DARK CIRCLES

STUDY TEMPLATE

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ABSTRACT

The primary objective of this clinical study is to assess the efficacy of a test product to change the characteristics of the skin around the eyes at Baseline and after four weeks to eight weeks of use.

Participant's captures are taken using Clarity Research 3D System digital photography at Baseline, Week 4 and Week 8.

Measurements for the Participants will be recorded at Baseline, Week 4 and Week 8 after using the test materials.

There was a statistically significant improvement in Dark Circles from Baseline to Week 8 which ranges from 80% to 83%.

Section 1: OBJECTIVE

The primary objective of this clinical study is to assess the efficacy of a test product to change the characteristics of the skin around the eyes 30 minutes post-application and after four weeks and eight weeks of use.

Section 2: STUDYDESIGN

Approximately 30 female Participants will be enrolled in this clinical study to assess the efficacy of a test material at Baseline and following four weeks and eight weeks of use and to obtain the consumer perceptions of the test material following eight weeks of use. Study evaluations will include Clarity Research 3D System imaging and consumer perception questionnaires.

A study schedule appears below.

Study Procedures and Evaluations	**Screening (Day -7 ± 2 Days)**	**Baseline**	**Week 4**	**Week 8**
Informed Consent Obtained	✓			
Inclusion and Exclusion Criteria Verified	✓			
Clarity Research 3D System Photography		✓	✓	✓
Test Material Application in the Laboratory		✓		
Test Material, Daily Diary, and Use Instructions Distributed		✓		
Test Materials and Daily Diaries Collected				✓

Consumer Perception Questionnaire				✓

✓ Test material will be applied for the first time in the laboratory following Baseline Clarity Research 3D System Imaging

Section 3: STUDY POPULATION

Approximately 30 Participants will be enrolled in this study.

3.1 INCLUSION CRITERIA

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

1. Participant is female between 30 and 65 years of age;
2. Participant exhibits mild to moderate fine lines and wrinkles in the crow's feet area;
3. Participant exhibits mild to moderate under eye puffiness;
4. Participant exhibits mild to moderate under eye dark circles due to circulation;
5. Participant agrees not to introduce any new cosmetic or toiletry products during the study;
6. Participant agrees to continue to use of regular products that are not eye serums or eye creams, that do not contain anti-aging properties or are used anywhere except the test area (crow's feet and under eyes);
7. Participant agrees to refrain from use of her current eye serum or eye cream and to use only the provided test material on the eye area and for the duration of the study;
8. Participant is dependable and able to follow directions as outlined in the protocol;
9. Participant is willing to participate in all study evaluations;
10. Participant is in generally good health and has a current Panellist Profile Form on file at Clarity Research Laboratory;
11. Participant agrees to sign a Photography Release Form, providing consent for the capture of digital images for use in relation to this clinical study;
12. Participant has completed a HIPAA Authorization Form in conformance with 45 CFR Parts 160 and 164;
13. Participant understands and is willing to sign an Informed Consent Form in conformance with 21 CFR Part 50: "Protection of Human Participants."

3.2 EXCLUSION CRITERIA

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

1. Participant is pregnant, nursing, planning a pregnancy, or not using adequate birth control;
2. Participant has received treatment with sympathomimetics, antihistamines, vasoconstrictors, non-steroidal anti-inflammatory agents, and/or systemic or topical corticosteroids within one week prior to initiation of the study;
3. Participant 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;
4. Participant is currently taking certain medications which, in the opinion of the Principal Investigator, may interfere with the study;
5. Participant has known allergies to skin treatment products or cosmetics, toiletries, and/or topical drugs.

Section 5: STUDY EVALUATIONS

Before starting the evaluation, participants must acclimate to the laboratory environment for at least 15 minutes.

5.1 Clarity Research 3D System

The Clarity Research 3D System features the latest technology in 2D and 3D skin modeling, boasting 3 cameras, each with 25 megapixels and SLR image capture in 16 bit. The Automated image recognition includes 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 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 Clarity Research 3D system is capable of detecting over 50 facial regions for analysis of fine lines, texture, skin tone evenness and discoloration, and contouring. The system is also able to perform 3D reconstruction of the skin topography and facial contour, facial volume analysis, and facial fine lines/deep wrinkle surface analysis and to analyse acne scars and lesions, redness scoring, subsurface pigment

detection, pore detection, and visible spot detection. Images will be obtained with eyes open and eyes closed.

The following parameters will be assessed at Baseline, Week 4, and Week 8:

- Under eye dark circles

5.1.1 SKIN FEATURE TO BE STUDIED

1. Dark Circles

Dark circles is the under eye pigmentation and bags

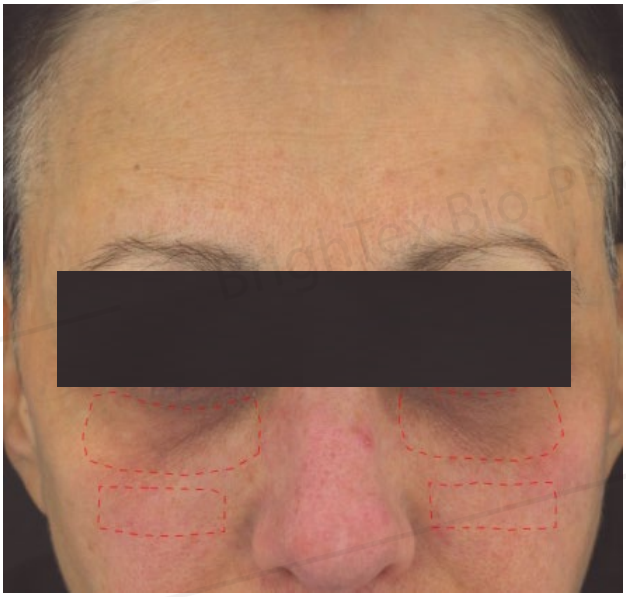
Measured Parameters: L star

L star: As L* increases the brightness in Skin tone increases.

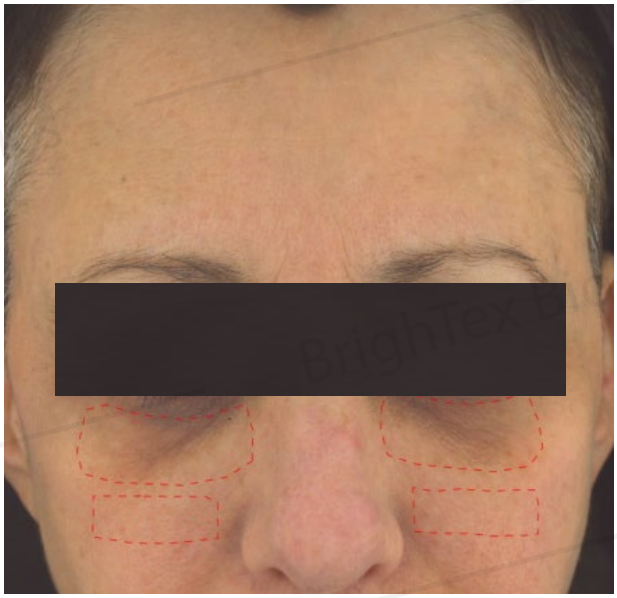
The lightness value, L*, represents the darkest black at L*= 0, and the brightest white at L* = 100.

i. Sample Result Images:

T0



T2



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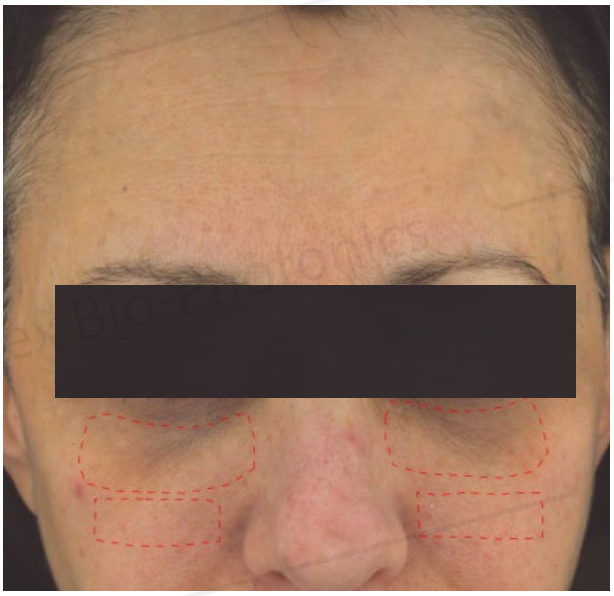
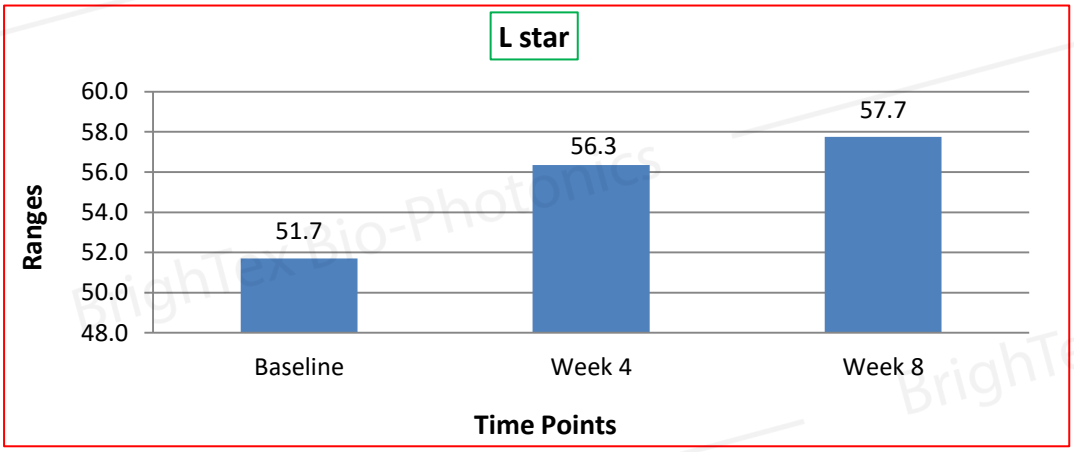
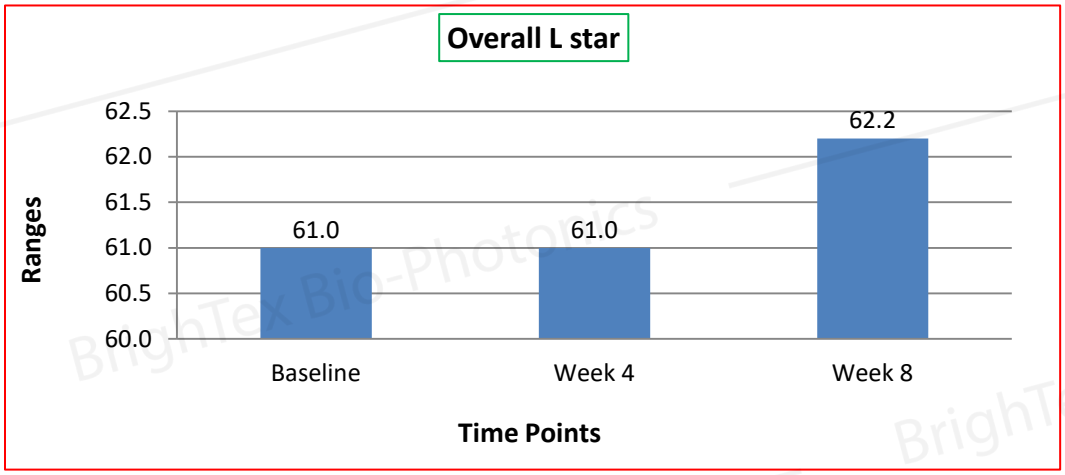


Participant 13 Results



L star Overall:



Test Results and Statistical Summary

Clarity™ Research 3D System – L star				
Parameter	Treatment	Visit	Number of participants showed improvement	% of Participant showed improvement
L star	Test Product	Week 4	24	80%
		Week 8	25	83%

Section 6: TEST METHOD

6.1 Participant Identification

All Participants will be initially identified by a permanent Clarity Research Laboratory identification number. Once the Participant meets qualification criteria, a study Participant number will be assigned. This permanent Participant number will be assigned in sequence as Participants are enrolled in the study.

6.2 SCREENING

Participants will report to the testing facility. Informed consent will be obtained. Inclusion and exclusion criteria will be verified. Participants will begin a 7-day (±2 days) conditioning phase and will refrain from applying their usual eye serum/eye cream and any facial moisturizers.

6.3 Baseline

Participants will return to the testing facility with clean faces, free from makeup. Participants will acclimate to ambient laboratory conditions for approximately 15 minutes. Clarity Research 3D System imaging will be captured. Participants will apply the test material for the first time in the laboratory under the supervision of Clarity Research Laboratory study staff. Approximately 30 minutes after application, Clarity Research 3D System imaging will be captured. Participants will receive the test material, use instructions, and a daily diary to record use of the test material. Participants will continue

to use regular products that are not eye serums or eye creams, that do not contain anti-aging properties or are used anywhere except the test area (crow's feet and under eyes).

6.4 Week Four Visit

Participants will return to the testing facility with clean faces, free from makeup. Participants will acclimate to ambient laboratory conditions for approximately 15 minutes. Clarity Research 3D System imaging will be captured.

6.5 Week Eight Visit

Participants will return to the testing facility with clean faces, free from makeup. Participants will acclimate to ambient laboratory conditions for approximately 15 minutes. Clarity Research 3D System imaging will be captured. Participants will complete a consumer perception questionnaire. Daily diaries will be reviewed for study compliance and collected. Unused test materials will be collected.

Section 7: Product Usage/Application Instructions

Use the test material once per day, in the evening. Gently squeeze the product from the tube onto the skin care device. Massage around and under the eye area including the crow's feet area after cleansing and before moisturizing.

Section 8: CONCLUSION

There was a statistically significant improvement in Dark Circles from Baseline to Week 8 which ranges from 80% to 83%.