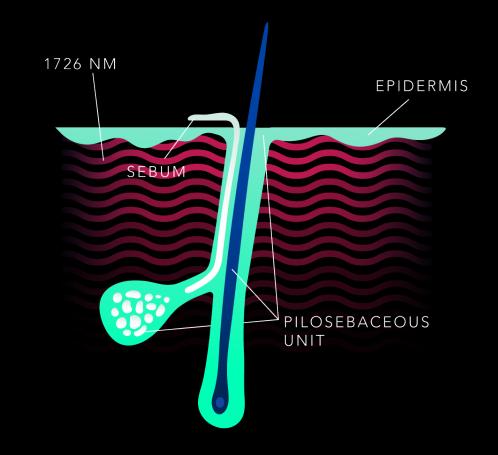
1726 nm Laser Treatment of Acne An Update

David J. Goldberg, MD, JD
Skin Laser & Surgery Specialists
Schweiger Dermatology Group
Icahn School of Medicine at Mt. Sinai

Mechanism of Action

Target acne at the source

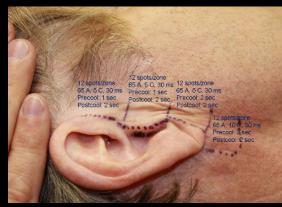
- Overproduction of sebum by the sebaceous glands is one of the leading causes of acne¹
- At 1726 nm sebum absorbs 2x more energy compared to H₂O
- This wavelength to selectively target and damage sebocytes
- Sebaceous glands shrink and sebum production decreases

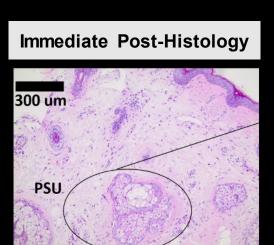


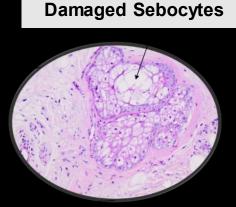
Clinical Innovation

- Initial Study treated facial tissue scheduled for excision (face-lift candidates).
- Reduced risk for the patient, as the overexposed tissue would be excised during face lift procedure.









Histology: Post-treatment with AviClear

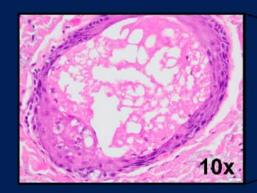
Histological studies show that can stop sebaceous glands from producing sebum without compromising the epidermis.

- Epidermis is intact
- Damage through the length of the sebaceous gland, indicating sebocyte cell death

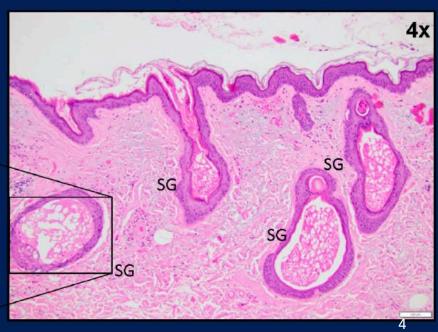
Healthy sebaceous gland



Damaged sebaceous gland



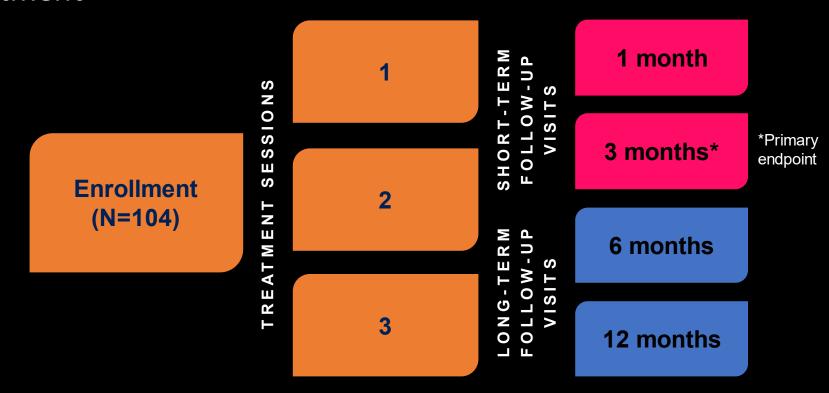
Five days after treatment



Pivotal Study Evaluation

Pivotal study design

- Non-randomized, open-label study
- Primary endpoint was the percentage of patients who achieved a 50% reduction in inflammatory lesion count by three months after the final treatment



Results and Performance Efficacy Endpoints – 3-Month Follow-Up Data

Primary Endpoint – Responder Rate

• 80% of subjects achieved a ≥ 50% reduction* in inflammatory acne lesion count (*P*<.001)

Secondary Endpoints

- Investigator Global Assessment (IGA)
 Improvement
 - 36% of subjects were assessed as having clear or almost clear skin
 - 47% of subjects achieved ≥ 2-point improvement in IGA score vs. baseline
 - 87% of subjects achieved ≥ 1-point improvement in IGA score vs. baseline (meaningful to the patient)
- Non-Inflammatory Lesion Count Reduction
 - Statistically significant reduction achieved (32%; P=.001)

^{*} Based on review by 3 trained expert lesion counters using a validated blinded photographic lesion count methodology



Downtime, Comfort, Satisfaction

Treatment Related Side Effects*:

- No downtime or medical intervention required
- All post-treatment effects were transient and self-resolving.



Treatment-Related Discomfort:

- All subjects tolerated treatment well without the need for topical anesthetic
- No treatment sessions ended prematurely due to discomfort

Subject Satisfaction:

• 75% of subjects were satisfied or extremely satisfied with improvement after 3 treatments and were "very likely" or "likely" to have laser treatment again.



Clinical results

1 MONTH AFTER FINAL **3 MONTHS AFTER FINAL** BASELINE TREATMENT SESSION TREATMENT SESSION MEDIAN 1 (Almost clear) **IGA SCORE** 3 (Moderate) 0 (Clear)

AGE: 17

SKIN TYPE: IV

Moderate to clear

1 MONTH AFTER FINAL **3 MONTHS AFTER FINAL** BASELINE TREATMENT SESSION TREATMENT SESSION MEDIAN IGA SCORE 3 (Moderate) 2 (Mild) 1 (Almost clear)

AGE: 17

SKIN TYPE: V

Moderate to almost clear

BASELINE



1 MONTH AFTER FINAL TREATMENT SESSION



3 MONTHS AFTER FINAL TREATMENT SESSION



MEDIAN IGA SCORE

4 (Severe)

3 (Moderate)

2 (Mild)

Severe to mild

AGE: 16

SKIN TYPE: II

BASELINE

1 MONTH AFTER FINAL TREATMENT SESSION



3 MONTHS AFTER FINAL TREATMENT SESSION



MEDIAN IGA SCORE

4 (Severe)

3 (Moderate)

2 (Mild)

Severe to mild

AGE: 21

SKIN TYPE: IV

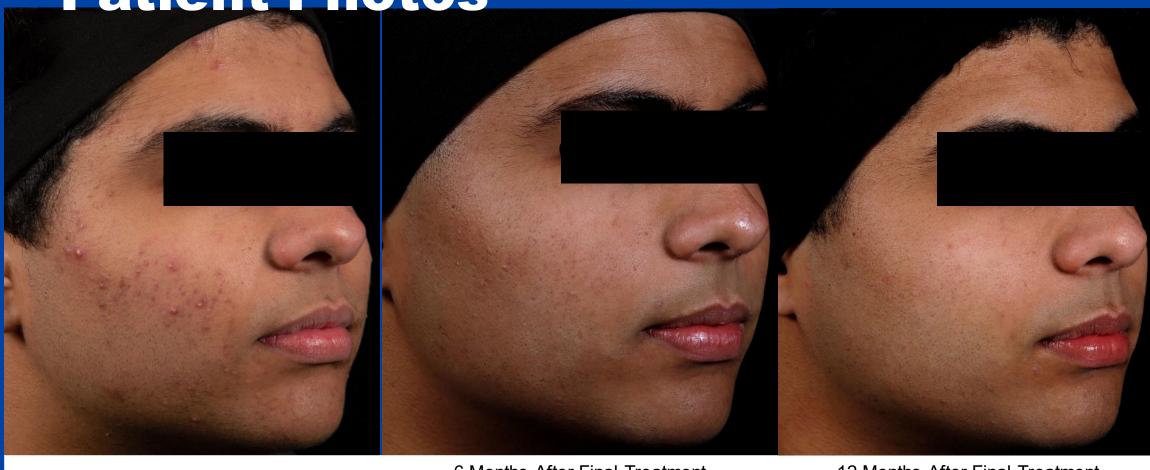
6-month results



Procedure Efficacy

3-, 6-, and 12-Month Data

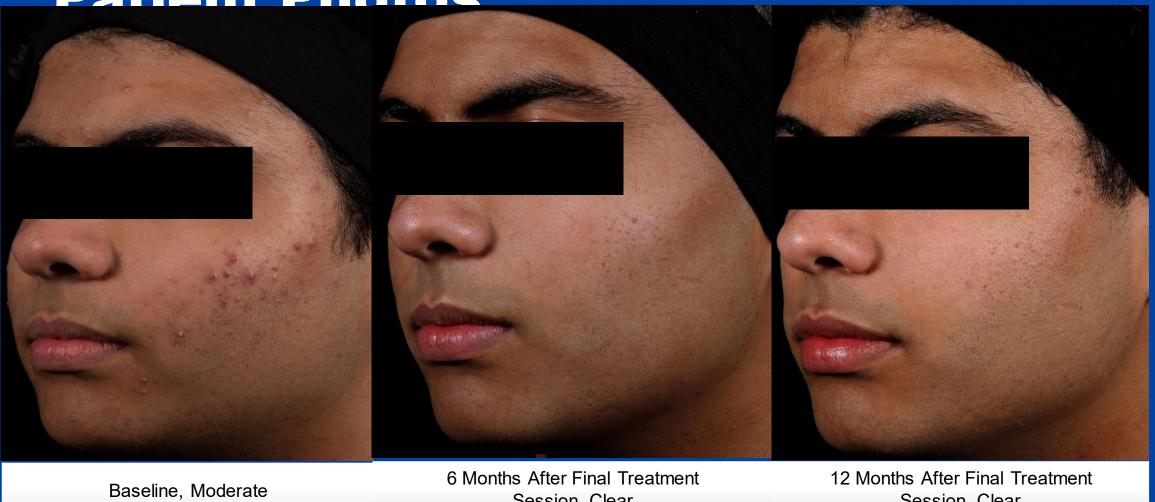
Efficacy Improvement (% Patients/Asian Patients)	at 3 Months	at 6 Months	at 12 Months
IGA Improvement 1+	87 (<mark>91</mark>)	90 (83)	93 (94)
IGA Improvement 2+	47 (41)	52 (56)	79 (82)
IGA Improvement Clear / Almost Clear	36 (<mark>36</mark>)	42 (44)	68 (71)
Inflammatory Lesion Count Improvement	91 (<mark>91</mark>)	96 (100)	96
Inflammatory Lesion Count Improvement of 50% +	80 (<mark>86</mark>)	87 (89)	92
Nodule Count Reduction	67 (<mark>83</mark>)	93 (90)	87
Comedonal Count Reduction	32 (<mark>24</mark>)	44 (45)	51
Patient Experience (% Patients)	at 3 Months	at 6 Months	
Patients feeling their Skin looks Better	88	80	
Patients feeling their Skin looks Smoother	85	82	



Baseline, Moderate

6 Months After Final Treatment Session, Clear

12 Months After Final Treatment Session, Clear



Session, Clear

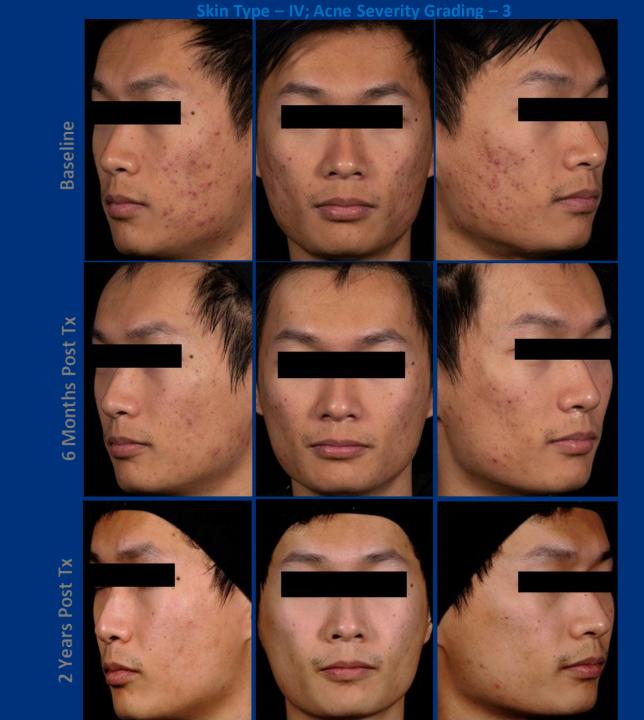
Session, Clear







24-Month Post Three Treatments



Efficacy Improvement	FDA at 12 Months	Real Life at 18 Months
Subjects	100	75
IGA Improvement Clear / Almost Clear	68	77
Inflammatory Lesion Count Improvement	96	93
Inflammatory Lesion Count Improvement of 50% +	92	89
Nodule Count Reduction	87	94
Comedonal Count Reduction	51	60

Caveats

Real life —stay on acne meds 1-2 months into treatment 1 patient did not respond 2 patients treated a second time at 18 month Complications are rare — but never zero



6 months after 3 treatments



12 months after 3 treatments



18 months after 3 treatments

High Success and Satisfaction

Failures are rare, but will never be zero (similar to isotretinoin)

Some patients will eventually need to be treated again (similar to isotretinoin)

Complications are rare - but can occur

6 months after tx
No response
PCOS and oral steroids



Laser induced herpetic infection



Pitting from high fluence/scanner



18 months post tx Seeks 2nd tx



What's Next?

- Truncal Acne
- Hormonal Acne
- Sebaceous Hyperplasia
- Acne Rosacea
- Pore Size



