REDNESS

STUDY TEMPLATE

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ABSTRACT

The objective of this study was to evaluate the efficacy and consumer opinion of a test product immediately post application, and following two weeks and four weeks of twice daily test material use.

Participant's captures are taken using Clarity Research 3D System digital photography at Baseline (Visit 1), 30 Minutes Post – Application, Week 2 and Week 4.

Measurements for the Participants will be recorded at Baseline (Visit 1), 30 Minutes Post – Application, Week 2 and Week 4 after using the test product and it was concluded that there was a statistically significant improvement in Redness Surface Area which ranges from 55.2% to 62.1%.

Section 1: OBJECTIVE

The objective of this study was to evaluate the efficacy and consumer opinion of a test product immediately post application, and following two weeks and four weeks of twice daily test material use.

Section 2: STUDY DESIGN

Candidates for study participation were identified from the Clarity Research Laboratory. This study included 29 female subjects between the ages of 36 and 65 years who met all of the inclusion criteria and none of the exclusion criteria. Eligible subjects were selected to participate in the evaluation of a facial serum. Study evaluations included Corneometer measurements, Derma lab measurementsand Clarity Research 3D System photography, and consumer perception questionnaires. A study schedule appears below.

Procedure	**Visit One**	**Visit Two**		**Visit Three**	**Visit Four**
	Screening (-7 ±3 Days)	**Baseline**	**30 Minutes Post – Application**	**Week 2**	**Week 4**
Informed Consent and Photography Release Form	✓				
Distribution of a non-moisturizing Purpose Soap and conditioning phase diary	✓				
Inclusion and Exclusion Criteria Verified	✓				
Collection of the conditioning phase diary					

Distribution of Test Material, SPF, and Daily Diary		✓			
Skin Care Device Measurements		✓	✓	✓	✓
Clarity Research 3D System Photography (eyes closed)		✓	✓	✓	✓
Consumer Perception Questionnaires			✓	✓	
Collection of Unused Test Material, SPF, and Daily Diary					✓

✓Indicatestest material will be applied for the first time in the laboratory following Baseline Clarity Research 3D System Imaging.

Section 3: STUDY POPULATION

A total of 29 subjects will be enrolled in this study. Subjects will be recruited from the LAB database. Interested candidates will report to the testing facility for screening and subjects who meet all of the inclusion criteria and none of the exclusion criteria will be enrolled.

3.1 INCLUSION CRITERIA

A Participant may be eligible for enrolment if all of the following criteria are met:

1. Subject is female between the ages of 30 and 65 years of age;
2. Subject has a Fitzpatrick Skin Type ofl, II, III, or IV;
3. Subject has mild to moderate facial redness;
4. Subject has self-perceived sensitive skin;
5. Subject has self-perceived mild to moderate dry skin (approximately 50% of study population) or self-perceived normal skin (approximately 50% of study population);

6. Subject has self-perceived hyper pigmentation (approximately 50% of studypopulation) or does nothave self-perceivedhyper pigmentation (approximately 50% of study population);

7. Subject agrees not to introduce any new cosmetic or skincare products, except for the non-moisturizing soap during the conditioning phase of the study and the test material and SPF provided for the duration of the study;

8. Subject agrees to only use their regular face products except for the providedtest material and sunscreen for the duration of the study;

9. Subject agrees to self-apply the test material twice daily at home for the duration of the study period;

10. Subject is free from any dermatological or systemic disorders which, in the opinion of the Principal Investigator, would interfere with the test results or increase the risk of an adverse reaction;

11. Subject is dependable and able to follow directions as outlined in the protocol;

12. Subject is willing to participate in all study evaluations and is able to returnfor all study visits;

13. Subject is in generally good health and has a current Panelist Profile Form on file at LAB;

14. Subject agrees to sign a Photography Release Form, providing consent for the capture of digital images for use in relation to this clinical study;

15. Subject has completed a HIPAA Authorization Form in conformance with 45 CFR Parts 160 and 164;

16. Subject understands and is willing to sign an Informed Consent Form m conformance with 21 CFR Part 50: "Protection ofHuman Subjects."

3.2 EXCLUSION CRITERIA

A subject may not be eligible for enrolment if any of the following criteria are met:

1. Subject is pregnant, nursing, planning a pregnancy, or not using adequate birth control;
2. Subjecthasknownallergiestocosmeticsorpersonalcareproducts;
3. Subject exhibits sunburn, rashes,scratches, burn marks,etc., which might interferewithevaluationoftestresults;

4. Subjectexhibitsand/orreportsahistoryof anacuteorchronicdermatologic conditionoftheface,which wouldprecludeapplication ofthetestmaterial and/orcouldinfluencetheoutcomeofthestudy.
5. Subjectiscurrentlyparticipatinginanotherfacialstudy.

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 VISIT ONE:SCREENING

Subjects 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 subject. Subjects who meet all of the study requirements will be enrolled.

Subjects will participate in a 7-day (±3 days) conditioning phase. Subjects will be provided with a Purpose Soap to be used for the conditioning phase and for the duration of the study. Subjects will be provided with a conditioning phase diary to record use of the PurposeSoap.

4.3 VISIT TWO:BASELINE AND IMMEDIATE MEASUREMENTS

Subjects will return to the laboratory following the 7-day (±3 days) conditioning phase with clean, bare faces, wearing no facial makeup and their conditioning phase diaries. Subjects will acclimate to ambient laboratory conditions for approximately 15 minutes. Clarity Research 3D System photography, Skin CareDevice measurements will be performed.

Subjects will be provided with the test material, sunscreen, Daily Diaries, verbal and written instructions outlining study requirements and restrictions, as well as dates and appointment times for subsequent study visits. Subjects will apply the test material in the laboratory according to the provided use instructions under the supervision of LAB study personnel.

Subjects will be instructed to apply the test material twice daily according to the provided use instructions. Subjects will be instructed to track their daily product usage in the Daily Diaries for the duration of the study.

Approximately 30 minutes post-application, Clarity Research 3D System photography and Skin Care Device measurements will be performed. Subjects will complete a consumer perception questionnaire.

4.4 VISIT THREE:WEEK 2

Subjects will return to the testing facility following 2 weeks of twice daily test material use with their daily diaries, clean, bare faces, wearing no facial makeup and having applied the test product at least 2 hours prior to the study visit. Subjects will acclimate to ambient laboratory conditions for approximately 15 minutes Clarity Research 3D System photography and Skin Care Device measurementswill be performed. Subjects will complete consumer perception questionnaires.

Daily diaries will be reviewed by the study personnel forcompliance.

4.5 VISIT FOUR:WEEK 4

Subjects will return to the testing facility following 4 weeks of twice daily test material use with clean, bare faces, wearing no facial makeup and having refrained from applying any facial products. Subjects will acclimate to ambient laboratory conditions for approximately 15 minutes. Clarity Research 3D System photography and Skin Care Device measurements will be performed.

Daily diaries will be reviewed by study personnel for 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 system also allows for simultaneous front, left and right profile capture with no repositioning requirements. The system is capable of detecting over 50 facial regions for analysis of fine lines, texture, skin tone evenness and discoloration, and contouring. The following parameters will be analyzed:

Facial Redness:

Clarity Research 3D System photography will be captured (eyes closed) at Baseline, 30 minutes (±5minutes) post-application and following two week and four weeks of test material use.

SKIN FEATURE TO BE STUDIED

5.1.1 Redness 2D

Redness, medical term erythema is abnormal redness on the skin signalling a pathological condition such as inflammation, infection or sunburn. Non-pathological conditions may include nervous blushes.

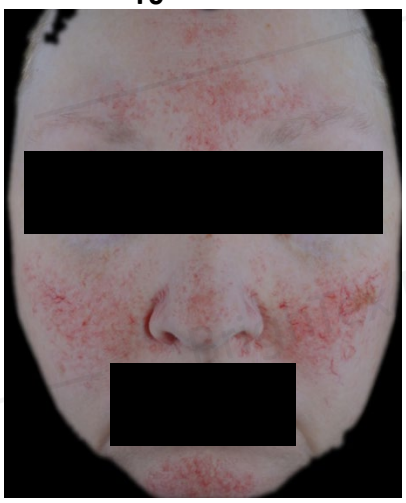
Measured Parameters:Surface Area (%)

i. **Surface Area (%):** Percentage of area affected by Redness pixels in the ROI recognized

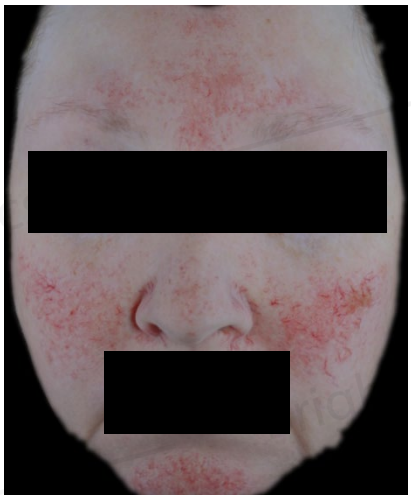
A decrease in these parameters will indicate improvement in facial redness

Sample Result Images:

T0



T1



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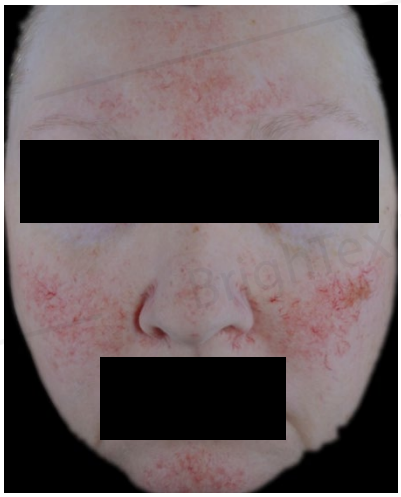

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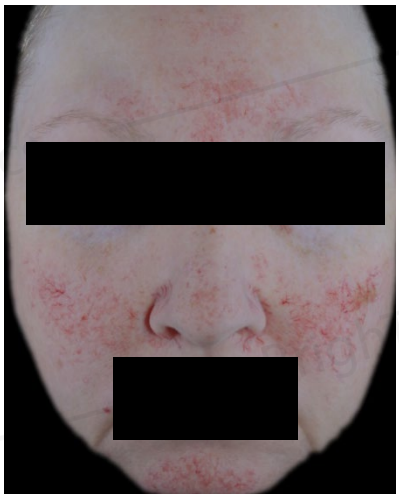
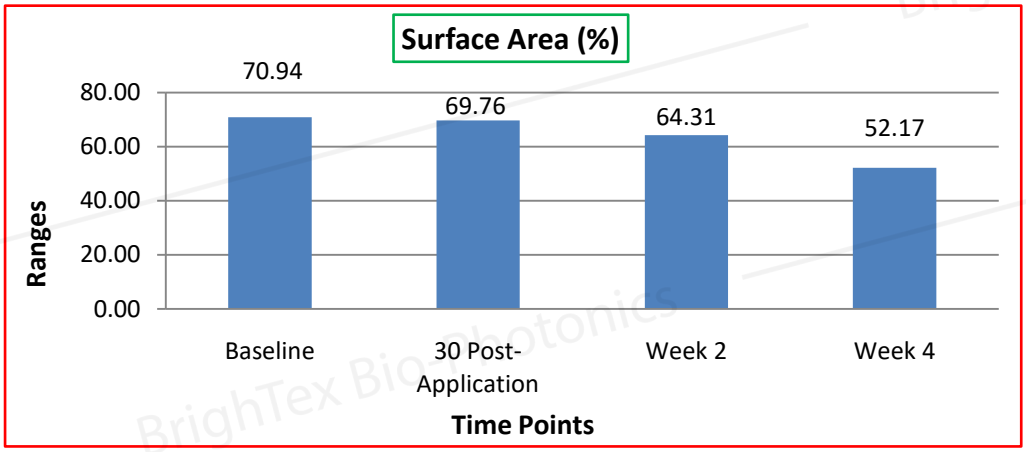
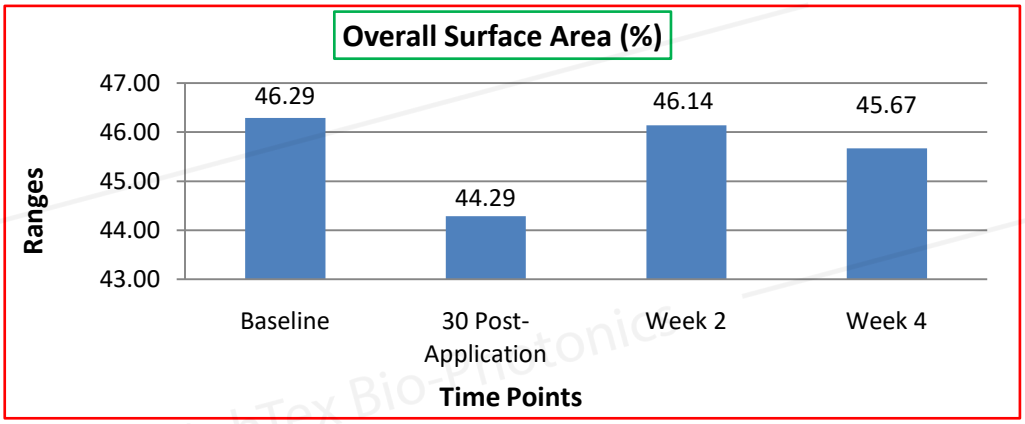


Participant 24 Results



Overall Surface Area (%):

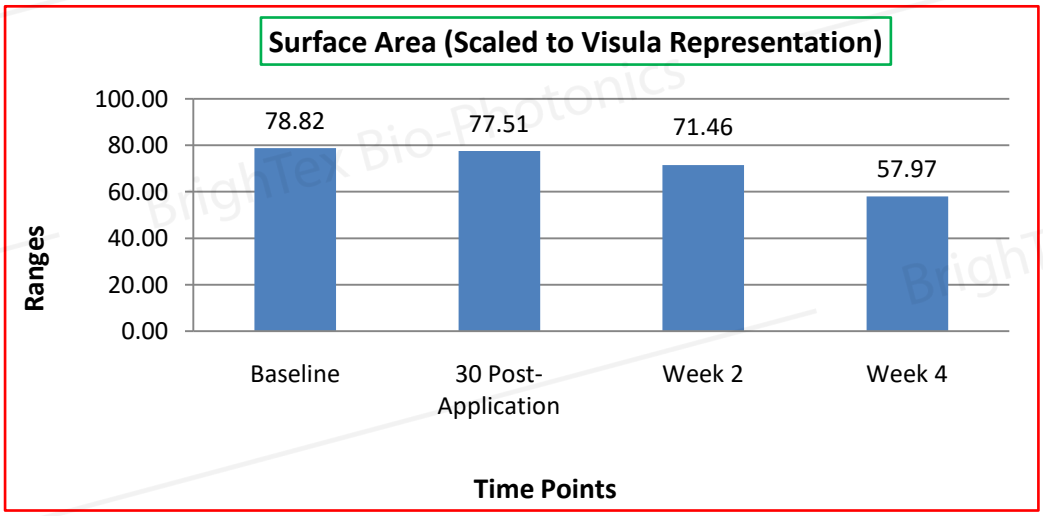


Test Results and Statistical Summary

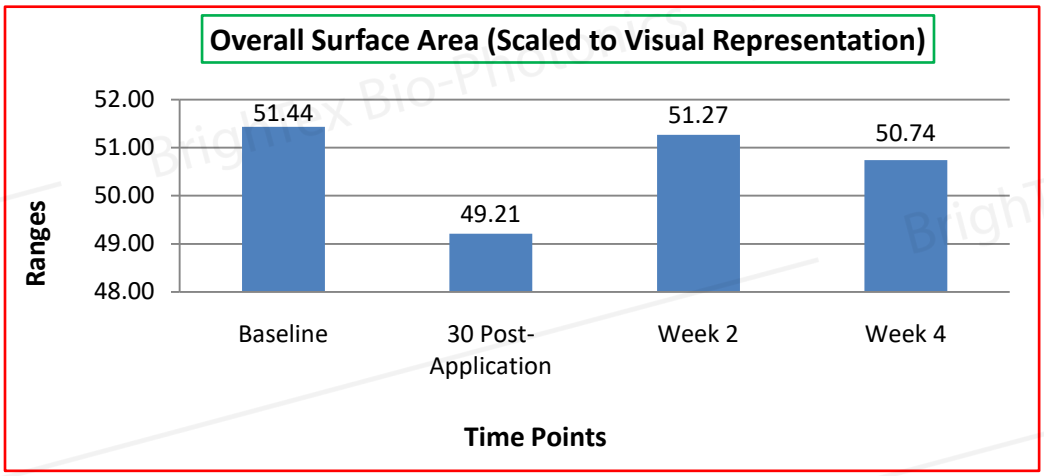
Clarity™ Research 3D System-Surface Area (%)				
Parameter	Treatment	Visit	Number of Participants showed improvement	% of Participants showed improvement
Surface Area (%)	Test Product	30 Minutes Post-Application	16	55.2%
		Week 2	18	62.1%
		Week 4	18	62.1%

ii. **Surface Area (Scaled to Visual Representation):** This is the same as the above, except the value has been scaled to align with how a dermatologist would visually assess the % of surface area of PIH. We have found that visual graders and dermatologists assess % of the surface area to be higher than the actual detected area by our algorithm.

Participant 24 Results



Overall Surface Area (Scaled to Visual Representation):



Test Results and Statistical Summary

Clarity™ Research 3D System-Surface Area (Scaled to Visual Representation)				
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Surface Area (Scaled to Visual Representation)	Test Product	30 Minutes Post-Application	16	55.2%
		Week 2	18	62.1%
		Week 4	18	62.1%

Section 6: Product Use Instructions

Apply to clean dry skin in the Day and Night time all over the face and neck.

Section 7: CONCLUSION

Under the conditions of this study and in this test population, the test material showed significant improvement in Redness Surface Area which ranges from 55.2% to 62.1%.