CLINICAL BULLETIN

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Smoothbeam® Acne Removal; One Pass vs. Two Passes

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Introduction

Acne is the most common reason for a visit to the dermatologist, affecting 80% of the population at some point in their lives. Current treatment modalities now include the use of 1450 nm (mid-infrared) laser energy (the Smoothbeam™ laser system from Candela Corporation), which yields long-term remission of acne. Topical treatments and most systemic treatments are maintenance regimens focused on reducing bacteria counts or skin-shedding mechanisms. The use of laser energy seems to compromise the function of the sebaceous glands to provide long-term remission of the condition without the significant side effects of systemic treatments.

To date, patient discomfort has been the single biggest factor limiting more widespread acceptance of this safe and effective treatment of acne. The purpose of this study is to identify treatment parameters for the Candela Laser Corporation, 1450 nm Smoothbeam laser system that prove efficacious for improving papular and pustular acne with less pain and to quantify the safety and effectiveness of those treatment parameters.

Method

Seven subjects were enrolled into the study protocol. One discontinued treatment. The remaining six completed the study treatment protocol and follow-up visit. Each subject had his or her acne papules/pustules counted and an acne severity rating recorded before beginning treatment, before each subsequent laser treatment, and six weeks following the fourth and final laser treatment. Digital photographs were taken before any treatments were administered, and six weeks following the last treatment. Subjective assessment of pain and clinical evaluation of side effects were recorded following each treatment and just prior to each subsequent treatment. Efficacy was determined four weeks following each treatment and at the six weeks' follow-up.

Subjects were pretreated with topical lidocaine cream applied evenly over treatment sites. Cream was left in place for 40 minutes and then washed off. The subject was then treated with the Smoothbeam laser delivering 1450 nm laser energy with a 6 mm spot diameter onto the cheeks and/or nose, chin, and forehead, using two different treatment protocols randomized to the left and right sides of the face. Laser pulses were administered at a rate of one to two pulses per second. One side of the face was randomized to receive a single-pass of 12 to 14 J/cm^2, using a Dynamic Cooling Device™ (DCD™) setting of 35. The contralateral side was treated using a lower energy setting of 8 to 11 J/cm^2, administered in two passes with DCD settings of 28 to 35. Subjects received a series of four treatments administered at four-week intervals, followed by a final visit six weeks following the final treatment. Subjects rated the discomfort associated with each treatment as well as improvement, following each treatment and at the follow-up visit. The treating physician evaluated side effects of treatment and improvement following each treatment and at the six-week follow-up visit.

with DCD

Smooth beam®

Results

Treatment Parameters
The treatment parameters were 13 to 14 J/cm^2 with a DCD setting of 35 on the high-fluence, single-pass side; and 8 J/cm^2 and a DCD setting of 28 for the low-fluence, double-pass side after the first treatment where an average setting of 10.25 J/cm^2 was used with an average DCD setting of 32.5.

Pain
Subjects self-assessed pain following each of their four treatments. Pain was assessed separately for the side receiving a double-pass, low-fluence treatment as compared to the single-pass, high-fluence treatment side. Subjects rated pain on a scale from zero to ten, with zero representing no pain and ten representing maximum endurable pain. Pain scores for the high-fluence, single-pass side (13 to 14 J/cm^2) ranged from one to nine and averaged 5.6. Pain scores for the low-fluence, double-pass side (of 8 J/cm^2), treatments two to four, ranged from one to two with an average of 1.3.

Side Effects
In assessing erythema and edema immediately following treatment, a zero to three scale was used with zero representing absent erythema or edema, and three representing severe edema or erythema. The average scores for erythema on the high-fluence, single-pass side were 1.6 as compared to 1.5 on the low-fluence, double-pass side. For edema, the scores were the same for both treatments, averaging 0.3 for the double- and single-pass treatments. No other side effects were present.

Improvement
To determine efficacy of treatment, the investigator made a global assessment of the degree of improvement using a zero to four scale with zero representing worsening, one–no improvement, two–mild improvement, three–moderate improvement, and four–marked improvement. The average global assessment was 2.5 for the single-pass, high-fluence side and 2.3 for the double-pass, low-fluence side.

Acne papules and pustules were counted prior to initiating each treatment, and six weeks following the last treatment. The average acne papule/pustule count went from 19.5 pre-treatment to 4.2 six weeks following the last treatment in the single-pass, high-fluence treatment sites. The average acne papule/pustule count in the double-pass, low-fluence treatment site was 16.2 pretreatment, as compared to 5.2 six weeks following treatment.

The Allen Smith1 acne severity grade was assessed by the investigator on a scale of zero to six, with zero being no acne and six being three-fourths of the face involved with lesions. The average acne severity grade on the single-pass, high-fluence side was 3.1 prior to initiating treatment, as compared to 1.0 six weeks following the last treatment. On the two-pass, low-fluence side, the average acne severity score was 3.2 pre-treatment as compared to 0.8 post-treatment (Figure 1).

Subjective Improvement (Self-Assessment)
The subjects scored their improvement subjectively following each treatment. They used a scale of zero to four to grade

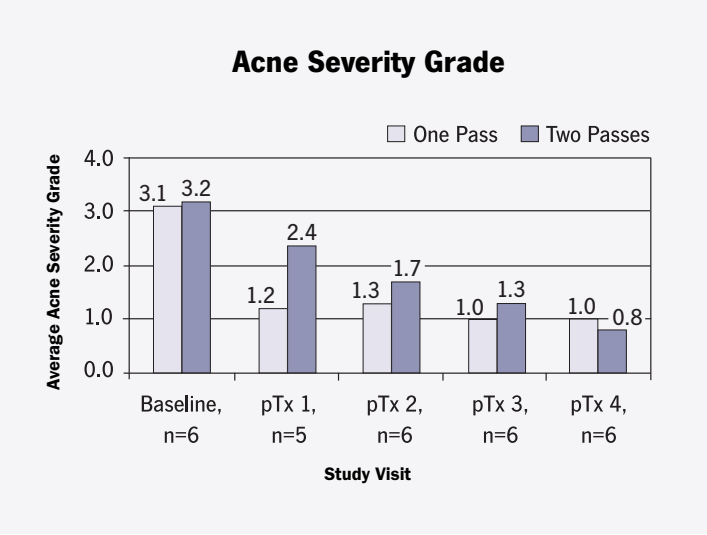

Figure 1: Acne Severity Grade
Bars represent reduction in the mean acne severity grade at study visits. Shaded bars are results from one pass, and solid bars are results from two passes.

improvement in their acne and acne scarring with zero being worse, one being no change, and four being marked improvement. The degree of improvement at the completion of the study for acne clearance in the single-pass, high-fluence side ranged from one to four with an average of 2.3. The low-fluence, double-pass side ranged from two to four also with

an average of 2.3. Two of the subjects noted that their skin texture was significantly improved following the series of treatments in unsolicited comments and not in response to a specific question.

Conclusion

This pilot study demonstrates that a low-fluence, double-pass treatment is roughly equivalent in efficacy to a single pass of a higher fluence, with significantly reduced pain during treatment. While conclusions regarding the efficacy of Smoothbeam laser treatments should be drawn cautiously from this study due to the small sample size, improvement in clinical outcome was noted to be equivalent for the two treatment arms. A fluence of 8 J/cm^2, with a DCD setting of 28, was found to be the maximum fluence deliverable with an excellent tolerance in terms of pain.

Overall, this study was a success in demonstrating the safety and efficacy of a low-fluence, double-pass treatment regimen, and in identifying the treatment parameters that maximize treatment fluence while minimizing pain.

Reference

1. Comparison to the reference photographs using severity grade referenced in Allen, B.S. and Smith, B.S., *"Various Parameters for Grading Acne Vulgaris,"* Archives of Dermatology, 118, 23 - 25, 1982.

Pre and Post-Treatment Results

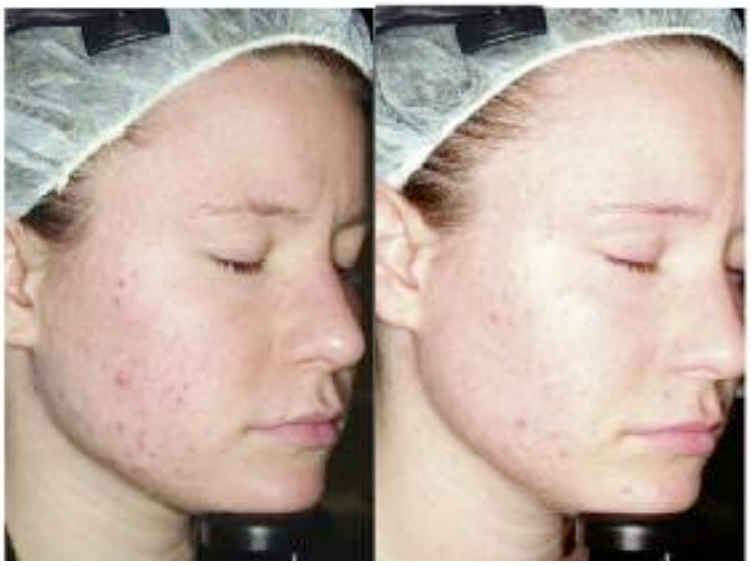

Figure 2: Subject 4 Pretreatment ***Post-treatment; one pass***

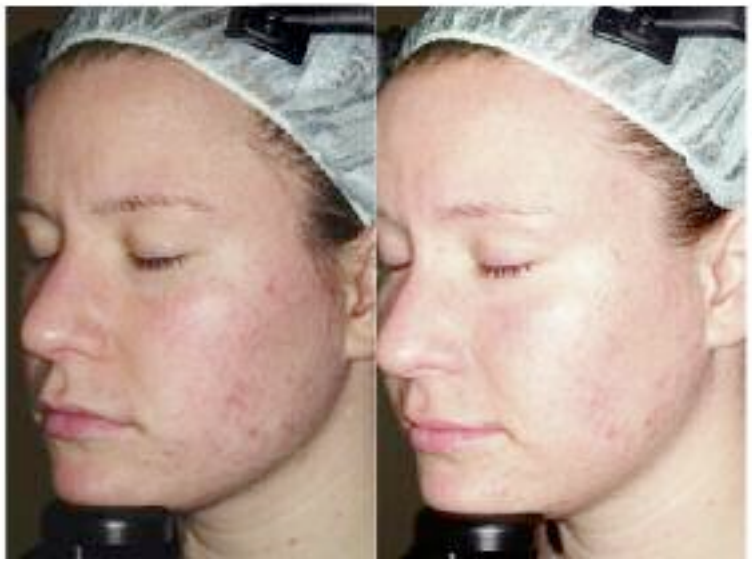

Figure 3: Subject 4 Pretreatment ***Post-treatment; two passes***

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