

# A TRIAL TO DEMONSTRATE THE POTENTIAL OF AN INGREDIENT TO REDUCE PROPIONIBACTERIUM ACNES

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## Abstract

Fluorescence spectroscopy evaluates the physical and chemical properties of tissues by analyzing the intensity and character of light emitted in the form of fluorescence. This technology has been utilized for the non-invasive detection and quantification of many skin deep conditions. Acne is such a condition that can benefit from the use of fluorescence spectroscopy as an evaluative measurement technique in order to identify and classify the stages of acne lesion formation. We present here a novel clinical study using skin biophysics and artificial intelligence to provide a comprehensive quantitative assessment of acne, from precursors of visible lesions to classification of active papules, pustules, cysts and characterization of post inflammatory hyper pigmentation. This study was intended to evaluate the effectiveness of a test ingredient in a panel of fifty subjects randomized in a 1:1 ratio to test and control products. Data from this study will be analyzed to determine whether the test product was effective in the reduction of P. acnes and evidence of its effects on facial skin, and whether it was more effective than another product in the reduction of P. acnes and its effects on facial skin.

## Background

The objective of this study was to evaluate the anti-acne potential of one test ingredient during normal usage conditions using clinical and bio-instrumental assessments. Specific attention was given to the following parameters:

- Reduce the presence of Propionibacterium acnes (P. acnes) on facial skin following four weeks of treatment.
- Demonstrate superior reduction of Propionibacterium acnes (P. acnes) on facial skin following four weeks of treatment compared to control product.
- To reduce the appearance of acne lesions, spots/scars (pigment) and pores after four weeks of treatment.
- Demonstrate superior reduction of the appearance of acne lesions, spots/scars (pigment) and pores after four weeks of treatment compared to control product.

Skin image analysis serves an important function for clinical evaluation and investigation of acne in this trial. Artificial intelligence is utilized in quantitative skin imaging for skin feature recognition based on parameters of interest, such as:

- Unhealthy Pores: Excess Sebum, P. acnes
- Non-Inflammatory Lesions: Open Comedones, Blackheads
- Inflammatory Lesions: Papules, Pustules, Cysts
- Post Inflammatory Hyperpigmentation

## Methodology

This was a four (4) week study, with a one-week washout period prior to baseline, wherein subjects were to discontinue use of all topical facial products, anti-aging and anti-acne medications (topical or systemic), and anti-inflammatory medications. Visits occurred at baseline and week four. One left-view image and one right-view image of the face was taken in two lighting modalities, sun spectral light and blue light captures, using the BTBP Clarity™ R&D system.

The BTBP Clarity R&D system reports the parameters of each acne-related feature detected and evaluated in this study: P. acnes and Post Inflammatory Hyperpigmentation.

P. Acnes Count- Count of number of pores identified with P. acnes; otherwise a state of altered pH which creates a breeding ground for acne causing bacteria.

Post Inflammatory Lesion Count - Number of lesions classified as post inflammatory hyperpigmentation- lesions consisting of a specific color signature and formation consistent with healing acne lesions; different classification criteria was used to filter out active lesions such as papules, pustules - utilizing white head recognition and degree of redness scoring, and cysts.

## Results

The test ingredient demonstrated statistically significant outperformance in the reduction of Propionibacterium acnes (P. acnes) on facial skin following four weeks of treatment compared to control product. P. acnes count in the BTBP Clarity R&D quantitative imaging system.



Figure 1. The recognition of P. acnes through the fluorescent signatures of the skin. Feature detection is derived in the blue light capture processed by the BTBP Clarity R&D system, utilizing a 365 nm wavelength light source to excite the follicles and obtain the emission spectra associated with P. acnes. P. acnes counts here are shown overlaid onto a diffuse light capture taken simultaneously with the fluorescent capture in the BTBP Clarity R&D quantitative imaging system.

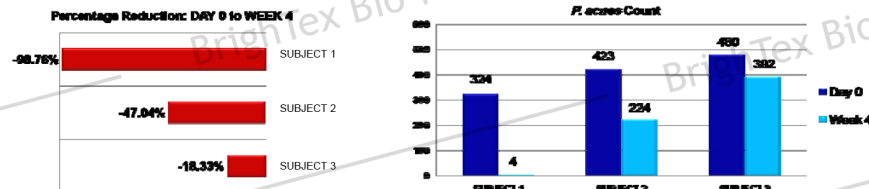
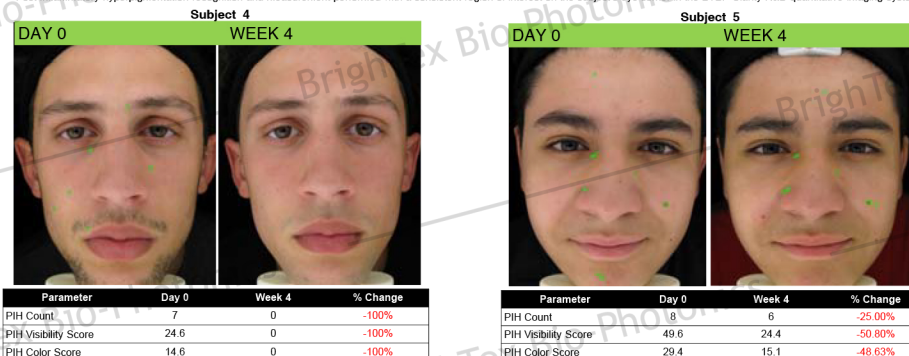


Figure 2. The P. acnes percentage reduction from Day 0 to Week 4 for each of the 3 Subjects identified above.

Post Inflammatory hyperpigmentation recognition and measurement performed with a consistent region of interest on the subject's eye/corner in the BTBP Clarity R&D quantitative imaging system.



| Parameter            | Day 0 | Week 4 | % Change |
|----------------------|-------|--------|----------|
| PIH Count            | 7     | 0      | -100%    |
| PIH Visibility Score | 24.6  | 0      | -100%    |
| PIH Color Score      | 14.6  | 0      | -100%    |

| Parameter            | Day 0 | Week 4 | % Change |
|----------------------|-------|--------|----------|
| PIH Count            | 8     | 6      | -25.00%  |
| PIH Visibility Score | 49.6  | 24.4   | -50.80%  |
| PIH Color Score      | 29.4  | 15.1   | -48.63%  |

## Results

| Variable       | Group 1           |                   | Group 2           |                   | Baseline P. Value | Week 4 P. Value |
|----------------|-------------------|-------------------|-------------------|-------------------|-------------------|-----------------|
|                | Baseline          | Week 4            | Baseline          | Week 4            |                   |                 |
| PIH Count      | 19.19 ± 17.50     | 14.69 ± 13.48     | 14.96 ± 8.67      | 16.33 ± 11.16     | 0.290             | 0.630           |
| PIH Visibility | 53.24 ± 19.38     | 49.12 ± 23.56     | 59.01 ± 24.50     | 56.93 ± 18.93     | 0.343             | 0.188           |
| PIH Color      | 12.04 ± 11.61     | 9.03 ± 10.96      | 13.03 ± 15.12     | 12.16 ± 16.29     | 0.788             | 0.417           |
| Sebum          | 2170.80 ± 1919.48 | 2251.84 ± 1711.51 | 1625.29 ± 1636.16 | 2057.29 ± 1737.97 | 0.265             | 0.683           |
| P. Acnes       | 1251.23 ± 1077.05 | 1090.23 ± 949.06  | 1088.46 ± 980.51  | 1262.07 ± 901.80  | 0.563             | 0.502           |

Figure 7. BTBP Clarity R&D Evaluations, Group Comparisons. PIH = Post Inflammatory Hyperpigmentation

| Variable       | Group 1-Change From Baseline |                | Group 2-Change From Baseline |                | Difference P. Value | Percent Change P. Value |
|----------------|------------------------------|----------------|------------------------------|----------------|---------------------|-------------------------|
|                | Difference                   | Percent Change | Difference                   | Percent Change |                     |                         |
| PIH Count      | -4.50 ± 5.18                 | -22.11%        | 2.14 ± 6.71                  | +12.10%        | <0.0001             | 0.001                   |
| PIH Visibility | -4.11 ± 13.87                | -7.75%         | -1.45 ± 17.24                | -6.73%         | 0.538               | 0.214                   |
| PIH Color      | -3.00 ± 7.56                 | -32.88%        | -1.96 ± 11.10                | -15.22%        | 0.063               | 0.010                   |
| Sebum          | +81.03 ± 1299.43             | +36.26%        | 364.92 ± 751.09              | +57.06%        | 0.339               | 0.001                   |
| P. Acnes       | -145.57 ± 537.68             | -5.46%         | 147.80 ± 460.23              | +42.90%        | 0.040               | 0.003                   |

Figure 8. BTBP Clarity R&D Evaluations, Mean Changes from Baseline- Group Comparisons. PIH = Post Inflammatory Hyperpigmentation

## Conclusions

A statistically significant reduction was shown in the total counts of acne lesions, spots/scars (pigment) and pores after four weeks of treatment. The test ingredient demonstrated superior reduction in post inflammatory hyperpigmentation after four weeks of treatment compared to control product.

Superior reduction of the appearance of acne lesions, spots/scars (pigment) and pores after four weeks of treatment compared to control product was also shown. Group 1 posted a reduction (improvement) in the mean difference in individual subjects' PIH counts from week 0 to week 4 compared with an increase (worsening) seen in same for Group 2. Therefore, Group 1 demonstrated statistically significant superiority in ability to improve individual PIH count over Group 2.

Group 1 also posted a negative mean percent change (improvement) in individual subjects' PIH counts from week 0 to week 4 compared while Group 2 posted a positive mean percent change (worsening) in same. The difference between groups for this variable was statistically significant. Further, Group 1 posted more than double the negative mean percent change (improvement) in PIH color from week 0 to week 4 as Group 2. The difference between group results for this variable was also statistically significant. Therefore, Group 1 demonstrated statistically significant superiority in ability to produce a larger improvement in PIH count and color than Group 2.

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