Smoothbeam Laser Treatment of Acne Vulgaris

Emerging Applications
About Acne Vulgaris

- Very common - Affects 80% of population
  - Almost every person experiences acne
- Most common reason to visit dermatologist
- Long-term scarring if not treated
- Devastating emotional / psychological effects
- Onset is tied to maturity (puberty)
- Genetic link
• Sebaceous follicles
  – Oil-producing glands
  – High concentration
    • face, upper chest, back and shoulders

• Structure
  – Large, multilobe sebaceous glands
  – Tiny, vellus hair
How acne forms

- **Hormonal change**
  - increase gland size and sebum output
- **Abnormal desquamation process**
  - shedding of dead cells
- **Sticky plug blocks opening**
- **Bacteria** (*P. acnes*)
  - thrive on sebum and proliferate
- **Inflammation**
  - Infundibulum distends
  - Formation of papules, pustules and cysts
Classification: Mild Acne

- Open or closed comedones
- No inflammatory lesions
- Grade I-II
  - <25 lesions per side of face
Moderate Acne

- Comedones & Papules, Pustules
- Grading
  - # of inflammatory lesions
Severe Acne

- Deep nodules
- Scarring
- No grading – classified by description
- Often requires surgery
- Acne is NOT cosmetic
Treatment Options

• Topicals
  – Benzoyl Peroxide - OTC
    • Kills bacteria
    • No affect on sebum production or keratinization process
    • Side Effects
      – Drying of skin

• Topical Antibiotic Lotions – prescription only
  – Prevent proliferation of bacteria (P.acnes)
  – Cannot reach P.acnes deep in follicle
  – Strains of bacteria are increasingly resistant to antibiotics
• Topical Retinoids (Retin-A)
  – Normalize the keratinization (“skin shedding”) process
  – Prevents “plugging”
• Side-effects
  – Extreme drying of skin
  – Irritating
    • Often severe enough to cease therapy
Treatment Options

• Systemic Therapies
  – Reserved for moderate to severe cases

• Hormone treatments - Oral contraceptives
  – Prescription only
  – Female hormones designed to counteract the effect of male hormones (androgens) on acne
  – Reduce size and sebum output of sebaceous gland.
Isotretinoin (Accutane™)
- Powerful, effective anti-acne drug
- Severe acne only
- Affects acne on 3 fronts
  - Reduces sebum production
  - Normalizes skin shedding process
  - Reduces bacteria counts in gland
- Dramatic side-effect profile
  - Severe birth defects possible
  - Directly linked to emotional depression and suicide
  - Costly ($2,000 -3,000 per treatment regimen)
Smoothbeam for Acne

• Emerging application
  – Acne Vulgaris

• Wrinkle histology
  – Noticed thermal effect in sebaceous glands
  – Dermal remodeling of sebaceous glands
Smoothbeam for Acne

• Feasibility study
  – Acne on the back
  – E. Victor Ross M.D.
    • Dermatology, Dept. of Navy, San Diego, CA
• Clinical study
  – 27 subjects
  – Bilateral areas / matched severity at baseline
  – Treated side – laser & cryo
  – Control side – cryo only
Smoothbeam for Acne

- Clinical study
  - 14-20 J/cm²
    - Painted entire clinical area including lesions and unaffected skin
  - Histology
  - Lesion counts (non-inflammatory / inflammatory)
  - Acne severity
  - Template to mark treated / control sites
  - Compared treated versus control sites
    - At 6, 12 and 24 weeks
Smoothbeam for Acne

- Immediate post-op
  - Erythema
- 98% reduction in acne lesions at 24 weeks
- Reduction noted 3 weeks after first treatment
  - 63% reduction in lesion counts after single treatment
- No change in lesion counts in control sites
- No hyper / hypo pigmentation or scarring reported
Acne Clinical Results

![Diagram showing percent reduction in mean lesion count over time for Treatment and Control groups.]

- **Percent Reduction in Mean Lesion Count**
  - 3-wks post Tx1: 63%
  - 3-wks post Tx2: 85%
  - 3-wks post Tx3: 91%
  - 6-wks post Tx4: 98%
  - 12-wks post Tx4: 98%
  - 24-wks post Tx4: 98%

- **Time of Follow-up**
  - 3-wks
  - 6-wks
  - 12-wks
  - 24-wks

Legend:
- Black: Treatment
- Gray: Control
Control – lesions present

Treated – no lesions present

3 weeks post 2\textsuperscript{nd} treatment with \textit{Smoothbeam}
• 4 mm spot
• 14J/cm² w/ DCD – 3
• 5 weeks after single treatment
How it works

• Mechanism of action
  – Thermal injury to gland was obvious in histology
    • alteration of structure of the gland
• 1450 nm Wavelength
  – Penetrates to ideal depth of sebaceous gland
  – Thermal profile to match gland location
How it works

- Acne inflamed lesion
How it works

- Dynamic Cooling
  - DCD cools the epidermis
  - Protects from thermal effects
How it works

- DCD cooling remains
- Laser penetrates to base of sebaceous gland
- Generates thermal effect in sebaceous gland and dermis
How it works

- Thermal injury to sebaceous gland and surrounding dermis
Lasers in Surgery and Medicine

Published paper

E. Victor Ross M.D

Acne Treatment With a 1,450 nm Wavelength Laser and Cryogenic Spray Cooling

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Background and Objectives: A laser with a wavelength in the mid-IR range targeting the depth in skin where sebaceous glands are located in combination with cryogen spray cooling was evaluated for treatment of acne. This non-ablative treatment, the laser energy heats the dermal volume encompassing sebaceous glands whereas the cold cryogen spray preserves the epidermis from thermal damage.

Study Design/Methods: Monte Carlo simulations and heat transfer calculations were performed to optimize the heating and cooling parameters. A variety of heating and cooling parameters were tested in an in vivo rabbit ear study to evaluate the histological effect of the device on sebaceous glands and skin. Similar experiments were performed on ex vivo human skin. A clinical study for the treatment of acne on backs of human volunteers was also conducted.

Results: Monte Carlo simulations and heat transfer calculations resulted in a thermal damage profile that showed epidermal preservation and peak damage in the upper dermis where sebaceous glands are located. Ex vivo human skin histology confirmed the damage profile qualitatively. In vivo rabbit ear histology studies indicated short-term thermal ablation of sebaceous glands with epidermal preservation. In the human clinical study on the back, a statistically significant reduction in lesion count on the treated side compared to the control side was seen (p < 0.001). Side effects were transient and few.


Key words: cryogen cooling, laser treatment of acne; Monte Carlo light transport modeling; non-ablative sebaceous glands

INTRODUCTION

Acne vulgaris is the most common skin disease in the United States, and accounts for 25% of all visits to dermatologists [1]. While the highest incidence of acne occurs between the ages of 15 and 30 years in both males and females, acne can begin at virtually any age and occasionally persist into adulthood. Because it most commonly affects the face and can lead to permanent scarring, acne can have profound and long-lasting psychological effects. Past treatments and current treatments are aimed at the potential impact on the patient’s greatest. Acne appears to be a condition that is difficult to control, perhaps even in the long term, the emotional well-being of patients [2].

Acne is a disease of the pilosebaceous unit of the skin wherein there is an inflammatory reaction in the oil-producing follicle [3]. The basic lesion is a comedo, an engorgement of the sebaceous follicle. The formation of the comedo begins with defective keratinization of the follicular duct, resulting in abnormal keratinization of the follicular duct and plugging of the duct with sebum and keratinous debris. When the lipid plug is blocked and the plug pushes up to the surface, it causes a blackhead (open comedo). When the opening is very tightly closed, the material builds up and causes a whitehead (closed comedo). Some comedones evolve into inflammatory papules, pustules, nodules, or chronic granulomatous lesions. Proliferation of Propionibacterium acnes (P. acnes) results in the production of inflammatory compounds resulting in neutrophil chemotaxis [2].

Acne patients usually receive two of topical or systemic therapies. Current treatment options include topical anti-inflammatory, topical peeling agents, topical and oral antibiotics, topical and oral retinoids, and hormonal agents and agents. These treatments must be used over long periods of time and are associated with several possible side effects. Oral antibiotics can lead to the emergence of resistance in P. acnes [4]. Systemic treatment has been successfully used in the treatment. However, it has sometimes been associated with significant side effects with at least mild acne or localized side effects [1]. With the exception of a psoralen derivative, traditional acne remedies do not alter the sebaceous glands from which acne lesions originate.
Summary: Acne

- Safe and effective for acne on the back
- 98% reduction in lesions
- Reduction in lesions seen after 1\textsuperscript{st} treatment
- Mechanism of action
  - Likely related to thermal injury to sebaceous gland
- Ease of use -- simple procedure
- \textit{Smoothbeam} – multiple applications (wrinkles)