3D FACIAL CONTOURS

STUDY TEMPLATE

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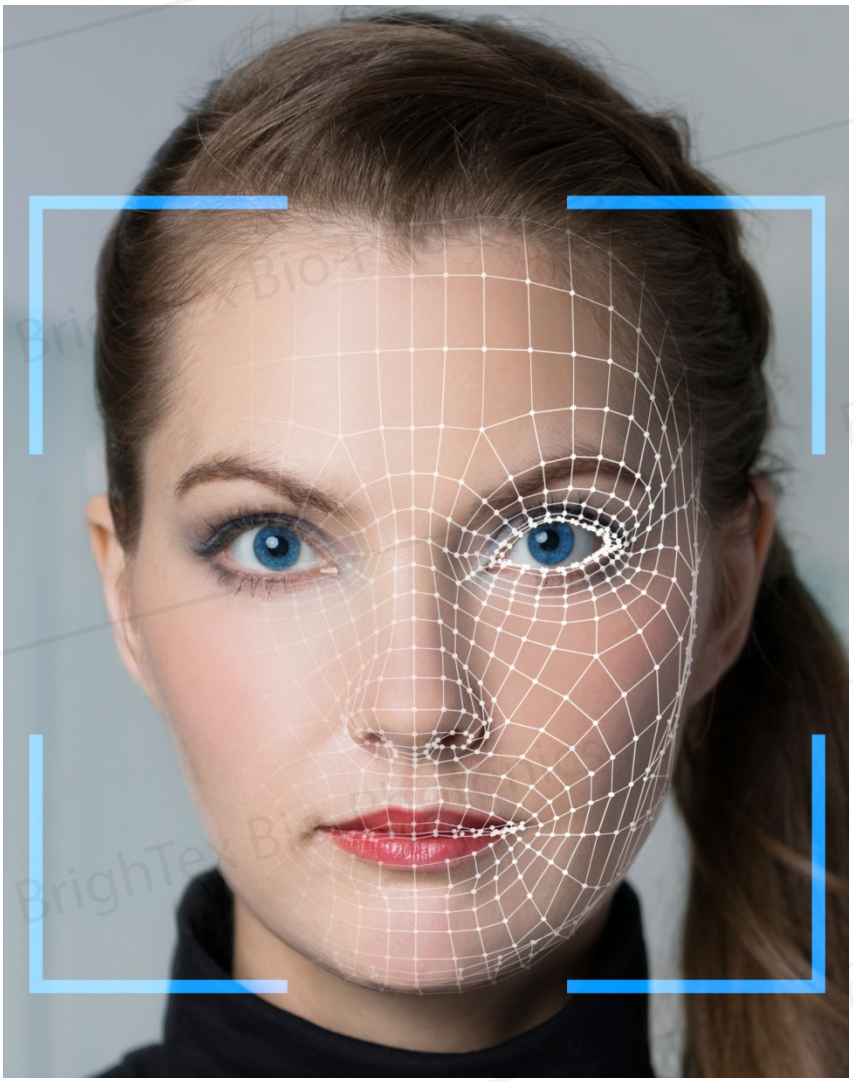
ABSTRACT

The objective of this study is to compare the safety and efficacy of a test product over an eight -week use period.

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

Measurements for the Participants will be taken before and after using the specially formulated skin care treatment cleansers.

There was a statistically significant improvement in the 3D Facial Contours from Baseline to Week 8 which ranges from 33.3% to 66.7%.



Section 1: OBJECTIVE

The objective of this study is to compare the safety and efficacy of a test product over an eight -week use period.

Section 2: STUDYDESIGN

Approximately 9 subjects with visible fine lines and wrinkles on the face will be enrolled in this study comparing the safety and efficacy of the test product over an eight-week use period. Subjects may also exhibit other signs of aging (i.e. rough skin texture, discoloration, skin dullness).

Procedure	Baseline	Week One	Week Four	Week Eight
Inclusion and Exclusion Criteria Verified	✓			
Informed Consent Obtained	✓			
Test Materials and Daily Diaries Distributed	✓			
Clarity Research 3D System Photography	✓+	✓	✓	✓
Test Materials and Daily Diaries Collected				✓

+Evaluations will be performed prior to test material application.

Section 3: STUDY POPULATION

Approximately 9 subjects will be enrolled in this study. Subjects will be admitted to the study at the discretion of the Principal Investigator or his/her designate based on medical history, findings of the pre-study interview and examination.

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 35 and 65 years of age of any skin type;
2. Participant has a Fitzpatrick Skin Type of I to IV;
3. Participant has visible fine lines and wrinkles on the face;
4. Participant agrees to only use the test device on the face, and agrees not to use the test device on the neck, chest, or any other part of the body;
5. Participant agrees not to allow any other person to use the device, and agrees not to use the device on others;
6. Participant agrees to avoid excessive sun exposure for the duration of the study;
7. Participant is using an adequate method of birth control;
8. Participant agrees not to introduce any new cosmetic or skincare products, except for the test material provided for the duration of the study;
9. Participant agrees to only use their regular face products for the duration of the study.
10. Participant 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;
11. Participant is dependable and able to follow directions as outlined in the protocol;
12. Participant is willing to participate in all study evaluations;
13. Participant is in generally good health and has a current Pan elist Profile Form on file at Clarity Research Laboratory;
14. Participant agrees to sign a Photography Release Form, providing consent for the capture of digital images for use in relation to this clinical study;

15. Participant has completed a HIPAA Authorization Form in conformance with 45 CFR Parts 160 and 164;

16. Participant understands and is willing to sign an Informed Consent Form in conformance with 21 CFR Part 50: “Protection of Human Subjects.”

3.2 EXCLUSION CRITERIA

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

1. Participant is known to be pregnant, nursing, or planning to become pregnant;
2. Participant is being treated for cancer or has a history of facial skin cancer on the test areas;
3. Participant has sunburn, moderate to pronounced suntan, uneven skin tones, tattoos, scars, or other disfiguration, dilated vessels or other conditions on the test area that might influence the test results;
4. Participant has any disease or condition of the skin that the Principal Investigator deems inappropriate for participation, including rosacea, eczema, and atopic dermatitis;
5. Participant is currently taking certain medications, which in the opinion of the Principal Investigator may interfere with the study. This would include but not be limited to routine high dosage use of anti-inflammatory drugs (aspirin, ibuprofen, corticosteroids), immunosuppressive drugs, or antihistamine medications (steroid nose drops and/or eye drops are permitted), and insulin, anti-hypertensive drugs, antibiotics or other topical drugs at the test sites;
6. Participant has uncontrolled metabolic diseases such as diabetes (Type I and II), hypertension, hyperthyroidism or hypothyroidism, severe chronic asthma, immunological disorders such as HIV positive, AIDS and systemic lupus erythematosus or mastectomy for cancer involving removal of lymph nodes;
7. Participant is participating in other facial clinical studies;
8. Participant has routinely used an alpha-hydroxy-acid (AHA) or a beta-hydroxy-acid (BHA) containing product within two weeks or Retin-A, Retin-A Micro, Renova, Differin, Avita, Tazorac, or Soriatane within one month of the study start or have taken Accutane within one year of the study start. Individuals who have used Retinol in the last six months;
9. Participant has inflammatory acne lesions (i.e., papules, pustules, cysts, nodules) at the test site;
10. Participant has had chemical peels or dermabrasion within the last six months;

11. Participant has known allergies to skin treatment products or cosmetics, toiletries, and/or topical drugs;

12. Participant is currently using topically applied prescription medications where the medication is applied on or near the test site;

13. Participant has participated in a similar study within the last seven days. That is, at least one week shall have elapsed since a Participant participated in a facial sting test;

14. Participant has a metal implant or electronic implanted device;

15. Participant has suspected or diagnosed epilepsy, or has ever suffered from a seizure;

16. Participant has metal braces on the teeth;

17. Participant is allergic to metal or is sensitive to contact with chrome;

18. Participant has open sores or wounds on the face;

19. Participant has sensitive skin;

20. Participant has a history of cardiovascular disease or an irregular heart rhythm;

21. Participant has area(s) of the face that are not sensitive to touch or lack normal sensation.

3.3 PARTICIPANT TERMINATION AND WITHDRAWAL

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

All Participants 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 to provide a reason for Participant withdrawals. The reason for the participant's withdrawal from the study will be specified in the participant's source documents and included in the final report.

Section 4: STUDY EVALUATIONS

4.1 CLARITY RESEARCH 3D SYSTEM

The Clarity Research 3D System features the latest technology in 2D and 3D skin modelling, boasting three 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 six 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.

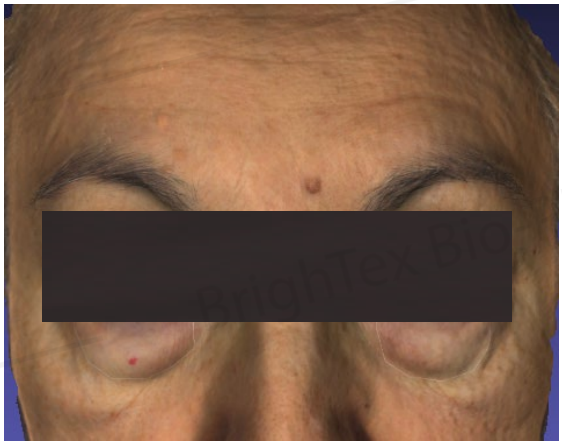
The Clarity Research 3D system is capable of detecting over 50 facial regions for analysis of fine lines, texture, skin tone evenness and discoloration, and contouring. The system will capture fine lines, texture, pore size, skin tone evenness and discoloration, radiance, luminosity, firmness, and contouring. Clarity Research 3D system photography will be captured at Baseline, Week One, Week Four, and Week Eight.

4.2 SKIN FEATURE TO BE STUDIED

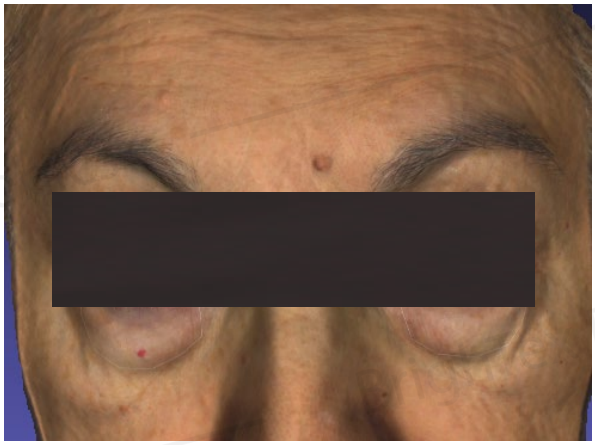
4.2.1 3D Facial Contours

Sample Result Images:

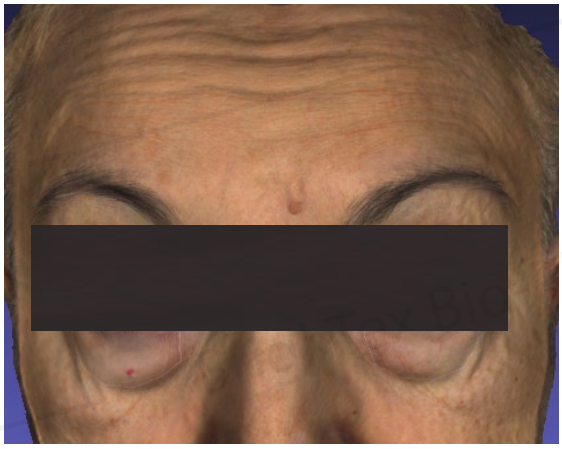
T0



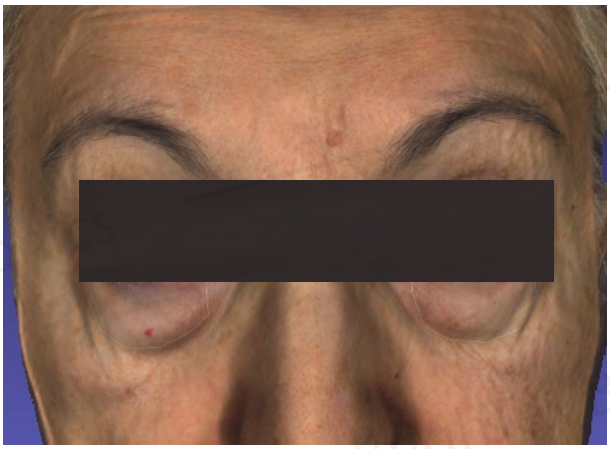
T1



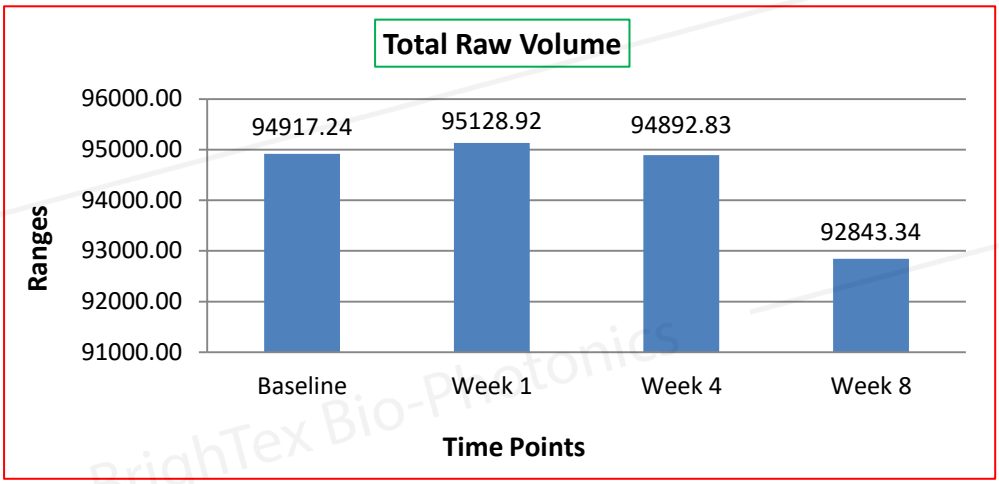
T2



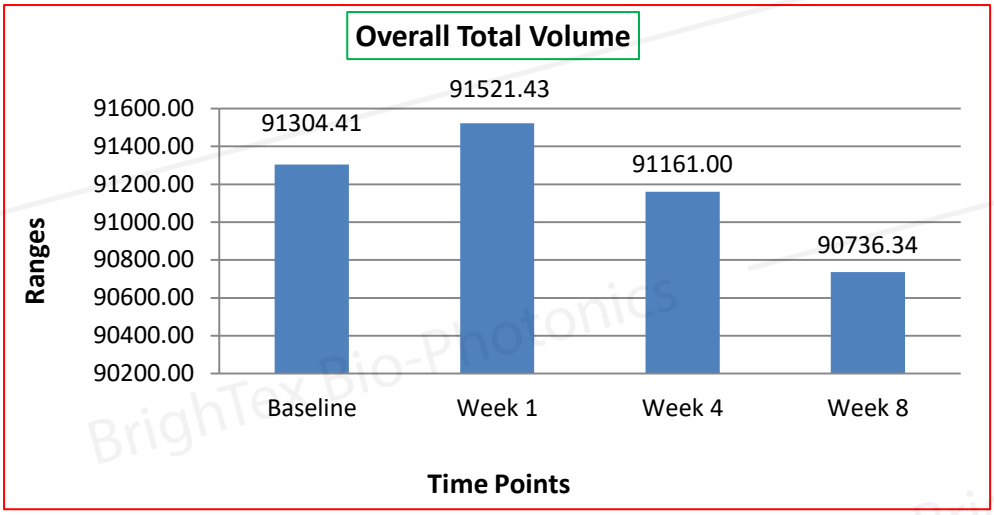
T3



Participant 08 Results



Overall Total Volume:



Test Results and Statistical Summary

Clarity™ Research 3D System – Total Raw Volume				
Parameter	Treatment	Visit	Number of Participants showed improvement	% of Participant showed improvement
Total Raw Volume	Test Product	Week 1	3	33.3%
		Week 4	6	66.7%
		Week 8	6	66.7%

Section 5: TEST METHOD

5.1 PARTICIPANT IDENTIFICATION

All Participants will be initially identified by a permanent Research centre panellist database 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.

5.2 BASELINE VISIT

Participants will arrive at the Clarity Research laboratory testing facility for the baseline visit with clean, bare faces, wearing no facial makeup and having refrained from applying any facial products. Inclusion and Exclusion Criteria will be verified and informed consent and photography release forms will be read and signed by each participant. Participants who meet all the study requirements will be enrolled.

Participants will acclimate to ambient laboratory conditions for approximately 15 minutes. Clarity™ Research 3D System images will be captured (eyes open) of each participant, as indicated in Section 4.1. A trained Research Laboratory technician will instruct the participant on how to properly use the device regimen. Participants will be instructed to use the device on the assigned side of the eye area only. The topical product will be applied to both under eye areas. The test material will be used for

the first time in the testing facility under the supervision of a trained Research Laboratory technician. One hour post-application Clarity 3D images will be captured.

Participants will be provided with the test material, Daily Diaries, and verbal and written instructions outlining study requirements and restrictions. Dates and appointment times for subsequent study visits will be arranged and documented. Participants will be instructed to use the test material according to the usage instructions for their group, as outlined in product usage instructions of this clinical study protocol. Participants will be instructed to track their daily product usage in the Daily Diaries throughout the duration of the study.

5.3 WEEK ONE VISIT

Participants will return to the testing facility following one week of twice daily test material use with clean, bare faces, wearing no facial makeup and having refrained from applying any facial products, with the exception of the test products, which should be applied at least two hours prior to the study visit. Participants will acclimate to ambient laboratory conditions for approximately 15 minutes. Clarity™ Research 3D System images will be captured of each participant, as indicated in Section 4.1.

Daily diaries will be reviewed by the study personnel for compliance.

5.4 WEEK FOUR VISIT

Participants will return to the testing facility following four weeks of twice daily test material use with clean, bare faces, wearing no facial makeup and having refrained from applying any facial products, with the exception of the test products, which should be applied at least two hours prior to the study visit. Participants will acclimate to ambient laboratory conditions for approximately 15 minutes. Clarity™ Research 3D System images will be captured of each participant, as indicated in Section 4.1.

Daily diaries will be reviewed by the study personnel for compliance.

5.5 WEEK EIGHT VISIT

Participants will return to the testing facility following eight weeks of twice daily test material use with clean, bare faces, wearing no facial makeup and having refrained from applying any facial products, with the exception of the test products, which should be applied at least two hours prior to the study visit. Participants will acclimate to ambient laboratory conditions for approximately 15 minutes. Clarity™ Research 3D System images will be captured of each participant, as indicated in Section 4.1.

Daily diaries will be reviewed by the study personnel for compliance.

Section 6: Product Usage Instructions

1. Moisten face with water.
2. Apply treatment cleanser to all areas of the face. Apply moisturizer twice daily (morning and evening) to clean and dry skin, avoiding eye areas for 8 weeks.
3. Wet treatment head by placing it under running water. Then turn on the device by pressing the On/Off button.
4. Slowly glide the treatment head back and forth over one of the areas of your face using broad strokes. Do not scrub or move across the face quickly. (The face is divided into four quadrants: 1. Forehead, 2. Right Cheek/Eye Area, 3. Chin/Jawline/Nose, 4. Left Cheek/Eye Area)
5. The device will do three brief stops every 30 seconds to prompt you to move from one area of the face to the next.
6. When the treatment is done, the device will stop. The device will turn off automatically.
7. Rinse your face with water to remove residual treatment cleanser.

Section 7: CONCLUSION

There was a statistically significant improvement in the 3D Facial Contours from Baseline to Week 8 which ranges from 33.3% to 66.7%.