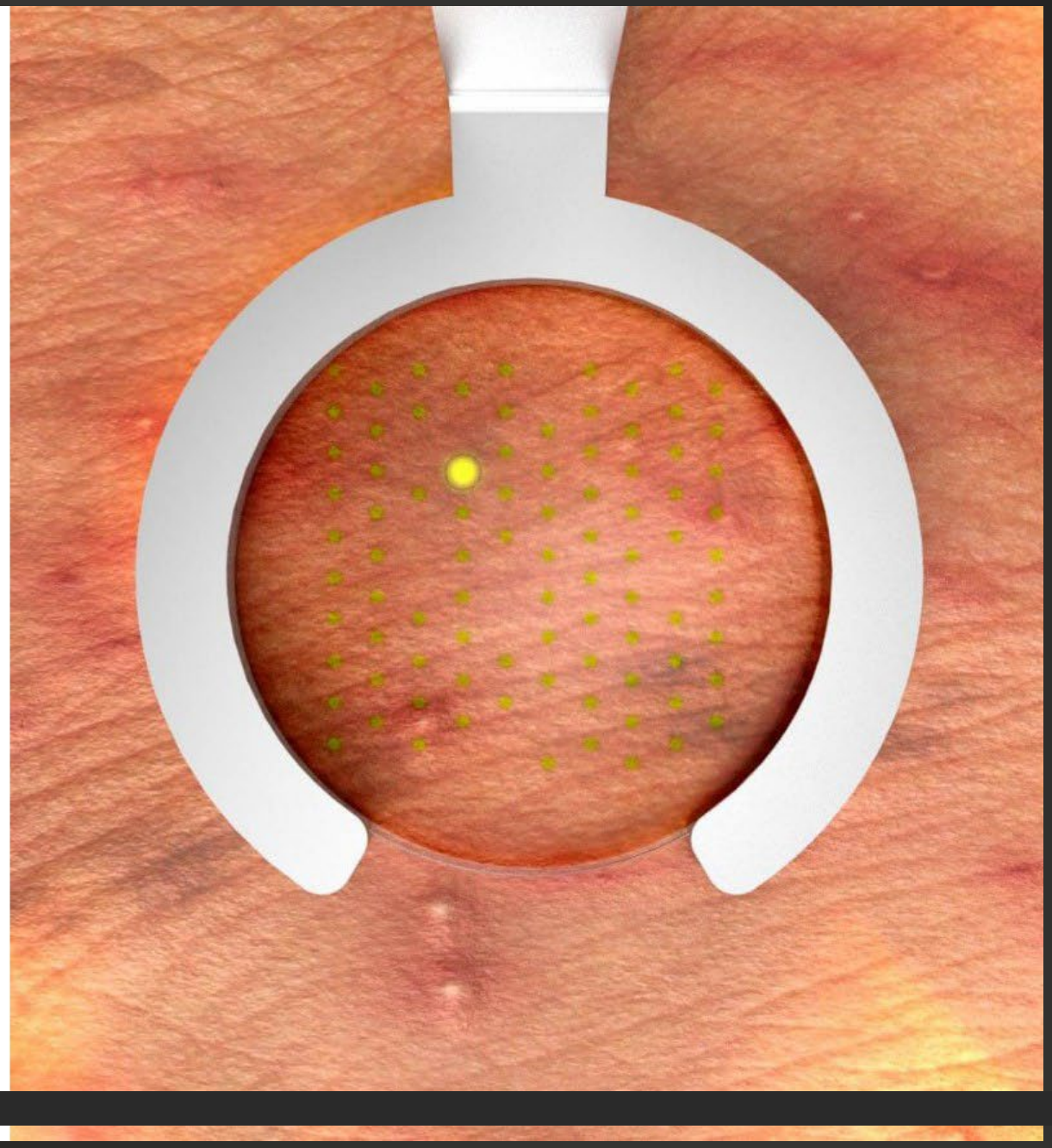
- No need to change hand pieces
- Ergonomic
- Light weight

Multiple patterns/options

- Single Spot 1 mm
- Circle Patterns:enlarged “spot size” to 2 and 3 mm respectively
- Line Patterns –3, 5 and 10
  - Rapid blanching of linear veins
  - “Painting”
- Square Patterns –5x5, 7x7 and 10x10
  - Treating larger areas

Repetition Mode

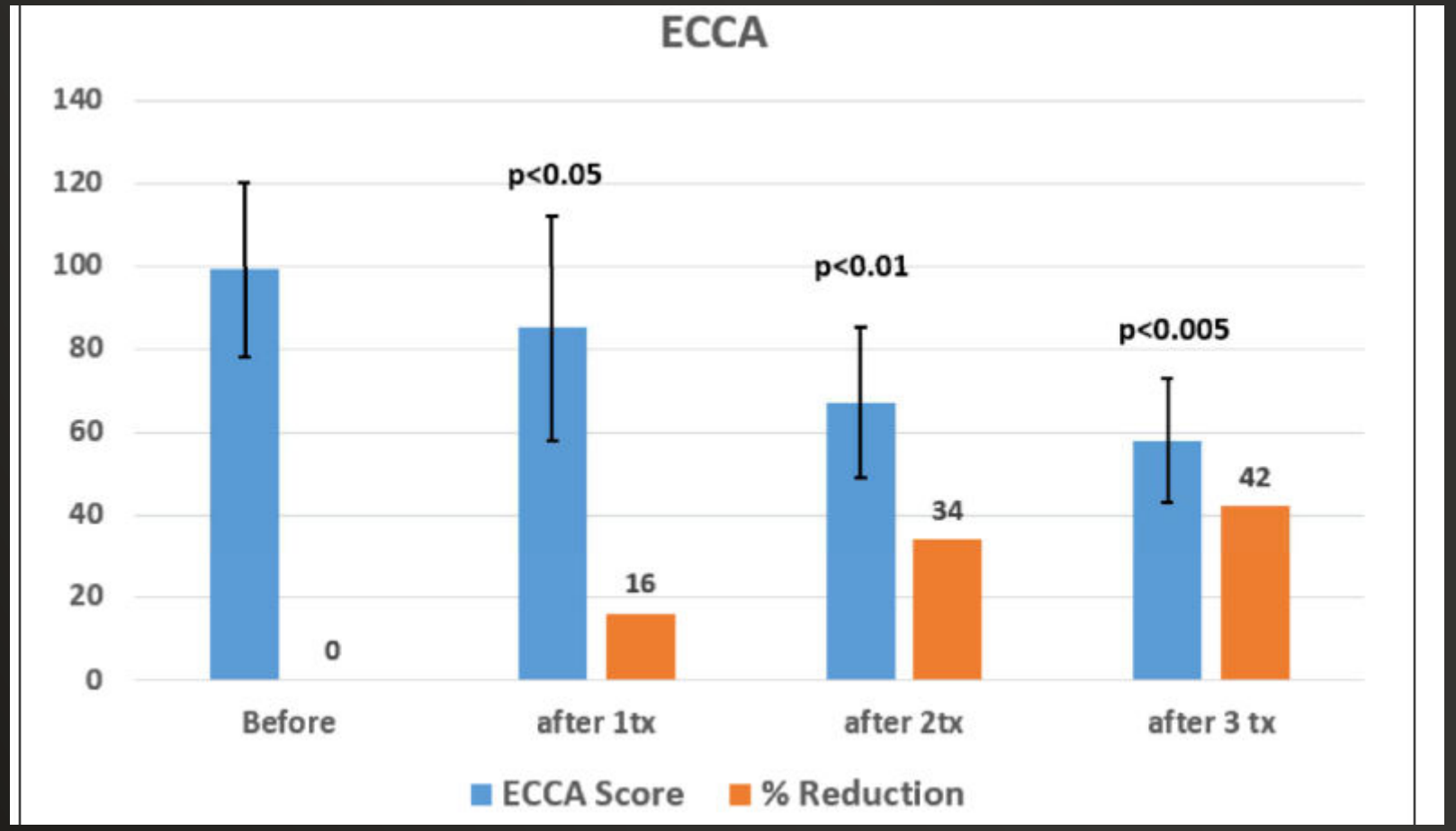
- User defined as Off or every .25 or .50 seconds
- Decreased treatment time



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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Email: serge.mordon@inserm.fr

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

Studies With IR in Acne Vulgaris

TABLE 5. Studies With IR in Acne Vulgaris

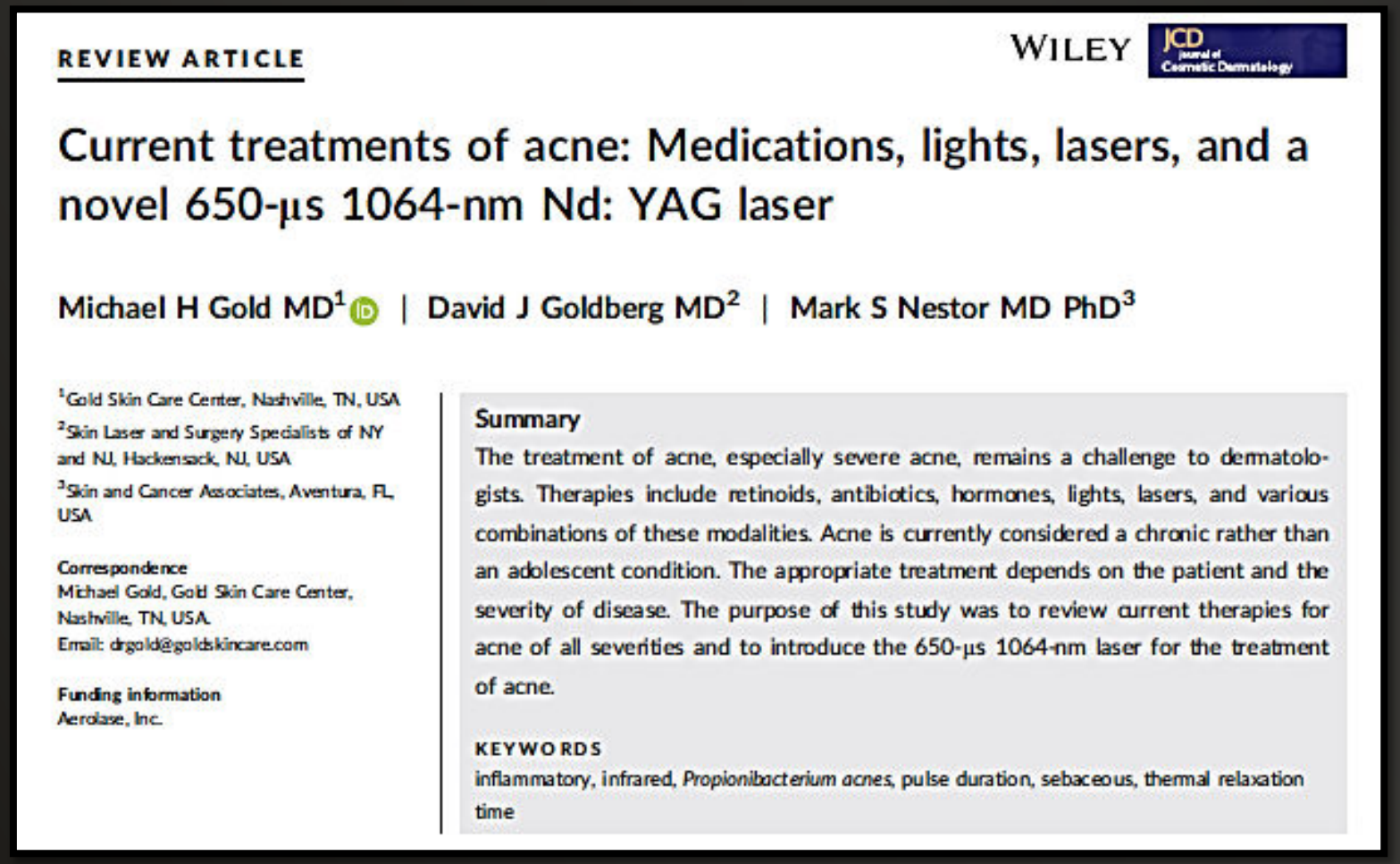
Author of Trial	*Type of Study*	*Device*	*Number of Patients in Study*	*Duration of Treatment*	*% Reduction in Inf or NI*
Aziz-Jalali and colleagues[38]	SBRCT split face	890-nm LLLT +2% topical clindamycin	28	Twice per week for 12 sessions	15 (Inf)
Sadick[47]	OL	830-nm LED + blue LED	11	Two 20-minute sessions per week for 4 weeks	44.2 ± 23.99 (Inf); 48.8 ± 23.99 (NI)
Orringer and colleagues[48]	SBRCT	1320-nm Nd:YAG	37	3 treatments every 3 weeks	0 (Inf); 27 (NI)
Deng and colleagues[49]	OL	1320-nm Nd:YAG	35	Every other week for 12 weeks	51 (Inf); 35 (NI)
Jih and colleagues[50]	OL	1450-nm Nd:YAG	20	Every 3 weeks for total of 3 sessions	70.6 (Inf)
Glaich and colleagues[51]	OL	1450-nm Nd:YAG +595-nm PDL	15	1 session every 4–6 weeks for total of 3 sessions	84 (Inf)

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

The Single Most Versatile Laser in the World. Period.

- 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

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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

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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,

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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 it's kind to be completed:

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

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doi:10.36849/JDD.2020.5108

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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

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JO00620

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

Authors and Disclosures

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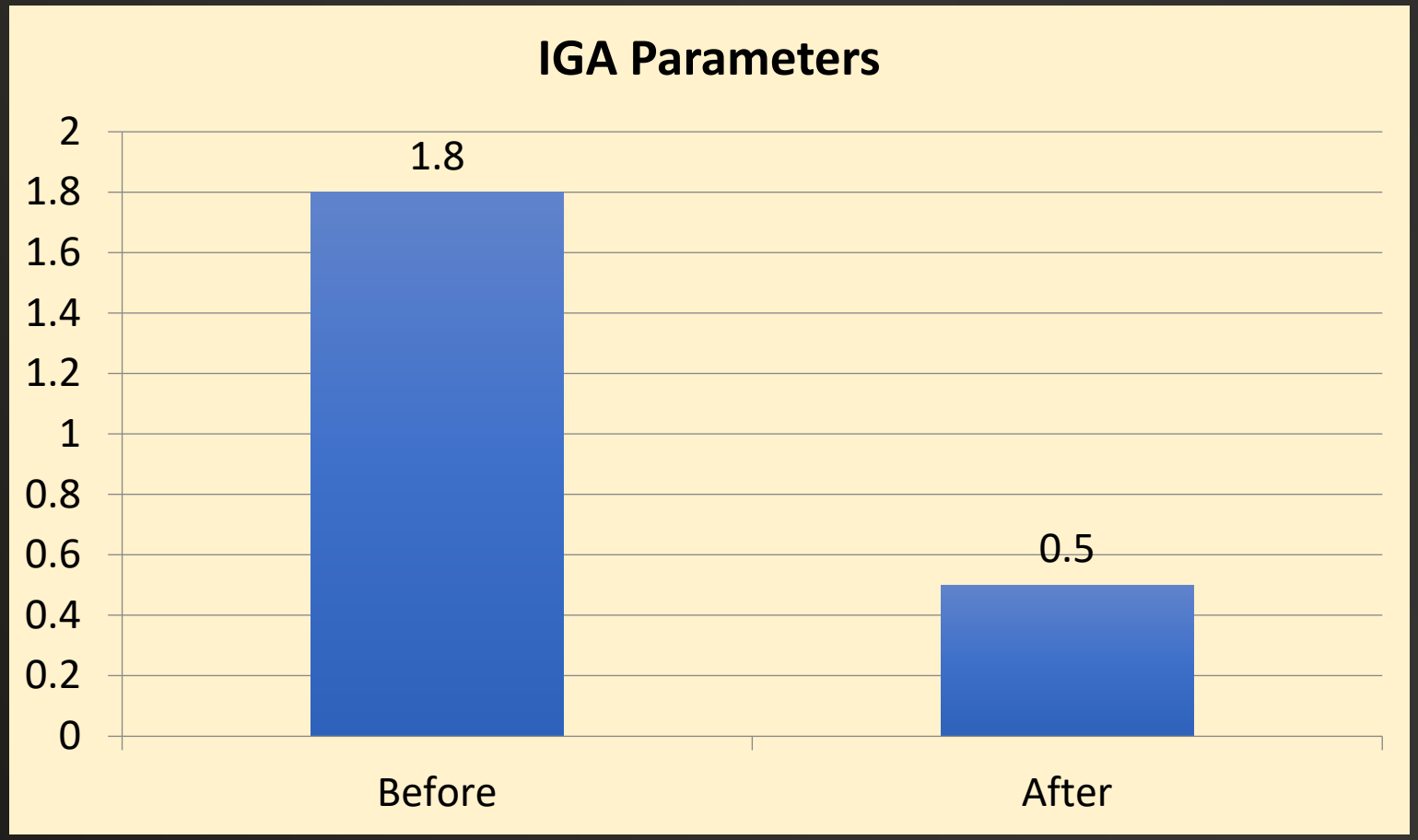
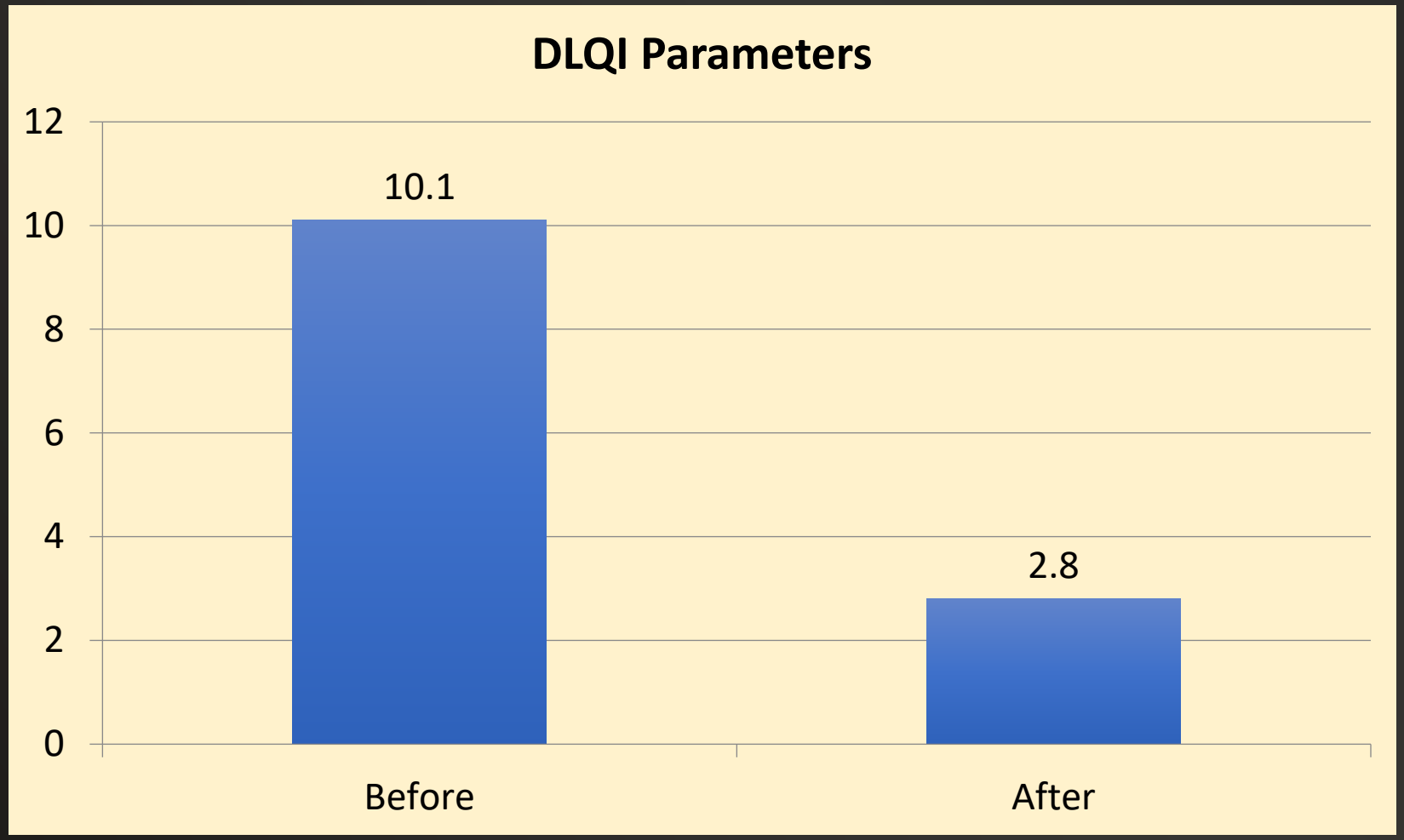
Results: IGA Parameters



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

- Cutera – AvaClear – FDA Approved March, 2022

- Accure – CE Cleared May, 2022

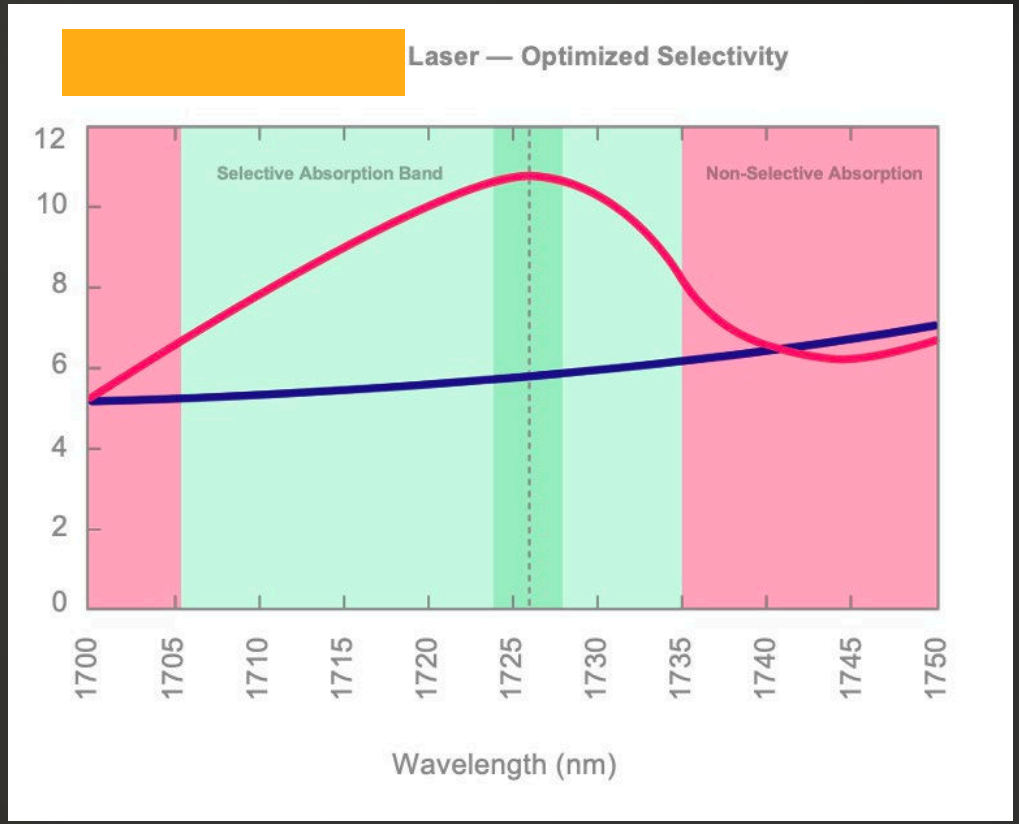
• Key Features

- **1726 nm**
  - Selectively targets sebum with twice the energy absorption of water to destroy sebocytes and suppress sebum production[1]
- **Sapphire cooling technology**
  - Monitors and maintains the temperature of the skin during treatment to increase comfort while sparing the epidermis
- **100W power**
  - Enables the perfect convergence of spot size and pulse duration at the proper wavelength to specifically target the sebaceous glands
- **All skin types and acne severities**
  - Effectively treat all skin types and all acne severities (mild, moderate, severe) with a high safety margin

- Selective Absorption of 1726 nm

- The 1726 nm wavelength is clinically proven to absorb 2x more energy in sebum compared to H2O1

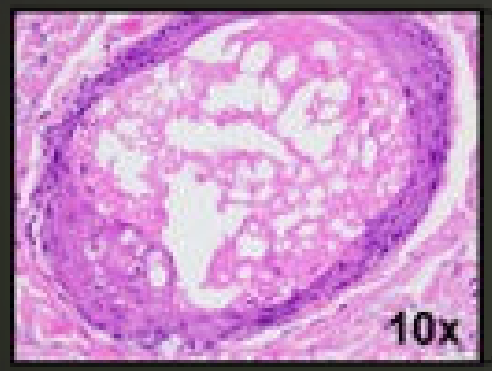
- The 1726 nm wavelength to selectively target and damage sebocytes to suppress s ebum production



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]

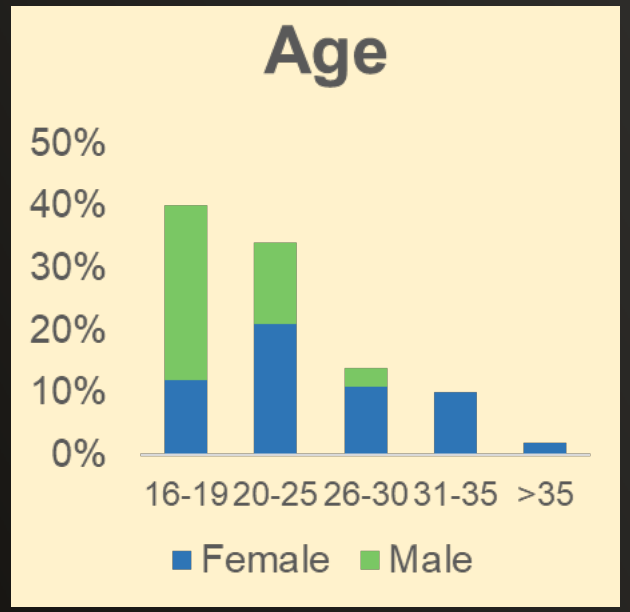
- Healthy sebaceous gland with nucleated sebocytes

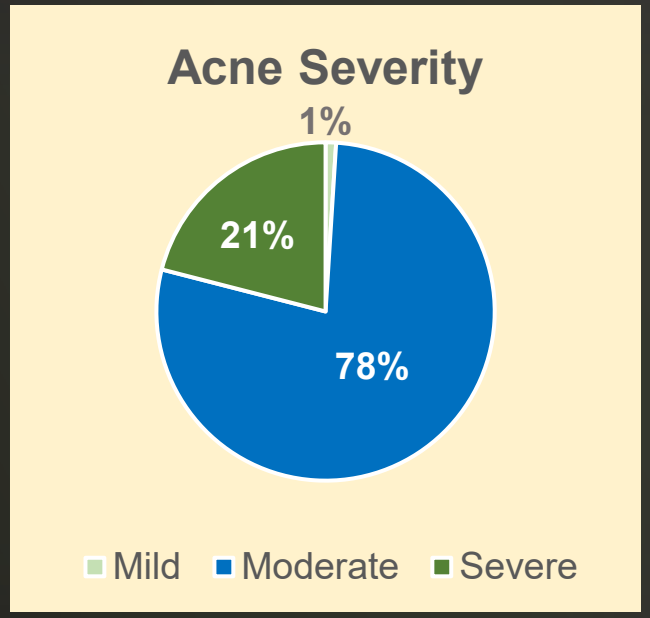


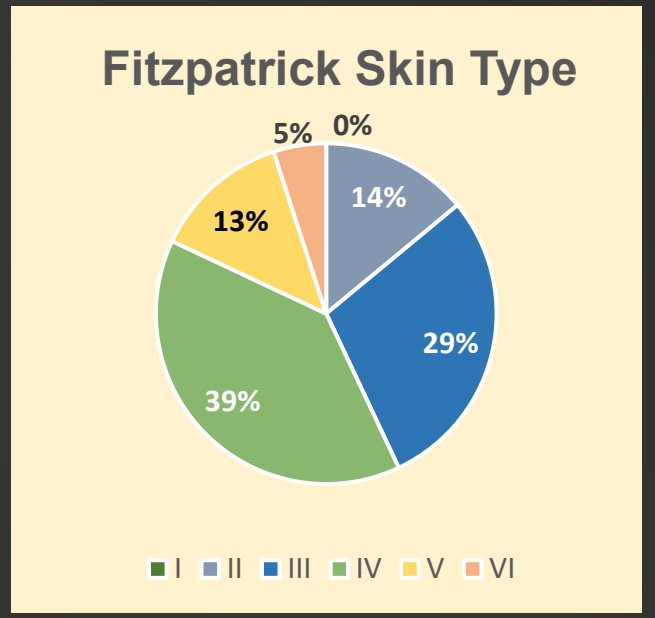
- 5 days post-treatment
- Destroys nucleated sebocytes
- Epidermis remains intact

Pivotal Clinical Study[3]

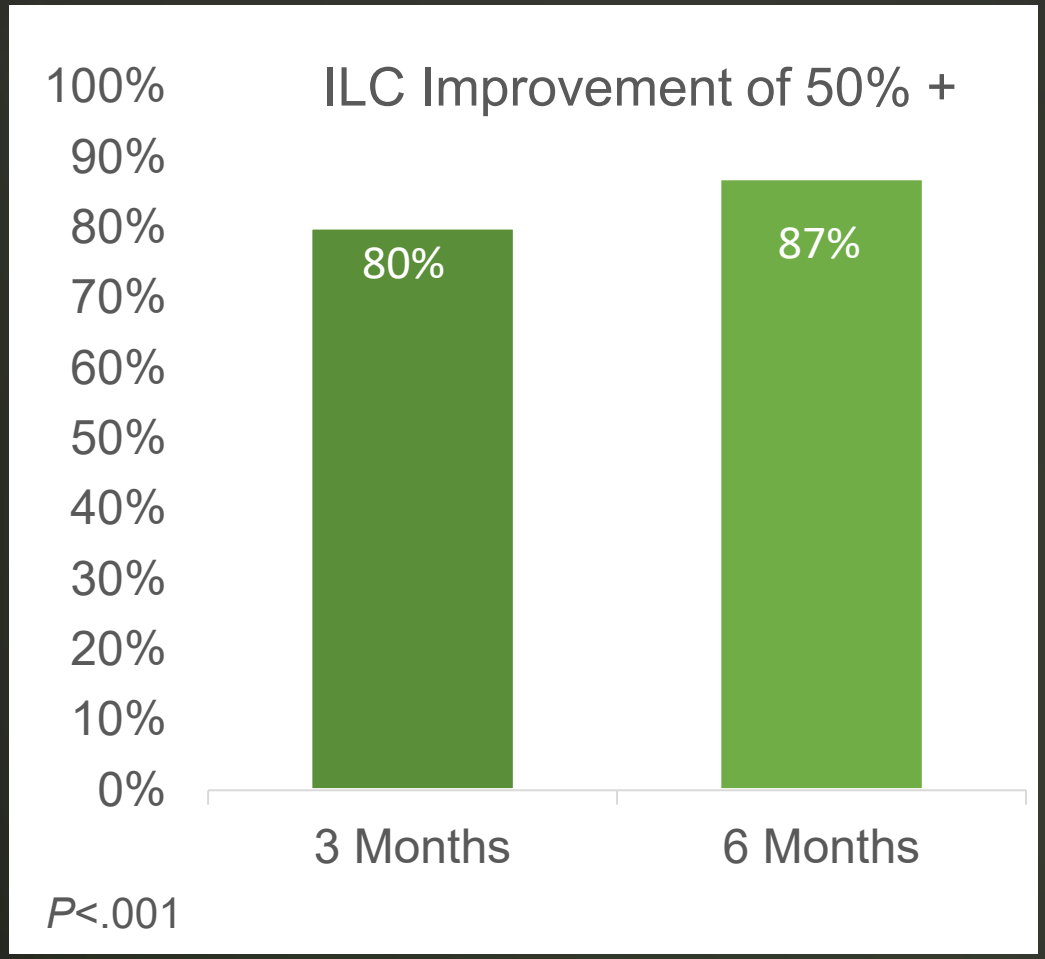
- Non-randomized open label study
- 104 subjects, ≥16 years, with mild to severe acne vulgaris
- Three, 30-minute laser treatments spaced 1 month apart
- Primary endpoint was patients who achieved a 50% reduction in lesion count by 3 months after fin al treatment.
- Post-treatment follow-ups at 1, 3, 6, 12 months after final treatment session





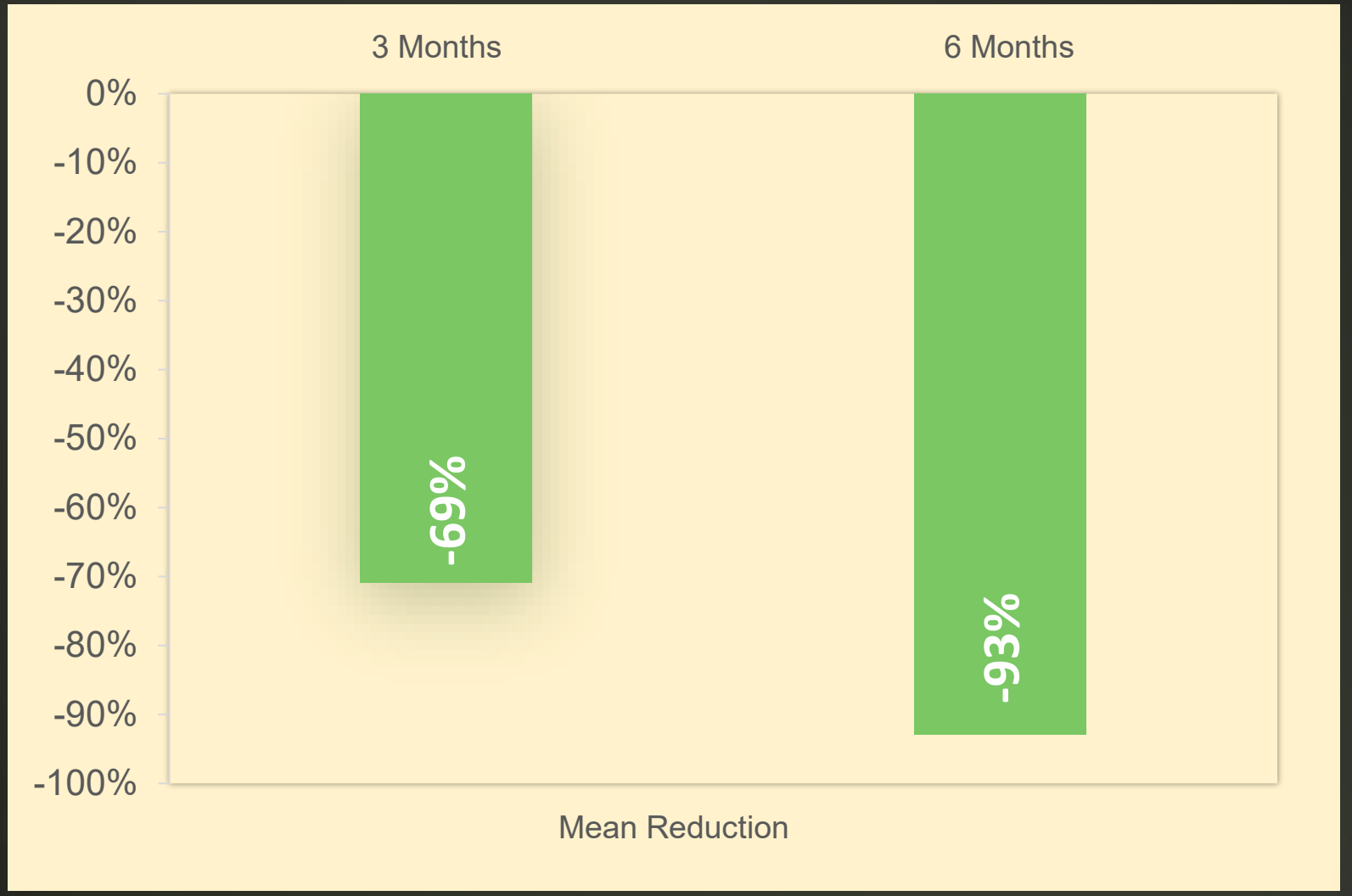


Primary Endpoint and Inflammatory Lesion Reduction[3]

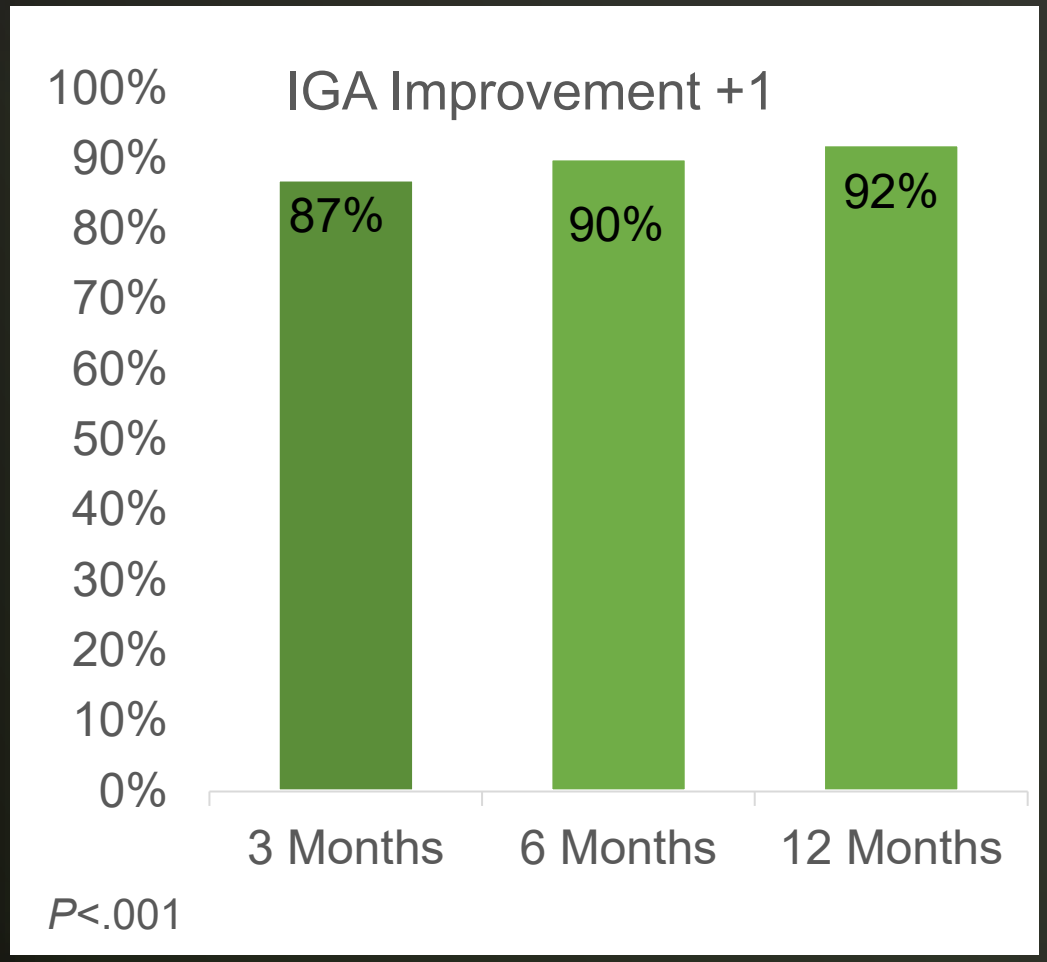


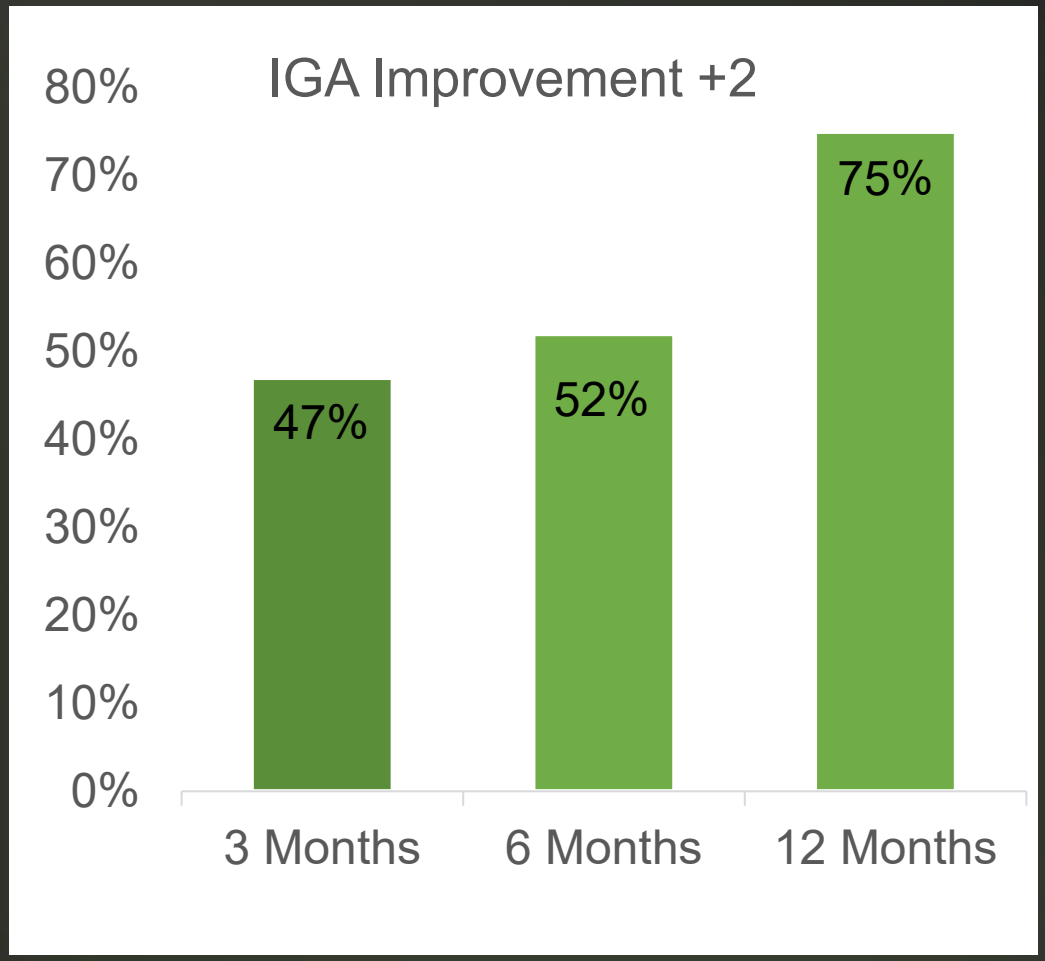
Nodule Reduction[3]

Published studies for isotretinoin report a range of nodule reduction between 67% and 70%.[4]



IGA Improvement at 3, 6 and 12-Months





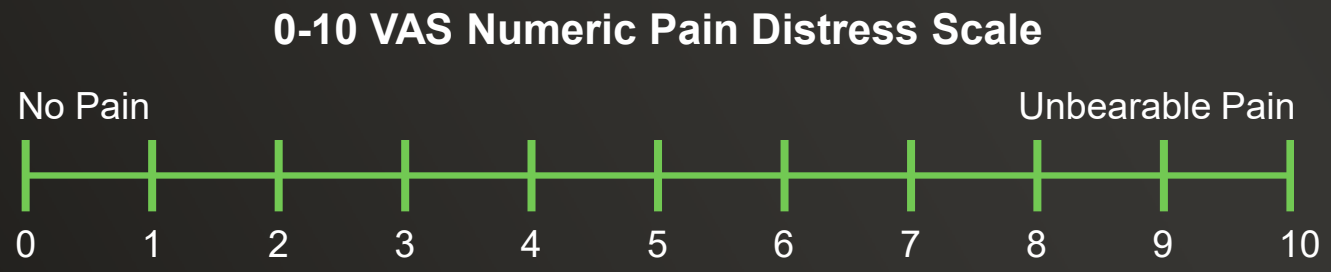
Safety[3]

Erythema and edema typically resolved in about an hour.

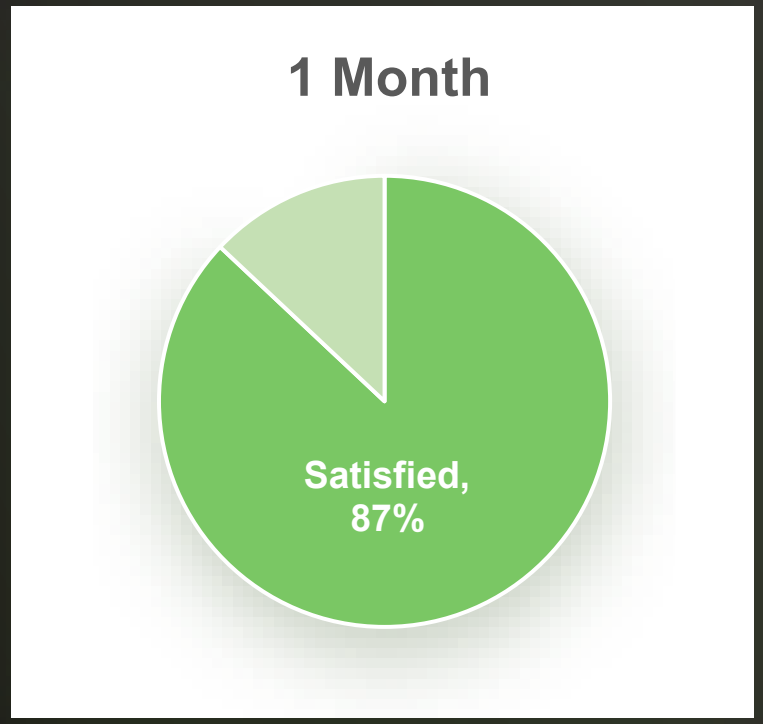
No prolonged effects and no adverse events were seen in clinical studies

MILD SIDE EFFECTS	INCIDENCE (%)
Erythema	100%
Edema	98%
Acne flareups	42%
Dryness	18%
Itchiness	2%

- Comfort[3]
  - **Built-in technology that helps maintain patient comfort and spare the epidermis during treatment.**
  - No topical anesthetic was used
  - Average VAS score during treatment was 3-5 out of 10
  - Described as a slight snapping sensation
  - No discontinuations due to discomfort
  - No pain mitigation was necessary



Patient Satisfaction



Satisfaction was defined as being "satisfied" or "very satisfied" with improvement at one month.[2]

Over 80% of patients reported their skin looking better and smoother 6 mos post treatment

- Key Takeaways

  - **1725 nm destroys sebocytes** while **sparing the epidermis** and keeping treatment **comfortable**.
  - **Energy is delivered with the perfect convergence** of spot size and pulse duration to **reach the se baceous glands** with the right wavelength.
  - Effective and safe across **all acne severities and Fitzpatrick Skin Types**.[2,3]
  - Results **continue to improve** with time.[2]
  - Clinical studies support efficacy and **long-term/durable results**
  - Patient **satisfaction** with treatment was high.[2]

The Accure Story

- **2012** Sakamoto and colleagues reported on the absorption characteristics of sebum and water. They identified a peak at 1726nm where there is a roughly 2 to 1 advantage of sebum to water
- **2019**: reported on the use of a 1726nm fiber laser with robust highly controlled air-cooling and real time temperature monitoring to produce safe and selective sebaceous gland damage
- **2020**: presented data using temperature as end-point that was possible because of the thermal monitoring system. The pilot clinical face and back safety and efficacy data was presented with 80% clearance at 12 weeks and no safety concerns.
- The device is CE Mark certified for the treatment of moderate inflammatory acne

The Solution:

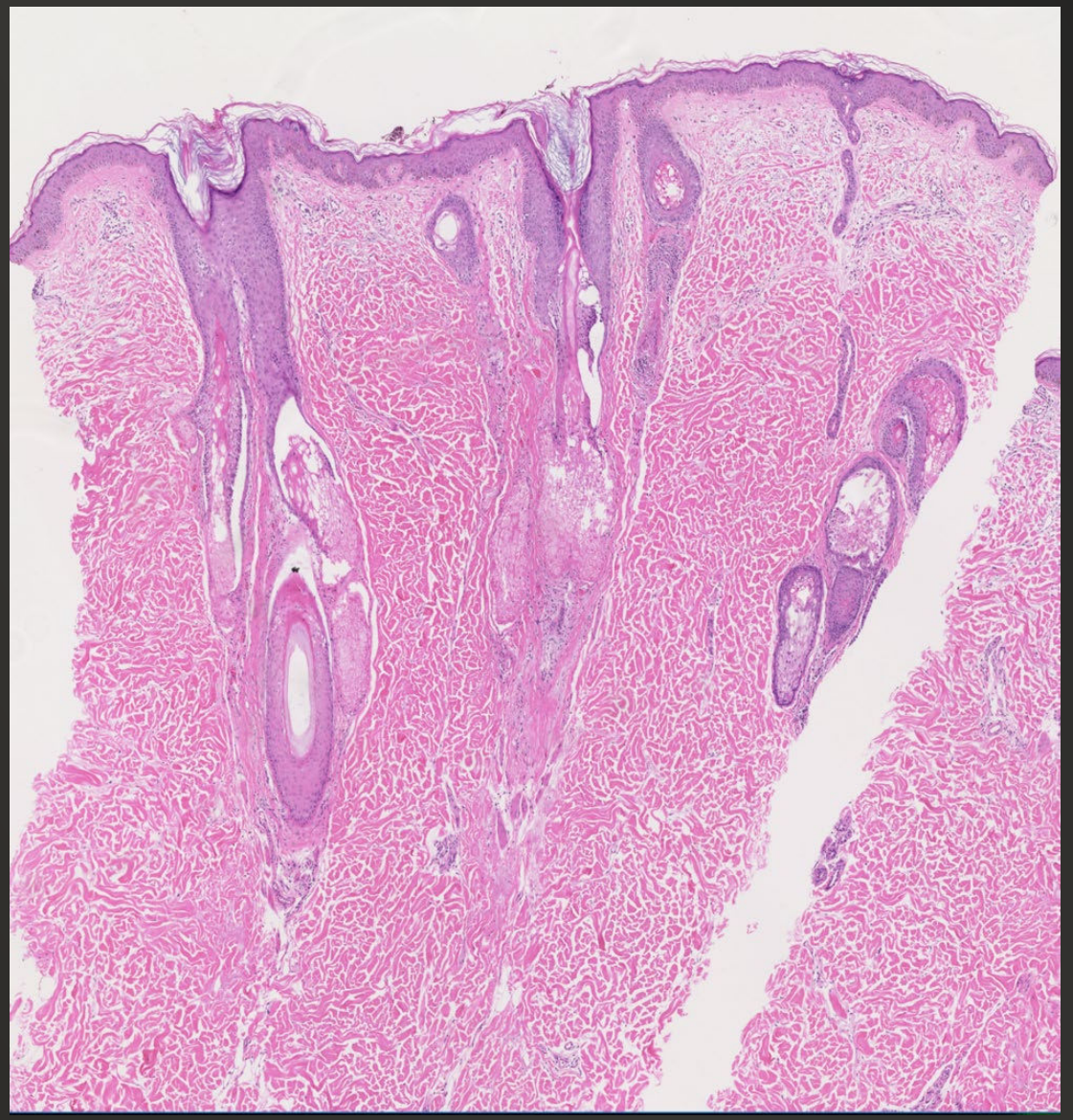
the only 1726nm laser with CE Mark certification for acne

- targets the sebaceous gland, the key to a durable solution

- more than this unique wavelength:
  - unique pulsing strategy
    - integrated temperature monitoring with IR camera
      - precise and safe closed-loop laser control

Histology Results

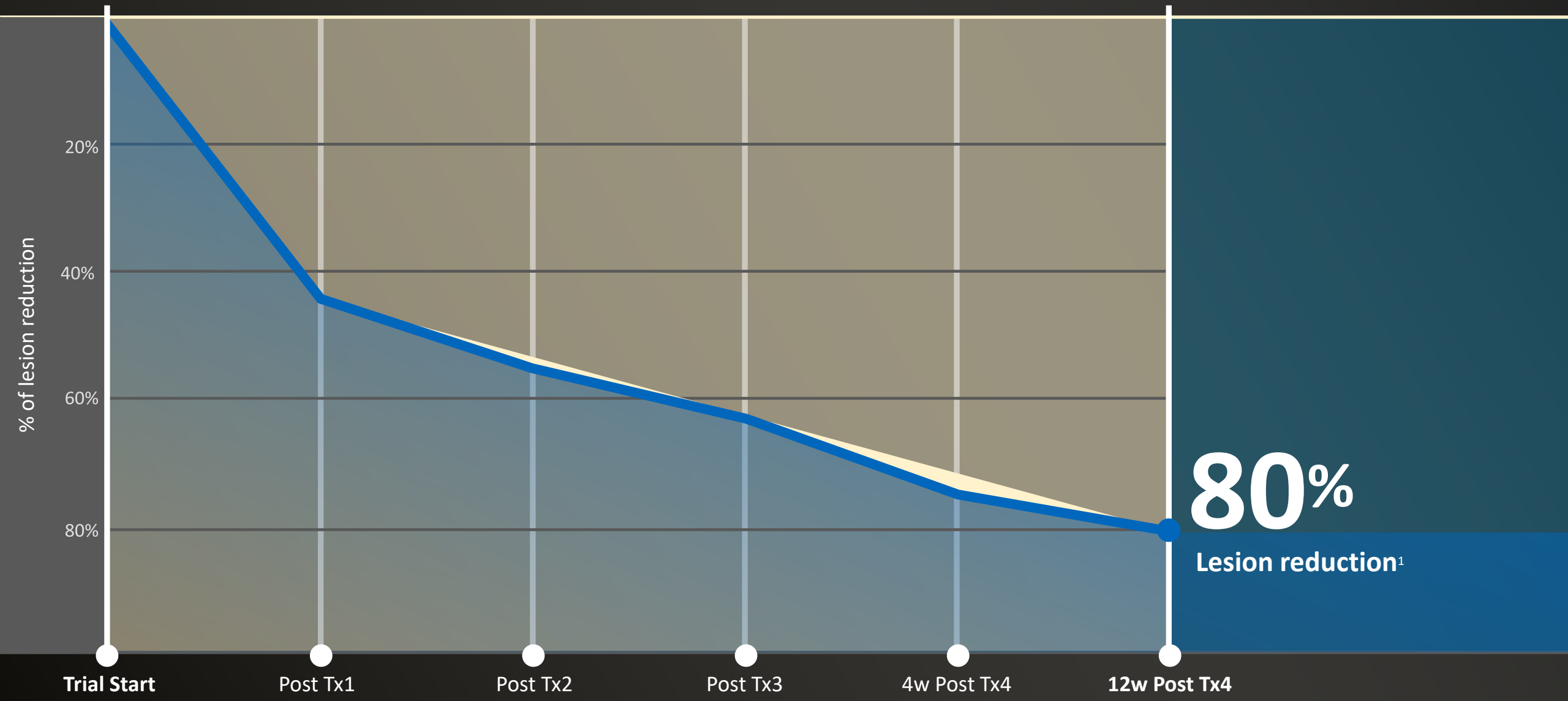
Selective sebaceous gland destruction with no obvious damage to the surrounding dermis, epidermis, or other follicular structures



Subject Back:
24 hrs post treatment

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

IRB-Approved Pilot Clinical Trials: Methods

Protocol

- **19 subjects, Fitzpatrick skin types I-V, aged 16+, were treated under two separate IRB-approved hemi-face trials with untreated side as control.** (focal area and full hemi-face)

- **16/19 subjects** received four treatments spaced ~ 1 month apart and were observed for a follow-up period of 3/6/9/12 months
- **3 subjects** received 2 treatments-trial was suspended due to COVID-19.

- **This was a single-modality treatment** (unless where noted) in which all regimen topicals/procedures were suspended prior to, during, and after the treatment course and follow-up period.

Inclusion/Exclusion Criteria

- **Males or females 16 years of age or older with a minimum of ten inflammatory acne lesions across both treatment and control areas.**

- **Subjects were excluded from study enrollment for use of:** photo-sensitizing medication and systemic steroids; clinically relevant history of keloids or other photosensitive disorders; open wounds or lesions, sunburn, metal stent or implant, or skin malignancy in any intended treatment area; human immunodeficiency virus (HIV), hepatitis B or hepatitis C; serious systemic disease; and pregnancy.

Pain Management

- **All subjects were injected with local lidocaine** to specific treatment area via multi-needle device w/ 3 or 5 prong needle array (i.e. Mesoram®)

- **Subjects reported little-to-no discomfort during and after laser procedure post-injection.** (2/10 VAS scores)

- **Company has developed and is currently testing a needle-free protocol**

Adverse Events and Post-Treatment Observations

- **No unexpected adverse events were observed.**
- **The most common side effects reported were erythema and edema**, resolving within 24-72 hrs post treatment.
- **Some subjects developed papules in the treatment area 24-72 hrs post-treatment** which resolved within 7-10 days with no intervention.

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

Aesthetic Lasers For Med Derm Issues

Introduction

- Psoriasis is an autoimmune inflammatory skin disease that is also associated with increased vascularity
- Treatments include topicals, orals, injectables, light and laser
- For decades, phototherapy (UVB, NB-UVB,PUVA) has been widely used to treat psoriatic lesions, including those on the trunk, scalp, arms and legs, and nails
- More recently a variety of more targeted light sources and lasers including Excimer laser, pulsed dye laser, and Short Pulse 650 µsec YAG Lasers have shown significant promise and success in treating psoriasis

Mechanisms of Action

- Phototherapy with light and laser appears to treat psoriasis by modulating local immune environment of the plaques (NB-UVB may trigger systemic immune modulation), and in the case of vascular lasers also reducing small blood vessels
- Measured immune changes include local down regulation of the Th17 pathway, increase T reg cells and restore T reg function via the up regulation of FOXP3, levels of VEGFR-2,3,and E-selectin protein were reduced, down regulation of TNF-α and IL-23 p19, reduced activated and memory effector Th cells in the dermis and cytotoxic T cells in the epidermis

Zhang P, Wu MX: A clinical review of phototherapy for psoriasis. Lasers Med Sci (2018) 33:173–180.

Issues and Practicalities

- Light Boxes for UVB, NB-UVB and PUVA have been utilized for extensive plaque psoriasis but have limitations:
  - Space in offices
  - Patient compliance
  - Reimbursement
  - Burns and Increased NMSC (PUVA)
- Lasers & EBDs are utilized more and more and have fewer limitations:
  - Small footprint
  - Fewer treatments
  - Better Reimbursement

Zhang P, Wu MX: A clinical review of phototherapy for psoriasis. Lasers Med Sci (2018) 33:173–180.

Lasers for Psoriasis

- Several laser systems have had success for treating psoriasis
- This presentation will cover some of them
- PDL
- Short Pulsed 1064 nm
- Excimer

Lasers for Psoriasis

- PDL is the preferred therapy for most superficial cutaneous vascular lesions

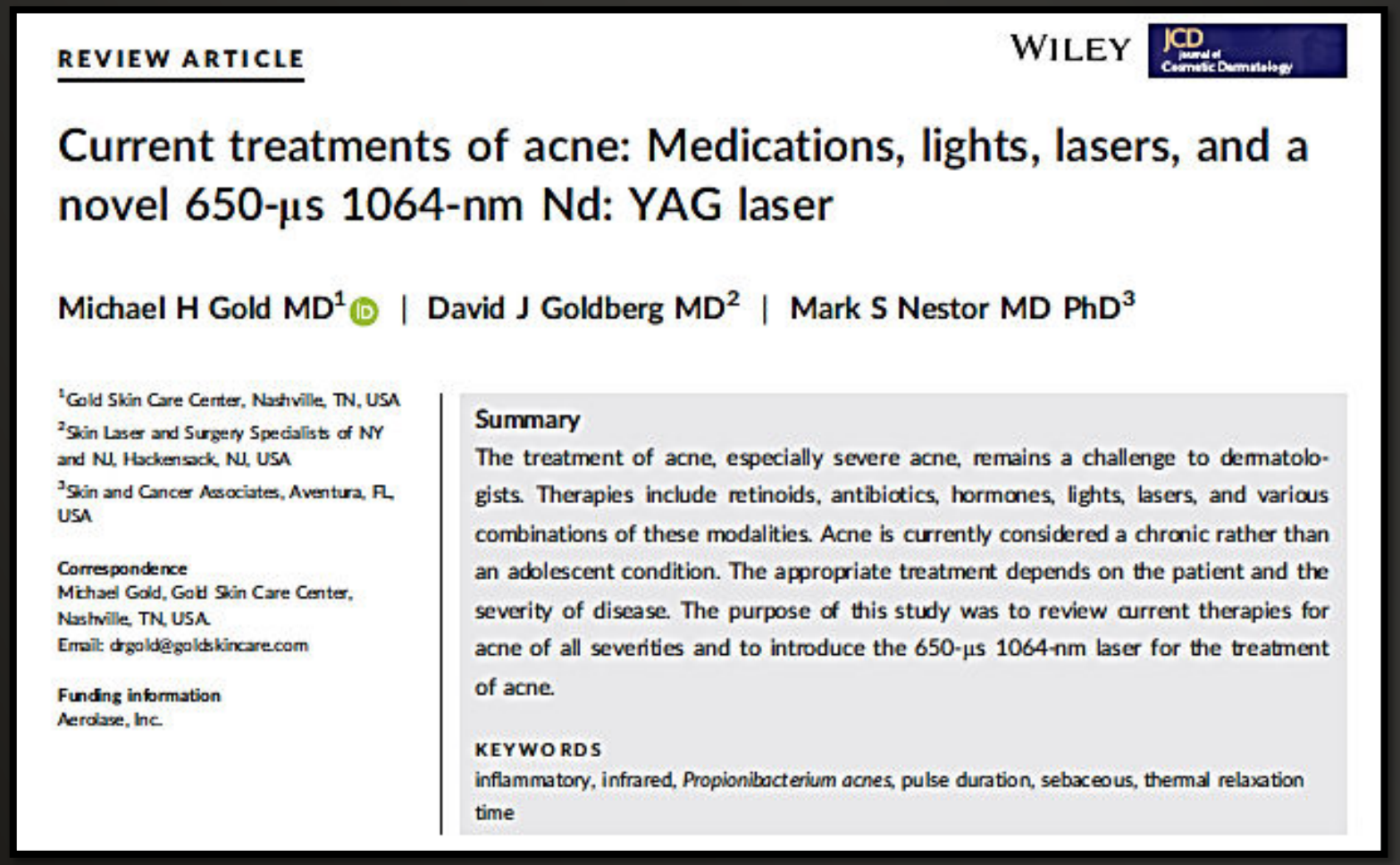
- It has been used in some clinical researches to treat non-vascular indications, such as psoriasis, acne vulgaris, papulopustular rosacea, hypertrophic scar (*Karsai S, Roos S, Hammes S, Raulin C J Eur Acad Dermatol Venereol. 2007 Aug; 21(7):877-90.)*

- Erceg et al. have reviewed the efficacy of PDL for inflammatory skin disease and concluded that PDL is an effective and safe method to treat localized plaque psoriasis (*Erceg A, de Jong EM, van de Kerkhof PC, Seyger MM J Am Acad Dermatol. 2013 Oct; 69(4):609-615.e8.)*

- A prospective randomized controlled study was performed to compare the efficacy of PDL with UVB-TL01 in plaque psoriasis. PDL parameters used were 585 nm, a pulse duration of 0.45 ms, and a spot size of 7 mm with spot overlapping about 20% at fluencies 5.5–6.5 J/cm^2 for a total of four treatments at an interval of 3 weeks between two treatments. Improvement of psoriasis lesions was noted at the 13th week, yet with no significant differences between PDL and UVB (*De Leeuw J, Van Lingen RG, Both H, Tank B, Nijsten T, Martino Neumann HA Dermatol Surg. 2009 Jan; 35(1):80-91.)*

- 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

Michael H Gold MD[1] | David J Goldberg MD[2] | Mark S Nestor MD PhD[3]

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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

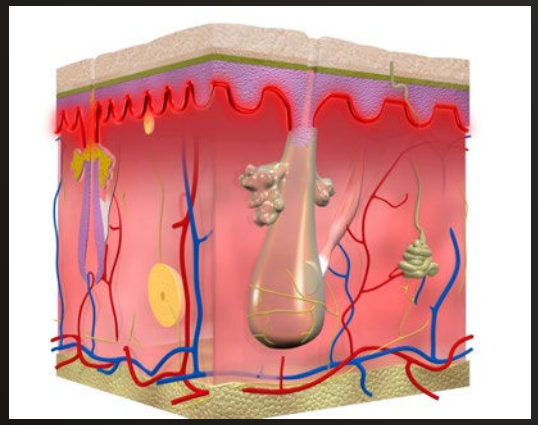
650-Microsecond 1064 YAG

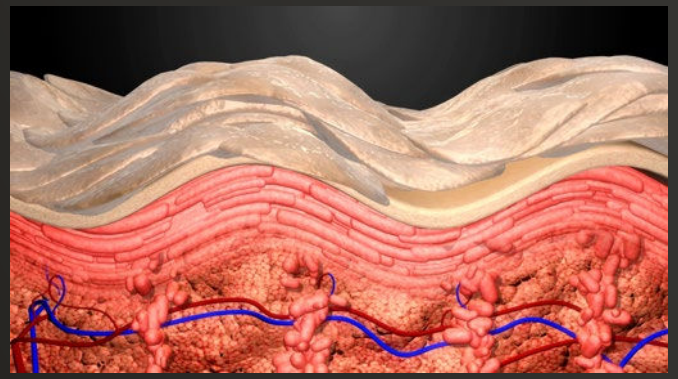
- Long pulse 1064 YAG has activity for inflammatory conditions including nail psoriasis but has limitations and is painful
- 650-Microsecond 1064 YAG has unique attributes due to its short energy burst including:
  - Decreased discomfort
  - Treatment of all skin types
  - High fluence delivery occurs below ‘burning’ threshold
  - Immune modulation
- Effective for multiple inflammatory conditions including acne, rosacea and psoriasis

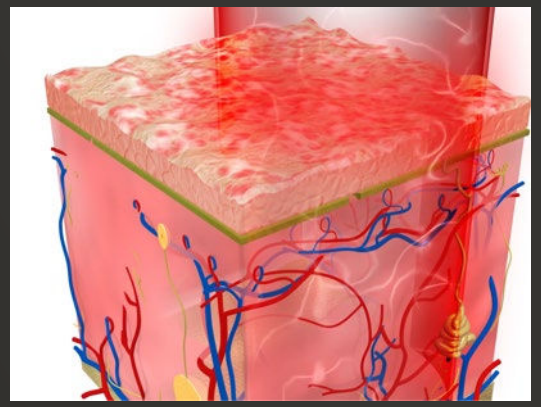
Gold M, Goldberg DJ, Nestor MS. Current treatments of acne: Medications, lights, lasers, and a novel 650-µs 1064-nm Nd: YAG laser. J Cosmet Dermatol. 2017;16:303–318.

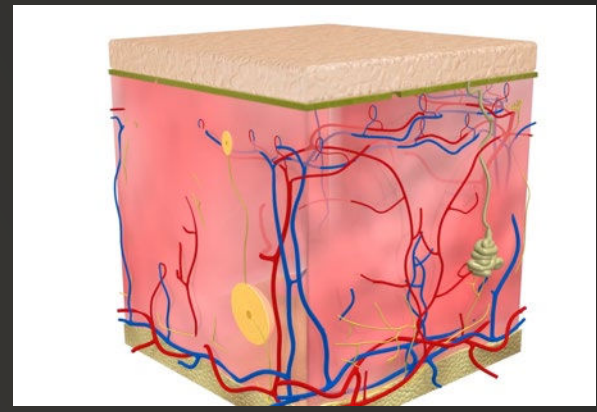
N[redacted]microsecond Technology
Mechanism of Action for Psoriasis

Suppressing inflammatory response that feeds angiogenesis and microvasculature









In psoriasis, the skin thickens with plaque as inflammation speeds up cell growth. Dermal vessels also become inflamed and widen.

The laser energy deeply penetrates through the plaque to suppress inflammation and clear the microvasculature network aiding plaque growth to quickly help skin return to normal.

“A Randomized, Investigator-Blinded Study to Evaluate the Efficacy and Tolerance of a 650 Microsecond, 1064 nm YAG Laser vs. a 308 nm Excimer Laser in the Treatment of Psoriatic Plaques Located on the Trunks/Limbs of Subjects with Mild to Moderate Psoriasis Vulgaris”

Mark Steven Nestor, MD, PhD

SCA Dermatology
Center for Clinical and Cosmetic Research
Aventura, FL
Department of Dermatology and Cutaneous Surgery
Department of Surgery, Division of Plastic Surgery
University of Miami, Miller School of Medicine

Psoriasis Clinical Study

Primary Objective:
To compare the efficacy and clearance of a 650 microsecond, 1064 nanometer, pulsed YAG laser against a 308 nm excimer laser in the treatment of psoriatic plaques located on trunks/limbs of subjects with mild to moderate psoriasis vulgaris

Secondary Objective:
To compare the tolerance and safety of a 650 microsecond, 1064 nanometer, pulsed YAG laser against a 308 nm excimer laser in the treatment of psoriatic plaques located on trunks/limbs of subjects with mild to moderate psoriasis vulgaris

Psoriasis Clinical Study

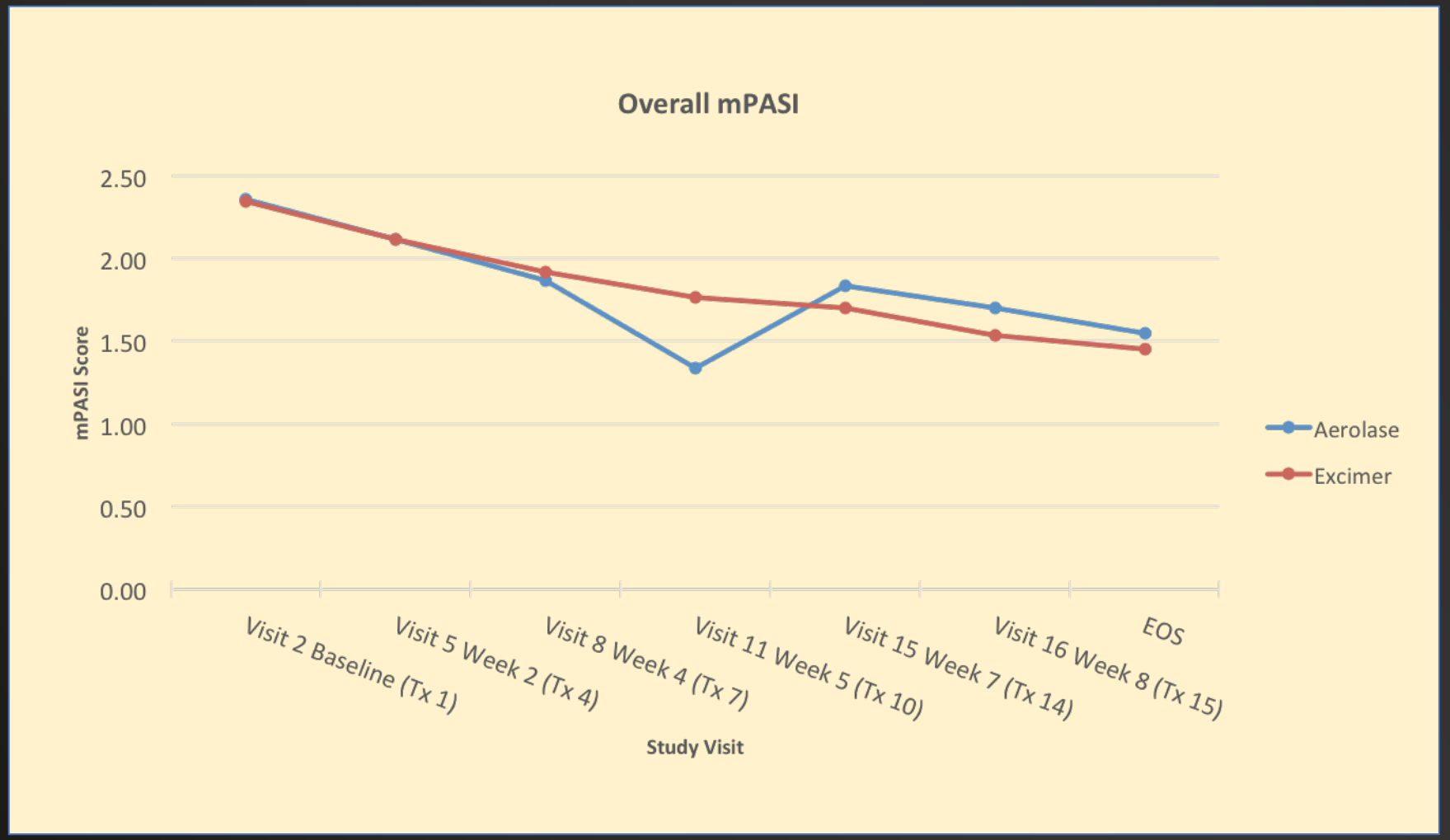
- Randomized, investigator-blinded

  15 subjects that present with mild to moderate psoriasis vulgaris.

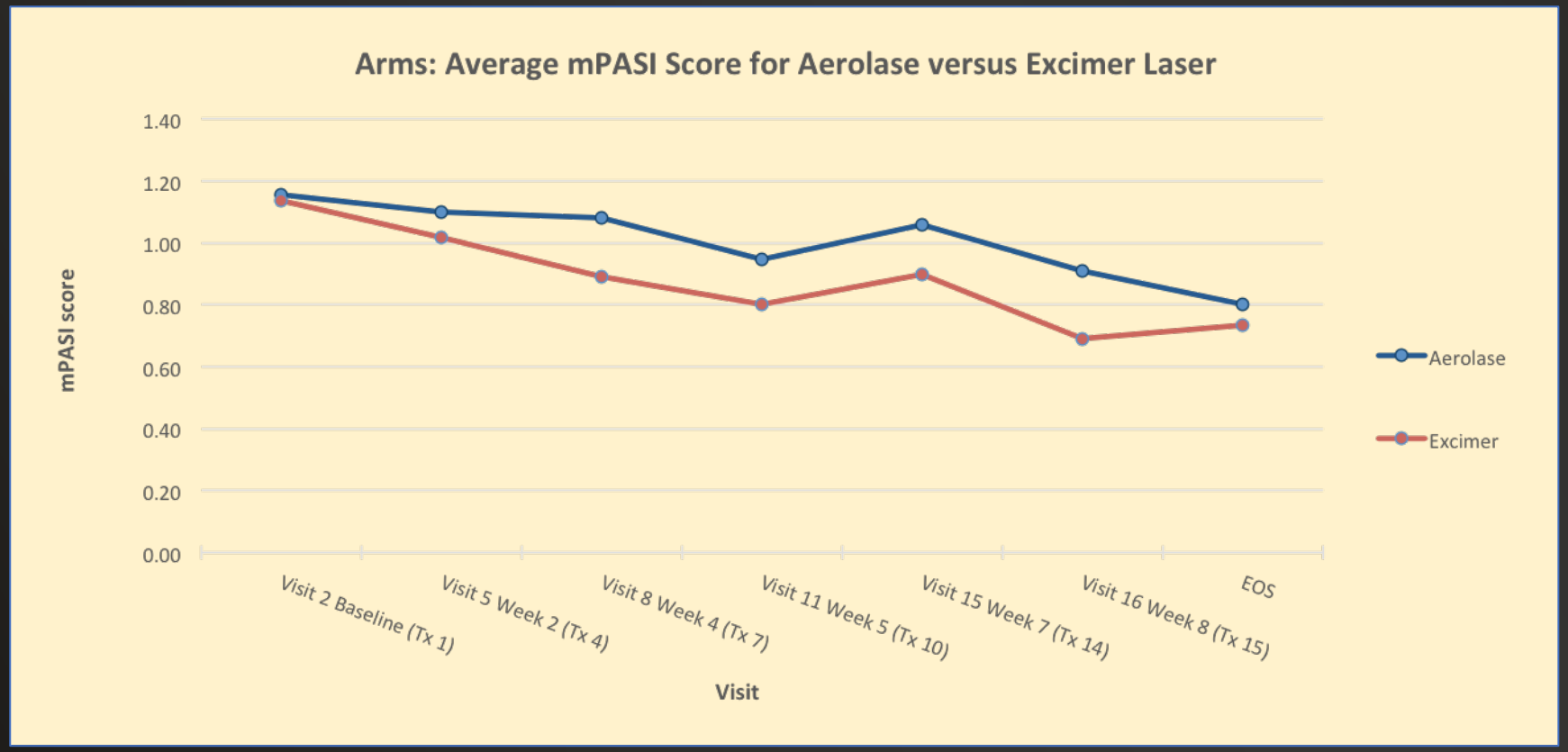
  A subject will be randomized to receive the 650 microsecond, 1064 nm YAG laser and the 308 nm excimer laser treatments on psoriatic plaques located on either the right or left side of the sagittal axis of the body.

  Maximum of 15 treatment visits in which treatment is administered (or until full clearance is observed). Treatment visits will occur twice per week +/- 2 days (excluding weekends) for a maximum of 8 weeks

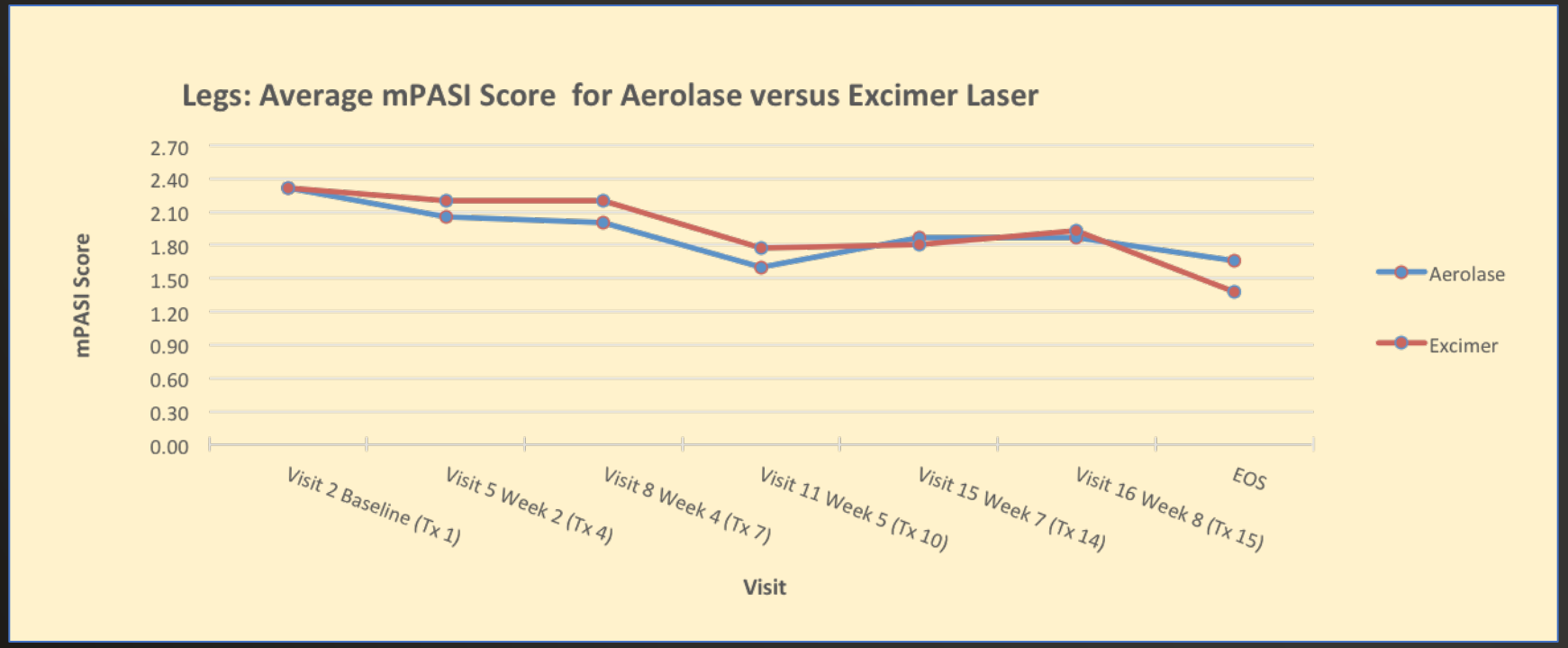
Psoriasis Clinical Study Results



Psoriasis Clinical Study Results



Psoriasis Clinical Study Results



Psoriasis Clinical Study
Results

- **LSR**: No Significant differences between treatments. Minor scaling is the most common LSR

  VAS: Aerolase had higher VAS scores but both were very tolerable

Psoriasis Clinical Study
Conclusions

- Over the course of 8 weeks, both the Aerolase YAG laser and the Excimer laser significantly reduced the appearance of psoriatic plaques when assessed by investigator rated mPASI scores.

  There was no statistically significant difference in efficacy and clearance between the Aerolase YAG laser and the Excimer laser in the treatment of psoriatic plaques located on the limbs of subjects with mild-to-moderate psoriasis vulgaris.

  When assessing safety there were no AE's or SAEs reported throughout the length of the study. Furthermore, all patients who completed the study on week 8 had an objective local skin reaction assessment of 0.

doi:10.36849/JDD.2020.4769

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Randomized, Investigator-Blinded Study to Compare the Efficacy and Tolerance of a 650-microsecond, 1064-nm YAG Laser to a 308-nm Excimer Laser for the Treatment of Mild to Moderate Psoriasis Vulgaris

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[a]Center for Clinical and Cosmetic Research, Aventura, FL

[b]Department of Dermatology and Cutaneous Surgery, Department of Surgery, Division of Plastic Surgery, University of Miami Miller School of Medicine, Miami, FL

ABSTRACT

Background: Phototherapy is a safe and effective modality for the treatment of mild to moderate psoriasis.

Objectives: To compare the efficacy and safety of the 650-microsecond, 1064-nm pulsed YAG laser with the excimer laser for the treatment of mild to moderate psoriasis vulgaris of the arms and legs.

Methods: Eligible subjects (n=15) aged 54.3 ± 11.7 years enrolled in a randomized, investigator-blinded study. Psoriatic plaques on one side of the body were treated with the 650-microsecond laser and plaques on the other side were treated with the 308-nm excimer laser. Subjects made up to 15 visits, twice weekly, or fewer if full clearance was achieved. Efficacy and tolerance were evaluated by the mPASI scores and local skin reactions, respectively.

Results: Both devices showed efficacy in treating psoriatic plaques. Differences between the two devices were not significant for redness, thickness, scaliness, mPASI scores for arms and legs, and overall mPASI scores for the treated psoriatic plaques on each side of the body. The investigator-assessed scores for erosion/ulceration, vesicles, erythema, scaling, edema, and atrophy were low and identical for both sides of the body.

Conclusion: The efficacy and tolerance of the 650-microsecond laser is equivalent to that of the excimer laser for the treatment of mild to moderate psoriasis vulgaris of the arms and legs.

J Drugs Dermatol. 2020;19(2)176-183. doi:10.36849/JDD.2020.4769

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INTRODUCTION

Current options for the treatment of psoriasis include systemic and topical modalities. Systemic therapies include immune inhibitors, immune modulators and, for moderate to severe disease, biological agents.[1] Primarily, for mild to moderate psoriasis, topical treatments comprise ointments, medicated bath with diastase or herbal extracts, and phototherapy. Phototherapy is safe, effective, and does not incur the side effects of systemic medications.[2]

The 308-nm excimer laser is considered first-line phototherapy for topical plaque psoriasis.[2] The efficacy and safety of this laser has been extensively evaluated for the treatment of psoriasis.[3-9] The advantage of the excimer laser is its ability to treat psoriatic lesions with high doses of monochromatic radiation while sparing unaffected skin.[2] Three protocols have been developed to optimize treatment: the minimal erythema dose, the induration, and the minimal blistering dose.[7]

A novel 650-microsecond 1064-nm Nd: YAG laser was introduced in 2009 by Khatri and colleagues who used the laser to remove unwanted hair.[10] Since then, other investigators have used the 650-microsecond laser to treat skin of color,[11,12] onychomycosis,[13] facial telangiectasias,[14] and acne.[15] The advantage of the 650-microsecond laser is that treatment does not require cooling or anesthesia because the pulse duration is shorter than or equal to the thermal relaxation time of the therapeutic target. This feature minimizes scarring, pigmentary changes, thermal damage to surrounding tissues, and discomfort during or after treatment.[15] The 650-microsecond laser has received FDA approval for the treatment of psoriasis.

The primary objective of this study was to compare the ability of the 650-microsecond, 1064-nm pulsed YAG laser (LightPod Neo®, Aerolase Corp., Tarrytown, NY) to clear psoriatic plaques with that of the 308-nm excimer laser (XTRAC Velocity 400®, PhotoMedex, Inc., Montgomeryville, PA). Plaques were located on the limbs of subjects with mild-to-moderate psoriasis vulgaris.

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RESULTS

Efficacy and tolerability equivalent to excimer laser for mild to moderate psoriasis of the arms and legs

Nestor MS, Fischer D, Arnold D. Randomized,investigator-blinded study to compare the efficacy and tolerance of a 650-microsecond, 1064-nm YAG laser to a 308-nm excimer laser for the treatment of mild to moderate psoriasis vulgaris. J Drugs Dermatol. 2020;19(2):176-183.

lasers which were tried for treatment of psoriasis. As a result, it affects both superficial and deep plaque vasculature, yet is gentler to the skin with a substantially reduced risk of bruising as compared to pulsed-dye lasers.

As proven in the recent study, the Neo Elite and excimer lasers are equivalent in terms of efficacy. When we compared the efficacy and clearance of the Neo Elite with a 308nm excimer laser in the treatment of psoriatic plaques on trunks/limbs of subjects with mild to moderate psoriasis vulgaris, both treatments were also equally effective. In our study, patients underwent a maximum of 15 treatments or until full clearance was observed. Treatment visits occurred twice per week +/- 2 days (excluding weekends) for a maximum of eight weeks.

During the course of the eight weeks, both the Neo Elite laser and the Xtrac Excimer laser reduced the appearance of psoriatic plaques when assessed by investigator-rated modified Psoriasis Area and Severity Index (mPASI) scores. There was no statistically significant difference in efficacy and clearance between the Aerolase Neo Elite laser and the Xtrac Excimer laser in the treatment of psoriatic plaques located on the limbs of subjects with mild-to-moderate psoriasis vulgaris.

No adverse events (AEs) and serious adverse events (SAEs) were reported throughout the length of the study. Subjects' discomfort sensation during treatment with the 650microsecond laser was slightly higher but did not appear to be clinically significant. Differences between the 650microsecond and excimer lasers were not significant for redness, thickness, scaliness, overall mPASI scores (arms and legs), and mPASI scores.

These findings are highly significant as no other laser has been shown to be as effective as the excimer until now. With that as the background, an advantage of Neo Elite is that this is not a UV laser. Its infrared 1064nm laser energy is clinically proven to be safe on skin tissue and is not associated with increased risks of skin aging and skin cancer linked to UV light.

The Neo Elite handpiece also does not contact the skin. This makes it a very sanitary treatment that is both easier and more convenient for the practitioner.

Separate from the clinical study, we have found that the Neo Elite is allowing for quick clearance on thicker skin areas. We were able to achieve significant clearance, even on recalcitrant cases of the hands and feet, in sometimes as few as two treatments.

COMBINATION THERAPY FOR PSORIASIS

The Neo Elite can be used with or without other psoriasis therapies to improve efficacy and time to clear. In a study, 34 patients with severe plaque psoriasis all received ustekinumab (Stelara) at weeks 0, 4, 16 and 28. After week 28, patients underwent eight laser treatments with the Neo Elite at 1-week intervals using energy of 25-28 J/cm^2 with 3-4 passes. After six months of biological therapy alone, the average values of the indices were: PASI 75, BSA 8. After completion of laser therapy, the average value of the indices was: PASI 90-100, BSA 2-0, the study showed.

Before (left) and after treatment with the Neo.

The tolerability of treatment was high in this study. No side effects were observed. The authors concluded that the 650 Microsecond 1064nm laser therapy improved PASI and BSA scores after biologic therapy.

REIMBURSEMENT AND OTHER INDICATIONS

The Neo Elite used for psoriasis can be reimbursed using the psoriasis laser codes 96920–96922. The codes are used depending on the BSA treated per individual treatment. Other clinical conditions for which Neo performs particularly well include: active acne and acne scars, melasma, rosacea and spider veins, rejuvenation, LHR and onychomycosis. Another important advantage of the Neo Elite laser is that it is safe for all skin types. Aerolase's Neo Elite uniquely provides a safe, effective and tolerable treatment for psoriasis patients of all ages and skin types. ■

Read this article at PracticalDermatology.com to see additional before/after images and for a list of articles for further reading.

Mark S. Nestor, MD, PhD, is Director of the Center for Clinical and Cosmetic Research and the Center for Cosmetic Enhancement in Aventura, FL. He is a Voluntary Professor in the Department of Dermatology and Cutaneous Surgery and the Department of Surgery, Division of Plastic Surgery, at the University of Miami, Miller School of Medicine.

Reimbursement Codes

96920 Laser* treatment for inflammatory skin disease (psoriasis); total area less than 250 sq. cm

96921 Laser* treatment for inflammatory skin disease (psoriasis); 250 sq. cm to 500 sq. cm

96922 Laser* treatment for inflammatory skin disease (psoriasis); over 500 sq. cm

*2018 CPT does not specify type of laser used for treatment

ICD 10 Psoriasis L 40.0

RESULTS

Combined with ustekinumab:

Ustekinumab results alone after 6-months were PASI 75 and BSA 8%

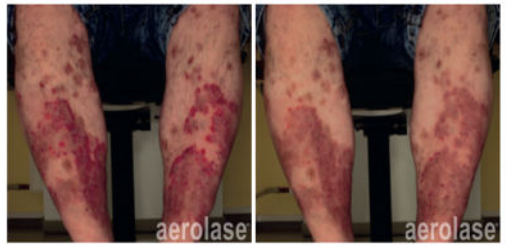
After 4 treatments with Neo Elite, PASI 90-100 and BSA 2-0%

"Systemic Biologic Therapy Combined with a 650 Microsecond Laser for Patients with Severe Forms of Psoriasis," Evgenievna M., Sergeevna K., Vladimirovna I., ASLMS 2019

A New Device for Mild to Moderate Psoriasis

TREATMENT UPDATE FOR MILD TO MODERATE PSORIASIS

A recent study shows that the efficacy and tolerance of a 650-microsecond 1064-nm laser is equivalent to that of the 308-nm excimer laser for the treatment of mild to moderate psoriasis of the extremities. The 650-microsecond laser can also be used in combination with a biologic medication and in patients with dark skin without cooling during treatment.



2 Treatments and 2 weeks between Treatments
Photos Courtesy of Aerolase Clinical Research / Klinika Ambroziak

NEO ELITE VS. EXCIMER LASER

It's well known that phototherapy is effective against psoriasis and lacks the side effects of systemic medications[1]. For plaque psoriasis, the 308-nm excimer has been considered first-line phototherapy[1-8]. Nestor and colleagues[9], in their randomized, investigator-blinded study, compared the efficacy and tolerability of a new device, the 650-microsecond, 1064-nm pulsed YAG laser (Neo® Elite, Aerolase Corp., Tarrytown, NY), to that of the excimer laser (XTRAC Velocity 400®, PhotoMedex, Inc., Montgomeryville, PA) for the treatment of mild to moderate psoriasis vulgaris of the arms and legs. The authors treated plaques on one side of the body with the Neo Elite and plaques on other side with the 308-nm excimer laser. They found that redness, thickness, scaliness, mPASI (Psoriasis Area Severity Index) scores for arms and legs, and overall mPASI scores did not differ significantly for the treated psoriatic plaques on each side of the body. They also reported that scores for erosion/ulceration, vesicles, erythema, scaling, edema, and atrophy were low and identical for both devices. The authors concluded that the efficacy and tolerance of the Neo Elite are equivalent to that of the excimer laser for the treatment of mild to moderate psoriasis vulgaris of the arms and legs.

Since reporting these findings, Nestor and colleagues have added that the Neo Elite also provides significant clearance in thicker psoriatic skin areas, even on recalcitrant cases of the hands and feet, sometimes in just several treatments.

A recent roundtable discussion[10] described findings that support those of Nestor and colleagues. Dr. Nazanin Saedi, who used the Neo Elite to treat plaque psoriasis, stated, "I've had good experience with plaque psoriasis patients who have either failed topical therapy, have hard-to-treat areas, or been sick or non-compliant with topicals. We see improvement shortly after initial treatment. For example, I had a woman, skin type II, with it (psoriasis) on the ear. I used the 6-mm spot at level six and four passes with the 650-microsecond laser. A week after her first treatment there's barely anything left."

TARGET FOR PSORIASIS

In 2009 Heidenreich and coworkers[11] reported that the formation of new blood vessels starts with early psoriatic signs and disappears with disease clearance, so these new vessels are a promising target for the treatment of psoriasis. Ten years later Ianosi and colleagues[12] demonstrated the efficacy of the long-pulse 1064-nm Nd:YAG laser in treating telangiectasias and reticular veins of lower extremities.

As stated earlier, the study of Nestor and colleagues[9] shows that the Neo Elite provides a highly effective

References:
1. Zhang P, Wu MX. A clinical review of phototherapy for psoriasis. Lasers Med Sci. 2018;33:173-180. **2.** Bónis B, Kemény L, Dobozy A, et al. 308 nm UVB excimer laser for psoriasis. Lancet. 1997;350(9090):1522. **3.** Taibjee SM, Cheung ST, Laube S, Lanigan SW. Controlled study of excimer and pulsed dye lasers in the treatment of psoriasis. Br J Dermatol. 2005;153:960-966. **4.** He YL, Zhang XY, Dong J, et al. Clinical efficacy of a 308 nm excimer laser for treatment of psoriasis vulgaris. Photodermatol Photoimmunol Photomed. 2007;23:238-241. **5.** Mudigonda T, Dabade TS, Feldman SR. A review of protocols for 308 nm excimer laser phototherapy in psoriasis. J Drugs Dermatol. 2012;11:92-97. **6.** Abrouk M, Levin E, Brodsky M, et al. Excimer laser for the treatment of psoriasis: safety, efficacy, and patient acceptability. Psoriasis (Auckl). 2016;6:165-173. **7.** Higgins E, Ralph N, Ryan S, et al. A randomised half body prospective study of low and medium dose regimens using the 308 nm excimer laser in the treatment of localised psoriasis. J Dermatolog Treat. 2017;28:8-13. **8.** Fritz K, Salavastru C. The 308 nm excimer laser for the treatment of psoriasis and inflammatory skin diseases. Hautarzt. 2018;69:35-43. **9.** Nestor MS, Fischer D, Arnold D. Randomized, investigator-blinded study to compare the efficacy and tolerance of a 650-microsecond, 1064-nm YAG laser to a 308-nm excimer laser for the treatment of mild to moderate psoriasis vulgaris. J Drugs Dermatol. 2020;19(2):176-183. **10.** Burgess C, Chilukuri S, Campbell-Chambers DA, et al. Practical applications for medical and aesthetic treatment of skin of color with a new 650-microsecond laser. J Drugs Dermatol. 2019;18:s138-s143. **11.** Heidenreich R, Röcken M, Ghoreschi K. Angiogenesis drives psoriasis pathogenesis. Int J Exp Pathol. 2009;90(3):232-248.

Smooth Skin & Palmar-Plantar Psoriasis

RESULTS

Average baseline BSA of 8.9%

After 8 Neo Elite treatment sessions, average BSA of 0.8%

90.8% reduction in BSA

Results to be published.

308-nm Excimer Laser for Targeted Phototherapy

• Introducing the XTRAC Momentum 1.0 Excimer Laser

- The **XTRAC® Momentum 1.0** is the Fastest, Most Powerful Excimer Laser in the world FDA cleared for Psoriasis, Vitiligo, Atopic Dermatitis and Leukoderma. XTRAC® is a targeted beam of 308nm UVB to treat affected skin.

Best in class excimer technology

Momentum 1.0 launched in 2022, Sleek design with smaller footprint

Established CPT Codes

2022 Medicare Average: $183*

150+ peer-reviewed clinical-studies

Multiple academic institutes in U.S. use XTRAC

2,000+ device installed base, worldwide

890 offices in the U.S. provide device access to over 3,000+ providers

10+ Million treatments performed

More than 500,000 patients treated

*Medicare Physician Fee Schedule for geographic indices and mix of CPT Codes 96920, 96921, 96922

Technology

- At the core of the 308-nm excimer laser system is a repetitively pulsed XeCl excimer laser with an output at 308 nanometers (nm).
- The 308-nm excimer laser provides laser energy via a special flexible fiber optic cable connected to an integrated delivery handpiece. This unique combination of UVB laser and flexible delivery system allows the clinician to easily treat large areas of *localized* tissue without affecting the nearby normal tissue.
- The laser power and energy are fixed at very specific and controlled levels intended to optimize the safety and efficacy of several dermatological indications.
- The system allows access to the handpiece and the Control Panel simultaneously, and the ability to initiate laser firing by using either the touch (finger) fire control mechanism or an optional foot control.
- The system has an integral green diode laser aiming beam.

FDA CLEARANCES

indicated for the treatment of:

- **Psoriasis**
- **Vitiligo**
- **Atopic Dermatitis**
- **Leukoderma**

have been specifically designed for the treatment of mild, moderate, and severe patients.

• The Treatment for Psoriasis

Clinical Protocol – 6.2 treatments to PASI 75

PASI - A **75**% reduction in the **Psoriasis** Area and Severity Index (**PASI**) score (**PASI 75**) is the current benchmark of primary endpoints for most clinical trials of **psoriasis**

Beam of UVB light applied to the affected area

UVB light induces apoptosis of the keratinocytes and T cells in the dermis

Promotes immunosuppression

Induces alterations in cytokine profile

PROVEN RESULTS IN OVER 60 CLINICAL STUDIES

- **Multi-Center Study**

Feldman SR, Mellen BG, Housman TS, Fitzpatrick RE, Geronemus RG, Friedman PM, Vasily DB, Morison WL. Efficacy of the 308-nm excimer laser for treatment of psoriasis: Results of a multicenter study. J Am Acad of Dermatol; vol. 46, no. 6, June 2002, pp. 900-906

- **Scalp Study**

Morison WL, Atkinson DF and Werthman L. Effective treatment of scalp psoriasis using the excimer (308nm) laser. Photodermatol Photoimmunol Photomed 2006; 22: 181-183

- **Induration Study**

Taneja A, Trehan M, Taylor C. 308-nm Excimer Laser for the Treatment of Psoriasis – Induration-Based Dosimetry. Arch Dermatol, Vol. 139, June 2003, pp. 759-764

- **High Dose Study**

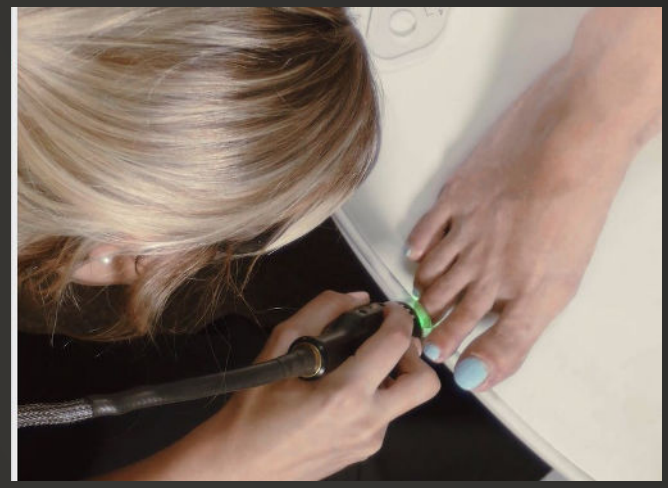
Trehan M, Taylor C. High-dose 308nm excimer laser for the treatment of psoriasis. J Am Acad Dermatol, vol. 46, no. 5, May 2002, pp. 732-737

- **Medium Dose Study**

Trehan M and Taylor CR, Medium-dose 308-nm excimer laser for the treatment of psoriasis, J Am Acad of Dermatol, vol. 47, no. 5, November 2002, pp. 701-708

- **Pediatric Study**

Pahlajani N, Katz BJ, Lonzano AM, Murphy F and Gottlieb A. Comparison of the Efficacy and Safety of the 308nm Excimer laser for the Treatment of Localized Psoriasis in Adults and in Children: A Pilot Study. Pediatric Dermatology Vol. 22 No. 2, March/April 2005, pp. 161-165



308-nm Excimer Laser Psoriasis Study Results

- Of patients in the standard protocol, 65.7% (67 of 102) achieved a >=90% clearance after 10 or less treatments; 87 of 102 patients (85.3%) achieved a >=90% or complete clearance after 13 treatments or less; median 10.8 treatments…
- Excimer laser-generated 308nm UVB radiation is one of the most effective treatment forms for moderate and chronic forms of psoriasis…
- UVB laser treatment for localized psoriasis has considerable advantages over current topical and conventional UVB treatment.
- We observed a faster clearance rate at less exposure and a greater risk-benefit ratio as there is less risk for uninvolved skin…
- Furthermore, the study has shown the excimer laser to be effective in treating thick, scaled plaques on the knees and elbows, which are often resistant to any conventional treatment.

- Gerber W, Arheilger B, Ha TA, Hermann J and Ockenfels HM, Ultraviolet B 308-nm excimer laser treatment of psoriasis: a new phototherapeutic approach, British J Derm, vol. 149, December 2003, pp. 1250-1258.

308-NM EXCIMER LASER SCALP PSORIASIS STUDY RESULTS

- All patients improved. 17/35 (49%) of patients cleared >95% (mean: 21 treatments; range 6-52) and 16/35 (45%) cleared 50-95%
- All patients have improved on treatment in terms of symptoms such as discomfort and pruritus and in area of scalp involvement.
- Essentially it is a form of narrowband ultraviolet B (UVB) phototherapy delivering 308-nm radiation but its high output makes it technically possible to treat individual areas of psoriasis in short periods of time.

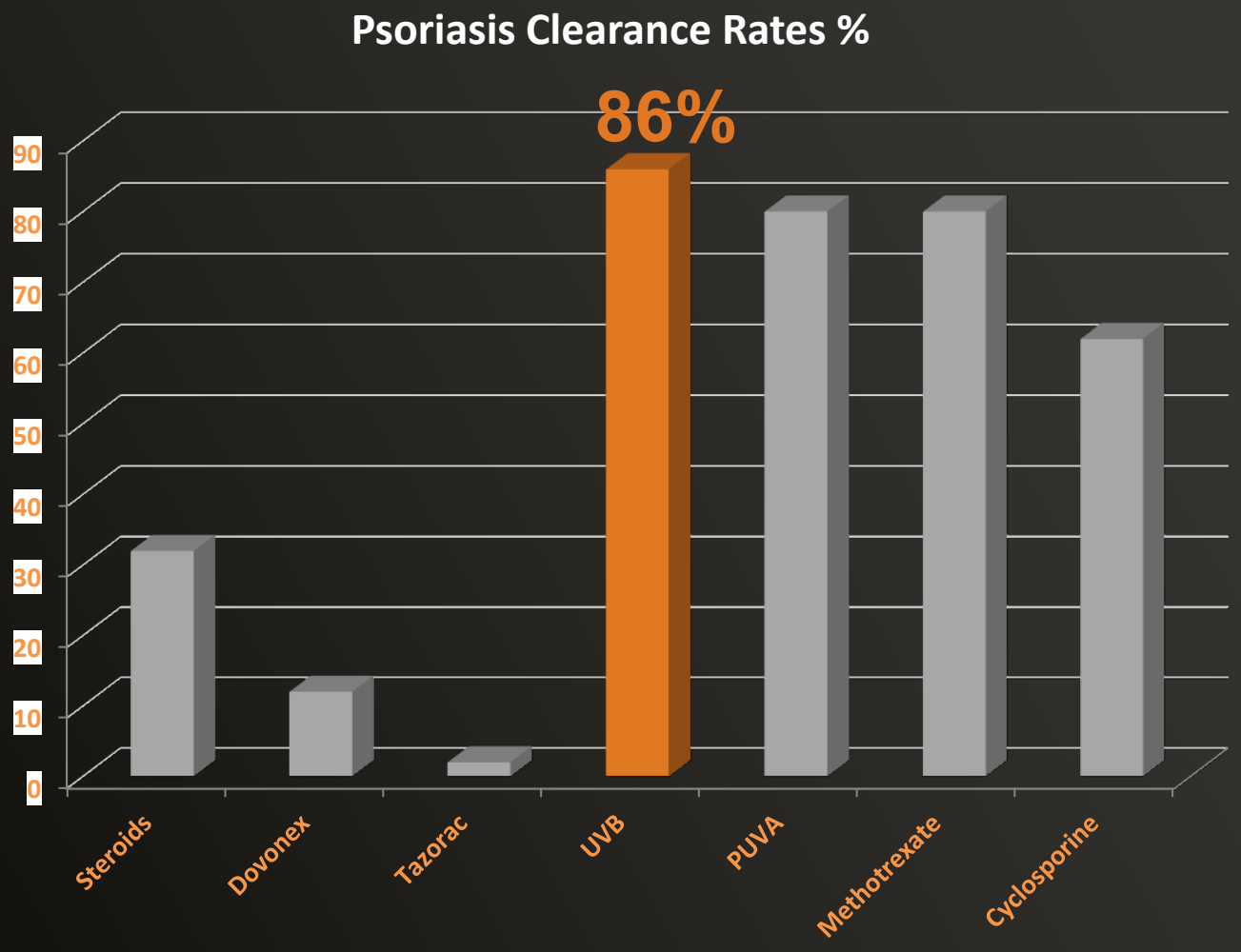
Morison, W.L., Atkinson, D.F., & Werthman, L., (2006). Effective treatment of scalp psoriasis using the excimer (308nm) laser. Photodermatology Photoimmunology and Photomedicine, 22(4), 181-3.

308-nm Excimer Laser Psoriasis Study Results

- 72% of patients (66/92) achieved at least 75% clearing in an average of 6.2 treatments.
- 84% of patients (95% confidence interval [CI], 79%-87%) reached improvement of 75% or better after 10 or fewer treatments.

- Feldman, S.R., Mellen, B.G., Housman, T.S., Fitzpatrick, R.E., Geronemus, R.G., Friedman, P.M., Vasily, D.B., & Morison, W.L., (2002). Efficacy of the 308-nm excimer laser for treatment of psoriasis: Results of a multicenter study. *Journal of the American Academy of Dermatology*, 46(6), 900-6.

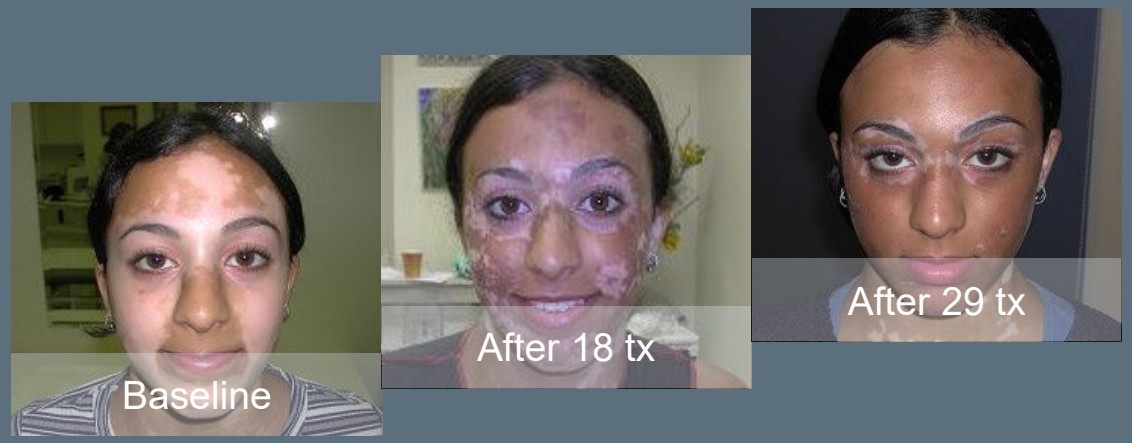
CLINICAL EXPECTATIONS FOR PSORIASIS



- Significant improvement in 6-10 treatments.
- Clearance in 10-20 treatments (depends on severity)
- Quick, easy & painless treatments
- Remissions of 4-6 months
- Most common side effects are hyperpigmentation and blistering – both are short lived and usually well tolerated.

J Amer Acad Dermatology 2000;42:796-802.

• The Solution For Vitiligo



Exclusive License for Treatment of Vitiligo Using Excimer Laser

Beam of UVB light applied to the affected area

UVB light reduces the immune system's attack on the melanocytes

Results in re-pigmentation

Simple, safe, effective + long-lasting

VITILIGO

Effective in treatment of vitiligo for all skin types.

RESPONSE RATES TO TREATMENT ACCORDING TO THE SITE OF THE LESIONS

REGION	# OF LESSIONS TREATED	>50% RESPONSE (%)	>75% RESPONSE (%)
Face	80	81.25	73.75
Neck and Scalp	29	79	62
Genitalia	11	72.7	54.5
Trunk	24	54	45.5
Extremities	48	54	33.3
Hands and Feet	29	24	6.8
TOTAL	221	64.25	50.6

Hadi, S., Tinio, P., Al-Ghaithi, K., Al-Qari, H., Al-Helalat, M., Lebwohl, M., & Spencer, J., (2006). Treatment of Vitiligo Using the 308-nm Excimer Laser. *Photomedicine and Laser Surgery*, 24(3), 354-7.

308 NM EXCIMER LASER ATOPIC DERMATITIS STUDY RESULTS

- Used the local eczema area severity index (EASI) to score AD. There was a mean reduction of 58% after treatment. No exacerbation of AD occurred at 1-month follow-up.[1]
- …at a 6-month follow-up, the excimer laser demonstrated greater improvement when compared with clobetasol ointment, as evaluated by the Physician Assessment of Individual Signs (PAIS), Physician Global Assessment (PGA), Patient Global ASSESSMENT (PaGA) and VAS.[2]

1.Baltas E, Csoma Z, Bodai L, Ignacz F, Dobozy A, Kemeny L. Treatmetn of atopic dermatitis with the xenon chloride excimer laser. *J Eur Acad Dermatol Venereol*. 2006; 20(6):657-660.
2.Brenninkmeijer EEA, Spuls PI, Lindeboom R, van der Wal AC, Bos JD, Wolkerstorfer A. Excimer laser vs. clobetasol propionate 0.05% ointment in prurigo form of atopic dermatitis: a randomized controlled trial, a pilot. *Br J Dermatol*. 2010;163(4):823-831.

Lasers for Psoriasis - Conclusions

- We have some very exciting Lasers and EBDs which can successfully treat psoriasis
- Patients are accepting of these targeted treatments
- It is also a differentiator – many clinics do not offer them – useful for you and your clinic and patients very satisfied with their outcomes as a result of you offering this