

# A PILOT STUDY TO ASSESS THE EFFICACY AND TOLERABILITY OF TWO NEW PROPRIETARY, PURE HYPOCHLOROUS ACID-BASED (HOCl) TREATMENTS FOR MILD-TO-MODERATE ACNE VULGARIS

Mark Steven Nestor, MD, PhD; Brian Berman, MD, PhD; Jigesh Patel, BS; Alec Lawson; Jessica L. Jones, DO; Taranch Matin DO.  
CENTER FOR CLINICAL AND COSMETIC RESEARCH, AVENTURA, FL.

## BACKGROUND

Hypochlorous acid (HOCl) has been shown to have anti-inflammatory properties<sup>1</sup> and immediate bactericidal activity against *Propionibacterium acnes*.<sup>2</sup> Clinically, HOCl has been shown to be an effective topical treatment for acne vulgaris.<sup>3</sup> New formulations of HOCl (Microcyn® Technology, IntraDerm™ Pharmaceuticals, a Division of Sonoma Pharmaceuticals. Recent successful studies support further development of these products).

The following pilot study was performed to assess the efficacy and tolerability of a HOCl-based solution and gel for the treatment of subjects with mild-to-moderate acne vulgaris.

Efficacy was assessed by acne lesion count. Tolerability was based on subject global assessment (SGA) of tolerability, daily diaries, local skin reactions (LSRs) and adverse events.

## METHODS

### Subjects

Male or female subjects (N=20) 12 to 40 years old with mild-to-moderate facial acne vulgaris defined as 10-90 noninflammatory lesions and 10-50 inflammatory lesions with no nodules or cysts.

### Procedures

Subjects were randomized 1:1 to receive monotherapy with HOCl-based liquid or gel formulation and instructed to apply their assigned product twice-daily using cotton pads.

Subjects attended six biweekly office visits for 12 weeks. Assessments during each visit included acne lesion counts, LSR values, digital images, review of daily diaries and adverse event assessments. Porphyrin counts were obtained as a measure of skin bacteria present (VISIA® Complexion Analysis, Canfield Scientific).

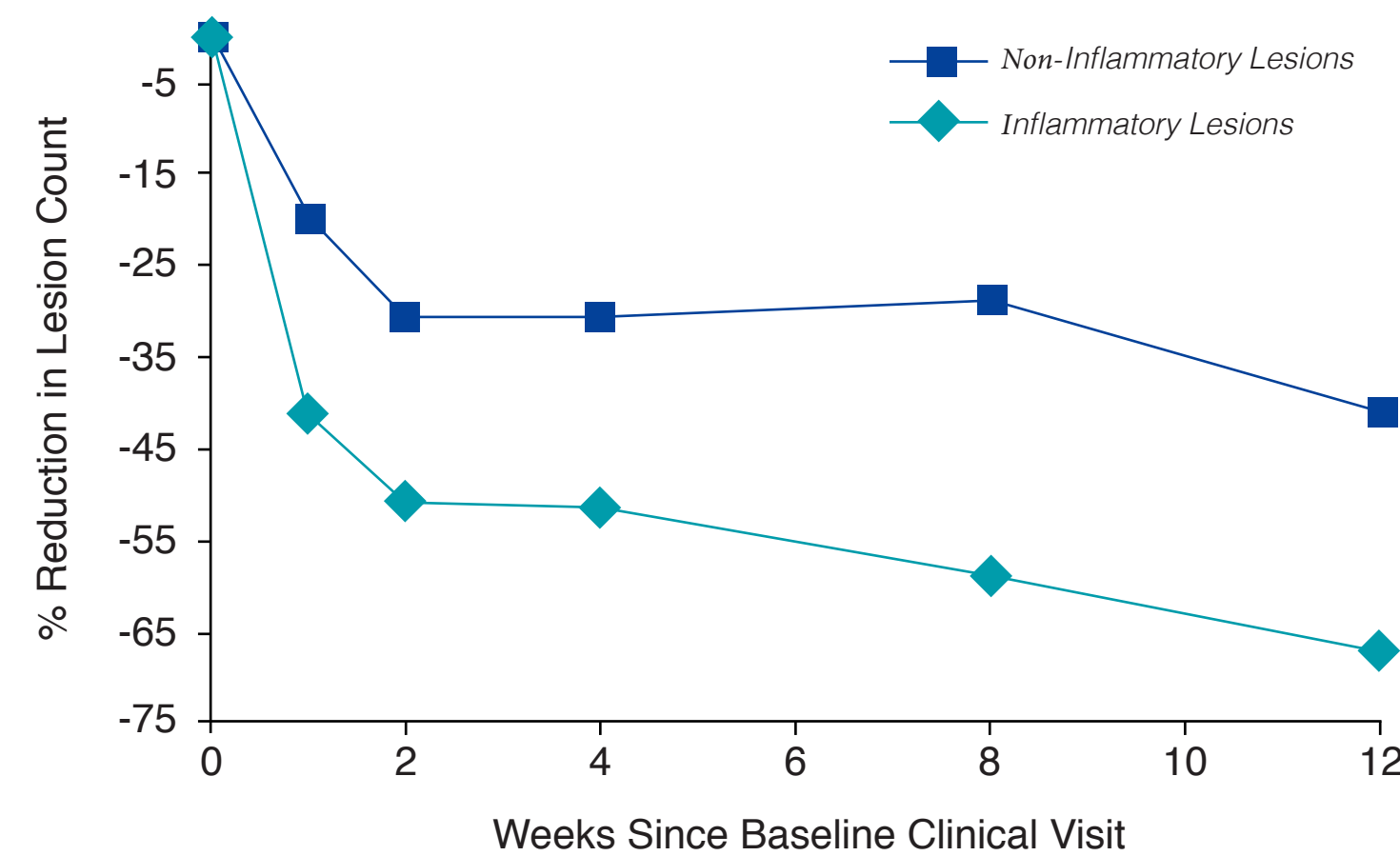
### Ethics

This study adhered to the Declaration of Helsinki, International Conference on Harmonisation Good Clinical Practice and US Code of Federal Regulations. The protocol was approved by a commercial IRB and informed consent was obtained from each subject.

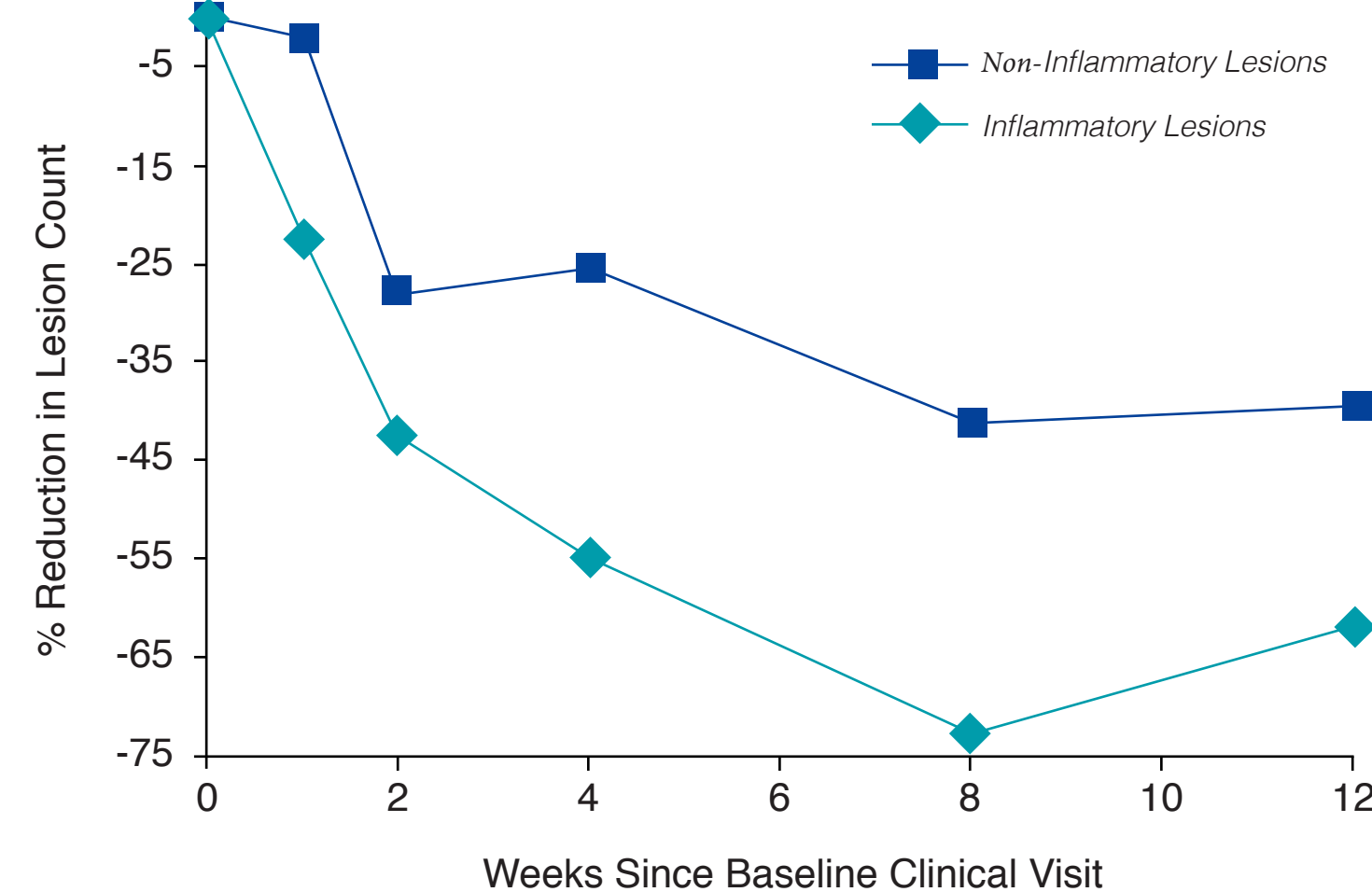
## RESULTS

The study was completed by 16 subjects. By week 12, use of HOCl solution resulted in a significant decrease in inflammatory (66%; p=0.0002) and noninflammatory lesions (43%; p=0.0025) (Figure 1). The HOCl gel also produced a significant decrease in inflammatory (64%; p=0.0031) and noninflammatory lesions (43%; p=0.0054) (Figure 2). There was no significant decrease in porphyrin counts.

**Figure 1.** Total Percent Lesion Reduction in Subjects Treated with Hypochlorous Acid (HOCl) Solution



**Figure 2.** Total Percent Lesion Reduction in Subjects Treated with Hypochlorous Acid (HOCl) Gel



Representative images of subjects treated with both products at Baseline and Week 12 are shown in Figure 3 and Figure 4.

**Figure 3.** Representative Subject at Baseline (left) and Following 12 Weeks of Treatment with Hypochlorous Acid (HOCl) Solution (right)

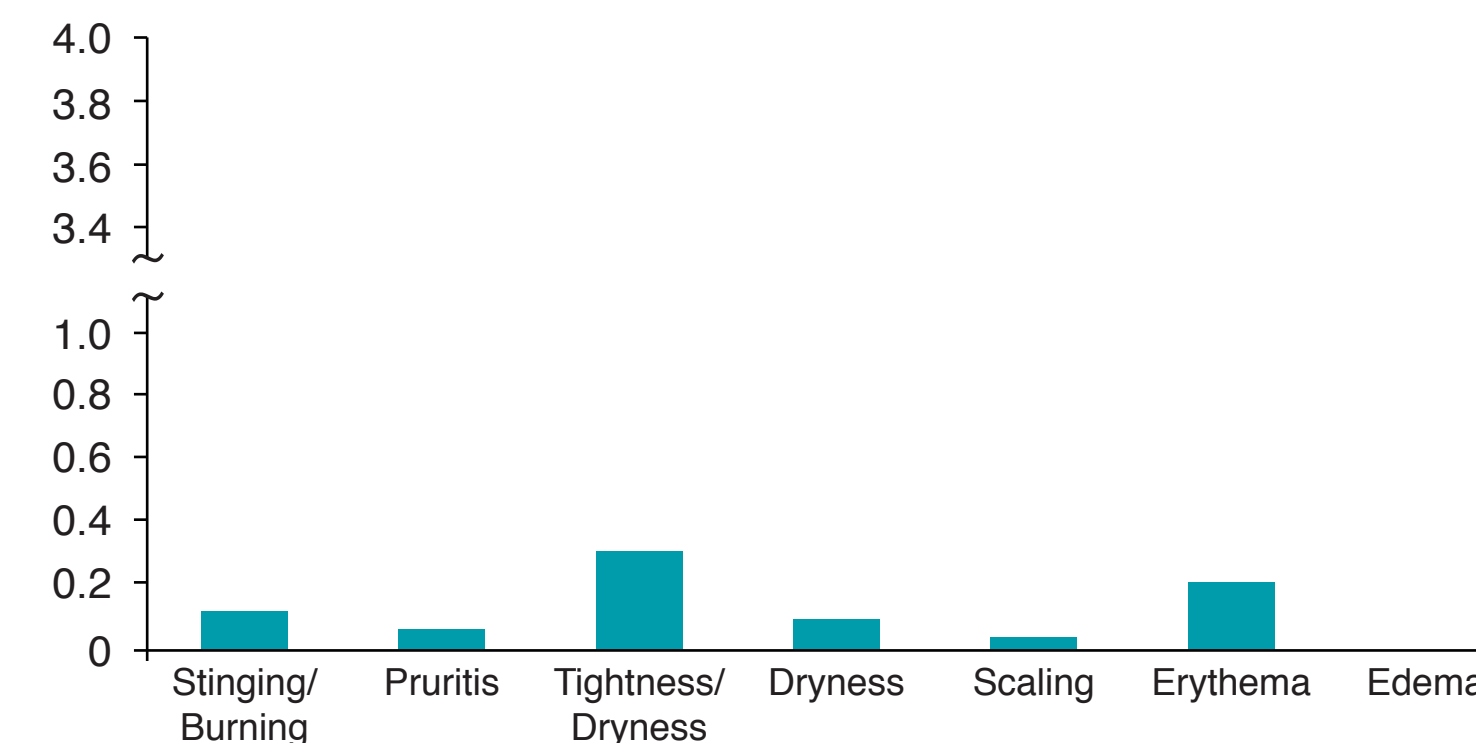


**Figure 4.** Representative Subject at Baseline (left) and Following 12 Weeks of Treatment with Hypochlorous Acid (HOCl) Gel (right)

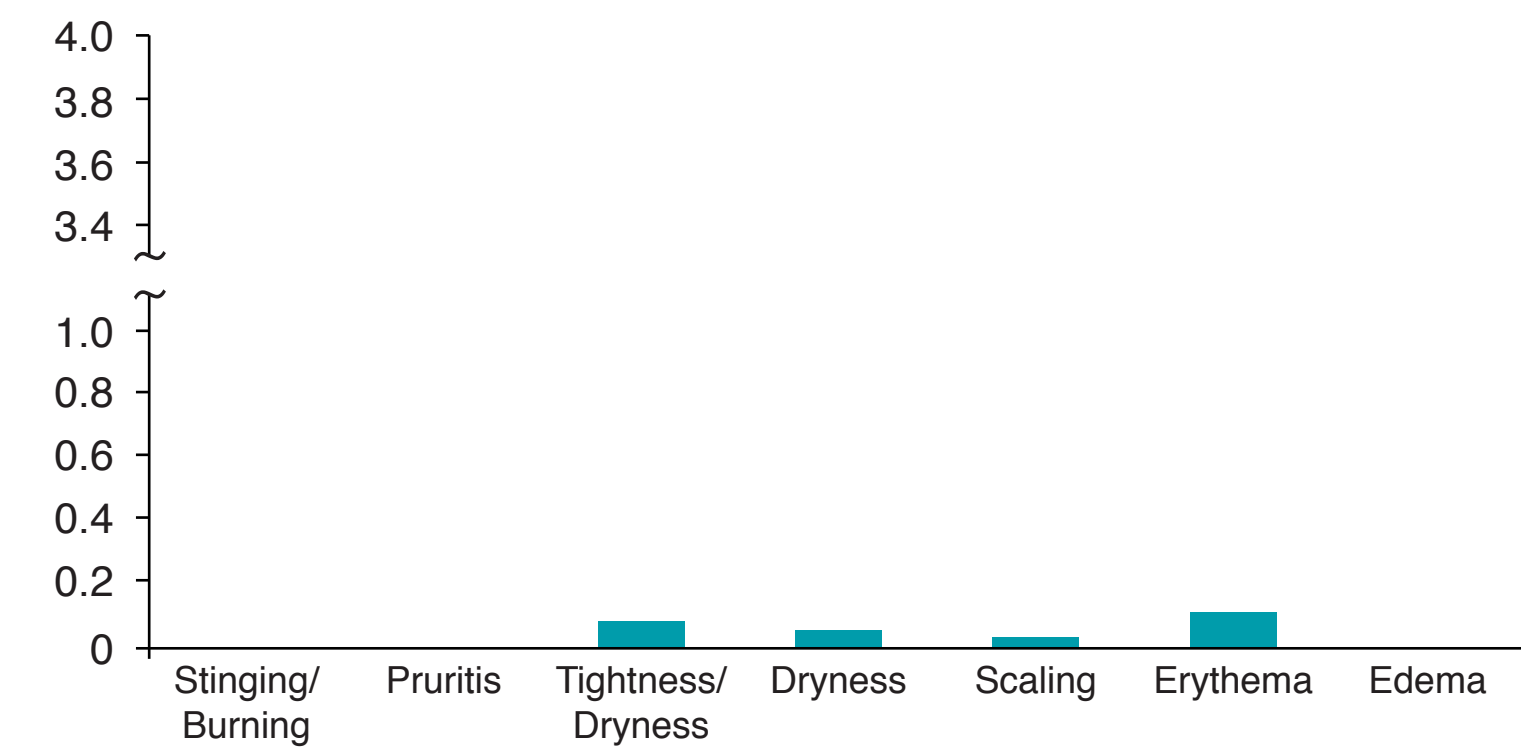


Product tolerability is summarized in Figure 5 and Figure 6. Both subjective and object local skin reactions were minimal to nonexistent. The liquid shows slightly more tendency for drying but it was minimal and not statistically significant. No adverse events were reported.

**Figure 5.** Mean SGA and LSR Scores for Subjects Treated with Hypochlorous Acid (HOCl) Solution



**Figure 6.** Mean SGA and LSR Scores for Subjects Treated with Hypochlorous Acid (HOCl) Gel



## DISCUSSION

Hypochlorous acid (HOCl) has been shown to be extremely safe and has been used in dermatology and ophthalmology for many years.<sup>4</sup> Since it is an endogenous substance that quickly breaks down to water and chlorine, it is even safe for use on children and pregnant women. Studies are now under way to assess efficacy of the new formulation to treat moderate-to-severe acne.

## CONCLUSION

This study demonstrates that both of these new products show significant efficacy for the treatment of mild-to-moderate acne and were both extremely well tolerated.

## REFERENCES

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## ACKNOWLEDGEMENT

This study was sponsored by IntraDerm™ Pharmaceuticals, Jamison, PA.