

EYE LASH

STUDY TEMPLATE

ABSTRACT

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

Participant's captures are taken using Clarity Research 3D System digital photography at Baseline and immediately post application (approximately 15 minutes after third coat application).

Measurements are taken at baseline before using the product and after using the product immediately post application (approximately 15 minutes after third coat application) to determine the efficiency of the product.

Various eye lash feature parameter measurements are recorded and it was observed that there is a significant improvement in all the feature measurements at Immediately Post-Application (Approximately 15 Minutes after Third Coat Application) as compared to baseline that ranges from minimum 0.4% to maximum 7.18%.



Section 1: OBJECTIVE

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

Mascara is a cosmetic commonly used to enhance the eyelashes. It may darken, thicken, lengthen, and/or define the eyelashes. Normally in one of three forms—liquid, cake, or cream—the modern mascara product has various formulas; however, most contain the same basic components of pigments, oils, waxes, and preservatives.

Section 2: STUDYDESIGN

Candidates for study participation will be identified from the Research centre panellist database. This study will include approximately 20 female subjects between the ages of 18 and 55 years who meet all of the inclusion criteria and none of the exclusion criteria. Eligible subjects will be selected to participate in the evaluation of an eyelash treatment product. Study evaluations included Clarity Research 3D System imaging and data analysis. Data were generated for change in eyelash volume, length, lift, and curl using the Clarity Research 3D system. Clarity Research 3D System digital photography will be taken at Baseline and immediately post-application (approximately 15 minutes after third coat application).

Procedure	Baseline	Immediately Post-Application (Approximately 15 Minutes After Third Coat Application)
Informed Consent and Photography Release Form	✓	
Inclusion and Exclusion Criteria Verified	✓	
Clarity Research 3D System Photography	✓	✓

✓ Indicates panellist visit to the Research and Imaging Study Centre

Section 3: 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 20 subjects will be enrolled, in an attempt to complete the study with 15 subjects. 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.

INCLUSION CRITERIA:

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

- Subject understands and is willing to sign an Informed Consent Form (ICF)
- Subject has medium lash thickness;
- Subject is female between the ages of 18 and 55 years of age;
- Subject has a Fitzpatrick Skin Type of I, II, or III;
- Subject is in generally good health and has a current Panellist Profile Form on file at Research Laboratories;
- Subject has medium length lashes;
- Subject is using an adequate method of birth control;
- Subject agrees not to introduce any new cosmetic or skincare products, except for the test material provided for the duration of the study;
- Subject agrees to self-apply the test material twice daily at home for the duration of the study period;
- Subject is free from any dermatological or systemic disorders which, in the opinion of the Principal Investigator, would interfere with the test results or increase the risk of an adverse reaction;

- Subject agrees to only use their regular face and eye products (excluding eyelash enhancing products) for the duration of the study;
- Subject is dependable and able to follow directions as outlined in the protocol;
- 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 is willing to participate in all study evaluations;

EXCLUSION CRITERIA:

A subject may not be eligible for enrolment if any of the following criteria are met:

- Subject has known allergies to cosmetics or personal care products;
- Subject is pregnant, planning a pregnancy, or is nursing;
- Subject exhibits and/or reports a history of an acute or chronic dermatologic condition of the face or that affects the eyelashes, eye diseases/disorders, which would preclude application of the test material and/or could influence the outcome of the study;
- Subject has eyelash extensions;
- Subject exhibits sunburn, rashes, scratches, burn marks, tattoos, piercings, etc., which might interfere with evaluation of test results;
- Subject is currently undergoing chemotherapy or radiation.

Section 4: SKIN FEATURE TO BE STUDIED

Skin feature to be studied – Eye Lash

Definition:

Eye lashes are the hairs that grow at the edge of the eye lid. They are the first barriers that protect the eye from the wastage produced and act at stimulus to warn that an object is near the eye.

Eye Lashes are of different types. Based on the length and volume the eye lashes are categorized into Thick, Sparse, Short, Medium and Long length eye lashes.

Thick Lashes: The space between the lashes is less and lashes are very strong



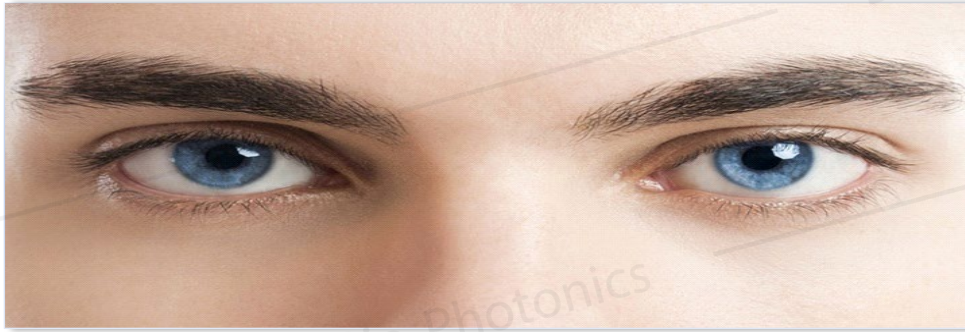
Sparse Lashes: Space between the lashes is more and the lashes are weak



Short Eye Lashes: Length of the eye lashes are short i.e. no curl



Medium Length: The lashes are of medium length



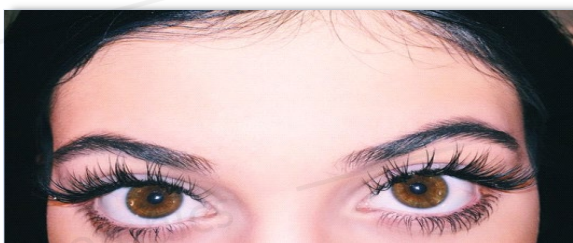

Long Length: The lashes will have curl



EYE LASH Matrix:

	SHORT
THICK - FULL	
THIN - SPARSE	

<p>THICK - FULL</p> <p>THIN - SPARSE</p>	<p style="text-align: center;">MEDIUM</p>  
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<p>THICK - FULL</p> <p>THIN - SPARSE</p>	<p style="text-align: center;">LONG</p>  
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Section 5: STUDY EVALUATIONS

CLARITY RESEARCH 3D SYSTEM

The Clarity Research 3D System features the latest technology in 2D and 3D skin modelling, boasting 3 cameras, each with 25 megapixels and SLR image capture in 16-bit. The Automated image recognition includes, image registration, artificial intelligence for facial and skin area recognition, high precision facial detection, automation for facial zoning and zoning by area of interest, and data tracking by region of interest. The system also allows for simultaneous front, left and right profile capture with no repositioning requirements. The system automatically detects over 50 facial regions for use in analysis, including detection of the face region. The system performs lash analysis on lash density, lash length, density, curl up angle, and lift up angle.

The following parameters will be analysed:

- Lift-up angle
- Curl-up angle
- Density (%)
- Average length (mm)
- Max length (mm)

Description of parameters:

Lift up Angle - Angle between edges of the eye lid to the root of the eye lash

Curl up Angle - Angle between the points where the curl begins to the tip of the eye lash

Density (%) - Percentage of eye lash pixels covered over the eyelash's region

Average Length (mm) - Measures the Average length of detected eye lashes, where 1 mm = 21 pixels

Max Length (mm) - Measures the maximum length of longest eye lash, where 1 mm = 21 pixels

Clarity Research 3D System photography will be captured (eyes closed) at Baseline, Week 4, Week 8, Week 12, and Week 16.

Section 6: MASCARA USAGE/APPLICATION INSTRUCTIONS

1. Open mascara. Start by placing the brush at the root of the lash and wiggle the brush toward the tip of the lash.
2. Repeat this step throughout all lashes, including bottom lashes.
3. Don't forget the inner corner and hard to reach lashes.
4. Wait 45 seconds before reapplying.
5. Put Brush back into container.
6. Repeat steps 1-5.
 - a. Total of 3 coats.

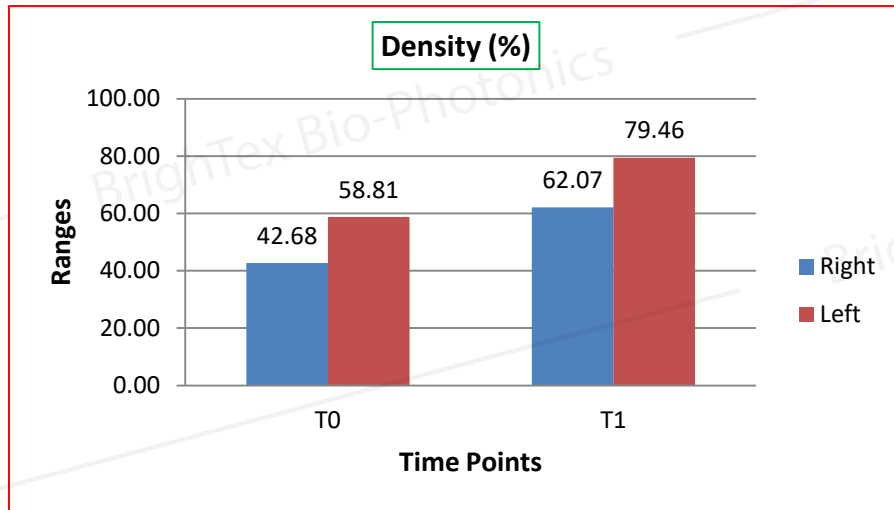
Compliance of Product Application:

A cosmetologist applies the test product in the laboratory.

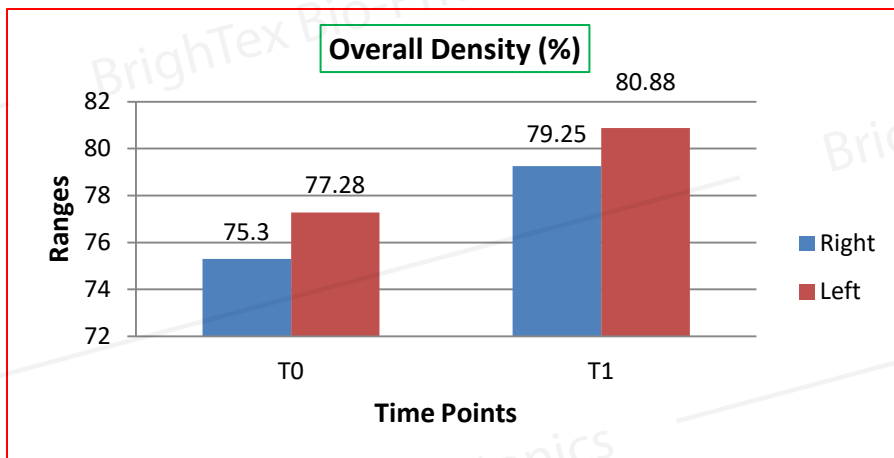
Section 7: 2D measurements & Data analysis with graphs and trends

7.1 Lash Density (%)

Subject 14 Results



Overall Lash Density (%) (Left + Right Eye Lash Surface Area)



Section 8: Data collected samples images

T0 (before applying Mascara/Lash enhancing product)

Original Right Eye Lash image



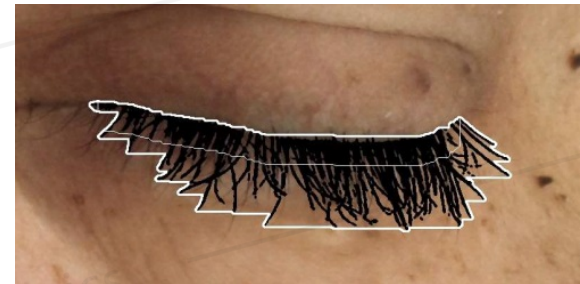
Recognized Right Eye Lash image



Original Left Eye Lash image



Recognized Left Eye Lash image

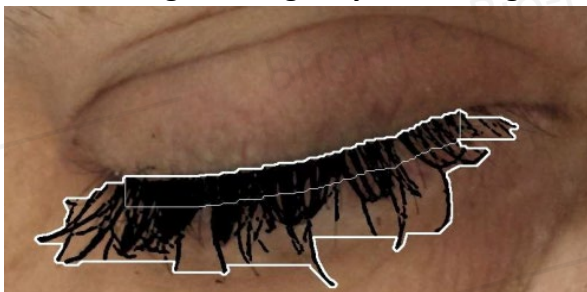


T1 (After applying Mascara/Lash enhancing product)

Original Right Eye Lash image



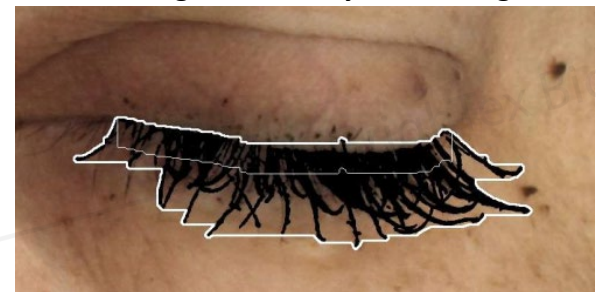
Recognized Right Eye Lash image



Original Left Eye Lash image



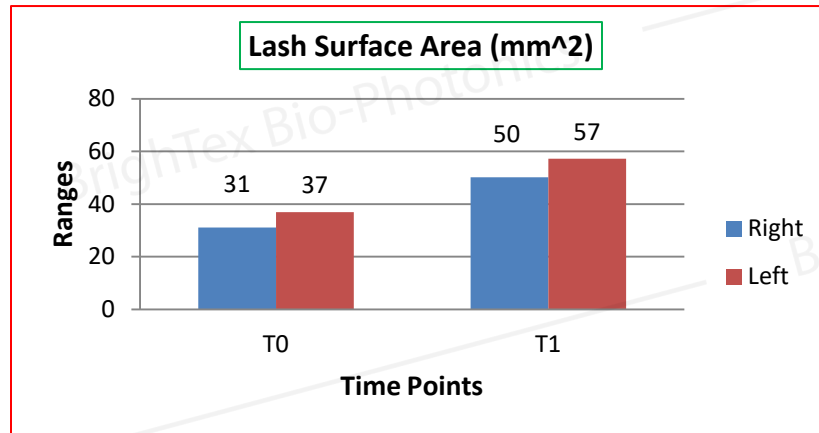
Recognized Left Eye Lash image



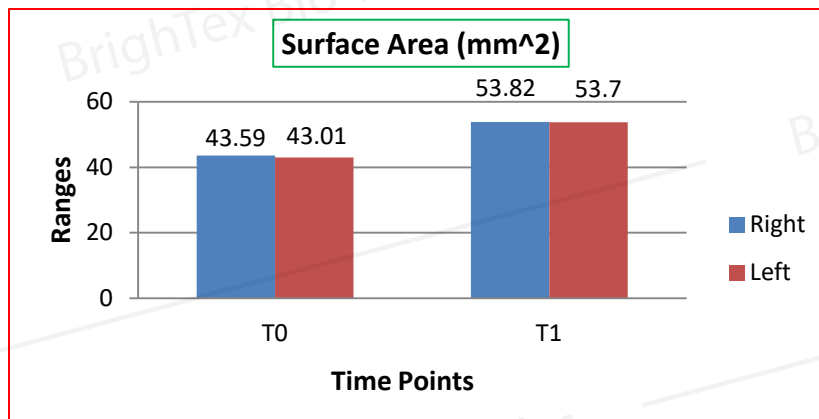
Section 9: 3D Measurements & Data analysis with graphs and trends

9.1 Lash Surface Area (mm²)

Subject 14 Results



Overall Lash Surface Area (mm²) (Left + Right Eye Lash Surface Area)



Section 10: Lash 3D

LASH 3D Example Images

Original Image - Before Applying Mascara



Recognized Image



Original Image - After Applying Mascara

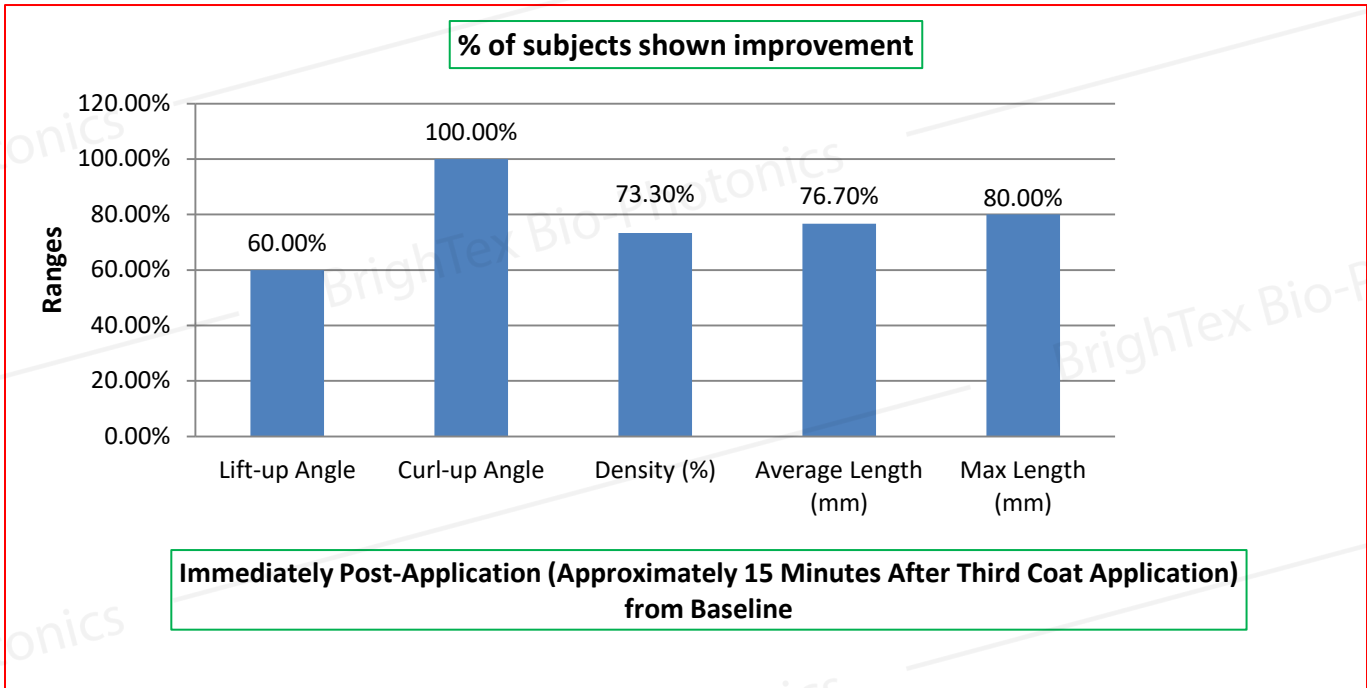


Recognized Image



Section 11: Test Results/Statistical Summary

Eye Lash Statistical Summary:



Conclusion from Data: Significant improvement was observed at Immediately Post-Application (Approximately 15 Minutes after Third Coat Application) as compared to baseline for curl up angle indicating more lifted lashes, Density, Average Length (mm) and Max Length (mm) indicating longer and thicker lashes.

The negative reading in lash volume is due to the below reasons:

1. The subjects share a common eyelash trait like thin and straight.
2. Lashes weigh down and look straight even after the product application.
3. Uneven application of the Mascara. Product clumping causes the lashes to join together, making the gaps in between larger and decreasing eyelash compactness.
4. When the overall density decreases, it is possible for average lash volume to increase.