

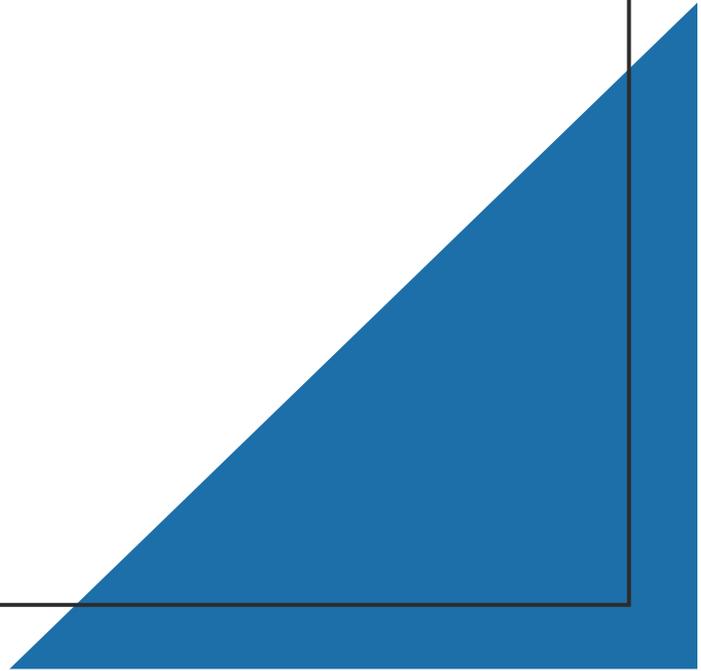
Treating to Temperature:

A New Approach using a 1726nm Laser to treat Acne

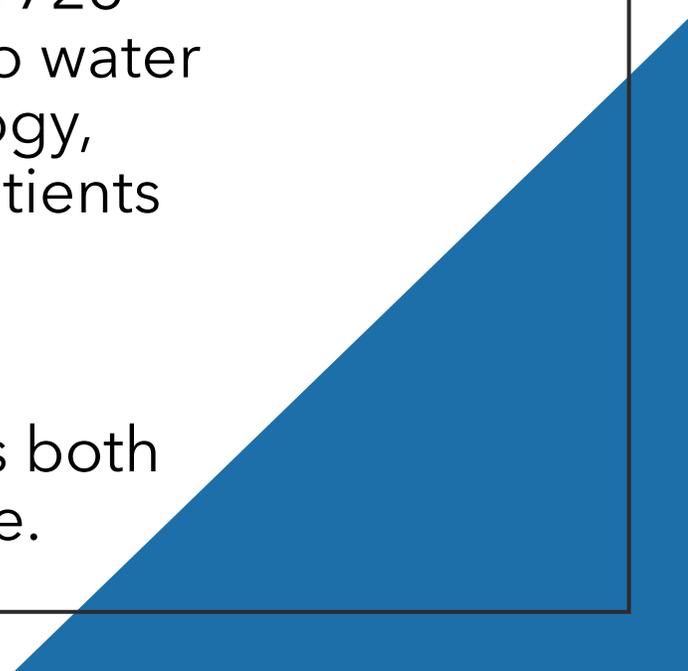
Joel L. Cohen, M.D.

Disclosures

Dr. Cohen has served as a clinical trial participant, consultant, and holds stock for Accure Acne, Inc.



Background

- Laser treatment of acne with durable results has remained an elusive and significant challenge for dermatologists and practitioners who use these modalities around the world.
 - We have previously reported on our success using a 1726 nm laser, with its small peak in absorption of sebum to water and will share our treating-to-temperature methodology, which allows for successful and safe treatments for patients with moderate inflammatory acne.
 - We will also share clinical evidence that demonstrates both short-term and possibly a sustained, durable response.
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Background: The Right Wavelength

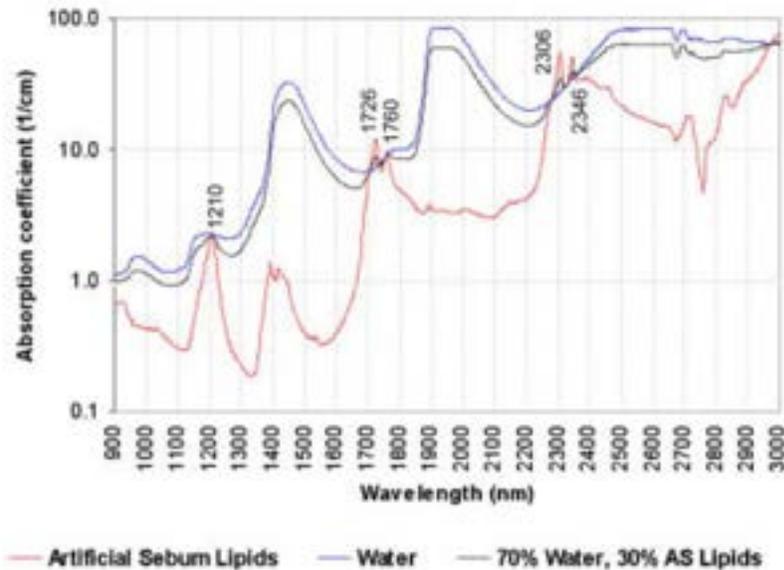


Fig. 1. Measured absorption coefficients (μ_a) in cm^{-1} of artificial sebum (AS) and water. For AS the 28% (w/w) solution and 1 mm pathlength cuvette used, $\mu_a = 23 \text{ OD}/0.25$, where OD is the measured optical density.

Sakamoto et al. Lasers in Surgery and Medicine 44:175–183
(2012)

- 1726nm is the wavelength of choice
- Low contrast between sebum and water ratio leads an **extremely narrow** therapeutic window
- No immediate clinical end-point requires new approach for safety and efficacy

Methods: The Device

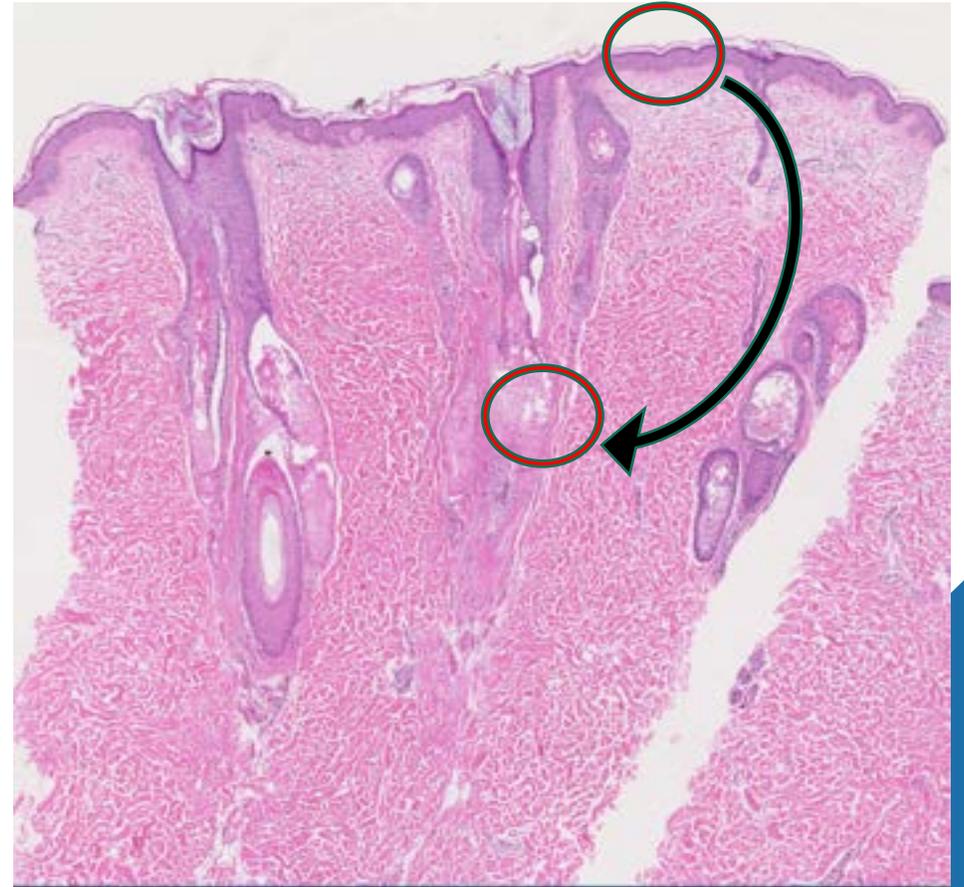
- 1726nm laser, 40W
- Robust, stable, integrated air-cooling
- Real-time temperature monitoring (pat. pend.)
- Software safety mechanism to automatically stop treatment if an excessive skin temperature is reached or projected
- **Open-loop:** physician directed power. The provider adjusts the power based upon the temperature readings
- **Enhanced Temperature Control (ETC):** a target skin temperature is set and max power is specified. The software adjusts power to achieve the target temperature



Methods: Clinical End-Points

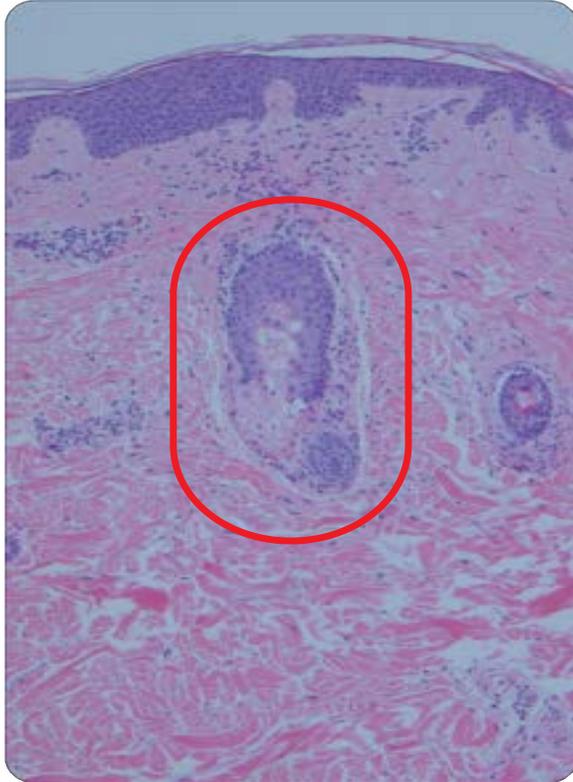
- Peak Epidermal Temperature, PET, is used as the proxy clinical end point
- PET is defined as peak skin surface temperature at the end of the pulse train
- PET correlated to sebaceous gland temperature via proprietary methods
- PET measured via a built-in monitoring system (pat. pend.)

“Treat to Temperature”

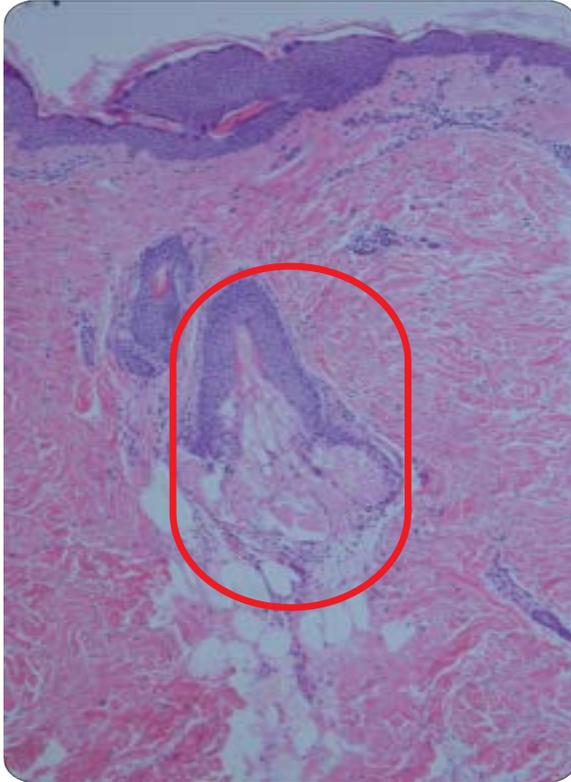


Courtesy: Emil Tanghetti, MD

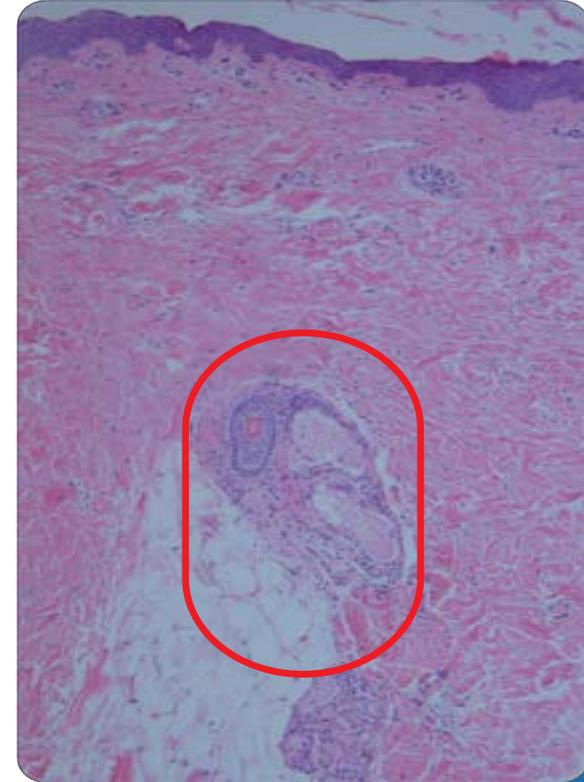
Methods: Histology Findings



~400 to 500-micron depth
with evidence of selective
SG damage



~1 mm depth with
evidence of selective SG
damage



~1.3 mm depth with
evidence of selective SG
damage

Methods: Facial Pilot Studies

- 19 subjects completed the 2 separate IRB-approved trials*
 - 14 subjects from site 1¹, 5 subjects from site 2²
 - Age of 16+ years
 - Fitzpatrick skin types I-V were represented
- Treatments completed:
 - 2 treatments (15.8%)
 - 4 treatments (84.2%)

*Some treatments halted at 2 sessions and follow-up appointments missed due to COVID-19 precautions

¹Center for Dermatology and Laser Surgery, Sacramento, CA (Emil Tanghetti, MD)

²Laser & Skin Surgery Center of New York, New York, NY (Roy Geronemus, MD)



Joel Cohen, MD is the Director of AboutSkin Dermatology and DermSurgery in Greenwood Village, CO and a Principal Investigator.

Results: Lesion Reduction

- Median improvement of inflammatory lesion count from baseline:
 - 4-week follow-up (73%)
 - 8-week follow-up (81%)
 - 12-week follow-up (78%)
- 52-week follow-up:
 - 90% had improvement of inflammatory lesion count
 - 67% maintained or continued to have improvement of inflammatory lesion count
from 8- and 12-week follow-up

Results: Clinical Evidence



**Before
Treatment**

**After
Treatment**

pre-treatment

12 Month follow-up
Courtesy of Emil Tanghetti, MD



**Before
Treatment**

**After
Treatment**

pre-treatment

3 month follow-up
Courtesy of Domenico Carella, MD



**Before
Treatment**

**After
Treatment**

pre-treatment

6 Month follow-up
Courtesy of Emil Tanghetti, MD



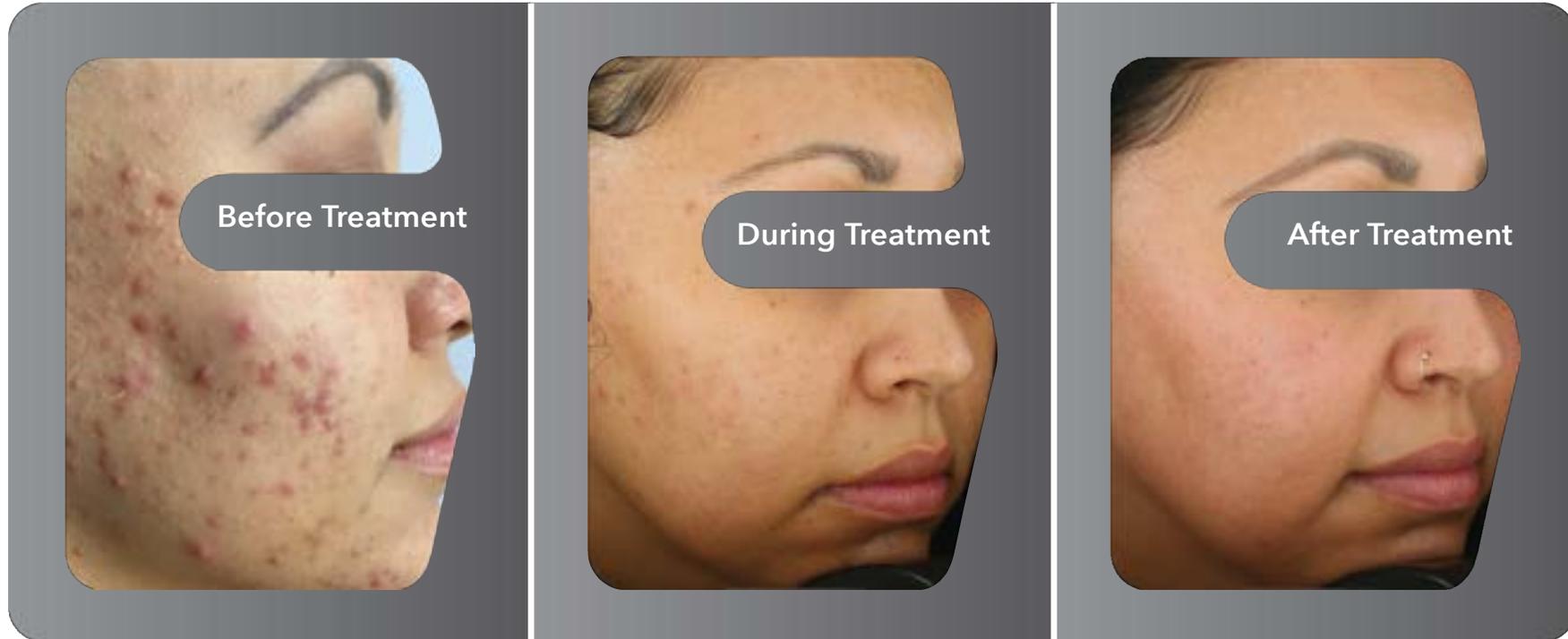
**Before
Treatment**

**After
Treatment**

pre-treatment

1 Month Follow-up
Courtesy of Christine Dierickx, MD

Results: Clinical Evidence



Baseline

3 Months Post Tx

2 Years Post Tx

Subject treatment course was supplemented with spironolactone at the 1-year post treatment mark and continued through the follow-up period.

Courtesy of Emil Tanghetti, MD

Results: Clinical Evidence



Start of Tx

6 Months Post Tx

2 Years Post Tx

Courtesy of Roy Geronemus, MD

Conclusion:

- This 1726nm laser is effective at improving moderate acne vulgaris
 - Improved inflammatory lesion counts
 - High responder rate with what appears to be a durable response
 - Clinical trials on-going
- 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 50,000 trigger pulls safely performed
- **Device has recently received FDA clearance for the treatment of mild to severe acne**