RADIANCE

Wrinkles and Surface Spots

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 assess the efficacy of a test product following four weeks and eight weeks of test material use.

Participant's captures are taken using Clarity Research 3D System digital photography at Baseline (Visit 1), Week 4 and Week 8.

Measurements for the Participants will be recorded at Baseline (Visit 1), Week 4 and Week 8 after using the test materials.

It was concluded that there was a statistically significant improvement from Baseline to Week 8 in Lstar which ranges from 70% to 80%, Surface Area (mm^2) & Average Depth under Wrinkles 3D which ranges from 40.0% to 63.3%, Average Severity, Average Width of emerging lines, fine lines, and deep lines and Emerging Wrinkles Average Length under Wrinkles 2D which ranges from 36.7% to 66.7% and Surface Spots size Distribution which ranges from 36.7% to 40.0%.

Section 1: OBJECTIVE

The objective of this clinical study is to assess the efficacy of a test product following four weeks and eight weeks of test material use.

Section 2: STUDY DESIGN

Approximately 30 female participants will be enrolled in this clinical study to assess the efficacy of the test product following four weeks and eight weeks of test material use. Study evaluations will include Clarity Research 3D System imaging measurements. A study schedule appears below

Procedures and Evaluations	Baseline	Week 4	Week 8
Informed Consent Obtained	✓		
Inclusion and Exclusion Criteria Verified	✓		
Distribution of Non-Moisturizing Soap Purpose Soap	✓		
Clarity Research 3D System Imaging	✓	✓	✓
Skin Care device Measurements	✓	✓	✓
Distribution of Test Materials, Use Instructions, and Daily Diaries	✓		
Collection of Test Materials and Daily Diaries			✓

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 30 Participants will be enrolled in the study. Participants are recruited from the Research centre panellist database.

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 75 years of age;
2. Participant has at least mild fine lines and wrinkles on the face;
3. Participant has uneven skin tone;
4. Participant has refrained from using moisturizers on the test site (face) for at least 3 days prior to their baseline visit;
5. Participant agrees to refrain from using cleansers, moisturizers, or products, with the exception of the provided. Purpose soap and the test material, for the duration of the study;
6. Participant agrees not to introduce any new cosmetic or toiletry products during the study;
7. Participant is dependable and able to follow directions as outlined in the protocol
8. Participant is willing to participate in all study evaluations;
9. Participant is in generally good health and has a current Panelist Profile Form on file at LAB;
10. Participant agrees to sign a Photography Release Form, providing consent for the capture of digital images for use in relation to this clinical study;
11. Participant has completed a HIPAA Authorization Form in conformance with 45 CFR Parts 160 and 164;
12. 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 sympathomimetic, 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.

3.3 PARTICIPANT TERMINATION AND WITHDRAWAL

A participant may be discontinued from study participation at any time if the Principal Investigator or designated medical staff 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 or designee 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: TEST METHOD

4.1 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.

4.2 BASELINE

Participants will report to the testing facility with clean faces, free from makeup having refrained from using any moisturizers on their test sites (face). Informed consent will be obtained. Inclusion and exclusion criteria will be verified. Participants will be instructed to refrain from using any facial cleansers, moisturizers, or facial products, with the exception of the provided non-moisturizing soap and the test material, for the duration of study. Participants will acclimate to ambient laboratory conditions for approximately 15 minutes. Clarity Research 3D System images will be captured. Skin Care device measurements will be obtained.

Participants will be provided with the test material, non-moisturizing soap, use instructions, and a daily diary to record each use of the test material.

4.3 WEEK 4

Participants will return to the testing facility after four weeks of product use with clean faces, free from makeup. Participants will acclimate to ambient laboratory conditions for approximately 15 minutes. Clarity Research 3D System images will be captured. Skin Care device measurements will be obtained.

4.4 WEEK 8

Participants will return to the testing facility after eight weeks of product use with clean faces, free from makeup. Participants will acclimate to ambient laboratory conditions for approximately 15 minutes. Clarity Research 3D System images will be captured. Skin Care device measurements will be obtained. Daily diaries will be reviewed for study compliance and collected. Unused test materials will be collected.

Section 5: STUDY EVALUATIONS

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, 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 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 analyze acne scars and lesions, redness scoring, subsurface pigment detection, pore detection, and visible spot detection.

Images will be obtained with eyes closed. The following parameters will be assessed:

5.2 SKIN FEATURE TO BE STUDIED

The general appearance of a soft, smooth skin depends on the presence of an adequate amount of water in the outermost layer of the skin.

Fine lines and wrinkles for Full Face:

Surface area, Average severity, Average depth, Average width of emerging lines, fine lines, and deep lines and Emerging Wrinkles Average Length (mm)

Radiance: L Star

Surface Spots Size Distribution

Clarity Research 3D System imaging will be captured at Baseline, Week 4, and Week 8.

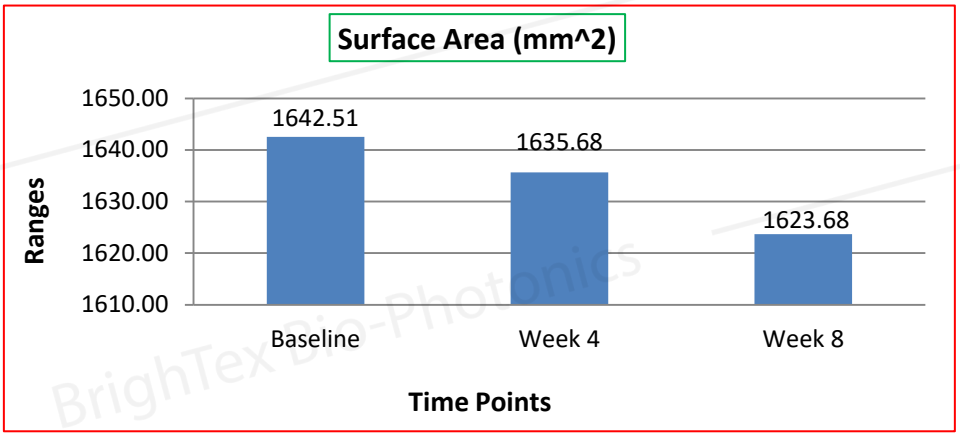
5.2.1 Wrinkles 3D

Structural changes in specific parts of the dermis and the subcutaneous tissue producing a fold, ridge or crease on the skin is considered as a wrinkle.

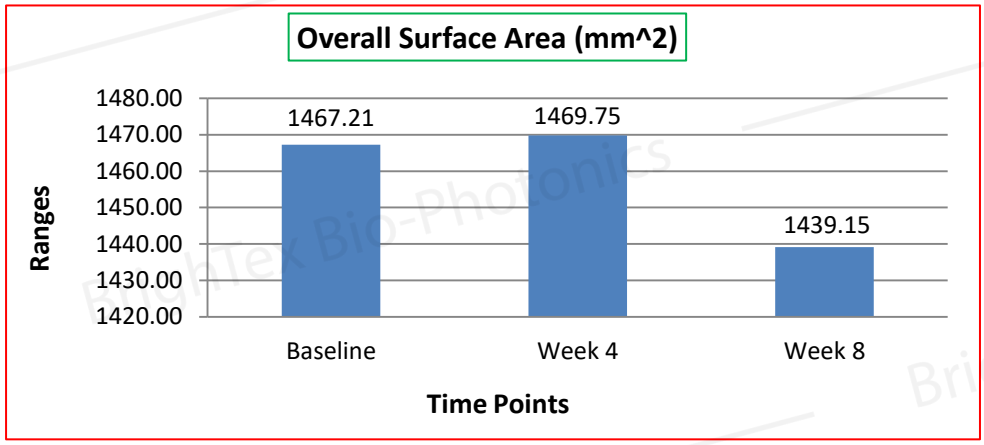
Measured Parameters: Surface Area (mm^2), Average Depth

i. **Surface Area (mm^2):** Percentage of area affected by Wrinkles recognized

Participant 03 Results



Overall Surface Area (mm^2):



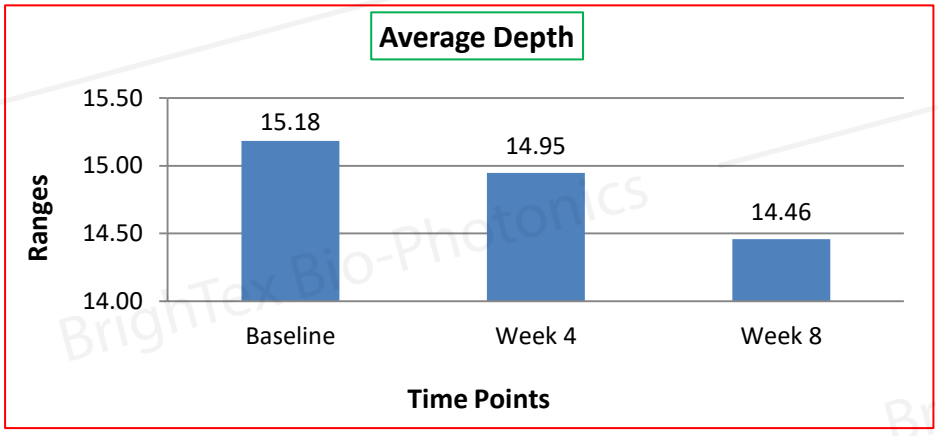
Test Results and Statistical Summary

Clarity™ Research 3D System-Surface Area (mm^2)				
Parameter	Treatment	Visit	Number of Participants showed improvement	% of Participants showed improvement
Surface Area (mm^2)	Test Product	Week 4	14	46.7%
		Week 8	19	63.3%

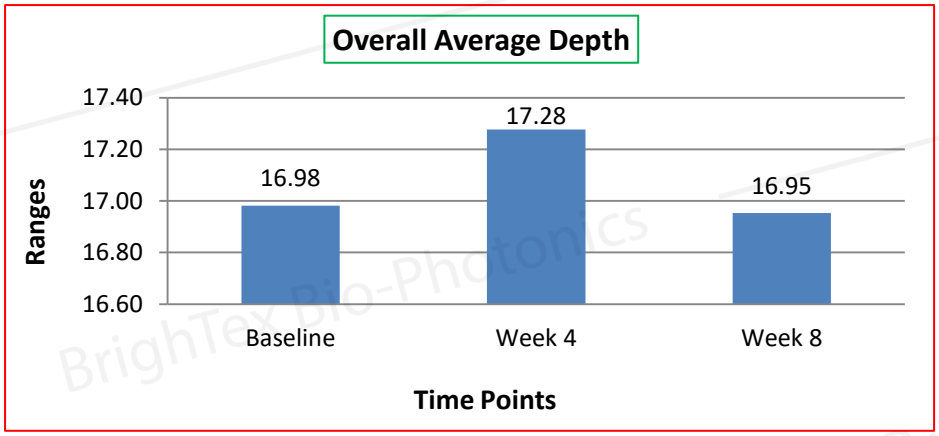
ii. Average Depth:

Average Depth of the recognized wrinkles

Participant 33 Results



Overall Average Depth:



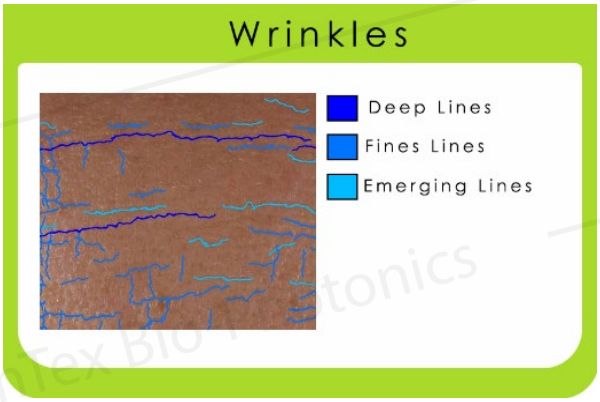
Test Results and Statistical Summary

Clarity™ Research 3D System-Average Depth				
Parameter	Treatment	Visit	Number of Participants showed improvement	% of Participants showed improvement
Average Depth	Test Product	Week 4	12	40.0%
		Week 8	15	50.0%

5.2.2 Wrinkles 2D

Structural changes in specific parts of the dermis and the subcutaneous tissue producing a fold, ridge or crease on the skin is considered as a wrinkle.

Wrinkles feature is sub-categorized into three types Fine Lines, Emerging Lines and Deep Lines based on the severity.



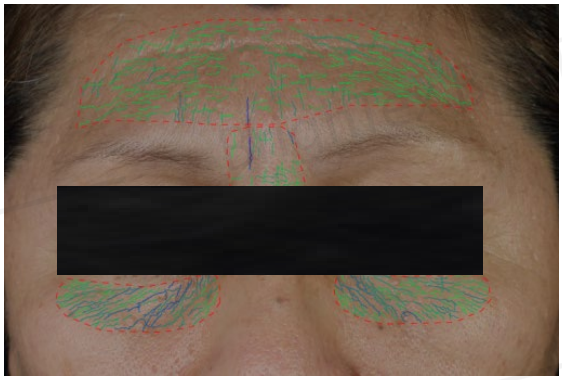
Measured Parameters: Average severity and average width of emerging lines, fine lines, and deep lines and Emerging Wrinkles Average Length (mm)

i. Average Severity:

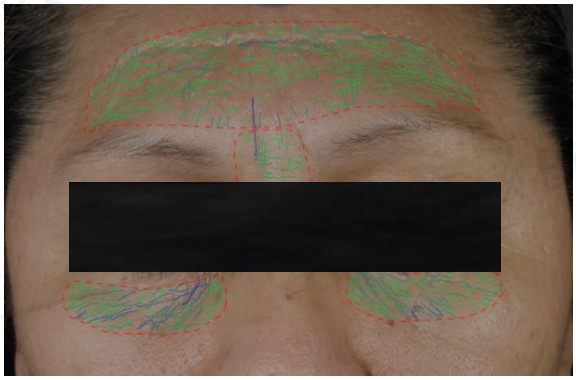
It is the average of intensity difference of each wrinkle from its start point to end point of the wrinkle.

Sample Result Images:

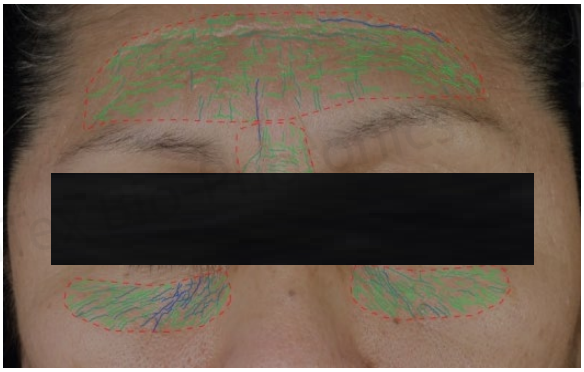
T0



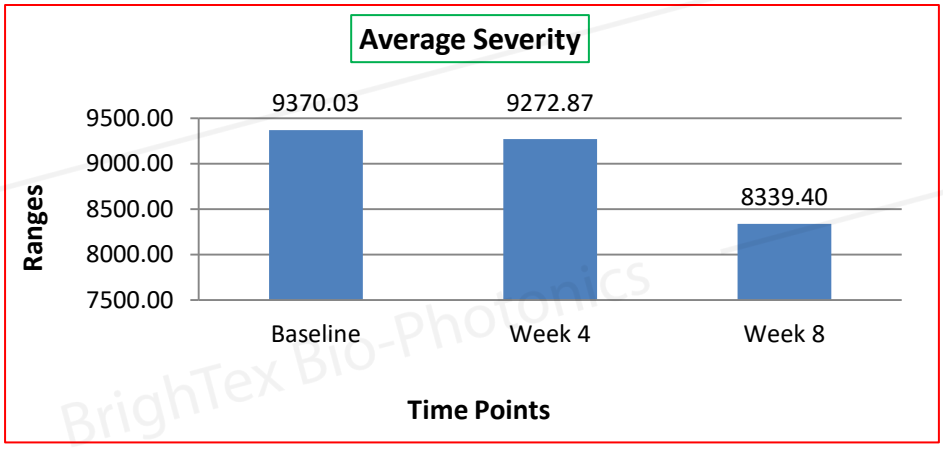
T1



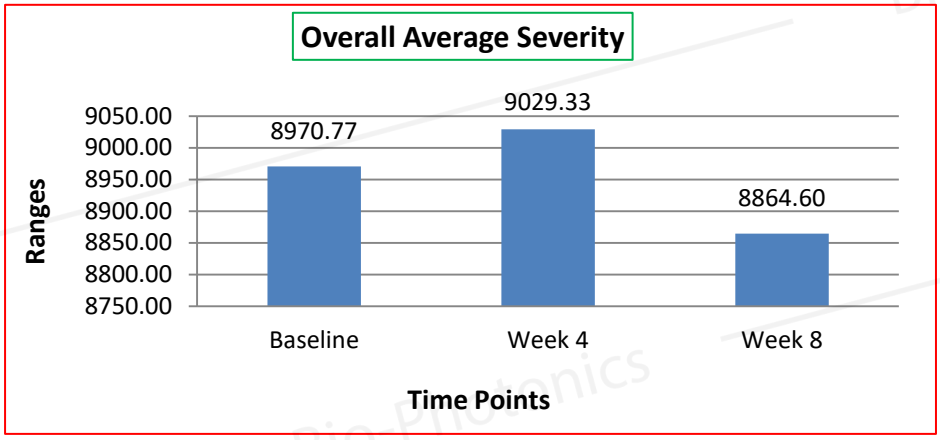
T2



Participant 18 Results



Overall Average Severity:



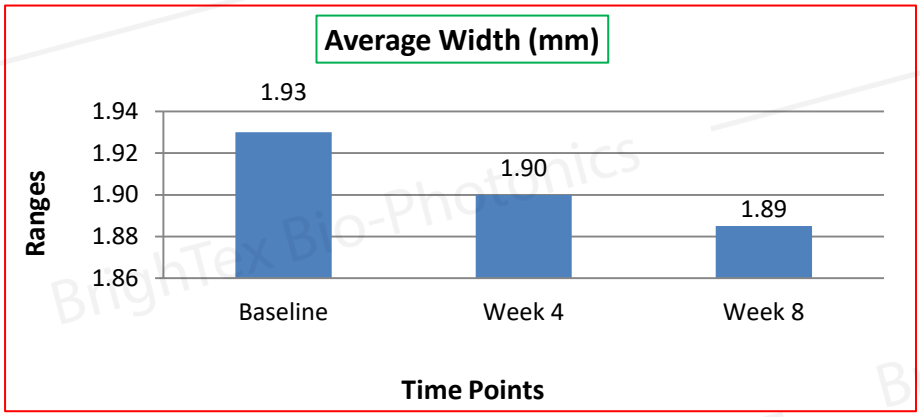
Test Results and Statistical Summary

Clarity™ Research 3D System-Average Severity				
Parameter	Treatment	Visit	Number of Participants showed improvement	% of Participants showed improvement
Average Severity	Test Product	Week 4	13	43.3%
		Week 8	14	46.7%

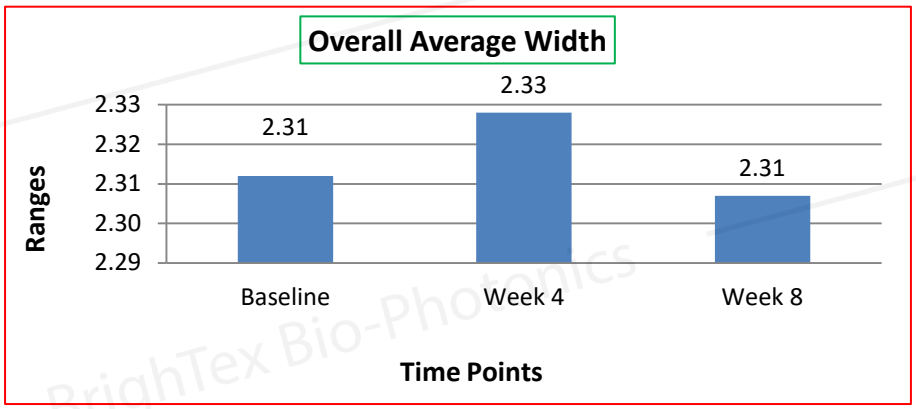
ii. Average Width (mm):

The Average Width of the wrinkles in each category i.e. Emerging, Fine, & Deep Wrinkles

Participant 18 Results



Overall Average Width



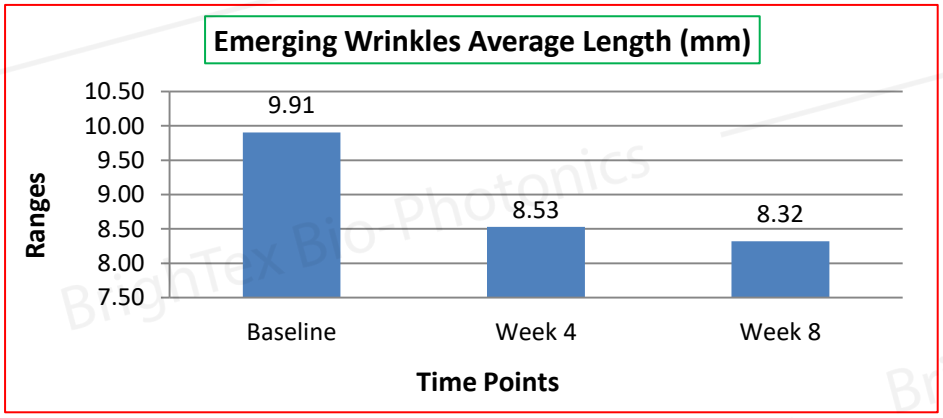
Test Results and Statistical Summary

Clarity™ Research 3D System-Average Width(mm)				
Parameter	Treatment	Visit	Number of Participants showed improvement	% of Participants showed improvement
Average Width(mm)	Test Product	Week 4	11	36.7%
		Week 8	15	50.0%

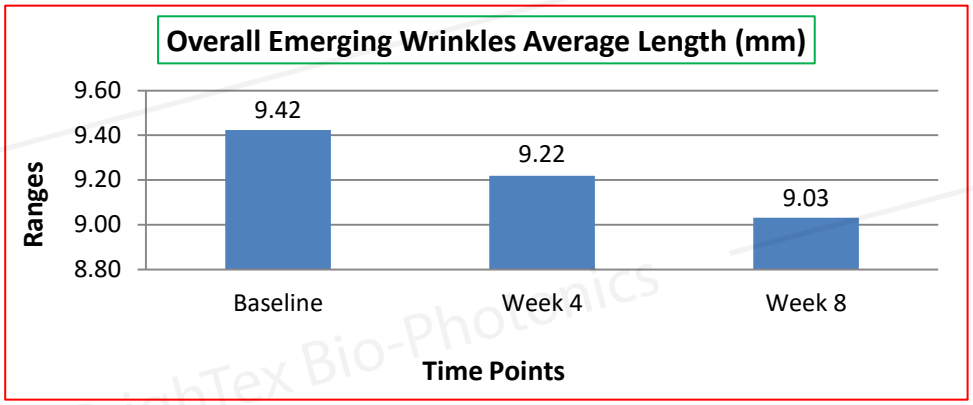
iii. Emerging Wrinkles Average Length (mm):

Average length of the emerging wrinkles in mm

Participant 16 Results



Overall Emerging Wrinkles Average Length (mm):



Test Results and Statistical Summary

Clarity™ Research 3D System-Emerging Wrinkles Average Length (mm)				
Parameter	Treatment	Visit	Number of Participants showed improvement	% of Participants showed improvement
Emerging Wrinkles Average Length (mm)	Test Product	Week 4	19	63.3%
		Week 8	20	66.7%

5.2.3 Radiance 2D

Radiance refers to skin brightness or luminosity. When skin loses its liveliness and brightness, it leads to a dull complexion. Moisture and oil present in the skin helps retain its smoothness and brightness. Skin damage and the accumulation of dead cells on the surface reduce the ability of skin to produce the required moisture and oil, thereby making the skin loses its radiance.

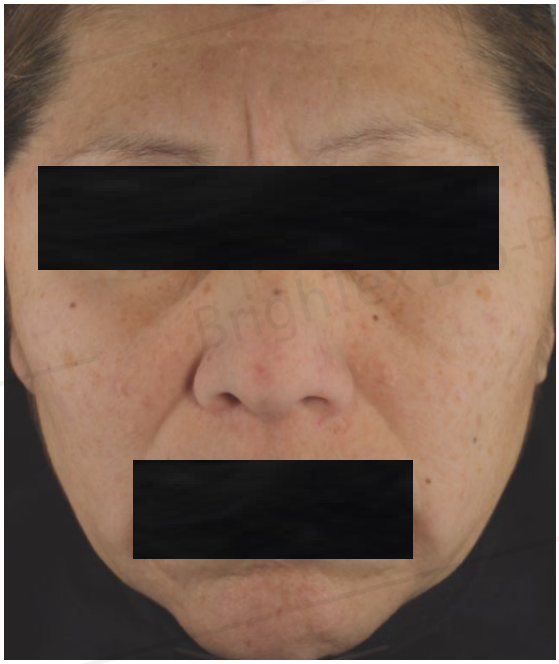
Measured Parameters: L Star

Lstar: 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.

Sample Result Images:

T0



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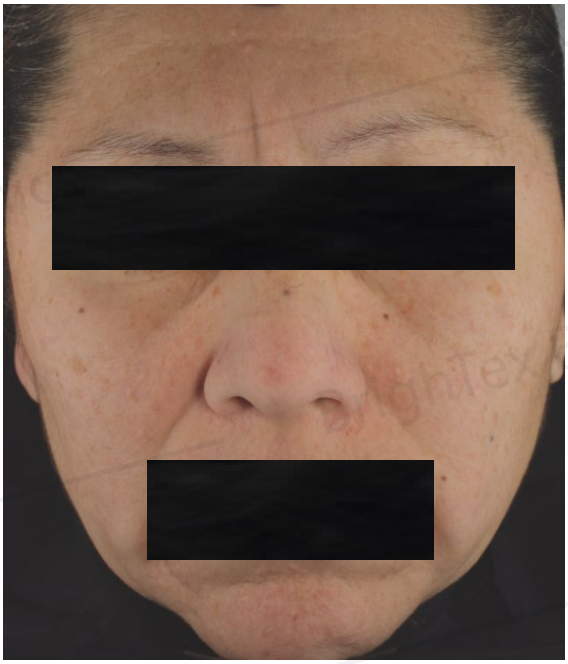
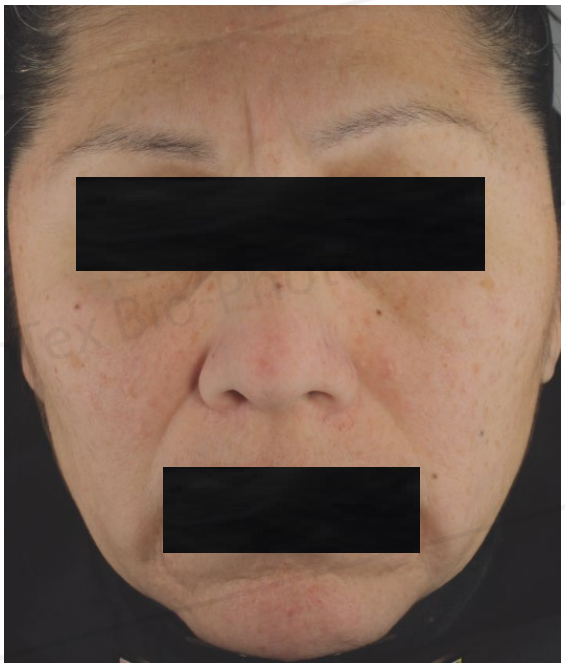
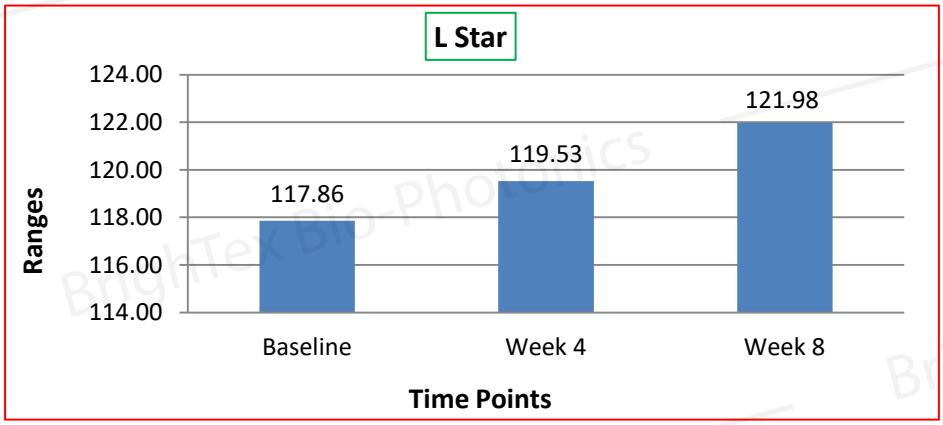


T2

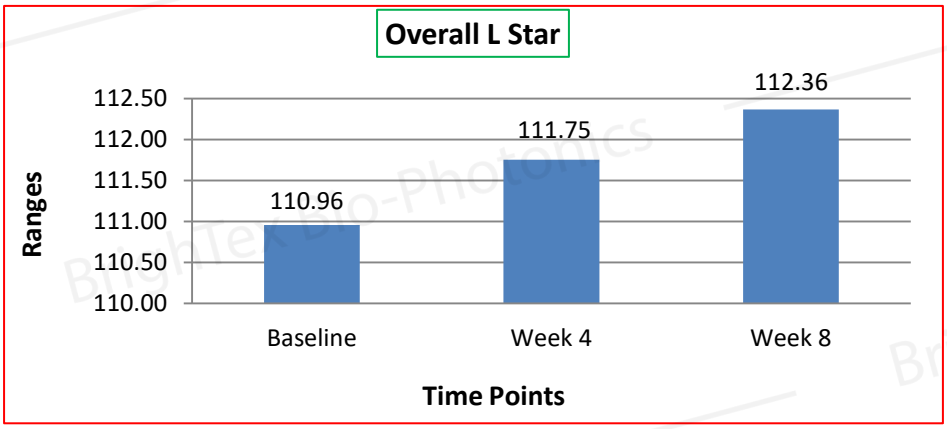


Participant 18 Results



Improvements Observed: Increase in Lstar from visit 1 to visit 4

Overall L Star:



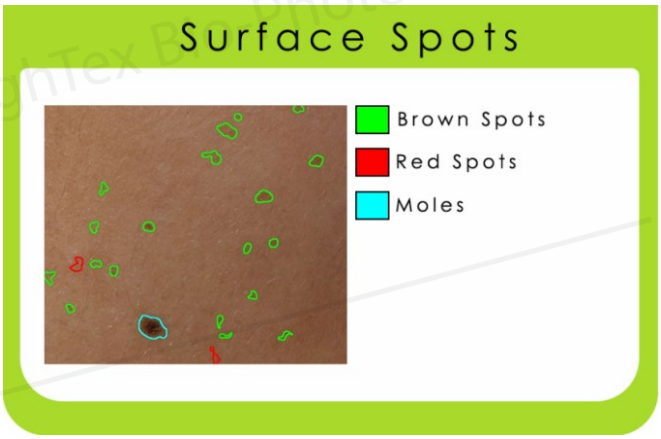
Test Results and Statistical Summary

Clarity™ Research 3D System-L Star				
Parameter	Treatment	Visit	Number of Participants showed improvement	% of Participants showed improvement
L Star	Test Product	Week 4	21	70%
		Week 8	24	80%

5.2.4 Surface Spots

Pigmentation or Spots is a localized change in skin color caused by the variation in the amount and type of melanin production underneath the skin.

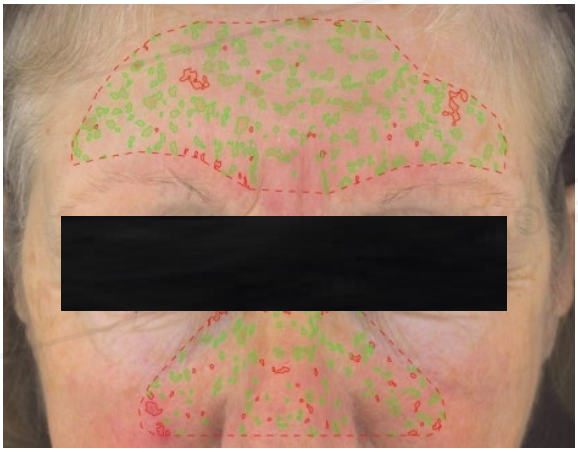
Surface Spots feature is sub-categorized into three types Brown Spots, Red Spots and Moles based on the severity.



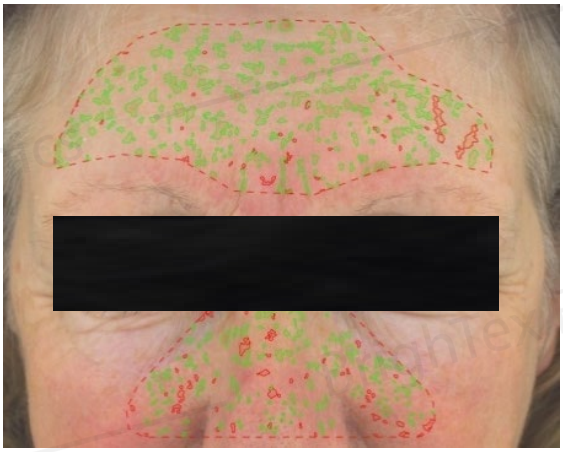
Measured Parameters: Size Distribution

Sample Result Images:

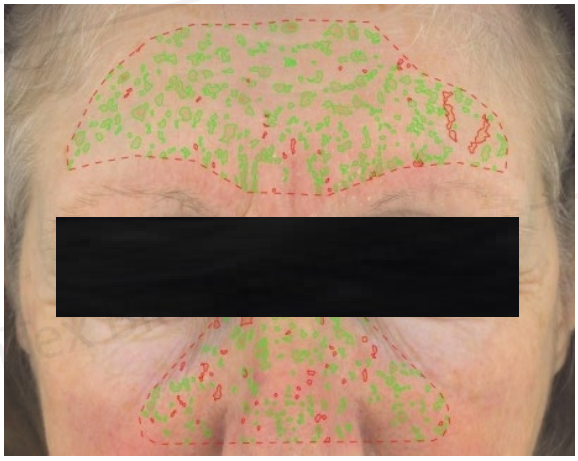
T0



T1

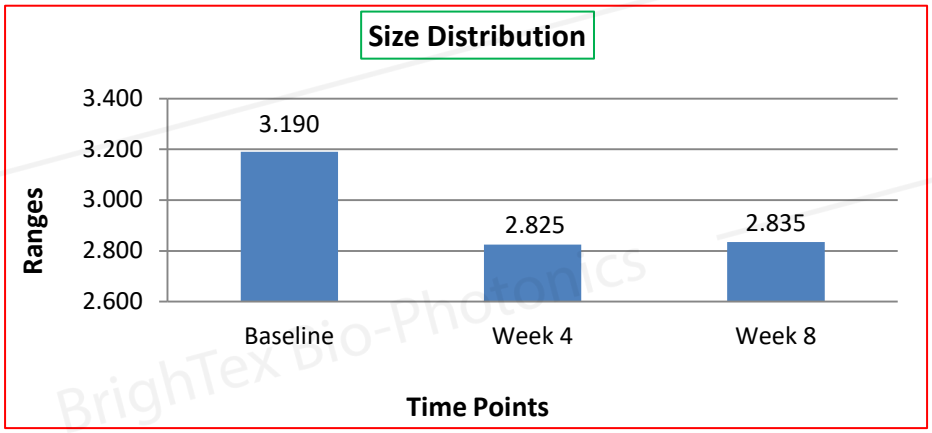


T2

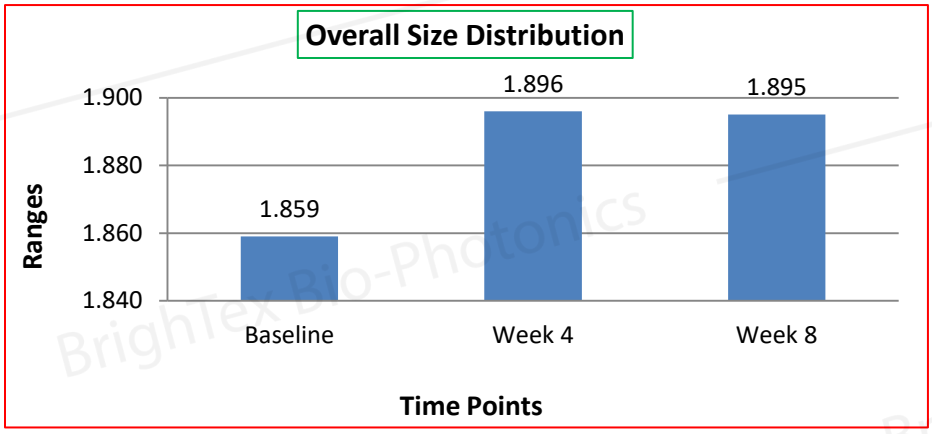


i. **Size Distribution:** Standard deviation of the recognized spots size

Participant 07 Results



Overall Size Distribution:



Test Results and Statistical Summary

Clarity™ Research 3D System-Size Distribution				
Parameter	Treatment	Visit	Number of Participants showed improvement	% of Participants showed improvement
Size Distribution	Test Product	Week 4	11	36.7%
		Week 8	12	40.0%

Section 6: Product Use Instructions

Apply 2 pumps to clean, dry skin twice a day (in the morning and in the evening)

Section 7: CONCLUSION

There was a statistically significant improvement in the Lstar (increase in brightness/radiance) from Baseline to Week 8 which ranges from 70% to 80%.

The following parameters showed improvements in Surface spots 2D:

Size Distribution showed significant improvement from Baseline to Week 8 which ranges from 36.7% to 40.0%.

The following parameters showed improvements in Wrinkles 3D:

Surface Area (mm^2), Average Depth showed significant improvement from Baseline to Week 8 which ranges from 40.0% to 63.3%.

The following parameters showed improvements in Wrinkles 2D:

Average Severity, Average Width of emerging lines, fine lines, and deep lines and Emerging Wrinkles Average Length showed significant improvement from Baseline to Week 8 which ranges from 36.7% to 66.7%.