JOWL

STUDY TEMPLATE

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ABSTRACT

The objective of this study is to determine whether there is an improvement in the appearance of the skin (forehead and Jowl) after using the Test Product consistently over a 12 week time period.

Participant's captures are taken using Clarity Research 3D System digital photography at Baseline (Visit 2), Week 4, Week 8 and Week 12.

Measurements for the Participants will be recorded at Baseline (Visit 2), Week 4, Week 8 and Week 12after using the test products.

It was concluded that there is a statistically significant improvement in Skin Type which ranges from 63.6% to 78.8%, Wrinkles which ranges from 36.4% to 75.8% and Facial Contours of Sagging Jowls which ranges from 15.2% to 42.4%from Baseline to Week 12.

Section 1:OBJECTIVE

The objective of this study is to observe improvement in the appearance and the effects of the Test Product when used consistently over a 12 week time period.

Section 2: STUDYDESIGN

Candidates for study participation will be recruited from the Research Laboratories, LLC database. 33participants will be enrolled.

Participants will be screened to determine eligibility and qualified participants will be enrolled. Following a 7 (±3) day washout period, participants will be required to return to the lab for Baseline assessments. After the conditioning phase, participants will return to the laboratory for Visit 2, Baseline. At Visit 2, participants will have baseline evaluations performed with the Clarity™ Research 3D System. Participants will return for Visit 3 (Week 4), Visit 4 (Week 8) and Visit 5 (Week 12). Clarity™ Research 3D System captures will be taken at Visit 3,Visit 4, and Visit 5. A study schedule appears below:

Procedure	**Visit 1 (Day -7 ± 3 days): Conditioning phase**	**Visit 2 Baseline**	**Visit 3 (Week 4)**	**Visit 4 (Week 8)**	**Visit 5 (Week 12)**
Informed Consent, Inclusion and Exclusion Criteria Verified	✓				
Distribution of Test Materials, Daily Diary, and Instructions to Participants		✓			
Compliance Check (review test materials and diaries)			✓	✓	✓
Test Material Weights		✓	✓	✓	✓

Clarity Research 3D System photography		✓	✓	✓	✓
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 33 Participants will be enrolled in the study to complete with thirty-five Participants. Participantsare recruited from the Research centre panellist database.

3.1 INCLUSION CRITERIA

A Participant may be eligible for enrollment in the study if she meets all of the following inclusion criteria:

1. Participant is female between 45 and 65 years of age (inclusive) with Fitzpatrick Skin Type I through III;
2. Participant presents with mild to moderate fine and coarse wrinkles on forehead at Screening and Baseline, with a score of 2-4 on a 0-5 Scale at screening for both areas
3. Participant presents with mild to moderate facial skin sagging/loss of firmness on lower cheeks and jawline at Screening and Baseline, with a score of 2-4 on a 0-5 Scale at screening and Baseline
4. Participant is willing to use the provided test materials (skin care regimen) which includes, test product, cleanser, moisturizer, and sunscreen (SPF30) for the duration of the study;
5. Participant is willing to undergo a 1 week washout phase using only the provided supplemental materials;
6. Participants using an adequate method of birth control;
7. Participant is free of any skin disease which might be confused with a dermal reaction from the test product;

8. Participant is willing to discontinue use of any facial products containing anti- wrinkle ingredients/benefits, with the exception of the provided test materials and supplemental materials, during the conditioning phase and for the duration of the study (Participants are permitted to use regular color cosmetics);
9. Participant agrees not to introduce any new cosmetic or toiletry products during the conditioning phase and for the duration of the study;
10. Participant is willing to avoid sun exposure, excessive (more 20 minutes) sun exposure, tanning lamps, and the use of any topical products on the test area during the conditioning phase and for the duration of the study;
11. Participant is willing to be photographed using the Clarity Research 3D and has signed a Photography Release Form;
12. Participant has signed an Informed Consent in conformance with 21 CFR Part 50: "Protection of Human Participants";
13. Participant has completed a HIPAA Authorization Form in conformance with 45 CFR Parts 160 and 164;
14. Participant is dependable and able to follow directions as outlined in the protocol;
15. Participant is in generally good health and has a current Panelist Profile on file.

3.2 EXCLUSION CRITERIA

A Participant may be eligible for enrollment in the study if she meets none of the following exclusion criteria:

1. Participant is pregnant, nursing, planning to become pregnant, or not using adequate birth control;
2. Participant exhibits any skin disorder, sunburn, scarring, tattoos, cuts, scrapes, or abrasions on the test site;
3. Participant has a current or past condition (e.g. psoriasis, rosacea, acne, eczema, seborrheic dermatitis, severe excoriations, facial sunburn, or excessively tanned facial skin, etc.) which, in the opinion of the Principal Investigator, will interfere with evaluation of the test products or places the Participant, study personnel, or the other participating Participants at undue risk;

4. Participant has a known allergies to cosmetic and toiletry products;
5. Participant who is currently participating or participated in the last 30 days in any other facial usage study in any clinical trial at LAB or at another research facility or doctor's office.
6. Participant who are currently using or during the last 3 months have used, Retin A, or other Rx/OTC Retinyl A, hydroquinone (skin lightening) or other astringent derived products or alpha hydroxyl acid treatments for photo-aging and fine lines/wrinkles.
7. Participant recently exposed to artificial U.V. (tanning beds) during 2 weeks before the baseline visit and who intend to be exposed to artificial U.V. during the study period.
8. Participant who have recently used suntan products during 2 weeks preceding the baseline visit.
9. Participants who are employees of LAB

3.3 PARTICIPANT TERMINATION AND WITHDRAWAL

A Participant may be discontinued or withdraw from study participation at any time if the Participant or a study doctor feels that it is not in the Participant's best interest to continue. The following is a list of possible reasons for study discontinuation:

- Participant withdrawal of consent
- Participant is not compliant with study procedures
- Adverse event that, in the opinion of the Principal Investigator, would be in the best interest of the Participant to discontinue study participation
- Protocol violation requiring discontinuation of test product use
- Lost to follow-up
- Sponsor request for early termination of study

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. Participants who withdraw or are disqualified for any reason from the study will not be replaced.

Section 4: TEST METHOD

4.1 RECRUITING AND PRE-SCREENING

Participants will be recruited from the Research centre panelist database. Participants who meet all of the Inclusion Criteria and none of the Exclusion Criteria will be screened at the screening and baseline visits, and then subsequently enrolled.

4.2 VISIT 1 (DAY -7 ± 3 DAYS): SCREENING

All Participants will be initially identified by their permanent Research centrepanelist database identification number. This Participant number will be assigned in sequence as Participants are enrolled in the study. A master roster will be kept of the permanent Research centre panelist database identification number and the corresponding sequential Participant number.

Participants will be provided with a cleanser, moisturizer, and sunscreen (SPF30), Washout Phase Diaries, and Instructions for Participants. Participants will be instructed to use the provided supplemental products as instructed in Section 6.1 for the washout phase and in Section 6.2 for the duration of the study.

Participants will be assessed for current smoker status.

4.3 VISIT 2 (DAY 1): BASELINE

Participants will return to the testing facility with clean faces, free from makeup with their conditioning phase diaries. Participants will acclimate to ambient laboratory conditions for a period of 15 minutes prior to study evaluations.

Temperature will be recorded hourly in the lab area where Participants are acclimating during study visit days.Clarity Research 3D System photography will be taken for the Face area (Front/Left/Right).

Participantswill be provided with the test material (pre-weighed), Daily Diaries, and Instructions. Participants will be instructed to use the test material daily, twice a day and the provided as instructed in Section 6.2 for the duration of the study.

4.4 VISIT 3 (WEEK 4)

Participants will return to the testing facility with clean faces, free from makeup. Participants will acclimate to ambient laboratory conditions for a period of 15 minutes prior to study evaluations.Temperature will be recorded hourly in the lab area where Participants are acclimating during study visit days.

Clarity Research 3D System photography will be taken of the Face area (Front/Left/Right)

The test material will be weighed and documented in the Sponsor provided Product Compliance form and Daily Diaries will be reviewed for compliance.

4.5 VISIT 4 (WEEK 8)

Participants will return to the testing facility with clean faces, free from makeup. Participants will acclimate to ambient laboratory conditions for a period of 15 minutes prior to study evaluations.

Temperature will be recorded hourly in the lab area where Participants are acclimating during study visit days.

Clarity Research 3D System photography will be taken for the Face area (Front/Left/Right)

The test material will be weighed and documented in the Sponsor provided Product Compliance form and Daily Diaries will be reviewed for compliance.

4.6 VISIT 5 (WEEK 12)

Participants will return to the testing facility with clean faces, free from makeup. Participants will acclimate to ambient laboratory conditions for a period of 15 minutes prior to study evaluations.

Temperature will be recorded hourly in the lab area where Participants are acclimating during study visit days.

Clarity Research 3D System photography will be taken of the Face area (Front/Left/Right).

Daily Diaries will be reviewed for compliance and test material will be weighed in the Sponsor provided Product Compliance form and collected.

Section 5: STUDY EVALUATIONS

5.1 CLARITY RESEARCH 3D SYSTEM

This instrument Laboratories features the latest technology in 2D and 3D skin modeling. The Clarity Research 3D System features 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 alsoable to perform 3D reconstruction of the skin topography, facial contour, and facial fine lines / deep wrinkle surface analysis and to analyze acne scars and lesions, perform lash analysis on length, density, and curl, and lip analysis of the surface, volume, and texture. Additional features include redness scoring, subsurface pigment detection, pore detection, and visible spot detection.

Diffused Light, Subsurface Melanin, Subsurface Hemoglobin, Surface, and 3D lighting modes will be selected for this study. Images will be obtained with eyes closed. Frontal and 45º images will be obtained.

Measurements Info:

Location: Forehead and Jowl

Measured Parameters:

1. Skin Type Classification

2. Wrinkles (Forehead): Wrinkles Object Count, Average Length, Width & Severity and Total Surface Area

3. Jowl: Facial contours of sagging jowls

5.2 SKIN FEATURE TO BE STUDIED

5.2.1 Skin Type

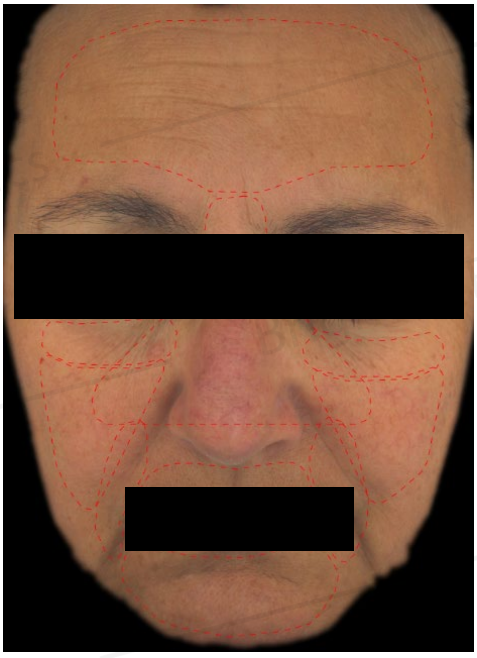
Human Skin type varies by region and ethnicity. The variance in skin color is primarily due to a pigment known as melanin present underneath the skin layers. Skin color generally ranges from a very dark brown to a near yellowish pink. Darker skin colors are due to the presence of melanin whereas lighter skin colors appear yellowish pink due to the presence of red blood vessels under the skin.

Measured Parameter: Lstar

Lstar: As L* increases the brightness in Skin color is increasing.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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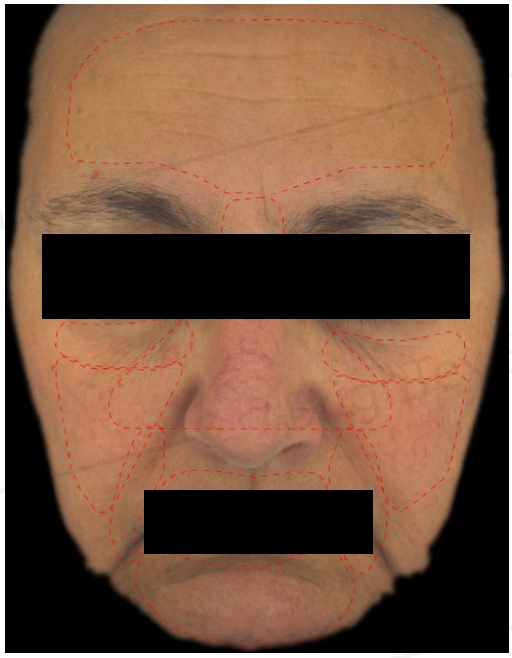

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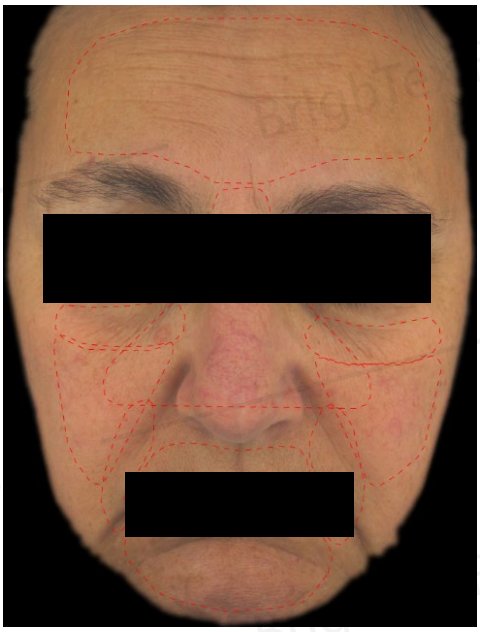

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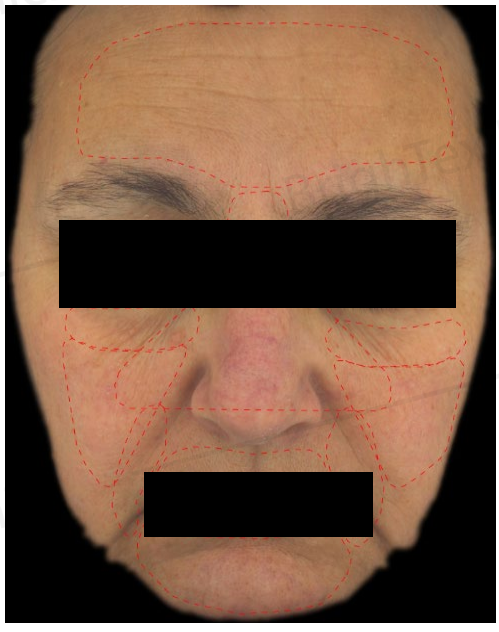
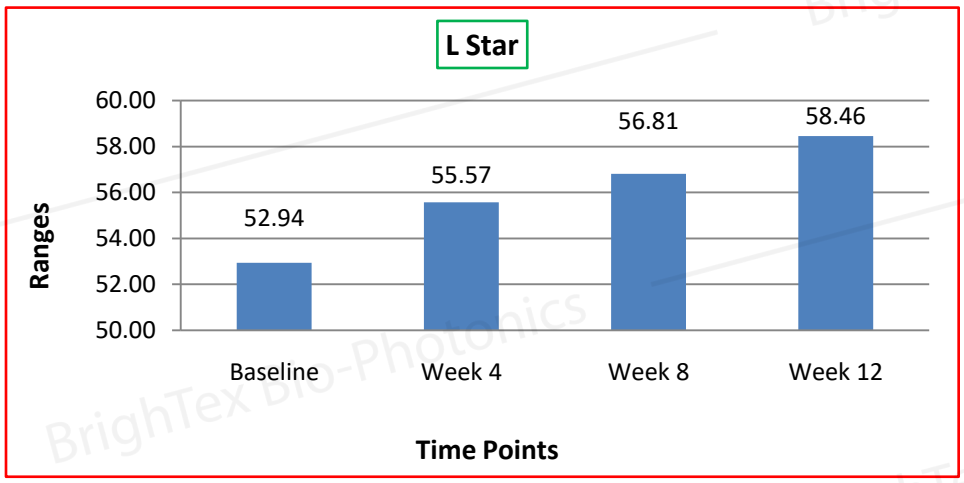


Participant 26 Results



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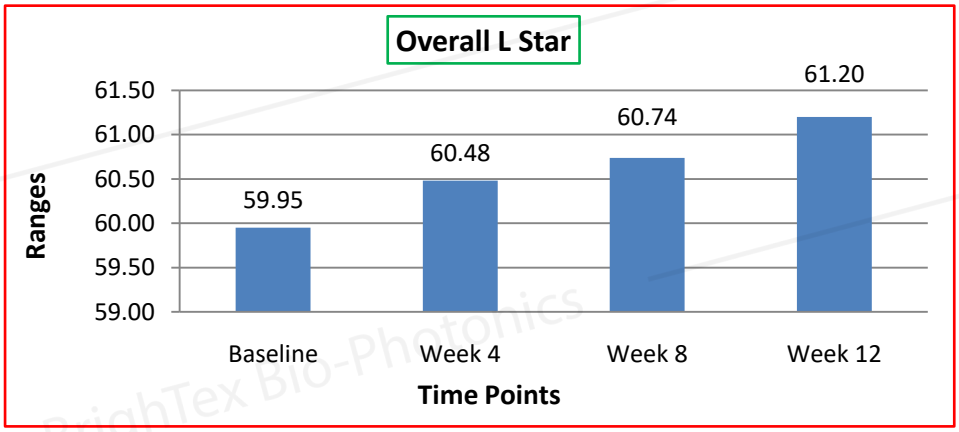
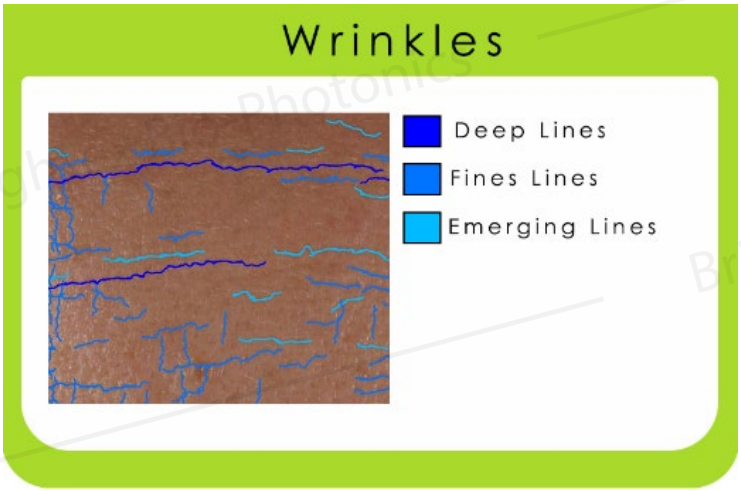


Test Results and Statistical Summary

Clarity™ Research 3D System-Skin Type				
Parameter	Treatment	Visit	% of Participant showed improvement	No of Participants showed improvement
Lstar	Test Product	Week 4	63.6%	21
		Week 8	78.8%	26
		Week 12	78.8%	26

5.2.2 Wrinkles

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 3 types: Deep Lines, Fine Lines and Emerging Lines.

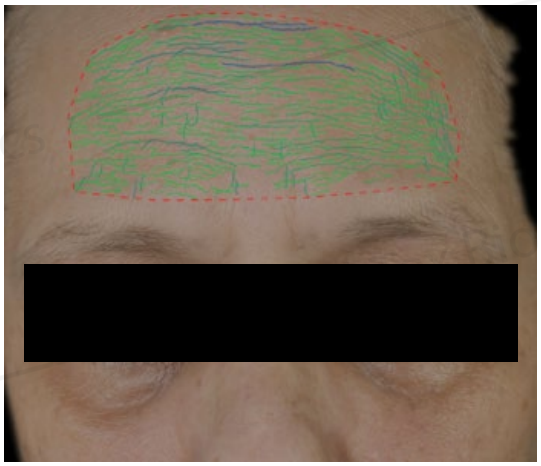


Measured Parameters: Total Count w/ Emerging, Fine and Deep Line Classification, Average Length, Average Width, Average Severity, Total Surface Area and Total Assessment Area

i. Average Length (mm): Average Length of the wrinkles in each category i.e. Emerging, Fine, & Deep Wrinkles.

Sample Result Images:

T0



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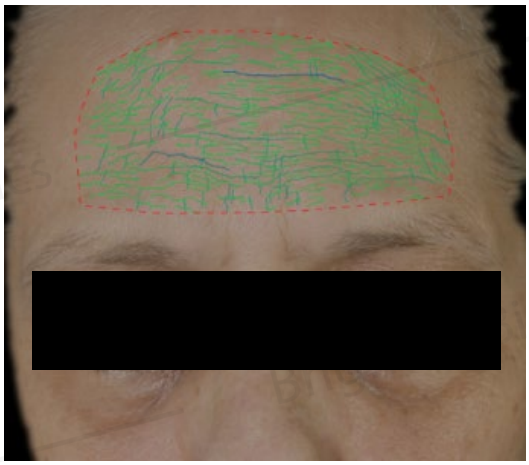

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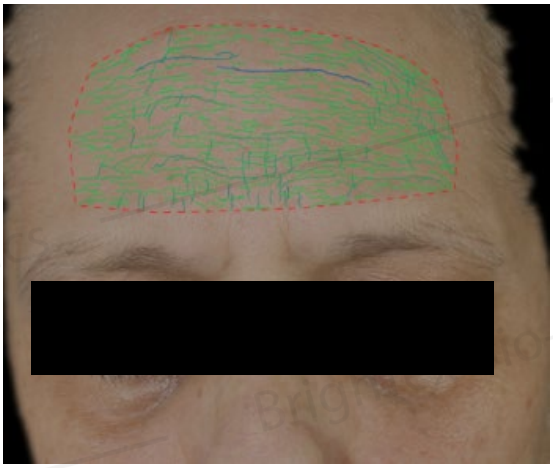

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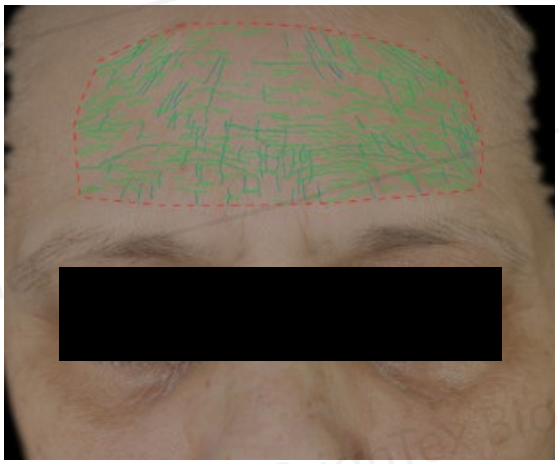
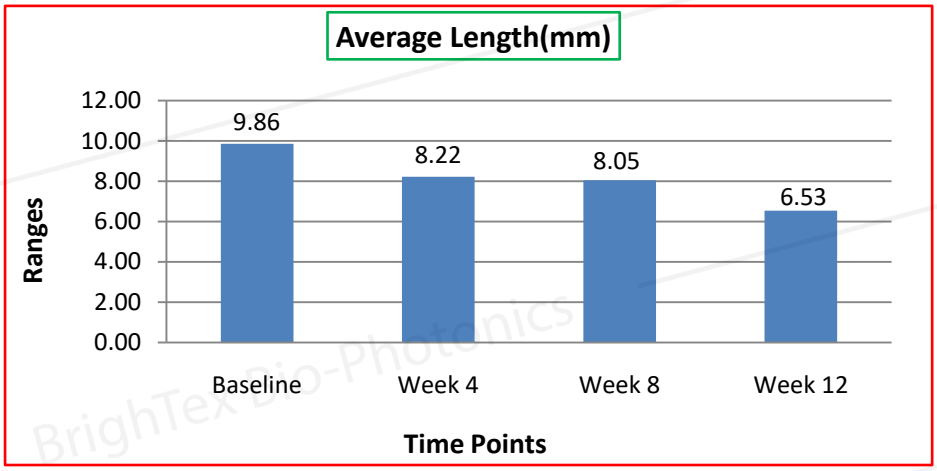
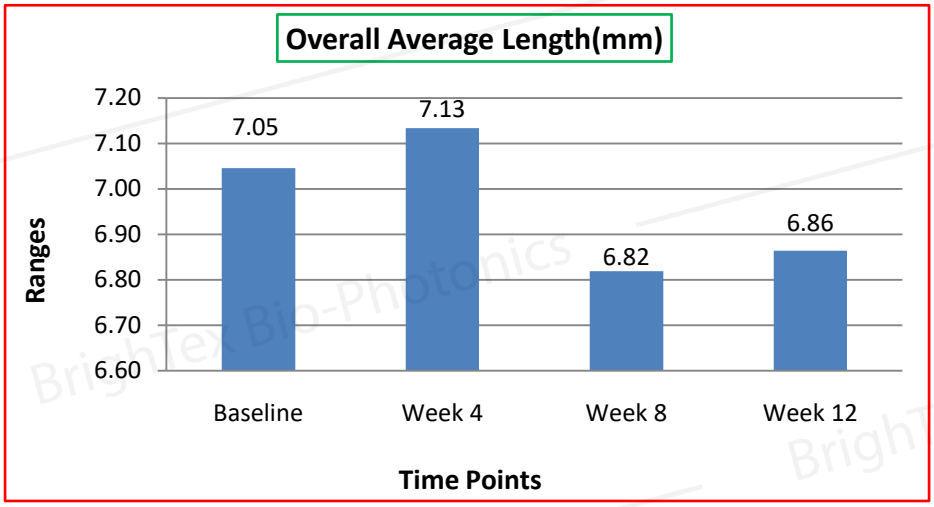


Participant 04 Results



Overall Average Length (mm):

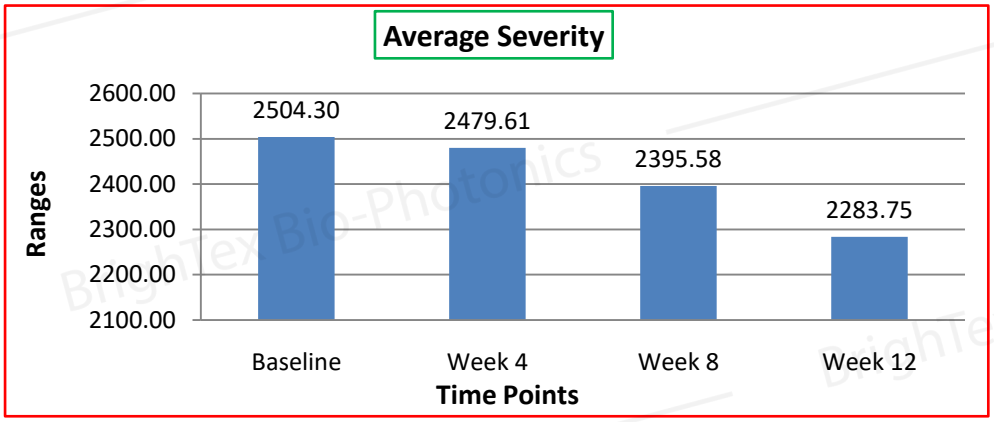


Test Results and Statistical Summary

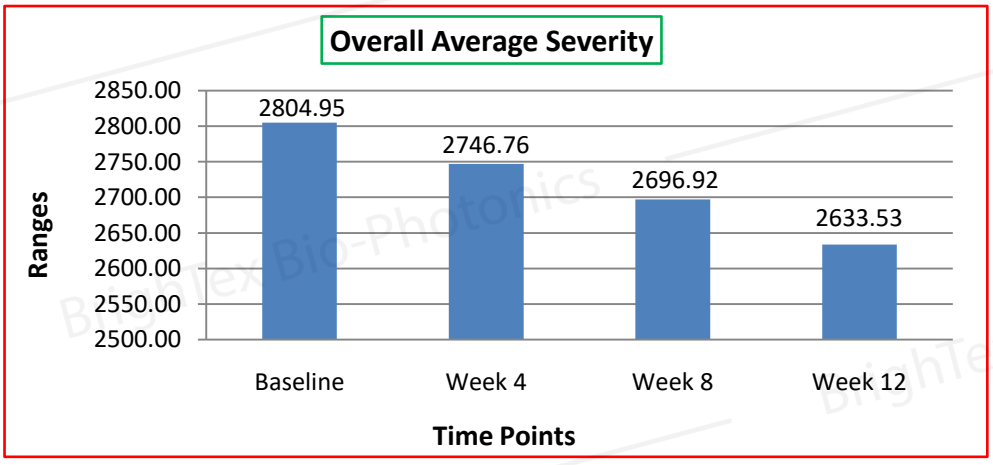
Clarity™ Research 3D System-Average Length (mm)				
Parameter	Treatment	Visit	% of Participant showed improvement	No of Participants showed improvement
Average Length (mm)	Test Product	Week 4	36.4%	12
		Week 8	60.6%	20
		Week 12	63.6%	21

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

Participant 02 Results



Overall Average Severity:

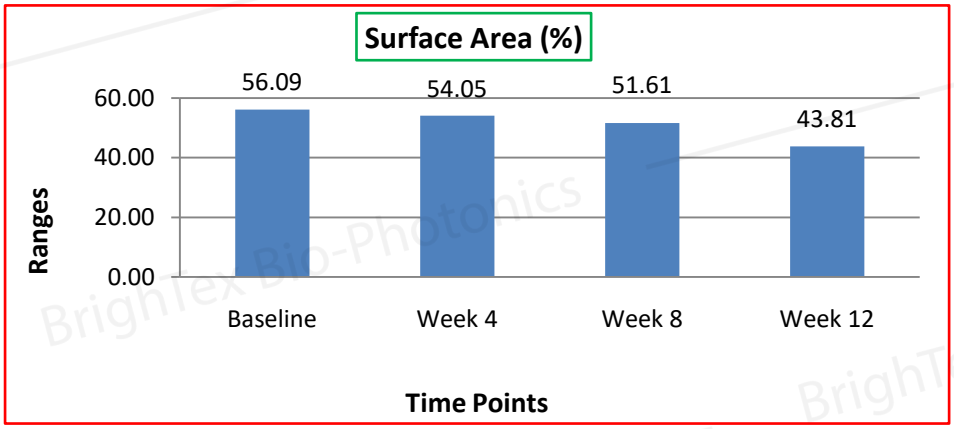


Test Results and Statistical Summary

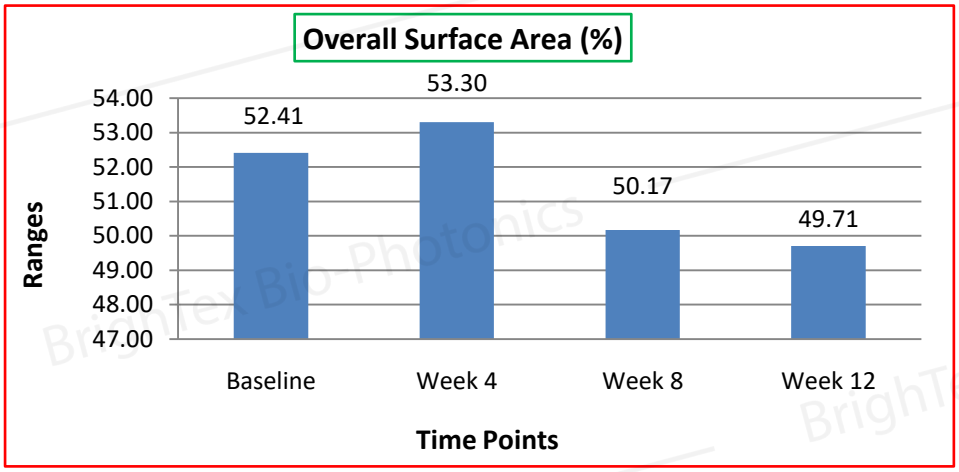
Clarity™ Research 3D System-Average Severity				
Parameter	Treatment	Visit	% of Participant showed improvement	No of Participants showed improvement
Average Severity	Test Product	Week 4	60.6%	20
		Week 8	75.8%	25
		Week 12	72.7%	24

iii. Total Surface Area (%): It is the Percentage Area effected by the Wrinkles recognized

Participant 12 Results



Overall Surface Area (%):

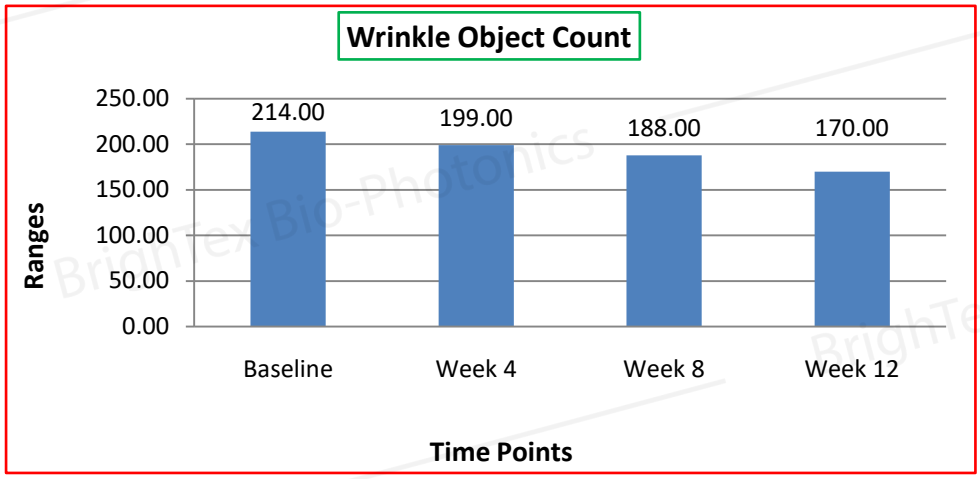


Test Results and Statistical Summary

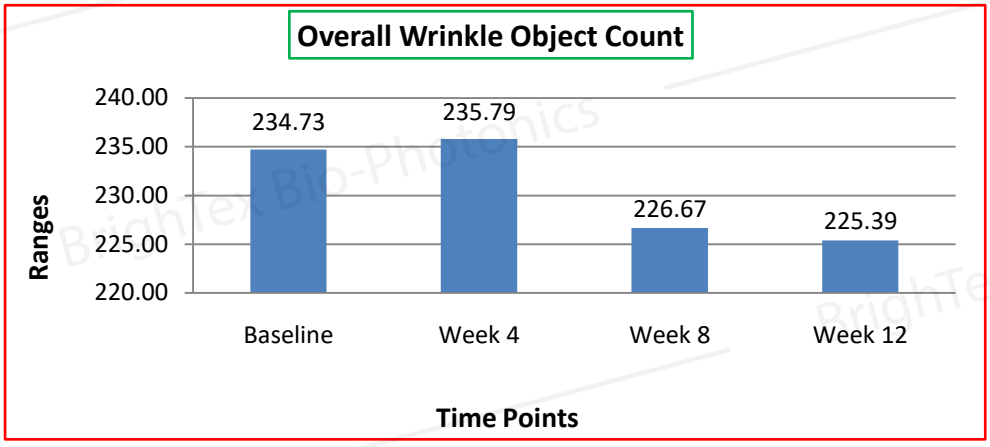
Clarity™ Research 3D System – Surface Area (%)				
Parameter	Treatment	Visit	% of Participant showed improvement	No of Participants showed improvement
Surface Area (%)	Test Product	Week 4	39.4%	13
		Week 8	63.6%	21
		Week 12	63.6%	21

iv. Wrinkle Object Count: Total Count of the wrinkles in each category i.e. Emerging, Fine, & Deep Wrinkles.

Participant 02 Results



Overall Wrinkle Object Count:



Test Results and Statistical Summary

Clarity™ Research 3D System – Wrinkle Object Count				
Parameter	Treatment	Visit	% of Participant showed improvement	No of Participants showed improvement
Wrinkle Object Count	Test Product	Week 4	42.4%	14
		Week 8	57.6%	19
		Week 12	69.7%	23

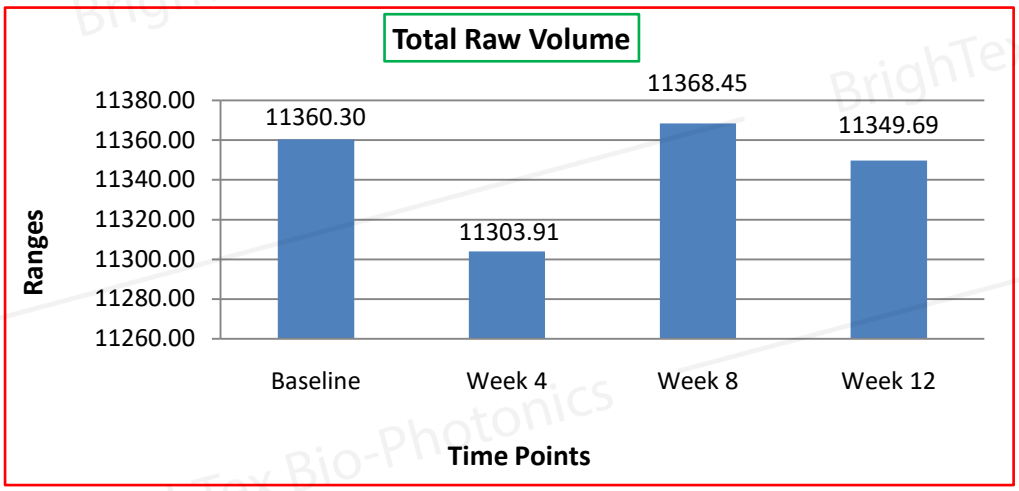
5.2.3 Facial Contours of Sagging Jowls

This defines the degree of convexitiesand concavities on the facial region.

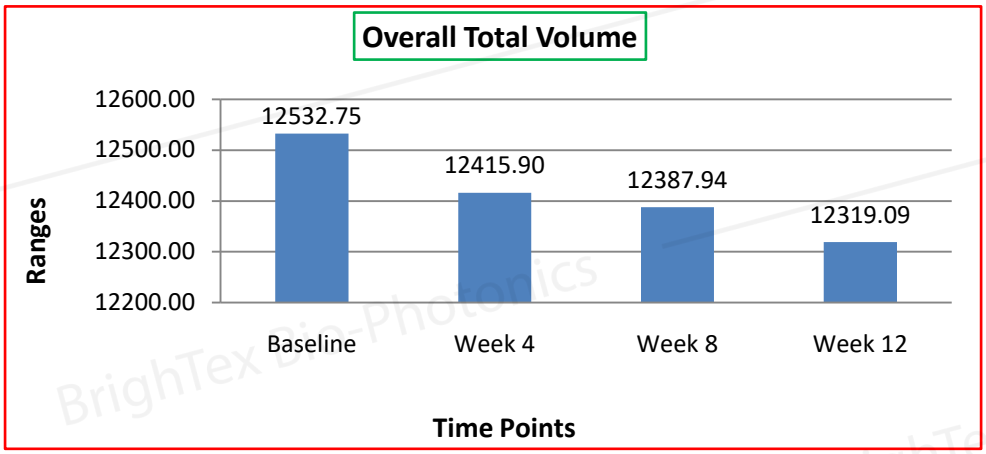
Measured Parameters: Total Raw Volume

i. **Total Raw Volume:**Total Intensity measured on displacement map for each zone.

Participant 25 Results



Overall Total Raw Volume:



Test Results and Statistical Summary

Clarity™ Research 3D System – Total Raw Volume				
Parameter	Treatment	Visit	% of Participant showed improvement	No of Participants showed improvement
Total Raw Volume	Test Product	Week 4	15.2%	5
		Week 8	33.3%	11
		Week 12	42.4%	14

Section 6: TEST MATERIALS

6.1 WASHOUT PHASE (1 WEEK)

6.1.1 In the Morning (AM)

1. Cleanse your face with the Supplemental Cleanser and pat dry.
2. Apply the Supplemental Sunscreen SPF30 over the face and neck.
3. Follow with the Supplemental Moisturizer, if needed.

6.1.2 In the Evening (PM)

1.Cleanse your face with the Supplemental Cleanser and pat dry.

2. Apply the Supplemental Moisturizer over the face and neck

6.2 TEST PRODUCT APPLICATION

Use the test product two times a day, in the morning and evening.

6.2.1 In the Morning (AM)

1. Cleanse face with the Supplemental Cleanser. Skin must be completely clean and dry before you apply the Test Product Test Product

2. Dispense Test Product Test Product onto fingertips and smooth serum on the face and neck in an upward and outward motion.

3. Apply the Supplemental Sunscreen SPF30 over the face and neck

4. Follow with the Supplemental Moisturizer, if needed.

6.2.2 In the Evening (PM)

1. Cleanse your face with the Supplemental Cleanser. Skin must be completely clean and dry before you apply the Test Product Test Product.

2. Dispense Test Product Test Product onto fingertips and smooth serum on the face and neck in an upward and outward motion.

3. Apply the Supplemental Moisturizer over the face and neck

Warning:

The product is for external use only. Avoid contact with eyes. If product gets into eyes, rinse thoroughly with water. Keep out of reach of children.

*Do not mix this test product with any product other than the assigned sunscreen. Do not use any products on the face, other than the assigned test materials and assigned sunscreen, for the duration of the study.

Section 7: CONCLUSION

It was concluded that Skin Type, Wrinkles and Facial Contours of Sagging Jowls showed significant improvement from Baseline to Week 12

The following parameters showed improvements in Skin Type:L star showed significant improvement from Baseline to Week 12 which ranges from 63.6% to 78.8%

The following parameters showed improvements in Wrinkles: Average Length, Average width, Average Severity, Total Surface Area (%) and Wrinkle Object Count showed significant improvement from Baseline to Week 12 ranges from 36.4% to 75.8%

The following parameters showed improvements in Facial Contours of Sagging Jowls:

Total Raw Volume showed significant improvement from Baseline to Week 12 which ranges from 15.2% to 42.4%.