EYE BROW

STUDY TEMPLATE

BrighTex Bio-Photonics, LLC
359 Piercy Road, San Jose,
CA 95138 USA
Tel : +1.408.960.3816
Fax : +1.408.960.2916
Website : www.btbp.org
Email : support@btbp.org

ABSTRACT

The objective of this clinical study is to determine whether the test product changes the appearance of eye brows after one use in the lab using Artificial Intelligence techniques.

Captures will be taken twice by using Clarity Research 3D system i.e., at baseline and immediately post-application of the third coat of test material (approximately 15 minutes). Measurements are taken before and after the application of brow gel product to determine the efficacy of the product.

It was concluded that the test material, Brow Gel, demonstrated a statistically significant improvement in eyebrow appearance immediately post-application for the parameters Average Brow Intensity (Color Intensity), Eyebrow Surface Area (%), Skin Surface Area (%) and Eyebrow Volume in the range from 19.71% to 32.45%.

Section 1: OBJECTIVE

The objective of this clinical study is to determine whether the test product changes the appearance of eye brows after one use in the lab

Section 2: STUDYDESIGN

Candidates for study participation will be identified from the Research centre panellist database. This will include approximately 30 subjects who meet all of the inclusion criteria and none of the exclusion criteria. The eligible participants will be enrolled in the study to assess the efficacy of a brow gel. Study evaluations will include Clarity Research 3D System imaging and data analysis. Data will be generated for change in color in two dimensions and change in volume in three dimensions using the Clarity Research 3D system. The Clarity Research 3D System digital photography will be taken at Baseline.

Procedure	**Baseline**	Immediately
Inclusion and Exclusion Criteria Verified	✓	
Informed Consent Obtained	✓	
Clarity Research 3D Imaging	✓	✓
Test Material Applications by Cosmetologist (Three Coats)	✓+	

+The test material will be applied following Baseline photography

Section 3: TEST MATERIALS AND RECORD RETENTION

3.1 IDENTIFICATION

The test materials will be identified by Clarity Research 3D Laboratories, LLC study, panel and subject numbers, in accordance with distribution. Test material identification is as follows:

Sponsor Identification	Research Laboratory Identification Number
Brow Gel	BG245

The Sponsor assumes responsibility for the purity, stability, characterization, and adequate preservation of the test materials. The Sponsor shall provide assurance that the test materials submitted have been determined to be safe for use in humans.

3.2 STORAGE AND RETENTION

Prior to distribution to study participants, the test materials will be stored at room temperature and humidity. All unused test materials will be retained by Clarity Research 3D Laboratory for a minimum of 6 months.

3.3 PRODUCT USE

Product usage instructions appear in Section 9 of this study protocol

Section 4: STUDY POPULATION

Each study's protocol has guidelines for who can or cannot (inclusion and exclusion criteria) participate in the study. These guidelines, called eligibility criteria, describe characteristics that must be shared by all participants as part of the informed consent. The criteria differ from study to study. They may include age, gender, medical history, and current health status.

A total of 30 subjects will be enrolled in this study. Subjects will be recruited from the Research centre panellist database. Interested candidates will report to the testing facility for screening and subjects who meet all of the inclusion criteria and none of the exclusion criteria will be enrolled.

4.1 INCLUSION CRITERIA

A subject may be eligible for study participation if all of the following criteria are met:

- Subject is female between 18 and 65 years of age;
- Subject has one of the following hair colors: blonde (approximately six subjects), auburn (approximately six subjects), light medium (approximately six subjects), medium dark (approximately six subjects), or black (approximately six subjects);
- Subject has sparse to medium natural eyebrows;
- Subject is a regular user of eyebrow products;
- Subject agrees not to introduce any new cosmetic or toiletry products during the study;
- Subject is dependable and able to follow directions as outlined in the protocol;
- Subject is willing to participate in all study evaluations;
- Subject is in generally good health and has a current Panelist Profile Form on file at Clarity Research3D Laboratory;
- Subject agrees to sign a Photography Release Form, providing consent for the capture of digital images for use in relation to this clinical study;
- Subject has completed a HIPAA Authorization Form in conformance with 45 CFR Parts 160 and 164;
- Subject understands and is willing to sign an Informed Consent Form in conformance with 21 CFR Part 50: "Protection of Human Subjects."

4.2 EXCLUSION CRITERIA

A subject is not eligible for study participation if any of the following criteria are met:

- Female subject is pregnant, nursing, planning a pregnancy, or not using adequate birth control;
- Subject has cosmetic eyebrow tattoos, micro blading, micro feathering, or micro shading;
- Subject has a history of acute or chronic dermatologic, medical, and/or physical conditions which would preclude application of the test material and/or could influence the outcome of the study;

- Subject is currently taking certain medications which, in the opinion of the Principal Investigator, may interfere with the study;
- Subject has known allergies to skin treatment products or cosmetics, toiletries, and/or topical drugs.

4.3 SUBJECT TERMINATION AND WITHDRAWAL

A subject may be discontinued from study participation at any time if the Principal Investigator or designated medical staffs feels that it is not in the subject's best interest to continue.

All subjects are free to withdraw from participation at any time, for any reason, specified or unspecified, and without prejudice. Reasonable attempts will be made by the Principal Investigator or designee to provide a reason for subject withdrawals. The reason for the subject's withdrawal from the study will be specified in the subject's source documents and included in the final report

Section 5: STUDY EVALUATIONS

CLARITY RESEARCH 3D SYSTEM

The Clarity Research 3D System features the latest technology in 2D and 3D skin modelling. The Clarity Research 3D System features 3 cameras, each with 25 megapixels and SLR image capture in 16-bit. The Automated image recognition includes artificial intelligence for facial zoning by area of interest, and data tracking by region of interest. The Clarity Research 3D System captures 6 types of skin images, including diffuse white light, melanin, haemoglobin, texture, 3D macro structure, and 3D micro structure. The system also allows for simultaneous front, left and right profile capture with no repositioning requirements.

The following parameters will be assessed:

- Change in Color of eyebrow (2D)
- Chang in brow volume (3D)
- Thickness (% of area covered)

Clarity Research 3D System, photography will be captured at Baseline and immediately post-application of the third coat of test material (approximately 15 minutes)

Section 6: TEST METHOD

6.1 SUBJECT IDENTIFICATION

All subjects will be initially identified by a permanent Research centre panellist database identification number. Once the subject meets qualification criteria, a study subject number will be assigned. This permanent subject number will be assigned in sequence as subjects are enrolled in the study.

6.2 STUDY VISIT

Subjects will report to the laboratory with clean faces, free from makeup. Subjects will acclimate to ambient laboratory conditions for approximately 15 minutes. Baseline Clarity Research 3D system photography (eyes closed) will be captured. Test materials will be distributed to subjects. The appropriate brow gel shade will be distributed to each subject in accordance with the subject's hair color. The cosmetologist will apply the brow gel and allow drying. The cosmetologist will apply a third coat of the test material and allow drying. Clarity Research 3D system photography will be captured immediately post-application of the third coat of test material (approximately 15 minutes).

Section 7: Product Usage/Application Instructions

1. Open brow gel. Start by placing brush at the front of the brow.

2. Move the brush from the front to the back of the brow.

3. Remember to fill in all sparse hairs with the brush

4. Put brush back into container

5. Wait 45 seconds before reapplying

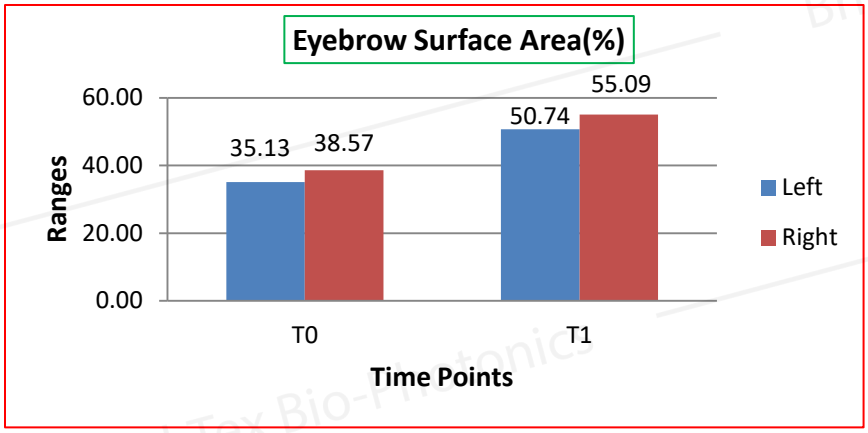
6. Repeat steps 1-5

6.1 Total of 3 coats

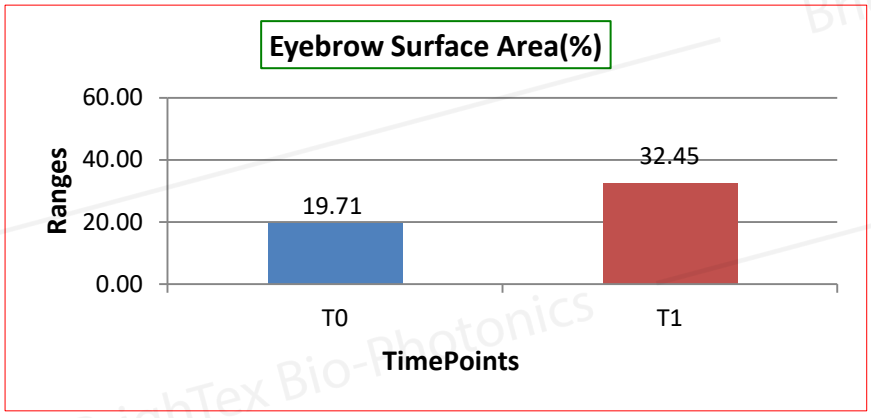
Section 8: 2D measurements & Data analysis with graphs and trends

8.1 Eye Brow Surface Area (%): is a measurement of area covered by the eyebrow within the eyebrow zone ROI, increase in this value indicate thickening of eyebrow

Subject 01 Results

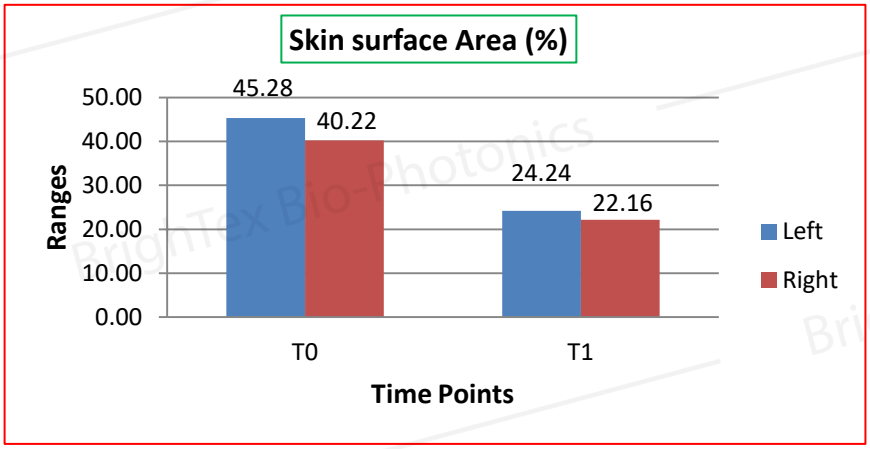


Overall Study Trends:

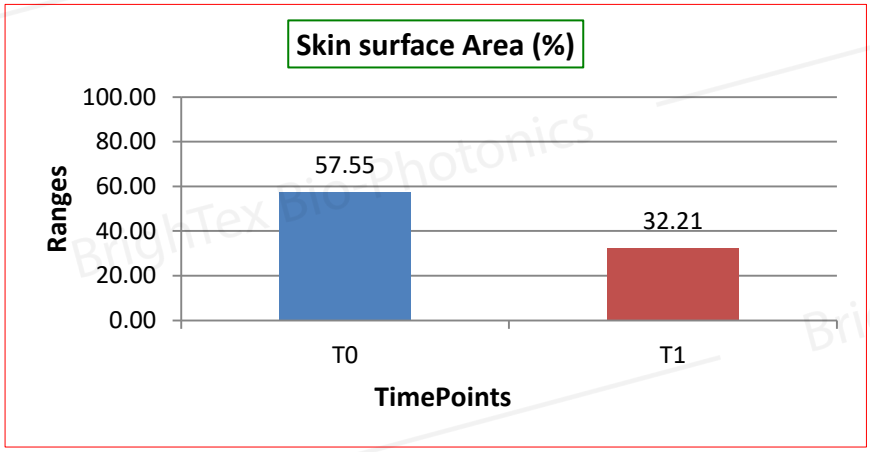


8.2 Skin Surface Area (%): is a measurement of area covered by the skin within the eyebrow shape detected, decrease in this value indicate filling up the gaps inside the eyebrow

Subject 01 Results

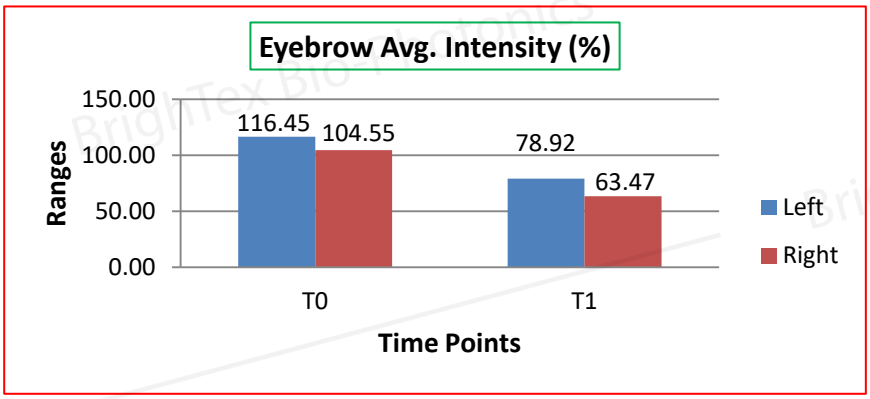


Overall Study Trends:

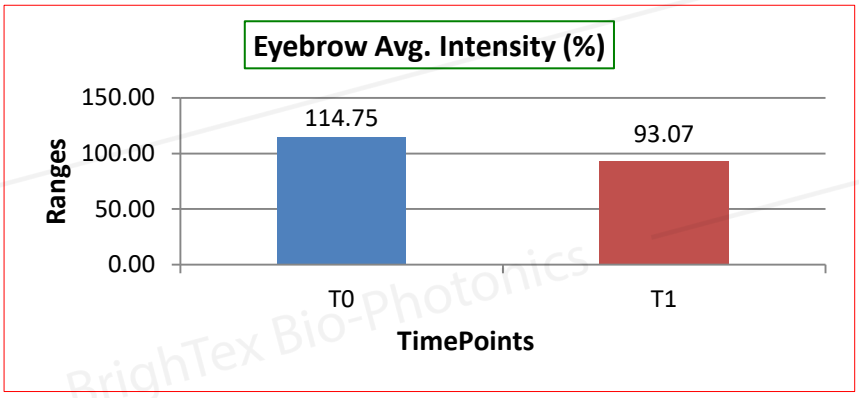


8.3 Average Intensity: is an average color Intensity measurement of an eyebrow area, decrease in this value indicate darkening of eyebrow

Subject 01 Results



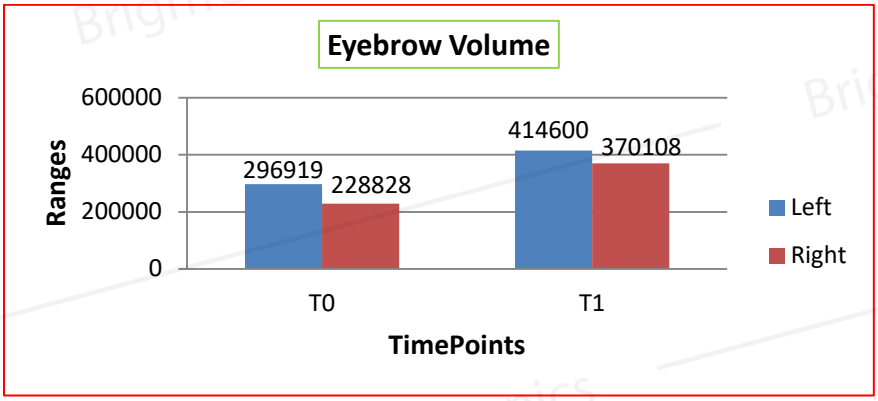
Overall Study Trends:



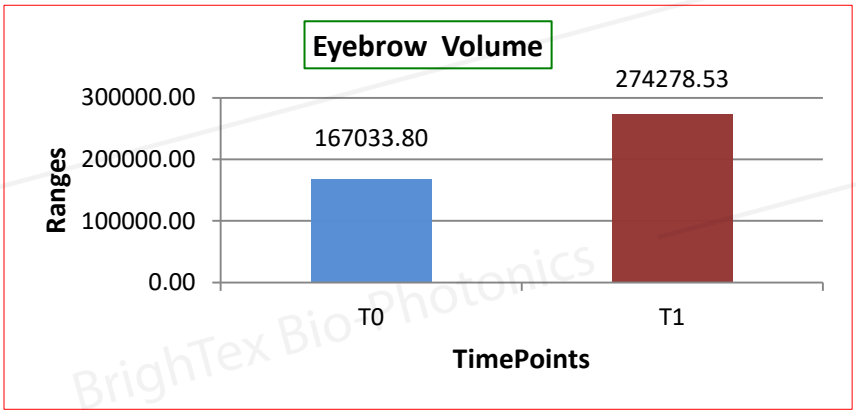
Section 9: 3D measurements & Data analysis with graphs and trends

9.1 Eye Brow Volume: is a total raw volume measurement of an eyebrow, increase in this value indicate raise in volume of eyebrow

Subject 01 Results



Overall Study Trends:



Section 10: Eye Brow 2D & 3D Sample Images

Definition: The strip of hair growing on the ridge above a person's eye socket

2D Images:

Before Applying Brow Gel

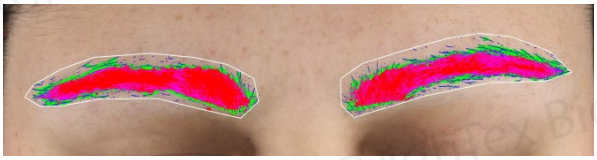
Input Image

Output Image

After Applying Brow Gel

Input Image

Output Image

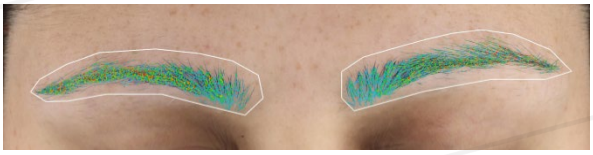


3D Images:

Before Applying Brow Gel

Input Image

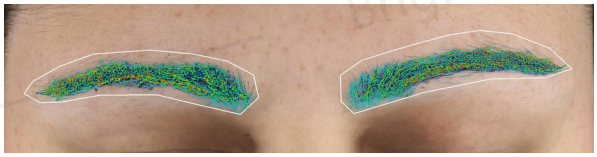
Output Image



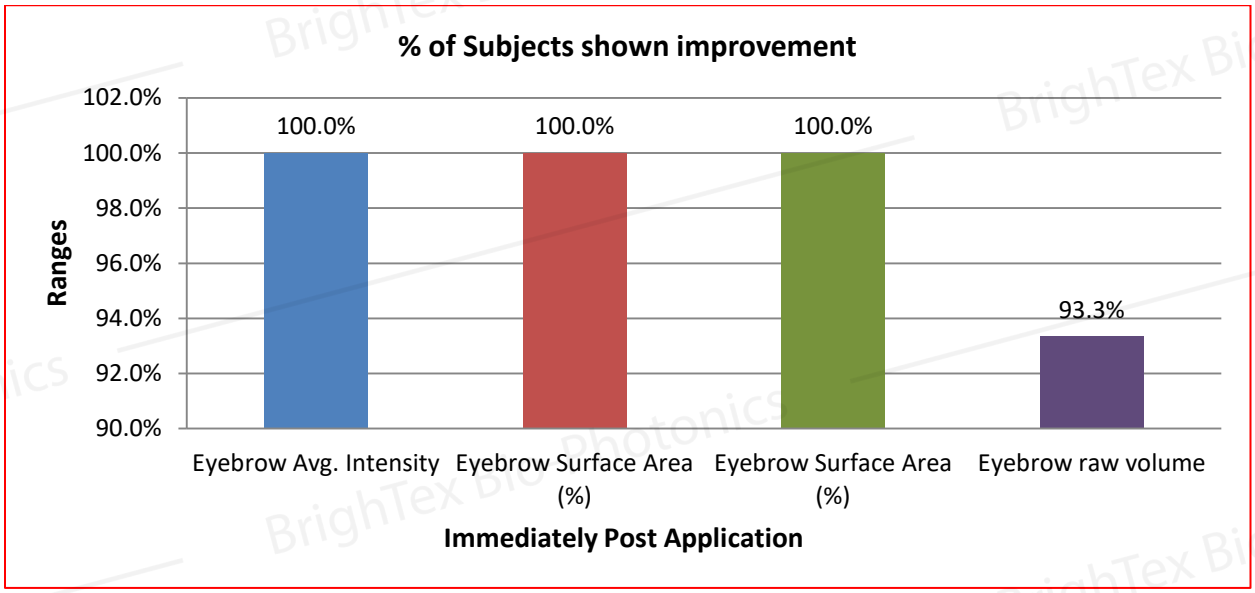
After Applying Brow Gel

Input Image

Output Image



Section 12: Test Results/Statistical Summary



Conclusion from Data:

Under the conditions of this study and in this test population, the test material, Brow Gel, demonstrated a statistically significant improvement in eyebrow appearance immediately post-application for the following parameters:

- Average Brow Intensity (Color Intensity)
- Eyebrow Surface Area (%)
- Skin Surface Area (%)
- Eyebrow Volume