TEXTURE

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

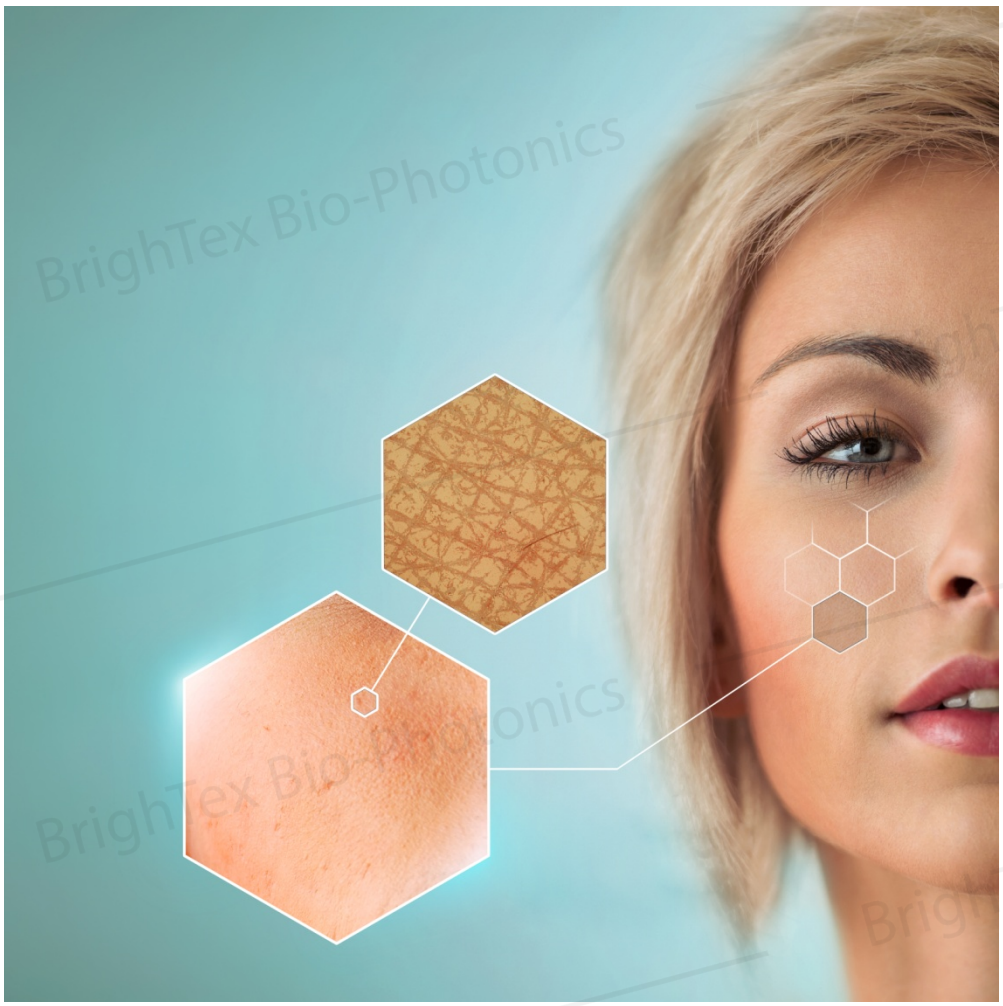
ABSTRACT

The objective of this study is to compare the anti-aging benefits under the eye area, in the crowfeet region, and under the eyebrow line of the test product which treats and cleanses the skin.

Participant's captures are taken using Clarity Research 3D System digital photography at Baseline, One Hour-Post Application, Week1, Week 2, Week 4, Week 8 and Week 12.

Measurements for the Participants will be recorded at Baseline, One Hour-Post Application, Week1, Week 2, Week 4, Week 8 and Week 12 after using the test materials.

It is concluded that there is statistically significant improvement in the Surface Area (%) which ranges from 25.0% to 75.0%, Total Volume which ranges from 16.7% to 75.0%, Average Roughness which ranges from 16.7% to 66.7% and Peak Density (pixels per mm) which ranges from 8.3% to 50.0% in Texture 3D and Texture 2D Roughness feature which ranges from 8.3% to 41.7%.



Section 1: OBJECTIVE

The objective of this study is to compare the anti-aging benefits under the eye area, in the crowfeet region, and under the eyebrow line of the test product which treats and cleanses the skin.

Section 2: STUDYDESIGN

Approximately 12 female Participants aged between 35 to 65 with sagging skin and/or visible fine lines and wrinkles on the crow's feet and under eye areas will be enrolled in this study assessing the efficacy of the test product over a twelve week use period. The study will include Clarity Research 3D System photography. A study schedule appears below.

Procedure	**Baseline**	**One Hour Post-Application (±15 Minutes)**	**Week One**	**Week Two**	**Week Four**	**Week Eight**	**Week Twelve**
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							✓

✓ Indicates the Participants visit to the Research & Imaging Study Centre laboratory

+ indicates, evaluations will be performed prior to test material application

Section 3: STUDY POPULATION

Approximately 12 female 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 sagging skin and/or visible fine lines and wrinkles around the under eye/crow's feet area;
4. Participant agrees to avoid excessive sun exposure for the duration of the study;
5. Participant agrees not to introduce any new cosmetic or skincare products, except for the test material provided for the duration of the study;
6. Participant agrees to only use their regular face wash and moisturizer, but not their regular eye cream, for the duration of the study;
7. 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;
8. Participant is dependable and able to follow directions as outlined in the protocol;
9. Participant is willing to participate in all study evaluations;
10. Participant is in generally good health and has a current Panelist Profile Form on file at Clarity Research 3D Laboratory;
11. Participant agrees to sign a Photography Release Form, providing consent for the capture of digital images for use in relation to this clinical study;
12. Participant has completed a HIPAA Authorization Form in conformance with 45 CFR Parts 160 and 164;
13. 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, planning to become pregnant, or excessive birth control;
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.

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: RANDOMIZATION

Side of the face that Participants will use the test product will be assigned in accordance with a computer-generated randomization schedule. Participant will use the test product on the opposite side of the face.

Section 5: STUDY EVALUATIONS

5.1 CLARITY RESEARCH 3D SYSTEM

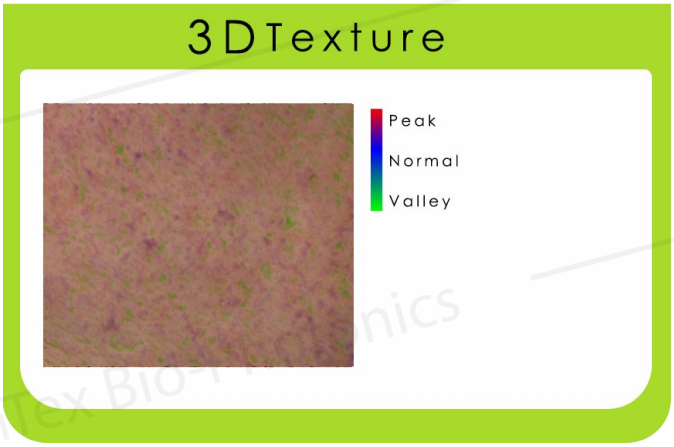
The Clarity Research 3D System features the latest technology in 2D and 3D skin modelling, boasting three cameras, each with 25 megapixels and SLR image capture in 16-bit. The Automated image recognition includes artificial intelligence for facial and skin area recognition, high precision facial detection, 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. Clarity Research 3D system photography will be captured at Baseline, One Hour Post-Application, Week One, Week Two, Week Four, Week Eight, and Week Twelve. Images will be captured with the eyes open.

5.2 SKIN FEATURE TO BE STUDIED

5.2.1 Texture 3D

Texture represents the measurement of the roughness or smoothness on the skin. It considers all the features causing skin variation such as acne, pigmentation, redness, subsurface pigmentation, wrinkles and enlarged pores.

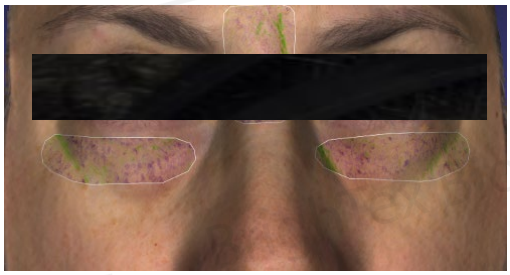


Measured Parameters: Surface Area (%), Total Volume, Average Roughness and Peak Density (pixels per mm)

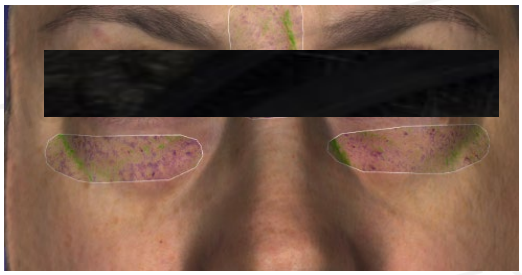
i. **Surface Area (%):** It is defined as the percentage area affected by texture recognized

Sample Result Images:

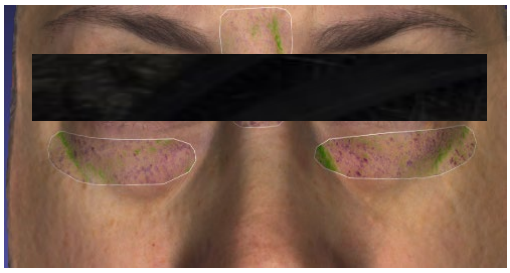
T0



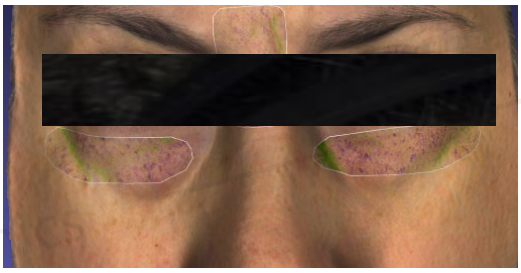
T1



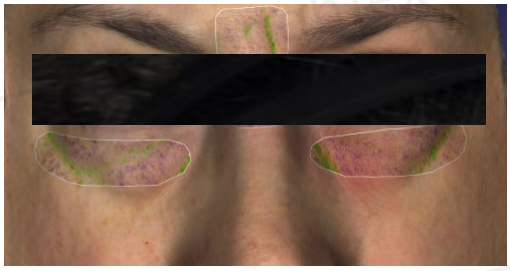
T2



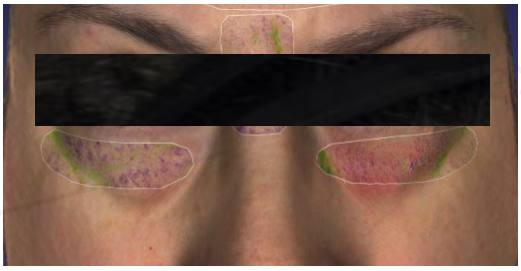
T3



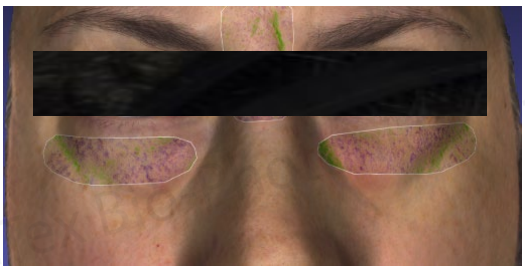
T4



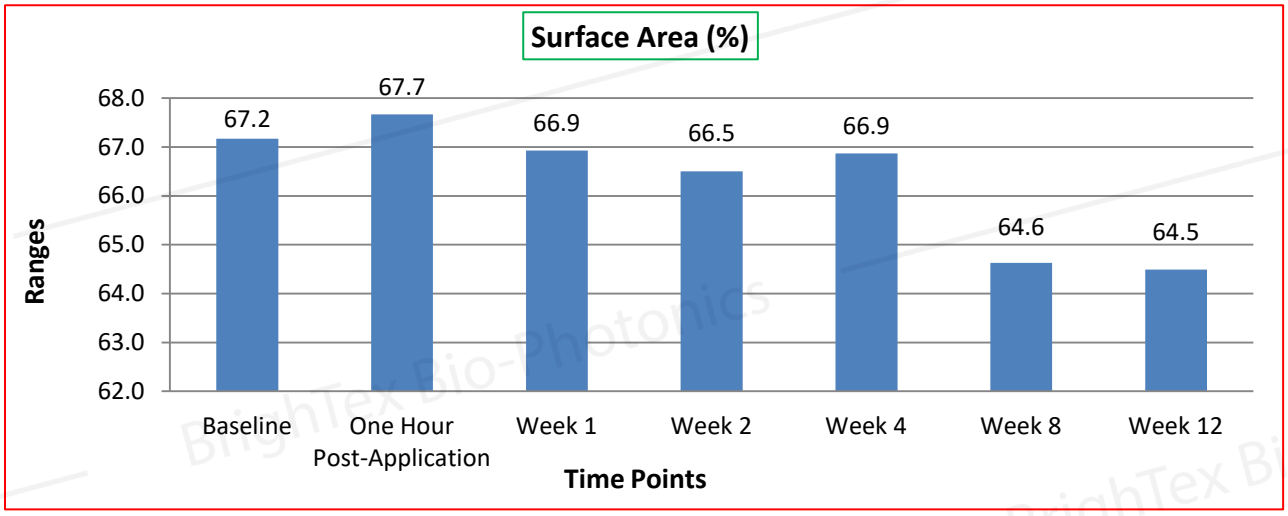
T5



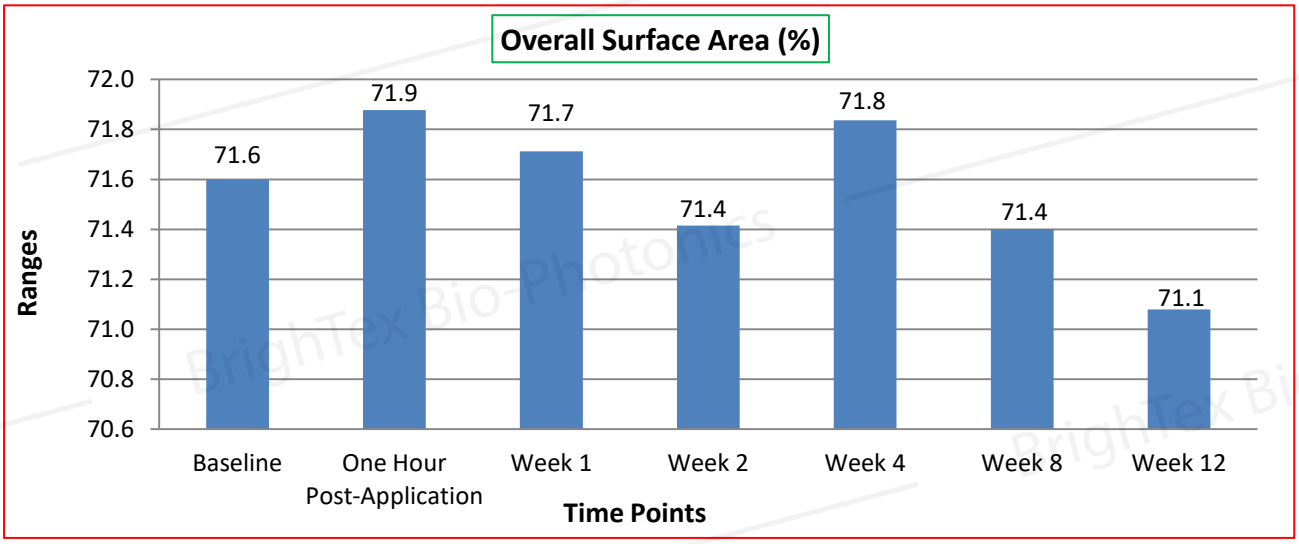
T6



Participant 05 Results



Overall Surface Area (%):

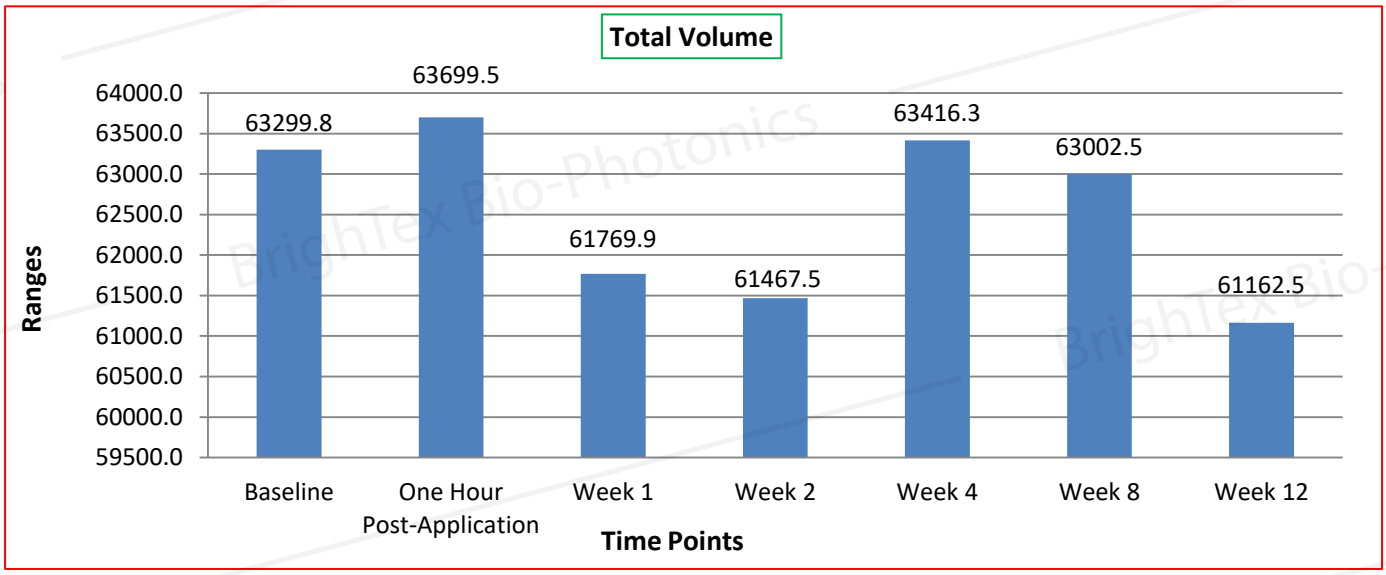


Test Results and Statistical Summary

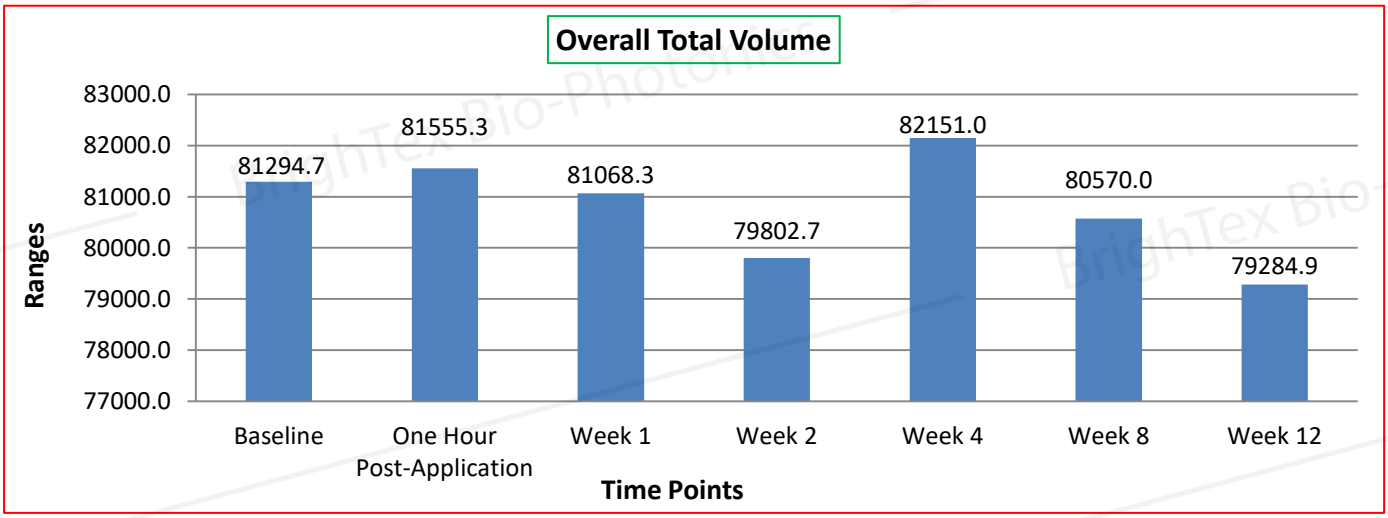
Clarity™ Research 3D System- Surface Area (%)				
Parameter	Treatment	Visit	Number of Participants showed improvement	% of Participants showed improvement
Surface Area (%)	Test Product	One Hour Post-Application	3	25.0%
		Week 1	7	58.3%
		Week 2	8	66.7%
		Week 4	6	50.0%
		Week 8	8	66.7%
		Week 12	9	75.0%

ii. **Total Volume:** It is defined as the total 2D volume of recognized texture in the ROI

Participant 06 Results



Overall Total Volume:

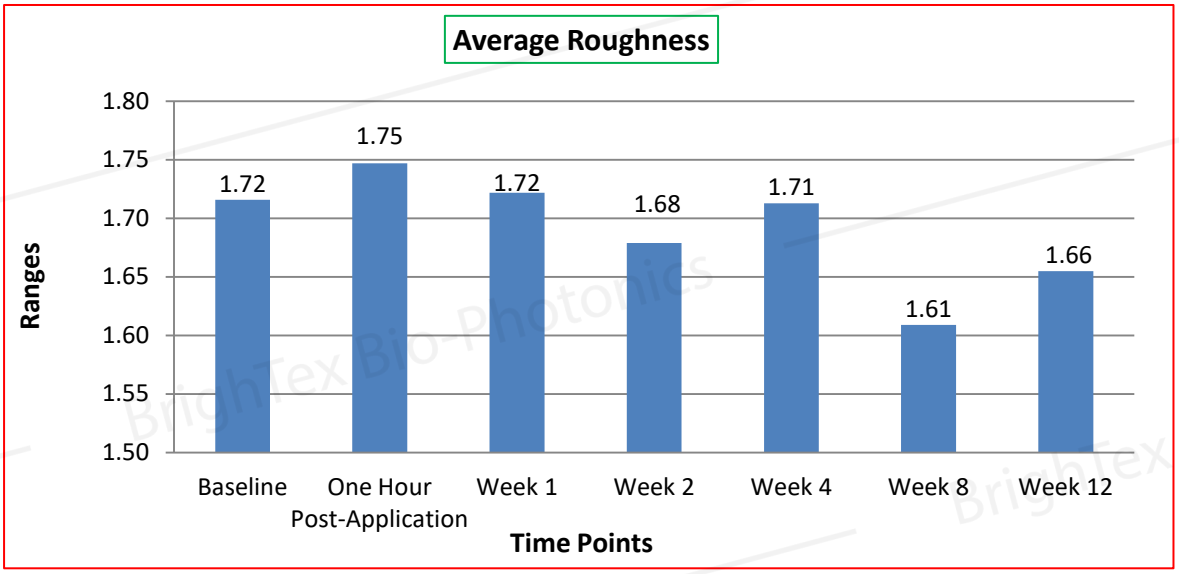


Test Results and Statistical Summary:

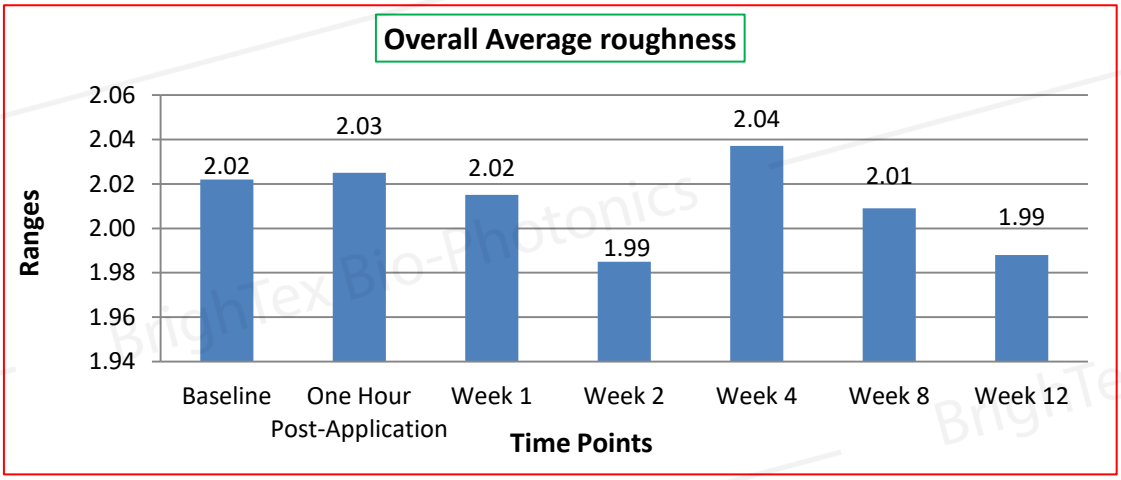
Clarity™ Research 3D System-Total Volume				
Parameter	Treatment	Visit	Number of Participants showed improvement	% of Participants showed improvement
Total Volume	Test Product	One Hour Post-Application	2	16.7%
		Week 1	6	50.0%
		Week 2	7	58.3%
		Week 4	5	41.7%
		Week 8	9	75.0%
		Week 12	8	66.7%

iii. Average Roughness: It is defined as the average 3D volume of recognized texture in the ROI

Participant 05 Results



Overall Average Roughness:

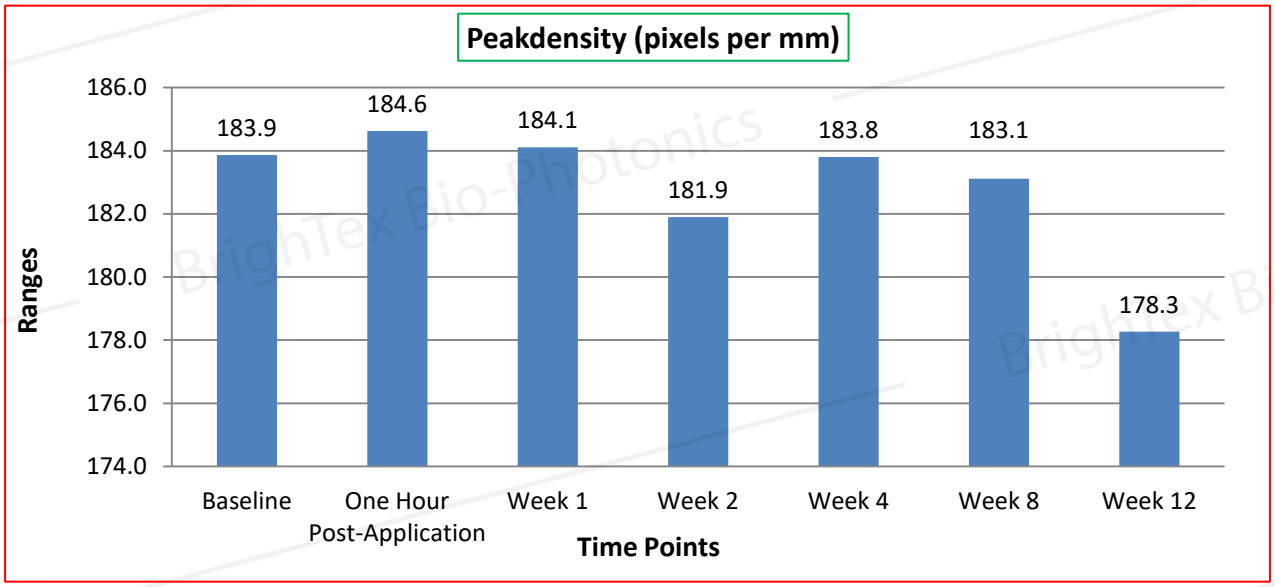


Test Results and Statistical Summary

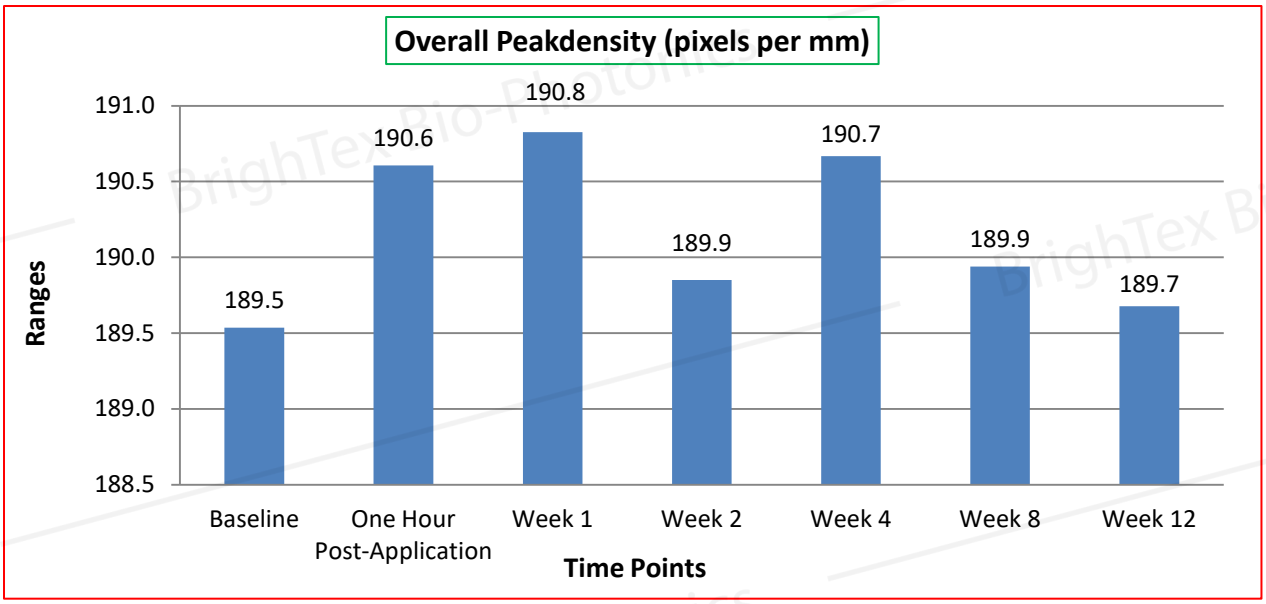
Clarity™ Research 3D System-Average Roughness				
Parameter	Treatment	Visit	Number of Participants showed improvement	% of Participants showed improvement
Average Roughness	Test Product	One Hour Post-Application	2	16.7%
		Week 1	6	50.0%
		Week 2	8	66.7%
		Week 4	6	50.0%
		Week 8	7	58.3%
		Week 12	8	66.7%

iv. Peak Density (pixels per mm): It is defined as the number of peak pixels per square mm

Participant 05 Results



Overall Peak Density (pixels per mm):

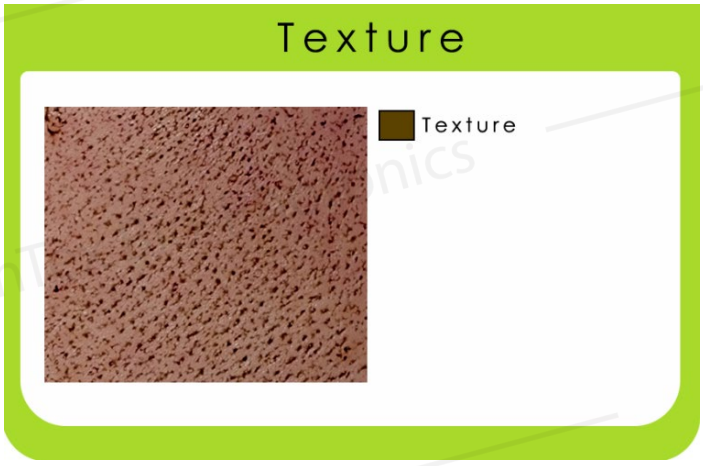


Test Results and Statistical Summary

Clarity™ Research 3D System-Peak Density (pixels per mm)				
Parameter	Treatment	Visit	Number of Participants showed improvement	% of Participants showed improvement
Peak Density (pixels per mm)	Test Product	One Hour Post-Application	3	25.0%
		Week 1	1	8.3%
		Week 2	5	41.7%
		Week 4	4	33.3%
		Week 8	4	33.3%
		Week 12	6	50.0%

5.2.2 Texture 2D

Texture represents the measurement of the roughness or smoothness on the skin. It considers all the features causing skin variation such as acne, pigmentation, redness, subsurface pigmentation, wrinkles and enlarged pores.



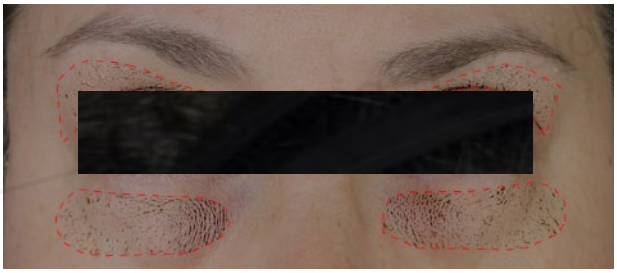
Measured Parameters: Roughness

i. Roughness:

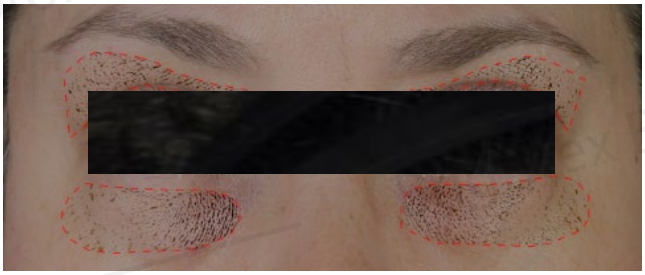
It is defined as the average 2D volume of recognized texture in the ROI

Sample Result Images:

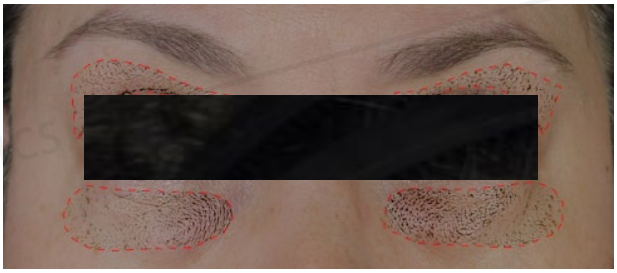
T0



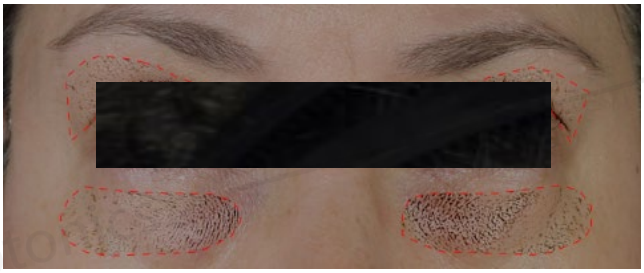
T1



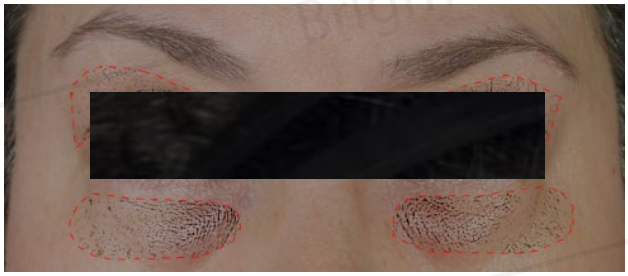
T2



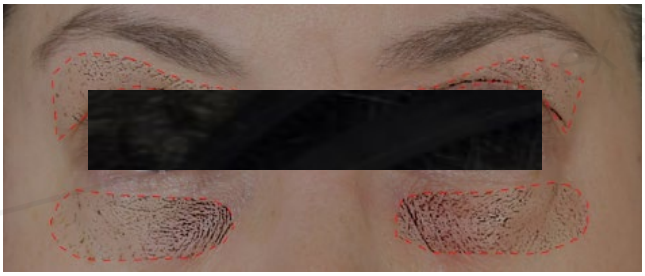
T3



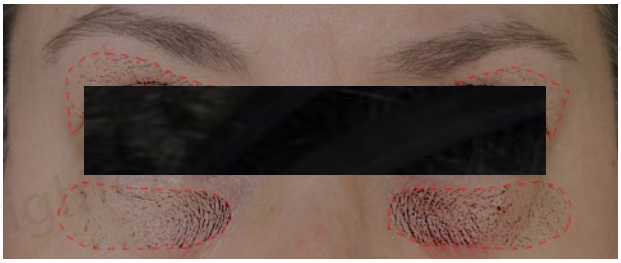
T4



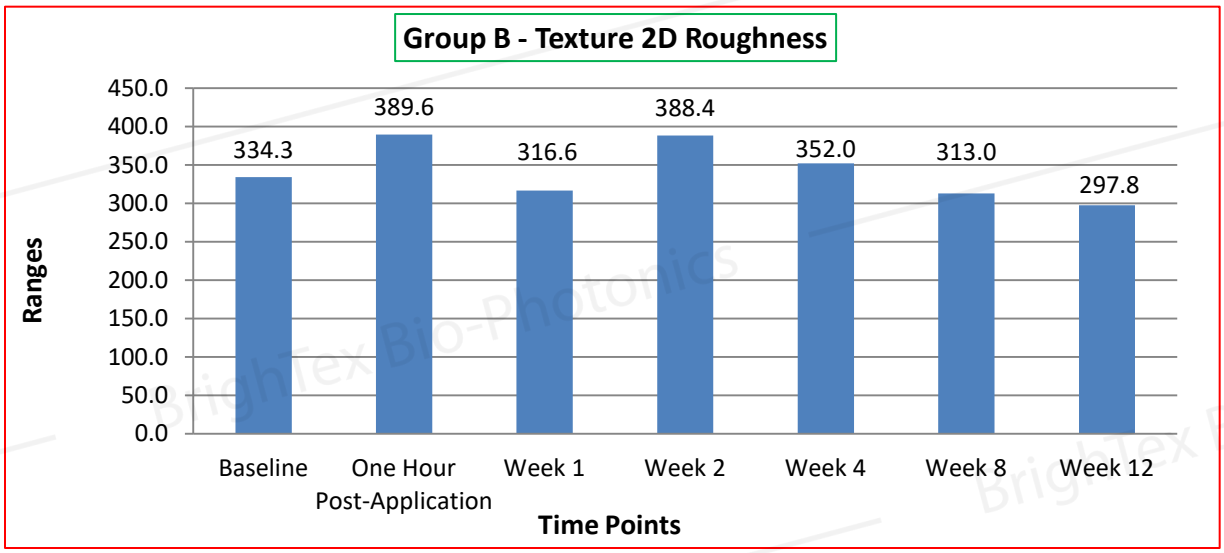
T5



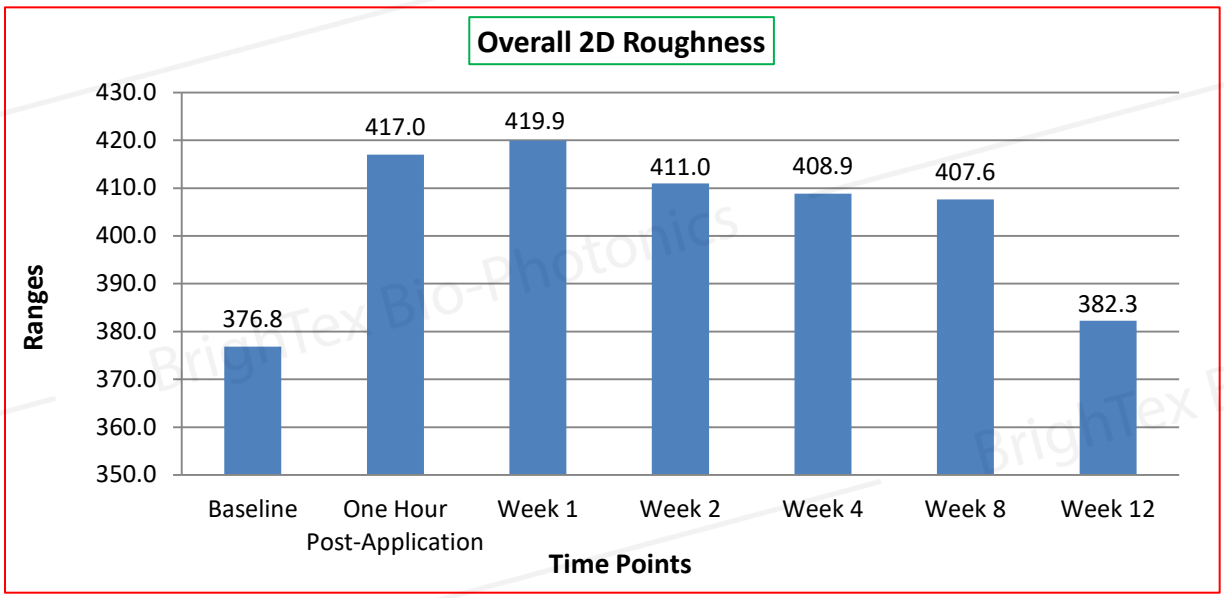
T6



Participant 13 Results



Overall 2D Roughness:



Texture 2D Test Results and Statistical Summary

Clarity™ Research 3D System- Texture 2D Roughness				
Parameter	Treatment	Visit	Number of Participants showed improvement	% of Participants showed improvement
Texture 2D Roughness	Test Product	One Hour Post-Application	1	8.3%
		Week 1	3	25.0%
		Week 2	3	25.0%
		Week 4	2	16.7%
		Week 8	2	16.7%
		Week 12	5	41.7%

Section 6: TEST METHOD

6.1 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.

6.2 BASELINE VISIT

Participants will arrive at the 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 5.1. A trained Research Laboratory technician will instruct the Participant on how to apply the product. 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, 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.

6.3 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 5.1.

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

6.4 WEEK TWO VISIT

Participants will return to the testing facility following two 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 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.

6.6 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.

6.7 WEEK TWELVE VISIT

Participants will return to the testing facility following twelve 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. Unused test materials will be collected.

Section 7: PRODUCT USAGE INSTRUCTIONS

Participant will use the test product on the under eye area/crow's feet and under eyebrow region one the other side. The treatment should be done twice daily.

Step 1

- After cleansing and toning, apply an ample amount of the test product to the desired area of your face.

Section 8: CONCLUSION

Various feature parameter measurements are recorded and it was concluded that Texture 2D and Texture 3D showed significant improvement at Week 12 compared to Baseline after using the test product.

The following parameters showed improvements in Texture 2D: Roughness which ranges from 8.3% to 41.7%.

The following parameters showed improvements in Texture 3D: Surface Area (%) which ranges from 25.0% to 75.0%, Total Volume which ranges from 16.7% to 75.0%, Average Roughness which ranges from 16.7% to 66.7% and Peak Density (pixels per mm) which ranges from 8.3% to 50.0%.