SUBSURFACE SPOTS

STUDY TEMPLATE

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ABSTRACT

The objective of this study is to evaluate the efficacy and safety of the test product and its effects on skin tone, skin brightening, hyper pigmentation, skin hydration and the appearance of fine lines and wrinkles on the face.

Participant's captures are taken using Clarity Research 3D System digital photography at Baseline, Week1, Week 4 and Week 8.

Measurements for the Participants will be recorded at Baseline, Week1, Week 4 and Week 8 after using the test materials.

It is concluded that there is statistically significant improvement in the Pigment Intensity, Pigment Darkness and Size Distribution from Baseline to Week 8 which ranges from 30.0% to 100.0%.

Section 1: OBJECTIVE

The objective of this study is to evaluate the efficacy and safety of the test product and its effects on skin tone, skin brightening, hyper pigmentation, skin hydration and the appearance of fine lines and wrinkles on the face.

Section 2: STUDYDESIGN

Ten participants with visible fine lines and wrinkles on the face were enrolled in this study comparing the safety and efficacy of the test product over an eight-week use period. Participants may have also exhibited other signs of aging (i.e. rough skin texture, discoloration, skin dullness). The study will include Clarity Research 3D System photography.

A study schedule appears below.

Procedures and Evaluations	Baseline	Week 1	Week 4	Week 8
Inclusion and Exclusion Criteria Verified	✓			
Informed Consent Obtained	✓			
Test Materials and Daily Diaries Distributed	✓			
Clarity Research 3D System Photography	✓	✓	✓	✓
Clinical Assessment of Skin Safety and Tolerability	✓	✓	✓	✓
Test Materials and Daily Diaries Collected				✓

Section 3: STUDY POPULATION

Approximately 10 participants will be enrolled in this study. Participants 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 Panellist Profile Form on file at LAB;
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 Participants."

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

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 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, hemoglobin, 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.

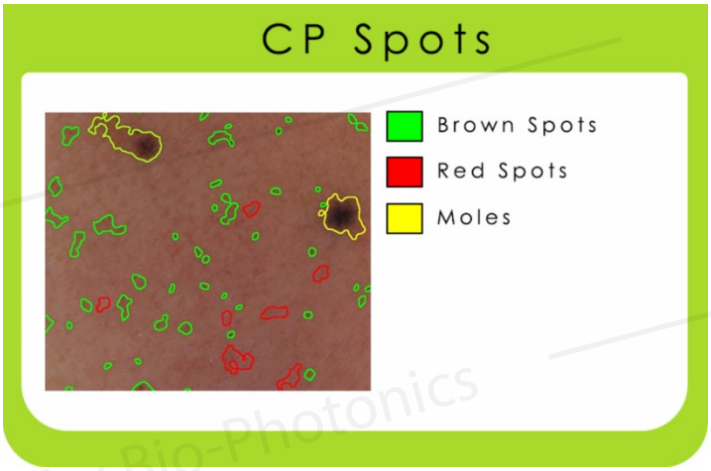
Clarity Research 3D system photography will be captured at Baseline, Week One, Week Four, and Week Eight.

5.1.1 SKIN FEATURE TO BE STUDIED

1. Subsurface Spots

Pigmentation not visible on the surface that lies underneath the skin is subsurface pigmentation. Generally, it is an indication of an internal damage caused by the sun.

Subsurface spots feature is sub-categorized into three types Brown Spots, Red Spots and Moles based on the severity.

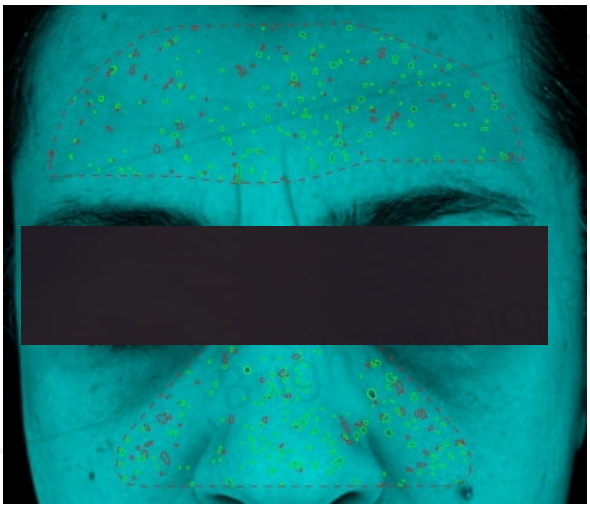


Measured Parameters: Pigment Intensity, Pigment Darkness and Size Distribution

i. Pigment Intensity: It is defined as the average Intensity of the Spot pixels

Sample Result Images:

T0



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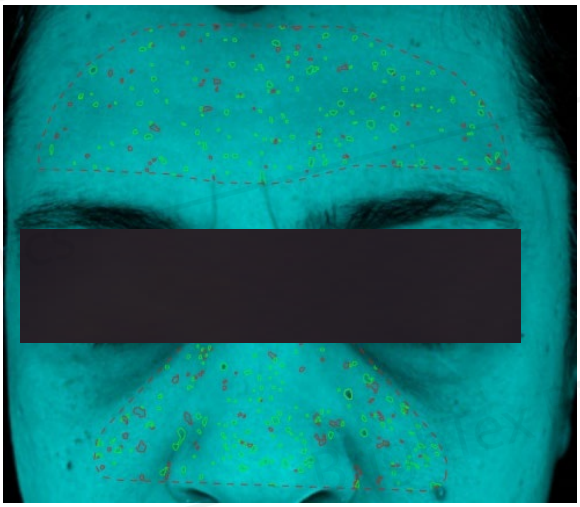
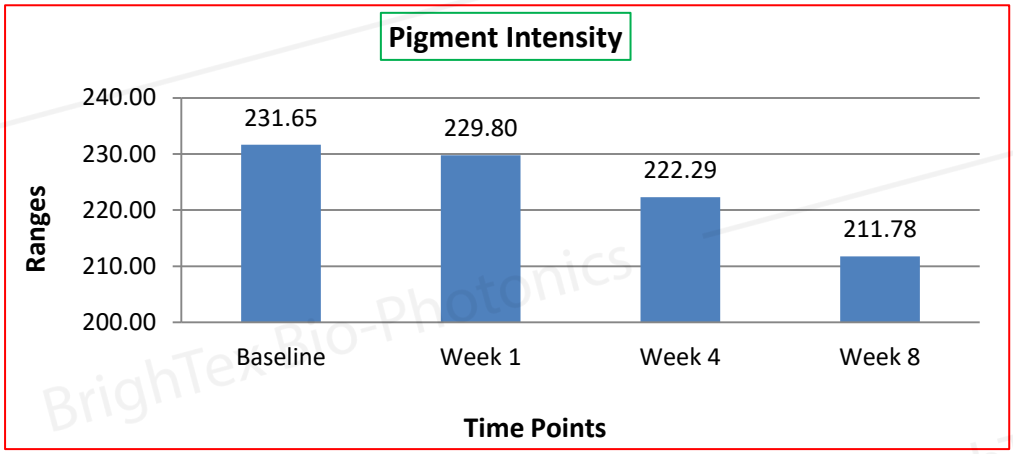


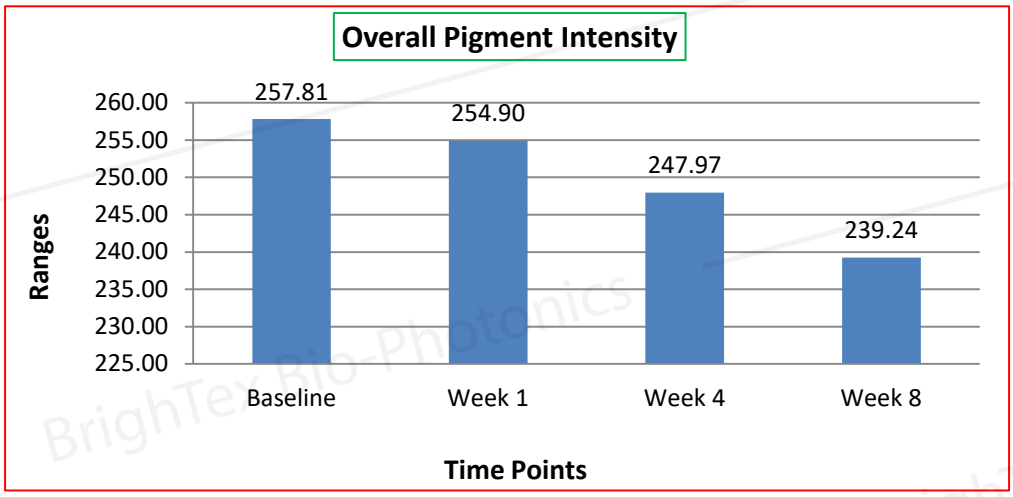
T2

T3

Participant 03 Results



Overall Pigment Intensity:



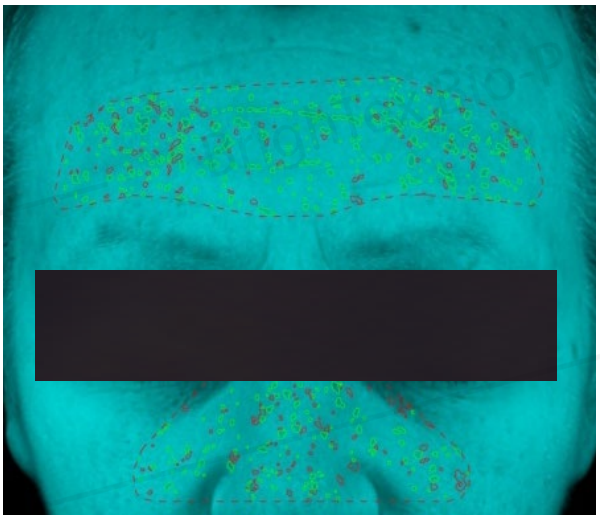
Test Results and Statistical Summary

Clarity™ Research 3D System – Pigment Intensity				
Parameter	Treatment	Visit	Number of participants showed improvement	% of Participant showed improvement
Pigment Intensity	Test Product	Week 1	8	80%
		Week 4	10	100%
		Week 8	9	90%

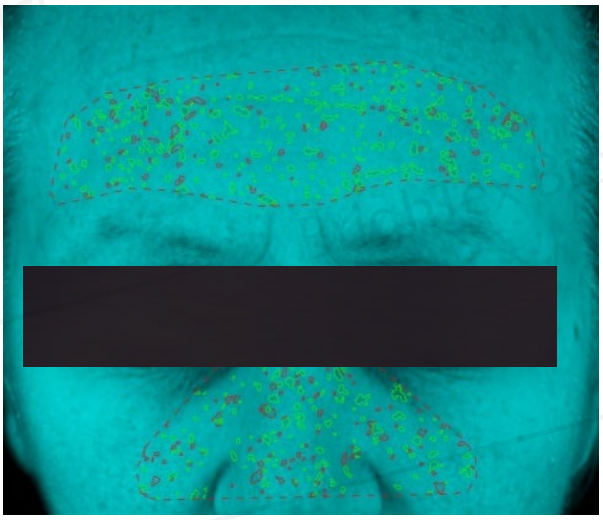
ii. Pigment Darkness: It is defined as the contrast in average Intensity of the Spot pixels to surrounding ROI skin pixels.

Sample Result Images:

T0



T1



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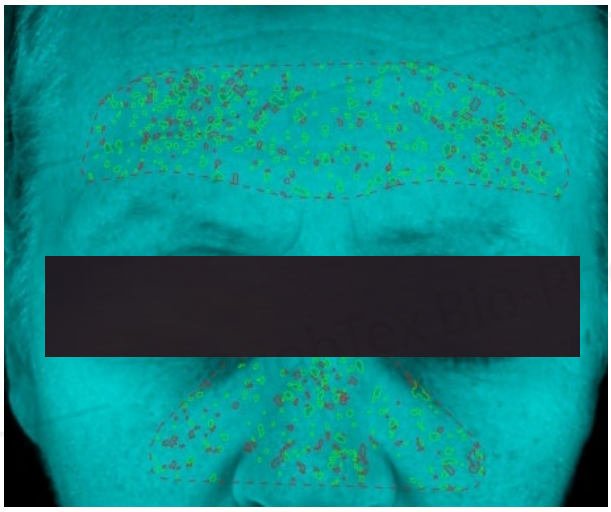

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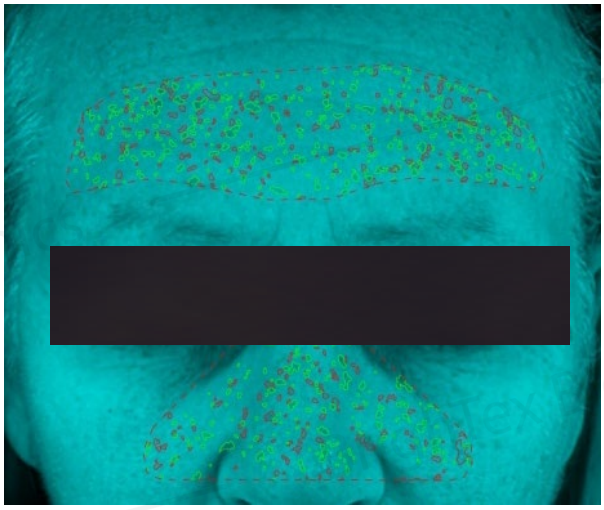
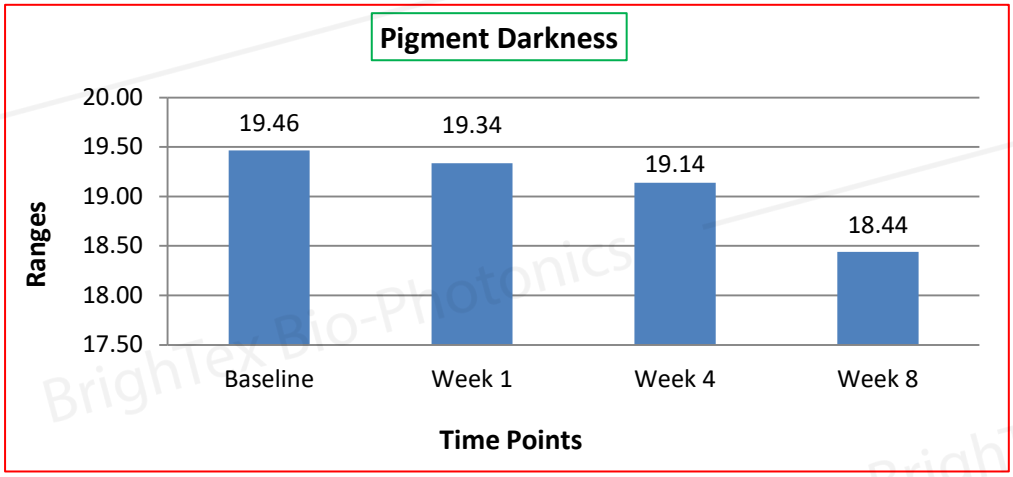
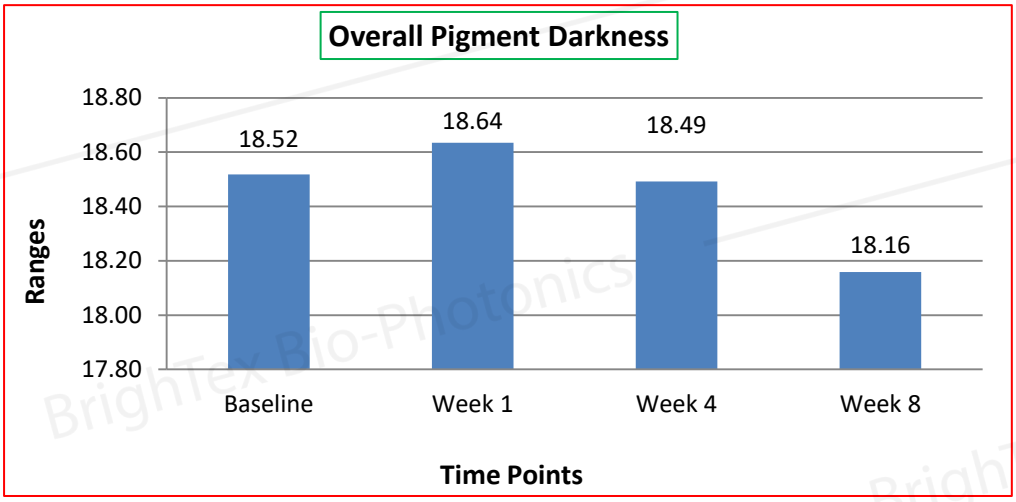


Participant 37 Results



Overall Pigment Darkness:

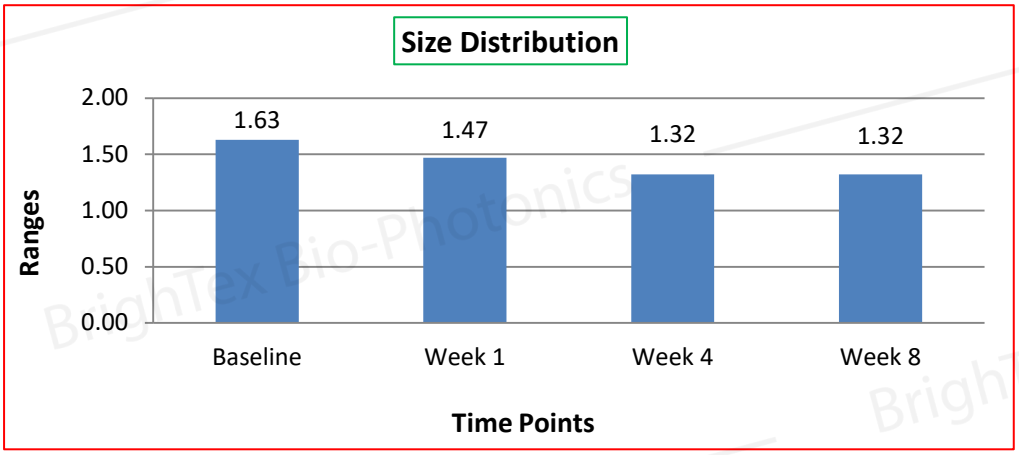


Test Results and Statistical Summary

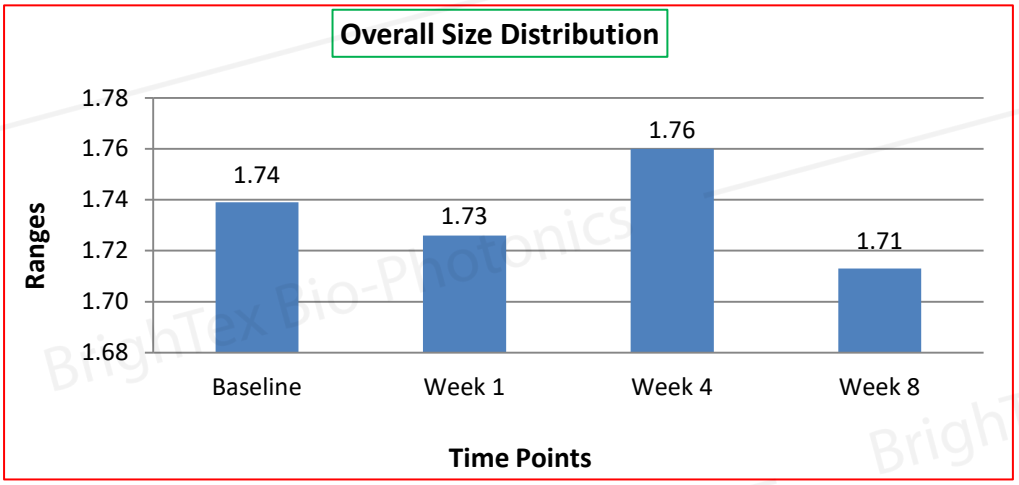
Clarity™ Research 3D System – Pigment Darkness				
Parameter	Treatment	Visit	Number of participants showed improvement	% of Participant showed improvement
Pigment Darkness	Test Product	Week 1	5	50%
		Week 4	7	70%
		Week 8	8	80%

iii. Size Distribution: It is defined as the standard deviation of the recognized spots size

Participant 03 Results



Overall Size Distribution:



Test Results and Statistical Summary

Clarity™ Research 3D System – Size Distribution				
Parameter	Treatment	Visit	Number of participants showed improvement	% of Participant showed improvement
Size Distribution	Test Product	Week 1	3	30%
		Week 4	4	40%
		Week 8	5	50%

Section 6: TEST METHOD

6.1 Participant Identification

All participants will be initially identified by a Permanent 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 Baseline

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 return to the testing facility with clean faces, free from makeup and having refrained from applying any facial products. Participants will acclimate to ambient laboratory conditions for approximately 15 minutes. Clarity™ Research 3D System images will be captured (eyes closed) of each participant, as indicated in Section 5.1.

A trained Clarity Research Laboratory technician will instruct the participant on how to properly use the assigned device regimen. The test material will be used for the first time in the testing facility under the supervision of a trained Clarity Research Laboratory technician.

Participants will be provided with the test material, Daily Diaries, 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 in Section 7. Participants will be instructed to track their daily product usage in the Daily Diaries throughout the duration of the study.

6.3 Week One Visit

Participants will return to the testing facility following one week of 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 5.1. Daily diaries will be reviewed by the study personnel for compliance.

6.4 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 5.1. Daily diaries will be reviewed by the study personnel for compliance.

6.5 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 5.1. Daily diaries will be reviewed by the study personnel for compliance and collected. Test devices and unused test materials will be collected.

Section 7: Product Usage/Application Instructions

Apply twice daily (morning and evening) to clean and dry skin, avoiding eye areas. Apply 4-5 drops of the product in the palm of the hand and massage the product with circular motions on the entire face, neck, and neckline, avoiding contact with eyes.

Use of your daily moisturizing cream is allowed as long as it does not contain glycolic acid or retinol. Do not apply the moisturizing cream or other daily routine products at the same time as this product. Avoid sun exposure, if you will be exposed to outdoor natural lighting, use a sunscreen that is SPF 50 or higher.

Section 8: CONCLUSION

There was a statistically significant improvement in the Pigment Intensity, Pigment Darkness and Size Distribution from Baseline to Week 8 which ranges from 30.0% to 100.0%.