SkinPen BY CROWN AESTHETICS

STUDY TO DETEMERMINE THE SAFETY AND EFFICACY OF MICRONEEDLING AS AN EFFECTIVE TREATMENT FOR ACNE VULGARIS

Mona L. Alqam, Brian C. Jones, Thomas M. Hitchcock | Published in Skin Health and Disease, Volume 3, Issue 5, October 2023.

100%
of subjects were satisfied two months following final SkinPen procedure

92%
of subjects saw a 50% or greater improvement in their acne

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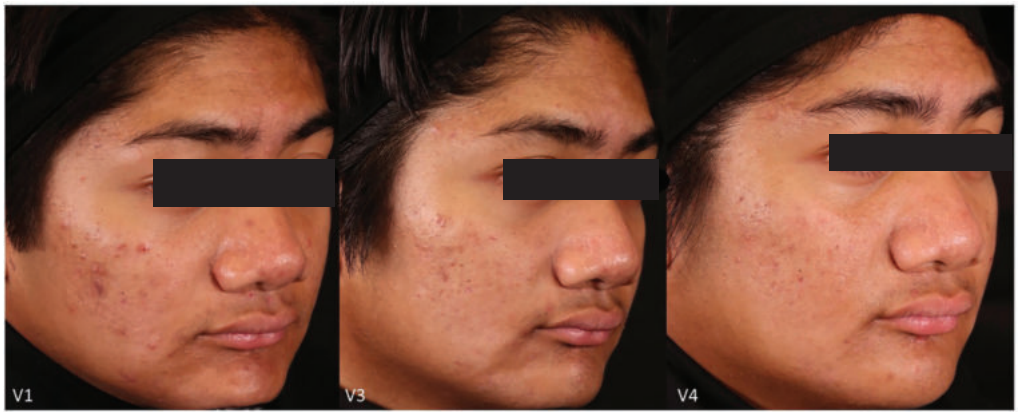

Fig. 1. *Age: 19 | Gender: Male | Fitzpatrick Skin Type: III | Group 1*

A clinically significant reduction in inflammatory and non-inflammatory lesions was observed at visit 3, after 2 microneedling treatments, and visit 4, the follow-up visit.

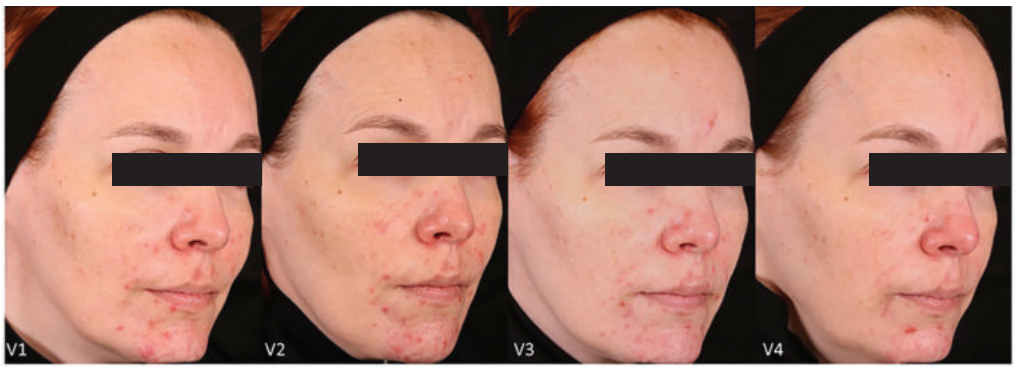

Fig. 2. *Age: 41 | Gender: Female | Fitzpatrick Skin Type: II | Group 2*

Visible improvement during active treatment and significant clinical improvement in acneic lesion count and a two-grade reduction in IGA score. Visit 4 is after 3 microneedling procedures, 2 weeks apart.

Background: Acne is an inflammatory disease of the pilosebaceous unit that occurs primarily in adolescents. There is no current ideal treatment for acne vulgaris, as many mainstay prescription treatment modalities can compromise the skin microbiome or have deleterious health effects. Further research is needed to investigate novel treatment modalities that account for the importance of the skin microbiome. Other developing treatment modalities for acne are still taking a similar mode of action as current treatments by trying to eliminate *Cutibacterium acnes* despite growing evidence that some *C. acnes* strains may be symbiotic in nature. The perception that microneedling will exacerbate the disease state and trigger more acneic lesions via the spread of acne-associated microbes has hindered research investigating whether microneedling is a safe and effective treatment. This pilot clinical study challenges such perceptions by clinical assessment to determine if microneedling may produce beneficial treatment outcomes without disrupting critical skin structure or skin microbiome.

Methods:

- Subjects randomly assigned to two groups:
  - Group 1 (n=9): Received **3** SkinPen Precision procedures at **4-week** intervals.
  - Group 2 (n=3): Received **4** SkinPen Precision procedures at **2-week** intervals.

  NOTE: Rationale for treatment at 2-week intervals was to be more targeted and capture an active acne flare-up state.
- Subjects received an acne assessment by an expert clinical grader at all clinical visits.
- Final follow-up visit 2 months after final procedure.
- Clinical endpoints:
  - Lesion count from baseline to the final visit
  - Investigator's Global Assessment (IGA)

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Results:

- 92% of subjects saw a 50% or greater improvement in their acne.
- Both inflammatory and non-inflammatory lesions had a statistically significant reduction at 2 months when compared to baseline for Group 1
- Subject Satisfaction: All subjects would recommend microneedling as a treatment for acne vulgaris.
  - 100% of subjects were satisfied at Visit 5

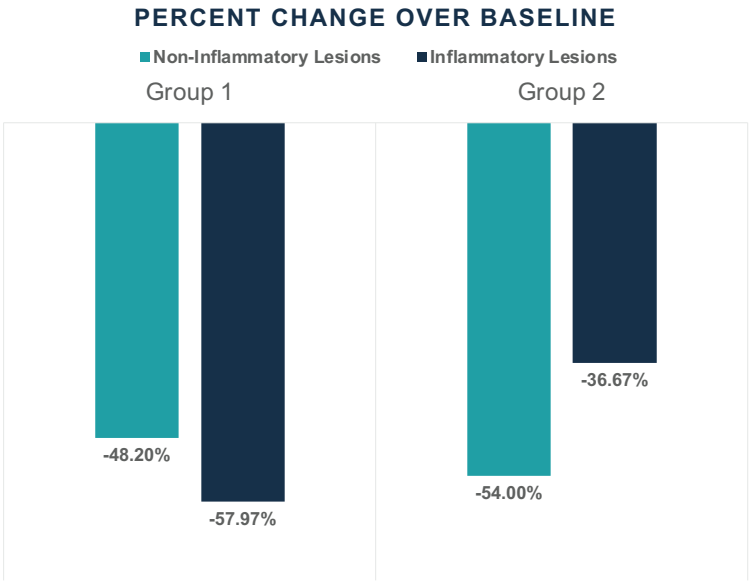

Fig. 3. *At their last visit, Group 1 and Group 2 saw a decline of 48.20% and 54.00% in non-inflammatory lesions and 57.97% and 36.67% in inflammatory lesions, respectively, compared to baseline.*

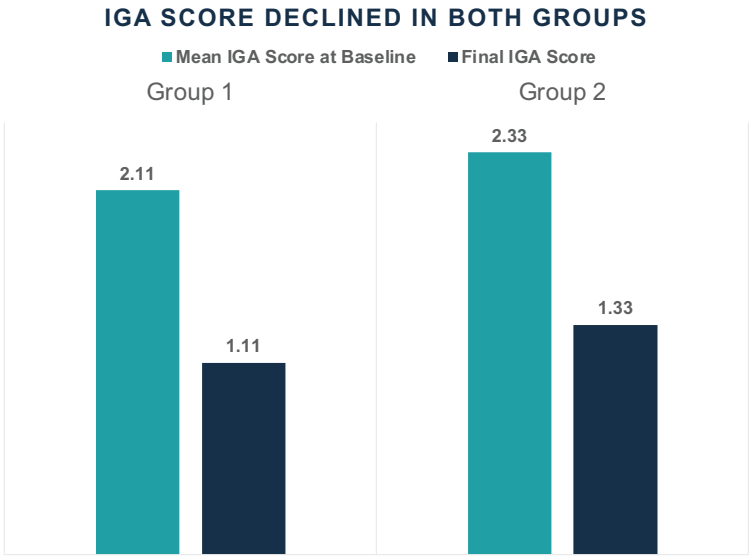

Fig. 4. *The mean IGA score at baseline for Groups 1 and 2 was 2.11 and 2.33, respectively. A decline in mean IGA scores was observed in both groups at the two-month follow up visit, Group 1 was 1.11 and Group 2 was 1.33.*

Conclusions:

1. **This study expands the utility of microneedling into a potential therapeutic modality for acne vulgaris.**
   - Microneedling may have the potential to be a well-tolerated option for those suffering from acne, being a treatment that neither damages the sebaceous glands nor disrupts the skin microbiome.
2. **This clinical study suggests that when appropriate pre- and post-procedure protocols are adhered to, microneedling may not present significant contraindications for acne treatment, based on scientific observations.**
   - Microneedling did not cause post-treatment complications and was seen to reduce acne lesions effectively.
3. **No adverse events related to treatment occurred in this study.**

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Disclaimers: SkinPen® Precision has not been approved by the FDA for use in acne vulgaris.
Indication: The SkinPen® Precision system is a microneedling device and accessories intended to be used as a treatment to improve the appearance of wrinkles of the neck for Fitzpatrick skin types II - IV and to improve the appearance of facial acne scars in adults with all Fitzpatrick skin types aged 22 years and older.
Contraindications: The use of the SkinPen® Precision should not be used on patients who have open wounds, sores, or irritated skin in the treatment area(s).
Precautions: The use of SkinPen® Precision has not been evaluated in the active acne patient population.
Study Limitations
1. Small sample size: A larger sample size would provide more robust evidence representative of a broader population.
   - Specifically, in Group 2 (n=3) where study subjects received 4 treatments at 2-week intervals. The small sample size limited statistical power.