

WRINKLE STUDY TEMPLATE

ABSTRACT

The objective of this study is to evaluate the efficacy of a facial cream with and without meditation in a population of female participants experiencing moderate to high perceived stress, following four weeks of twice daily test material use.

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

Measurements for the Participants will be recorded at Baseline, Week 2 and Week 4 after using the test product and it was concluded that there was a statistically significant improvement in Surface Area (%), Deep Wrinkles Surface Area (%), Deep Wrinkles Average Length (mm), Fine Wrinkles Average Length (mm) under Wrinkles 2D from Baseline to Week 4 which ranges from 25.0 % to 75.0 % with meditation and Fine Wrinkles Average Length which ranges from 31.6% to 57.9% without meditation.

Wrinkles 3D Total Volume feature showed significant improvement from Baseline to Week 4 which ranges from 65.0% to 80.0% with meditation.



Section 1: OBJECTIVE

The objective of this study is to evaluate the efficacy of a facial cream with and without meditation in a population of female participants experiencing moderate to high perceived stress, following four weeks of twice daily test material use.

Section 2: STUDY DESIGN

Approximately 20 female participants will be selected to evaluate the efficacy of a facial cream with and without meditation in a population of female participants experiencing moderate to high perceived stress, following four weeks of twice daily test material use. Study evaluations will include Clarity 3D Research System imaging and data analysis, and a consumer perception questionnaire.

A study schedule appears below.

Study Procedures and Evaluations	Screening(Day – 7 ± 3 Days	Baseline	Week 2	Week 4
Informed Consent Obtained	✓			
Inclusion and Exclusion Criteria Verified	✓			
Distribution of NonMoisturizing Soap and Conditioning Phase Diary	✓			
Collection of Conditioning Phase Diary		✓		
Clarity Research 3D System Imaging		✓	✓	✓
Test Material Application in the Laboratory		✓		

Test Materials, Daily Diary, and Use Instructions Distributed		✓		
Test Material and Daily Diary Collected			✓	
Consumer Perception Questionnaire		✓	✓	✓

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. Approximately 20 participants will be enrolled in this study. An attempt will be made to enrol participants balanced between the two groups (with and without meditation) on the following attributes (in this order): PSS Perceived Stress Scale, age and global wrinkle score.

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;
2. Participant has mild to moderate fine lines and wrinkles on the forehead, crow's feet, and under eye area;
3. Participant exhibits mild to moderate facial skin roughness;
4. Participant exhibits mild to moderate facial skin dryness;
5. Participant works indoors or is a homemaker;
6. Participant scores a 20 or greater in the Perceived Stress Scale (PSS) assessment questionnaire and scores a 5 or greater on the Pittsburgh Sleep Quality Index (PSQI);
7. Participant in the meditation group has a functioning CD player and is willing to devote approximately 30 to 40 minutes per day to complete daily meditation sessions for 21 days;

8. Participant agrees to discontinue use of their current facial cleanser and facial products for the conditioning phase and for the duration of the study;
9. Participant agrees not to introduce any new cosmetic or toiletry products during the study, with the exception of the test material and the provided non-moisturizing soap;
10. Participant is dependable and able to follow directions as outlined in the protocol;
11. Participant is willing to participate in all study evaluations;
12. Participant is in generally good health and has a current Panelist Profile Form on file at Clarity Research Laboratory;
13. Participant agrees to sign a Photography Release Form, providing consent for the capture of digital images for use in relation to this clinical study;
14. Participant has completed a HIPAA Authorization Form in conformance with 45 CFR Parts 160 and 164;
15. 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.

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 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.

4.2 SCREENING

Potential participants will report to the testing facility to be screened for study enrolment. Participants will complete the Perceived Stress Scale (PSS) assessment and the Pittsburgh Sleep Quality Index (PSQI). Participants must have a score of 20 or greater on the PSS assessment and a score of 5 or greater on the PSQI to be eligible for enrolment. Informed consent will be obtained and inclusion and exclusion criteria will be verified.

Qualified participants will be enrolled in the study. Participants will be provided with a non-moisturizing soap for use on the face and a conditioning phase diary. Participants will be instructed to use the non-moisturizing soap, and to refrain from using their current cleanser, for the conditioning phase. Participants will also be instructed to refrain from using any facial products (except the facial cleanser provided) on the face for the duration of the conditioning phase.

4.3 BASELINE

Participants will return to the testing facility following the 7-day (± 3 day) conditioning phase with clean faces, free from makeup. Conditioning phase diaries will be reviewed for study compliance and collected.

Participants will acclimate to ambient laboratory conditions for approximately 15 minutes. Clarity Research 3D System imaging will be captured. Participants will complete consumer perception questionnaires.

The test material, daily diary, and use instructions will be distributed. Trained clinical staff will instruct the participants regarding test material application. Participants will be instructed to continue using the non-moisturizing soap for all facial washing for the duration of the study. Participants will also be instructed to refrain from using any products on the face, with the exception of the provided test material, for the duration of the study.

Approximately half of the participants will be assigned to the meditation group, and will be required to listen to the provided meditation CDs once daily for the first 21 days of the study. Participants will note the date and time of each meditation session (mediation group only) and product application on the daily diary. Participants in the non-meditation group will apply the test material for the first time in the testing facility. Participants in the meditation group will apply the test material for the first time at home, prior to the first meditation session. Participants in the meditation group will be provided with the meditation CDs and additional instructions regarding meditation requirements. Participants in the non-meditating group will complete consumer perception questionnaires in the testing facility immediately post-application. Participants in the meditation group will be provided with paper questionnaires, to be completed at home following the first application and first meditation session.

4.4 WEEK 2

Participants will return to the testing facility following two weeks of test material use with clean faces, free from makeup. Daily diaries will be reviewed for study compliance.

Participants will acclimate to ambient laboratory conditions for approximately 15 minutes. Clarity Research 3D System imaging will be captured. Participants will complete consumer perception questionnaires.

4.5 WEEK 4

Participants will return to the testing facility following four weeks of test material use with clean faces, free from makeup. Unused test materials will be collected. Daily diaries will be reviewed for study compliance and collected. Participants will be required to present meditation CDs to confirm study compliance, but will be allowed to keep the CDs upon completion of the study.

Participants will acclimate to ambient laboratory conditions for approximately 15 minutes. Clarity Research 3D System imaging will be captured. Participants will complete consumer perception questionnaires.

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.

The following parameters will be assessed using the Clarity Research 3D System:

Fine lines and wrinkles of the crow's feet area and Forehead: Surface area, average severity, average length, and average width of emerging lines, fine lines, and deep lines and Wrinkle object count.

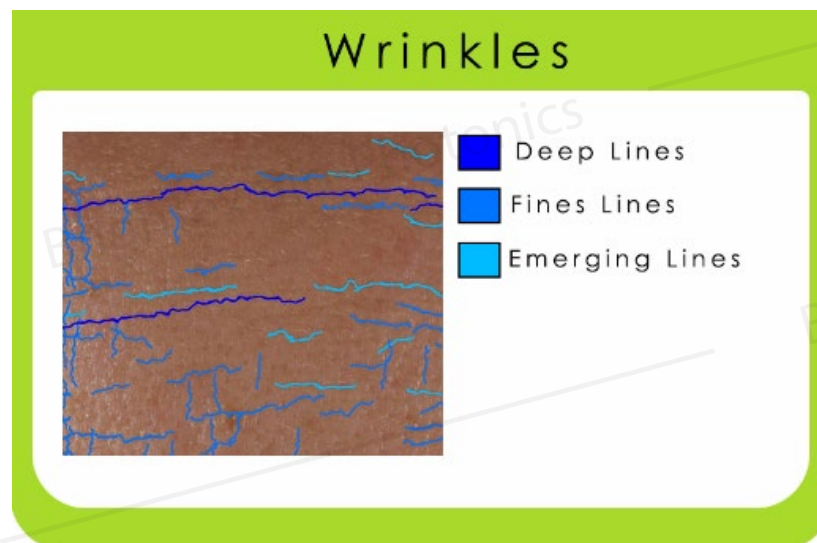
Clarity Research 3D System imaging will be captured at Baseline, Week 2 and Week 4. Images will be obtained with eyes closed.

5.2 SKIN FEATURE TO BE STUDIED

5.2.1 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.

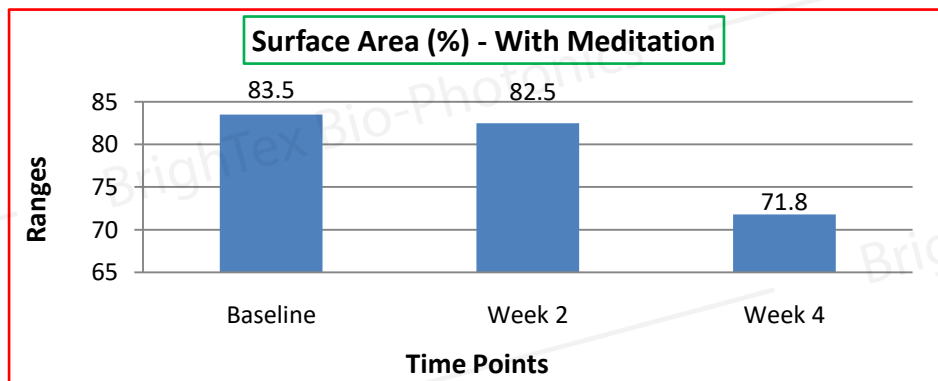
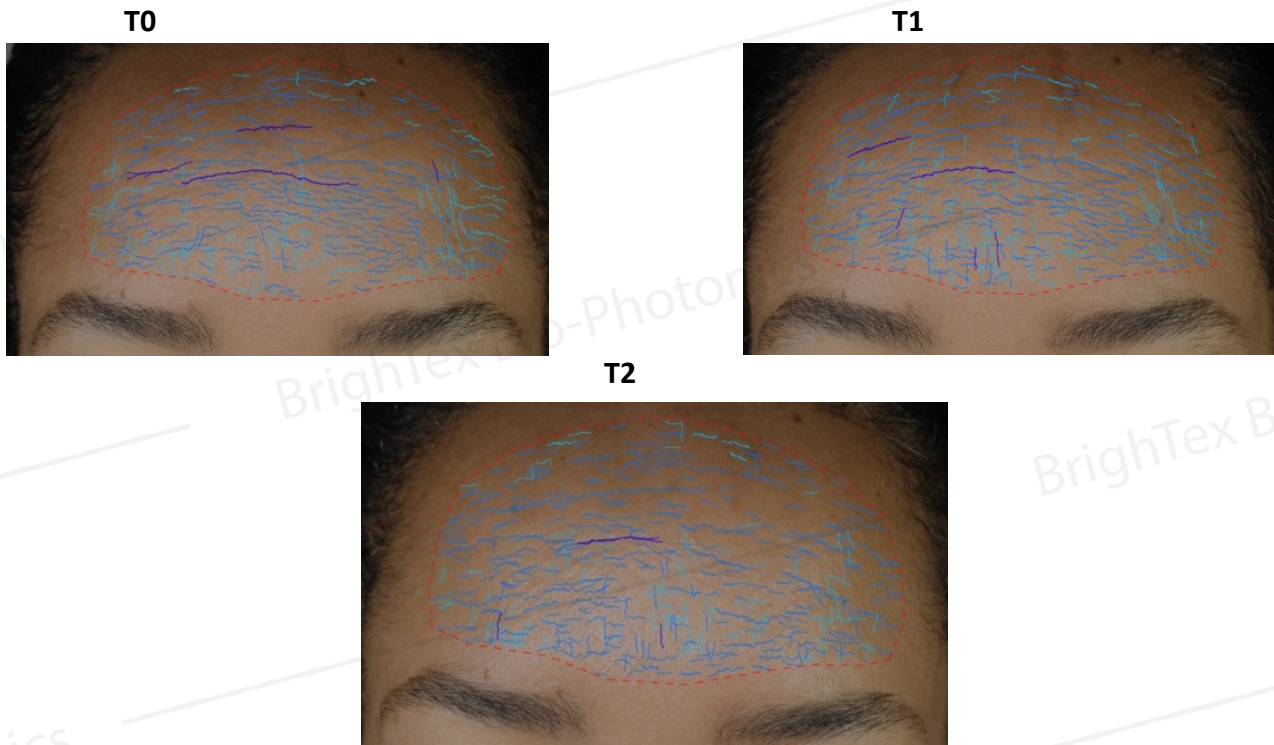


Measured Parameters: Surface Area (%)

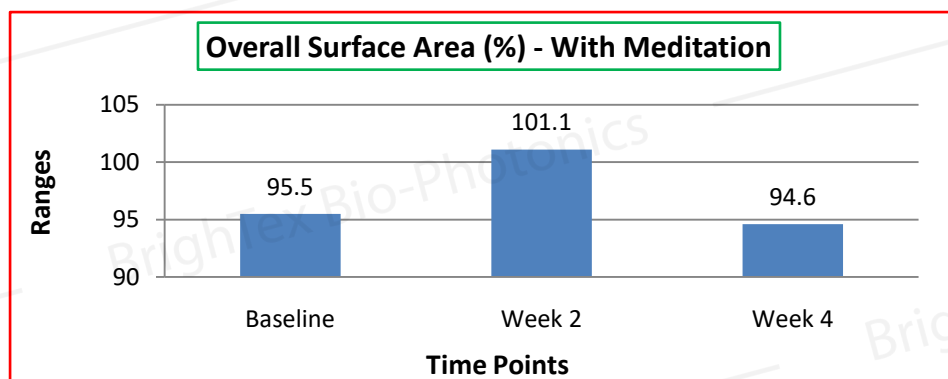
i. Surface Area (%):

It is defined as the percentage area affected by Wrinkles recognized.

Sample Result Images:



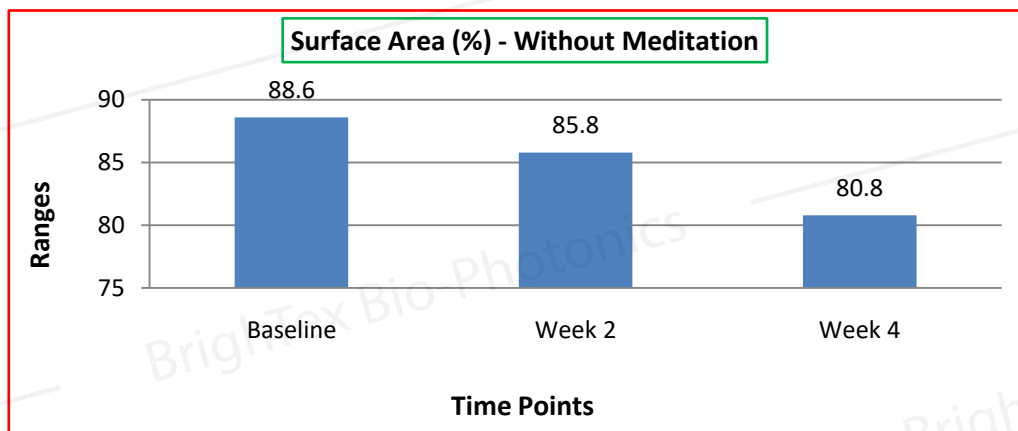
Overall Surface Area (%):



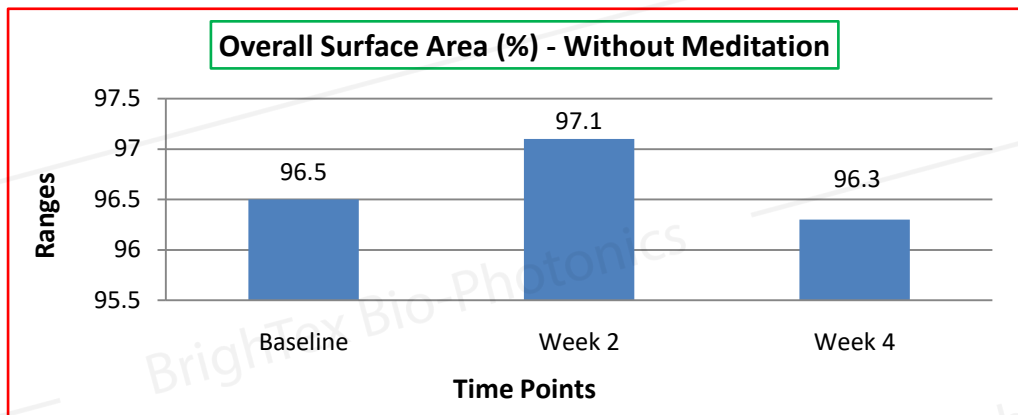
Test Results and Statistical Summary

Clarity™ Research 3D System-Surface Area (%) – With Meditation				
Parameter	Treatment	Visit	Number of Participants showed improvement	% of Participants showed improvement
Surface Area (%)	Facial Cream	Week 2	5	25.0%
		Week 4	13	65.0%

Participant 13 Results



Overall Surface Area (%):

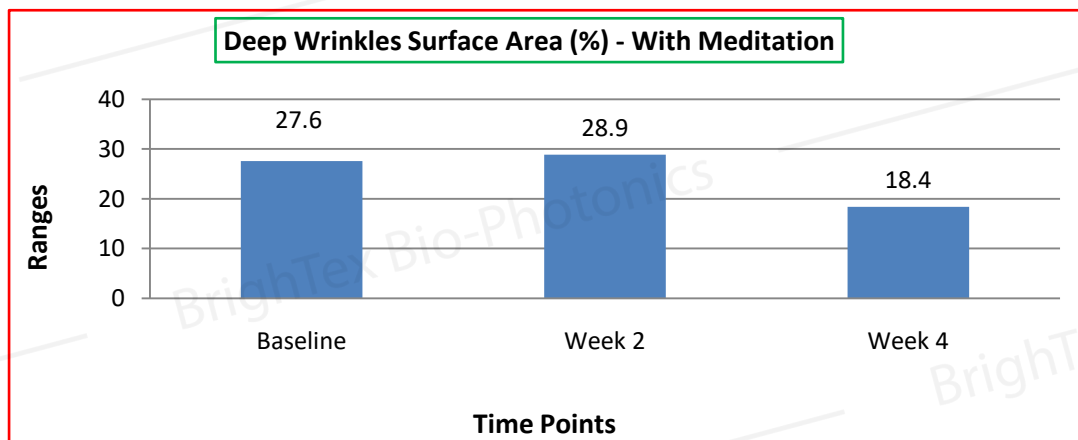


Test Results and Statistical Summary

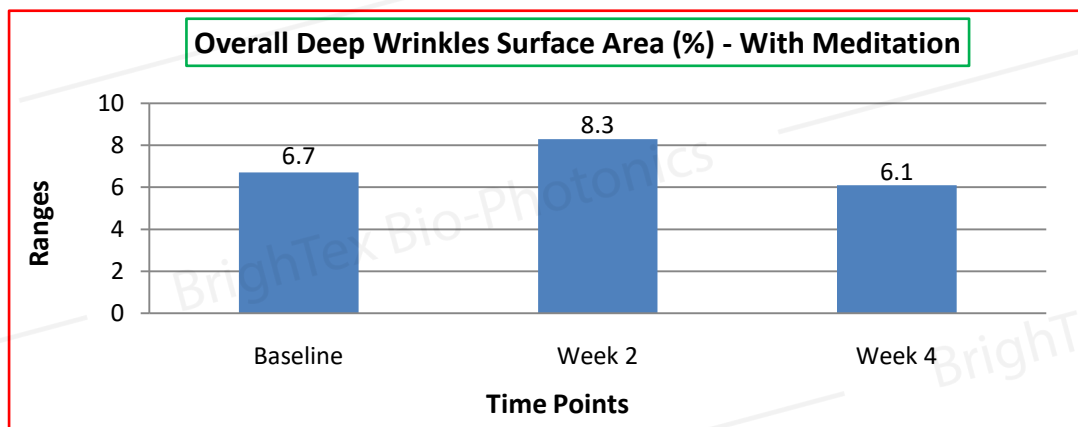
Clarity™ Research 3D System-Surface Area (%) – Without Meditation				
Parameter	Treatment	Visit	Number of Participants showed improvement	% of Participants showed improvement
Surface Area (%)	Facial Cream	Week 2	8	42.1%
		Week 4	8	42.1%

ii. **Deep Wrinkles Surface Area (%):** It is defined as the percentage of area effected by Deep Wrinkles

Participant 19 Results



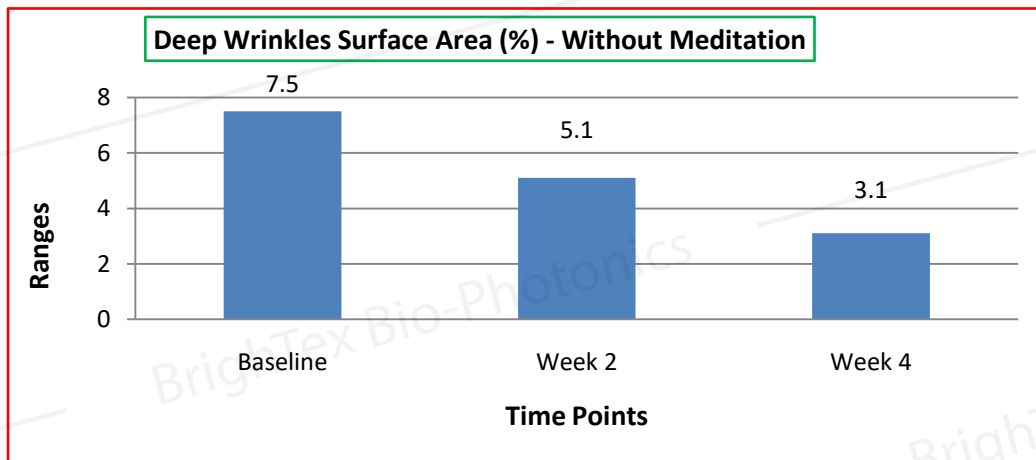
Overall Deep Wrinkles Surface Area (%):



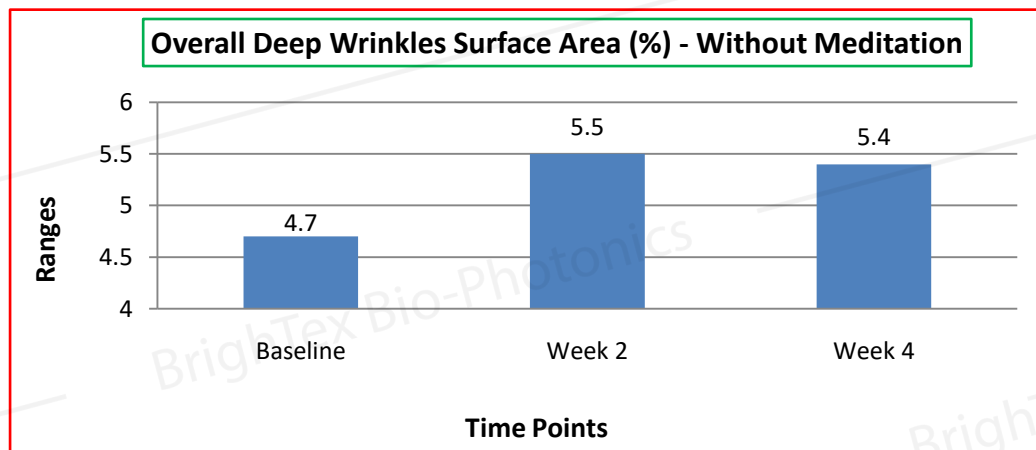
Test Results and Statistical Summary

Clarity™ Research 3D System-Deep Wrinkles Surface Area (%) – With Meditation				
Parameter	Treatment	Visit	Number of Participants showed improvement	% of Participants showed improvement
Deep Wrinkles Surface Area (%)	Facial Cream	Week 2	8	40.0%
		Week 4	13	65.0%

Participant 19 Results



Overall Deep Wrinkles Surface Area (%):

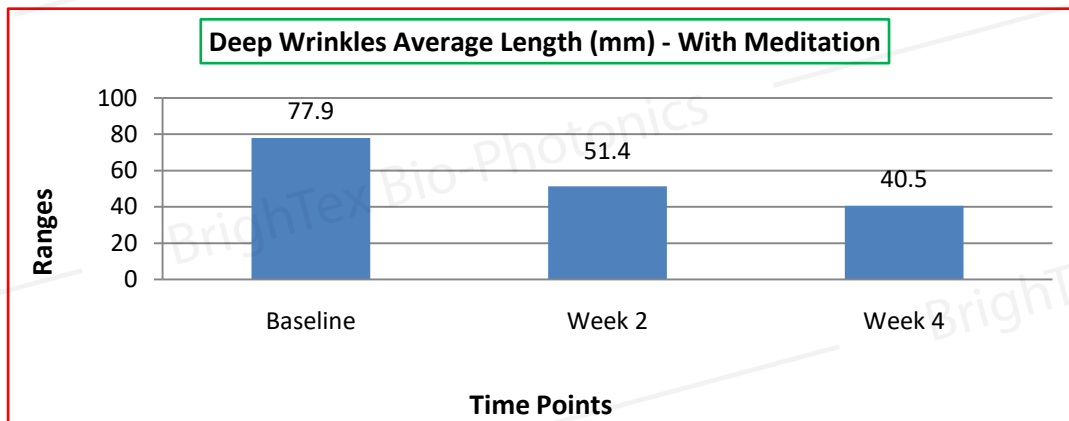


Test Results and Statistical Summary

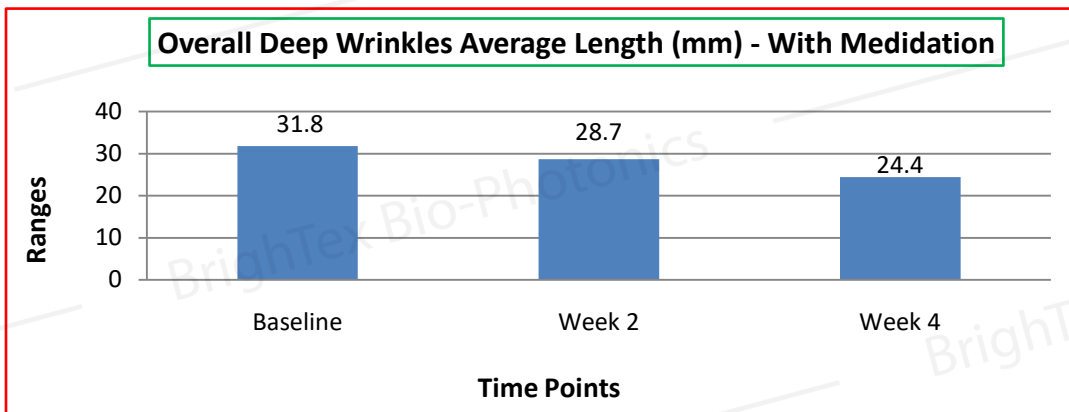
Clarity™ Research 3D System-Deep Wrinkles Surface Area (%) – Without Meditation				
Parameter	Treatment	Visit	Number of Participants showed improvement	% of Participants showed improvement
Deep Wrinkles Surface Area (%)	Facial Cream	Week 2	9	47.4%
		Week 4	9	47.4%

iii. **Deep Wrinkles Average Length (mm):** It is defined as the percentage of area affected by the Deep Wrinkles.

Participant 19 Results



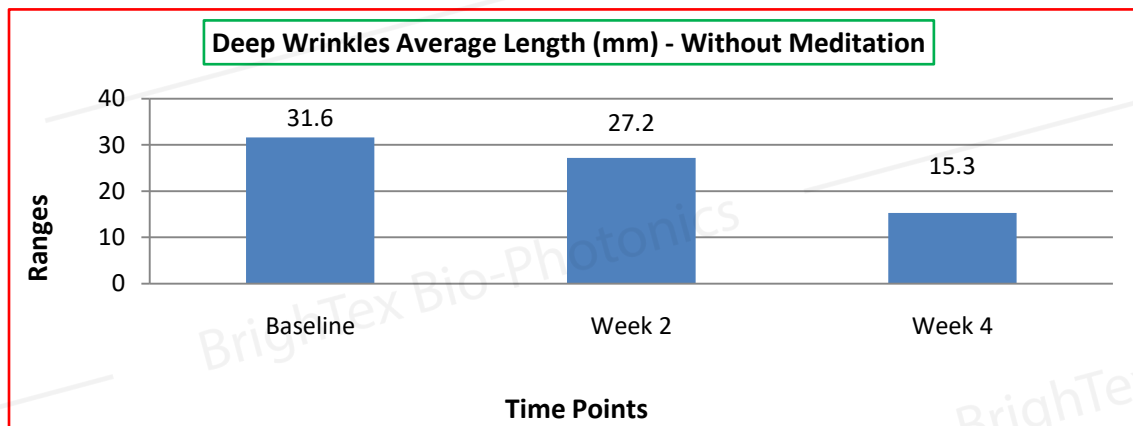
Overall Deep Wrinkles Average Length (mm):



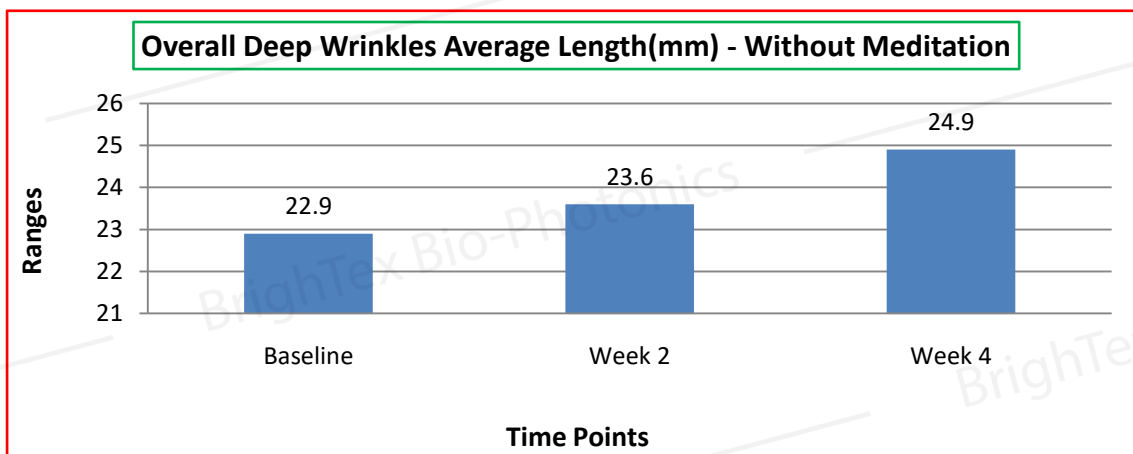
Test Results and Statistical Summary

Clarity™ Research 3D System-Deep Wrinkles Average Length (mm) – With Meditation				
Parameter	Treatment	Visit	Number of Participants showed improvement	% of Participants showed improvement
Deep Wrinkles Average Length (mm)	Facial Cream	Week 2	11	55.0%
		Week 4	15	75.0%

Participant 19 Results



Overall Deep Wrinkles Average Length (mm):

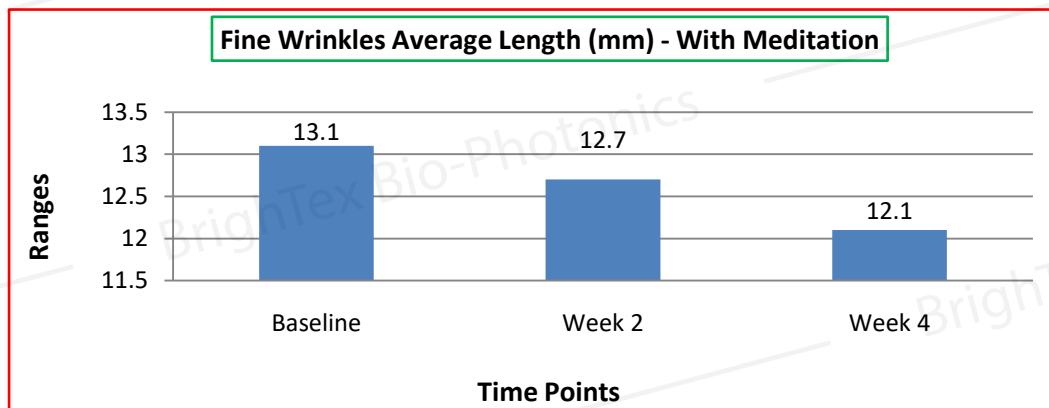


Test Results and Statistical Summary

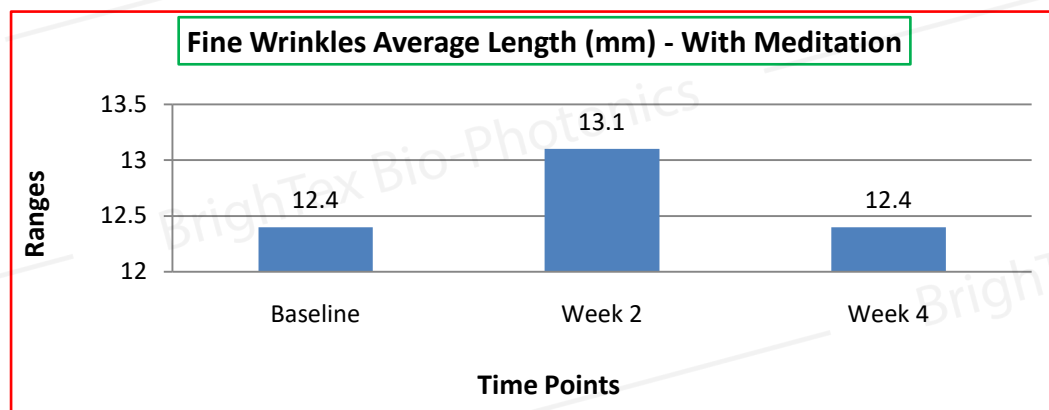
Clarity™ Research 3D System-Deep Wrinkles Average Length (mm) – Without Meditation				
Parameter	Treatment	Visit	Number of Participants showed improvement	% of Participants showed improvement
Deep Wrinkles Average Length (mm)	Facial Cream	Week 2	9	47.4%
		Week 4	7	36.8%

iv. **Fine Wrinkles Average Length (mm):** It is defined as the average length of the fine wrinkles.

Participant 10 Results



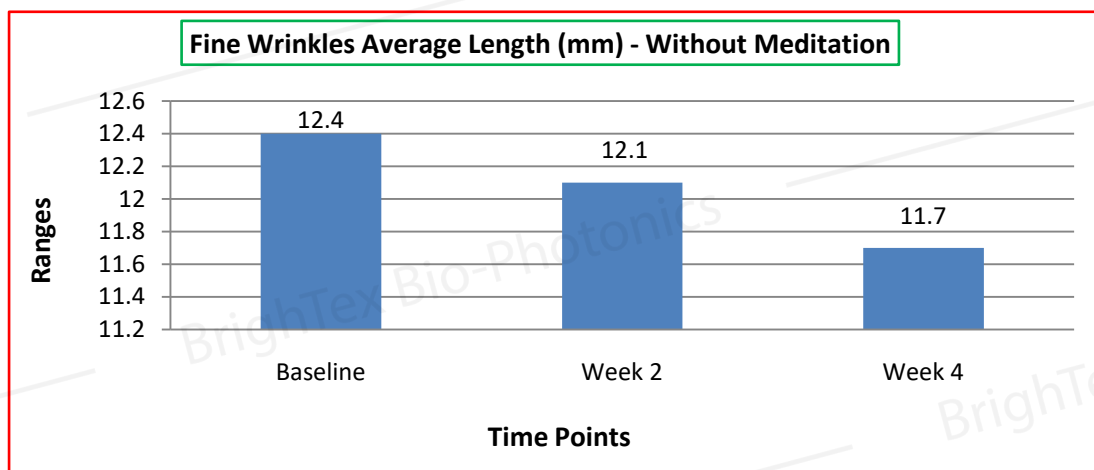
Overall Fine Wrinkles Average Length (mm):



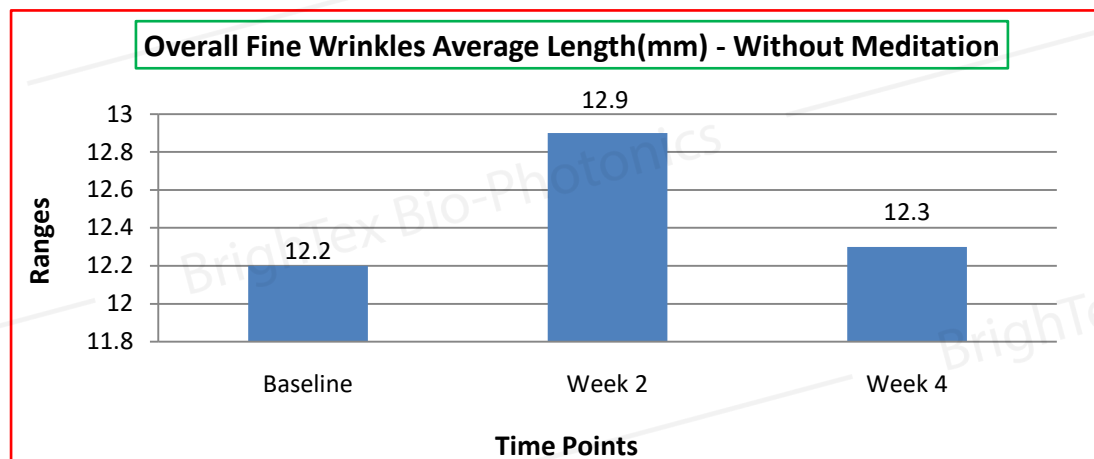
Test Results and Statistical Summary

Clarity™ Research 3D System-Fine Wrinkles Average Length (mm) – With Meditation				
Parameter	Treatment	Visit	Number of Participants showed improvement	% of Participants showed improvement
Fine Wrinkles Average Length (mm)	Facial Cream	Week 2	5	25.0%
		Week 4	11	55.0%

Participant 10 Results



Overall Fine Wrinkles Average Length (mm):



Test Results and Statistical Summary

Clarity™ Research 3D System-Fine Wrinkles Average Length (mm) – Without Meditation				
Parameter	Treatment	Visit	Number of Participants showed improvement	% of Participants showed improvement
Fine Wrinkles Average Length (mm)	Facial Cream	Week 2	6	31.6%
		Week 4	11	57.9%

5.2.2 WRINKLES 3D

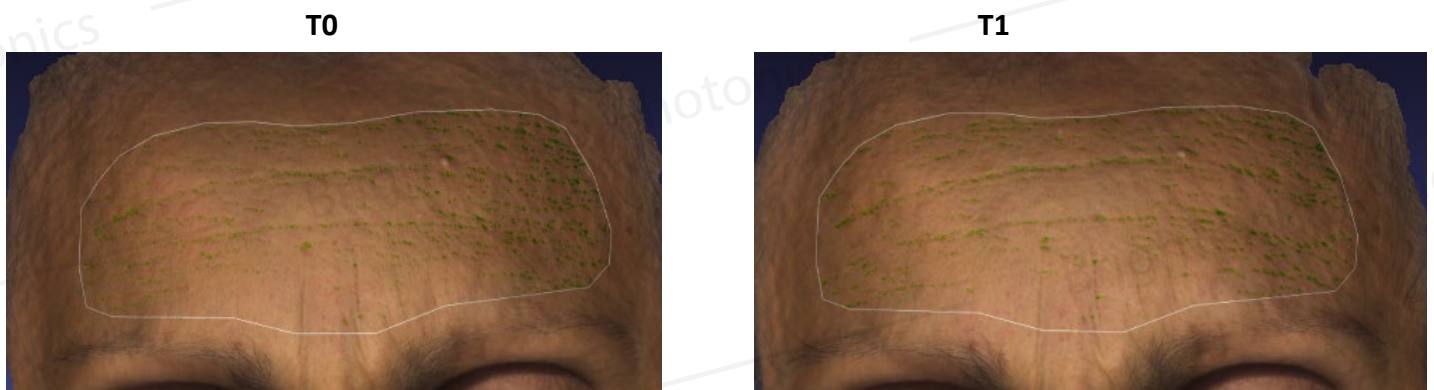
Structural changes in specific parts of the dermis and the subcutaneous tissue producing a fold, ridge or crease on the skin is considered as a wrinkle.



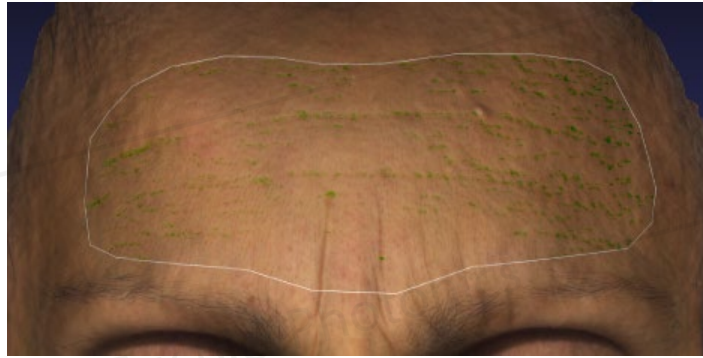
Measured Parameters: Total Volume

i. **Total Volume:** It is defined as the total wrinkle volume of recognized wrinkles

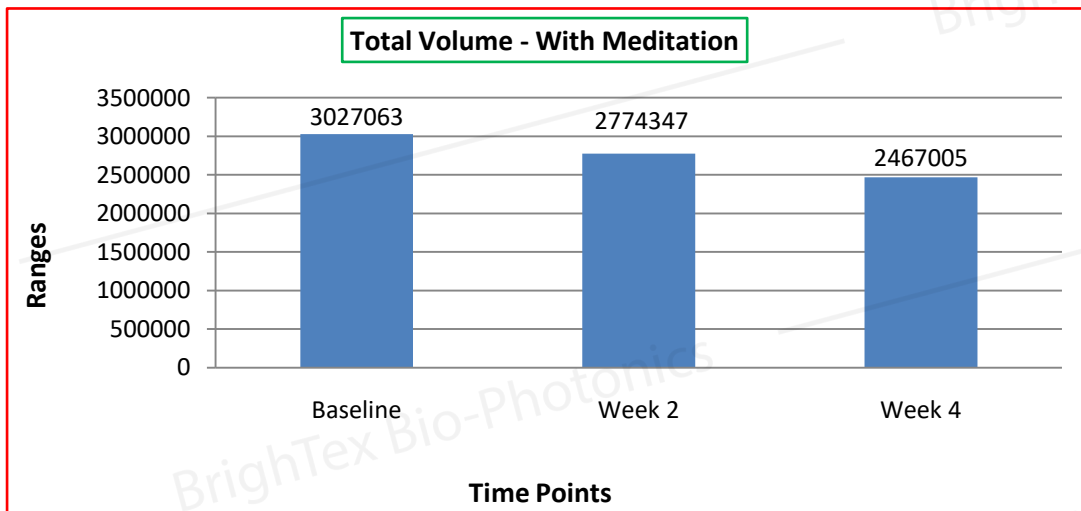
Sample Result Images:



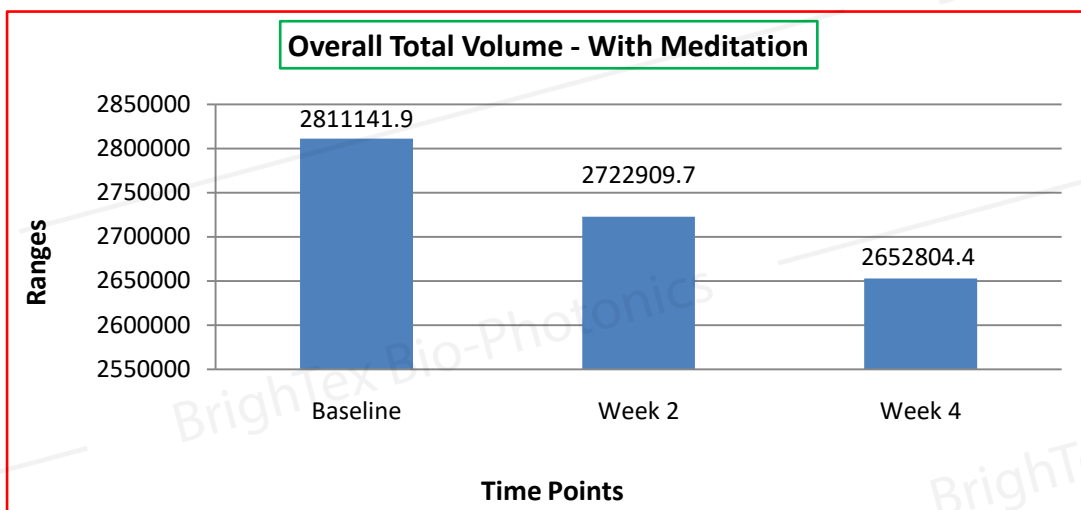
T2



Participant 18 Results



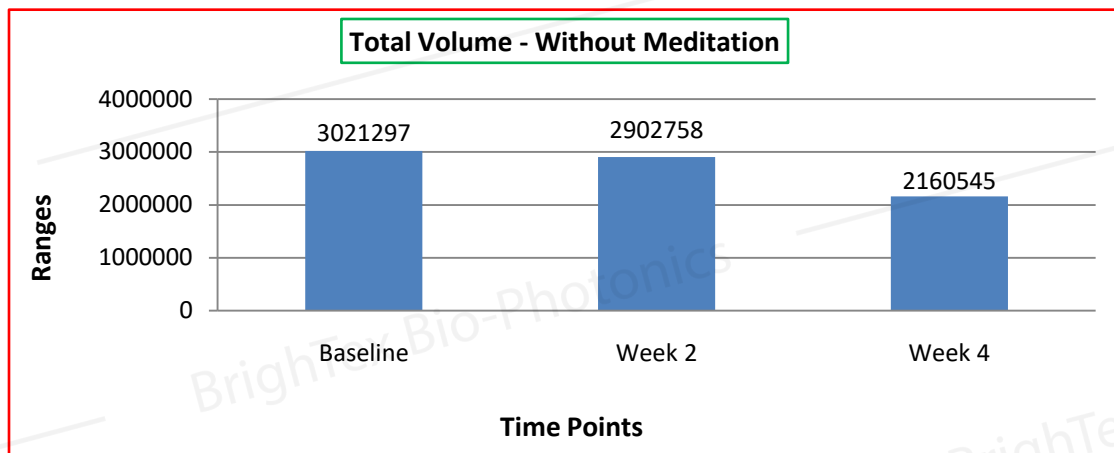
Overall Total Volume:



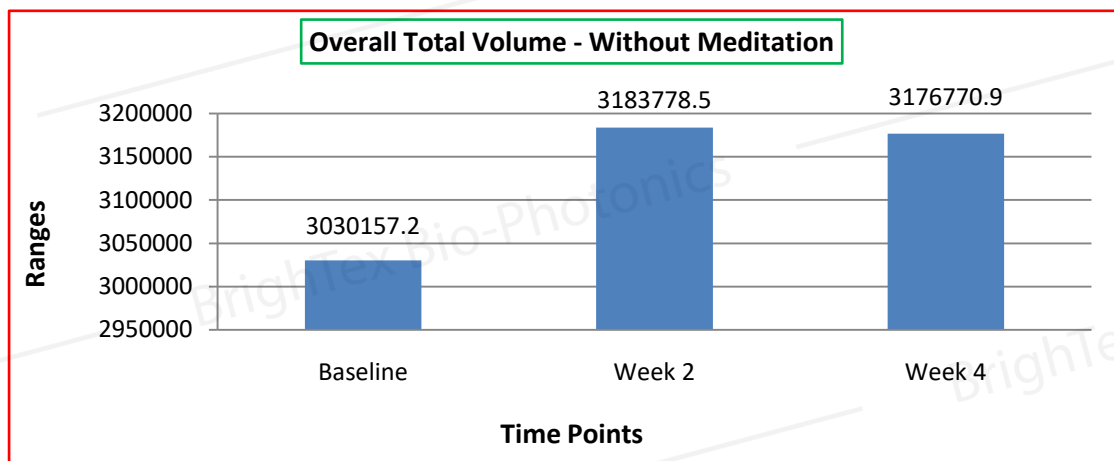
Test Results and Statistical Summary

Clarity™ Research 3D System-Total Volume – With Meditation				
Parameter	Treatment	Visit	Number of Participants showed improvement	% of Participants showed improvement
Total Volume	Facial Cream	Week 2	13	65.0%
		Week 4	16	80.0%

Participant 19 Results



Overall Total Volume:



Test Results and Statistical Summary

Clarity™ Research 3D System-Total Volume – Without Meditation				
Parameter	Treatment	Visit	Number of Participants showed improvement	% of Participants showed improvement
Total Volume	Facial Cream	Week 2	12	63.2%
		Week 4	9	47.4%

Section 6: Product Use Instructions

Apply to clean face and neck in the morning and evening.

Caution: Avoid direct contact with eyes.

Section 7: Consumer Perception Questionnaire

Cream only group Use 5-choice scale for each question: **Strongly Agree, Agree, Neither Agree nor Disagree, Disagree, Strongly Disagree**

7.1 Immediate

1. I feel that reduced stress equals better skin.
2. My skin looks smoother.
3. My skin feels and looks healthier.
4. My face appears with a youthful glow.
5. My skin feels ultra-hydrated.
6. My skin looks vibrant.
7. I feel I have a softer and suppler complexion.

7.2 Week 1

1. I feel that reduced stress equals better skin.
2. This moisturizer helps correct the most visible signs of aging.
3. This product visibly reduces facial lines.
4. My skin looks smoother.
5. My skin feels and looks healthier.
6. My face appears with a youthful glow.
7. My skin is more resilient.
8. My skin feels ultra-hydrated.
9. My skin looks vibrant.
10. I feel I have a softer and suppler complexion.

7.3 Week 2

1. I feel that reduced stress equals better skin.
2. This moisturizer helps correct the most visible signs of aging.
3. This moisturizer reduces the appearance of wrinkles.
4. My wrinkles look visibly reduced.
5. My deep wrinkles appear less noticeable.
6. The lines on my neck are less visible.
7. This product visibly reduces facial lines.
8. My skin looks smoother.
9. My skin feels and looks healthier.
10. My face appears with a youthful glow.
11. My skin is more resilient.
12. My skin feels ultra-hydrated.
13. My skin looks vibrant.

7.4 Week 4

1. I feel that reduced stress equals better skin.
2. This moisturizer helps correct the most visible signs of aging.

3. This moisturizer reduces the appearance of wrinkles.
4. My wrinkles look visibly reduced.
5. My deep wrinkles appear less noticeable.
6. The lines on my neck are less visible.
7. This product visibly reduces facial lines.
8. My skin is more resilient.
9. My skin feels ultra-hydrated.
10. My skin looks vibrant.

Section 8: CONCLUSION

The following parameters showed improvements in Wrinkles 2D: Surface Area (%), Deep Wrinkles Surface Area (%), Deep Wrinkles Average Length (mm) and Fine Wrinkles Average Length (mm) showed significant improvement from Baseline to Week 4 which ranges from 25.0% to 75.0 % with meditation and Fine Wrinkles Average Length showed significant improvement which ranges from 31.6% to 57.9% without meditation.

Wrinkles 3D Total Volume feature showed significant improvement from Baseline to Week 4 which ranges from 65.0% to 80.0% with meditation.