

# BIO-EC

## STUDY TEMPLATE

## ABSTRACT

The purpose of this study is to evaluate the global anti-aging activity between two products (975 vs. 618) with the equipment of BIO-EC laboratory and BrighTex Bio Photonics Research3D Clarity on a group of volunteers. The Products 975 and 618 are recommended to the group of volunteers to apply on the hemi-face from Day 1 to Day 56 with product randomization mechanism. Measurements are taken at Day 0 before using the products and after using the products at different time points i.e., Day 14, Day 28 and Day 56 to determine the efficiency of the products. Various skin feature measurements are recorded and it was observed that there is a positive change in multiple features that ranges from minimum 0.3% to maximum 46.8%.

It was concluded that out of 2 products there is a positive visible impact on the skin with Product 975 in comparison to Product 618 on various skin features.





## Section 1: OBJECTIVE

A split face study is conducted to assess the products impact on skin. The primary objective is to evaluate the global anti-aging activity of the Product vs. Placebo (normal cream) with the equipment of BIO-EC laboratory and BrighTex Bio-Photonics Research 3D Clarity device (Mini3D)

## Section 2: STUDYDESIGN

Candidates for study participation will be identified from the BIO-EC Laboratory. This study will include approximately 20 female subjects aged above 50 years who meet all of the inclusion criteria and none of the exclusion criteria. Eligible subjects will be selected to participate in the study. Clarity Research 3D System digital photography will be taken 4 times i.e., on Day 0, Day 7, Day 28 and Day 56.

Procedure	Day 0	Day 7	Day 28	Day 56
Check out of the criteria of inclusion and non-inclusion	✓			
Check out of the well understanding of the study	✓			
Signing of the Consent by the volunteers	✓			
OPTION: Dermatological exam	✓	✓	✓	✓
OPTION Handed the questionnaire	✓			
Biometrical measures on each hemi face : AEVA (fringes projection) Cutometer Corneometry Goniospectrocolorimeter Face photography by VISIA Clarity	✓	✓	✓	✓
Products to test is given to the volunteers	✓			
OPTION: Return of questionnaire and product				✓
Indemnisation				✓

✓ Indicates panellist visit to BIO-EC laboratory

The panellist has to apply the products on each hemi-face twice daily on face from Day 0 to Day 56 without fail.

**Area of application:** Face. Half face with active vs. placebo on the other half

**Area of measurements:** Hemi-Face (cheek, wrinkles of crow's feet)

Using BTBP Artificial Intelligence algorithms, anti-aging features (wrinkles, spots, redness) are detected and measured.

## 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 volunteers 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 25 subjects will be enrolled, in an attempt to complete the study with 20 subjects.

Subjects will be recruited from the BIO-EC panellist 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.

### INCLUSION CRITERIA:

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

- Females Persons aged over 50 years old.
- Caucasian with wrinkles, Spots, Redness
- The volunteers should commit themselves to use the products in conformity with recommendations.

### EXCLUSION CRITERIA:

- Pregnancy or breastfeeding
- Persons having dermatological problems
- Persons following a medical treatment susceptible of interfering on the measured parameters.

## Section 4: STUDY EVALUATIONS

**Day 0:** Captures are taken using Clarity Research Application. Products to test is given to the volunteers and asked to apply the products twice a day on hemi-face from Day 0 to Day 56.

**Day 14:** Volunteers visit and captures are taken using Clarity Research Application.

**Day 28:** Volunteers visit and Captures are taken using Clarity Research Application.

**Day 56:** Volunteers visit and Captures are taken using Clarity Research Application.

- These captures are processed by BTBP Clarity Research Software to measure both 2D & 3D skin features for each hemi face zones separately

- Based on each feature measurement % change from Day 0 to Day 56, the global anti-aging activity product is evaluated

## Section 5: STUDY EVALUATIONS

### CLARITY RESEARCH 3D SYSTEM

The Clarity Research Mini 3D System features the latest technology in 2D and 3D skin modelling, 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 automatically detects over 50 facial regions for use in analysis, including detection of the face region.

### SKIN FEATURE TO BE STUDIED

#### 1. Texture3D

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:** Maximum Peak Height

**Maximum Peak Height:** Decrease in highest peak (bump/height) in the ROI

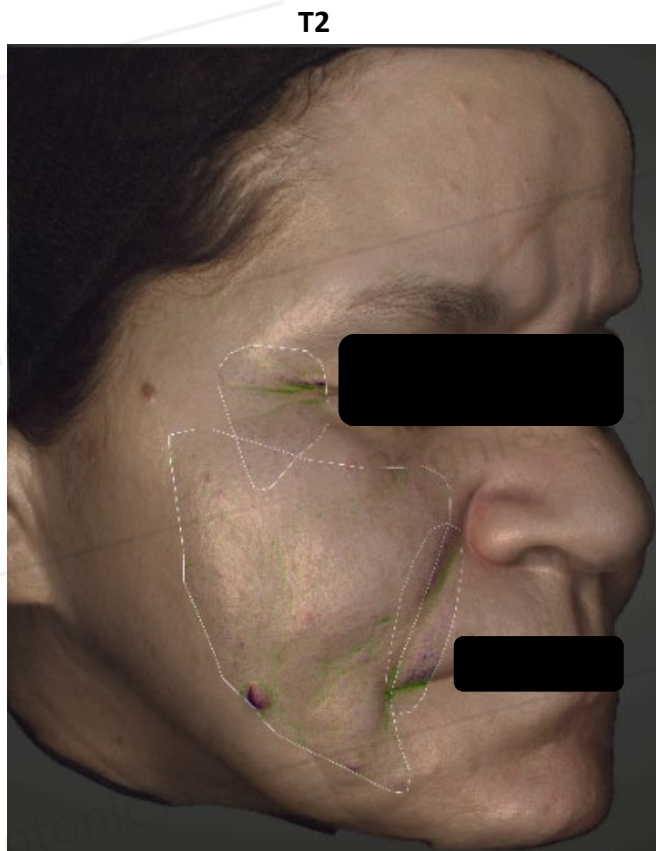
**Right Profile, Product: 618**

T0

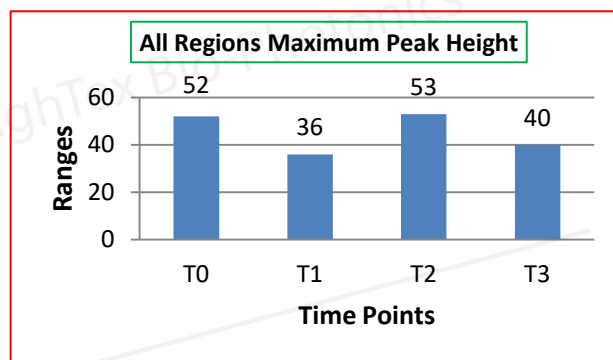


T1

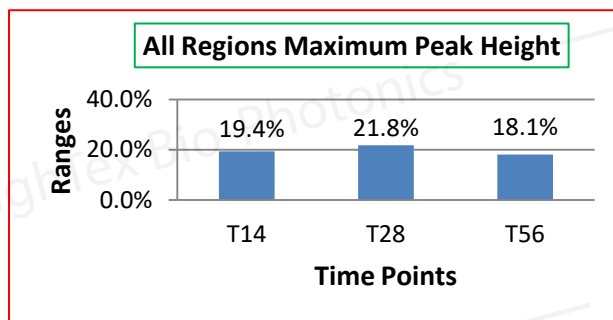




Subject 11 results



Overall Study Trends:



**Improvements Observed:** Decrease in Maximum Peak Height from visit 1 to visit 4

Texture 3D Test Results and Statistical Summary

Clarity™ Mini3D System-Texture 3D				
Parameter	Treatment	Visit	Number of subjects showed improvement who has baseline out of 12 subjects	% of Subject showed improvement
Maximum Peak Height	Product 618	Day 7	9	75.0%
		Day 28	6	50.0%
		Day 56	10	83.3%

Left Profile, Product: 975

T0



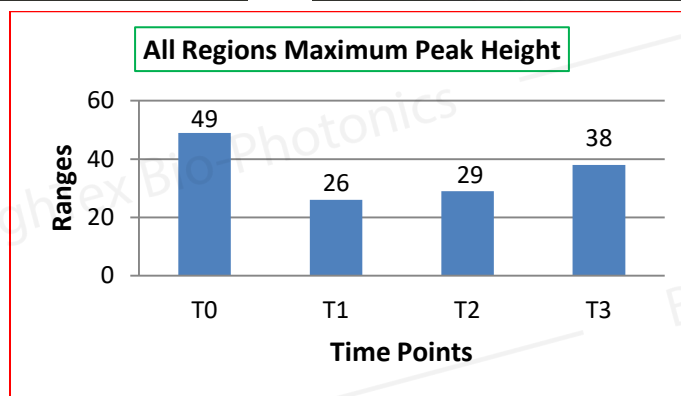
T1



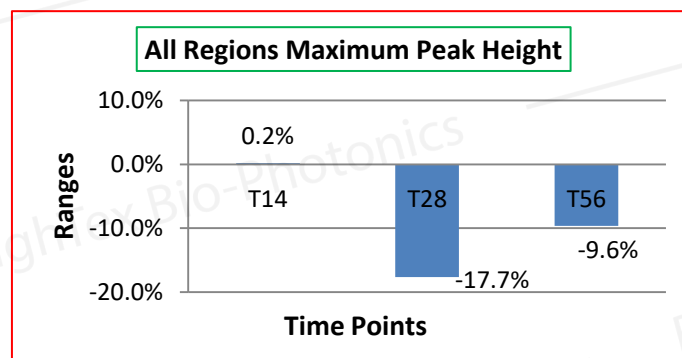




Subject 11 results



### Overall Study Trends:



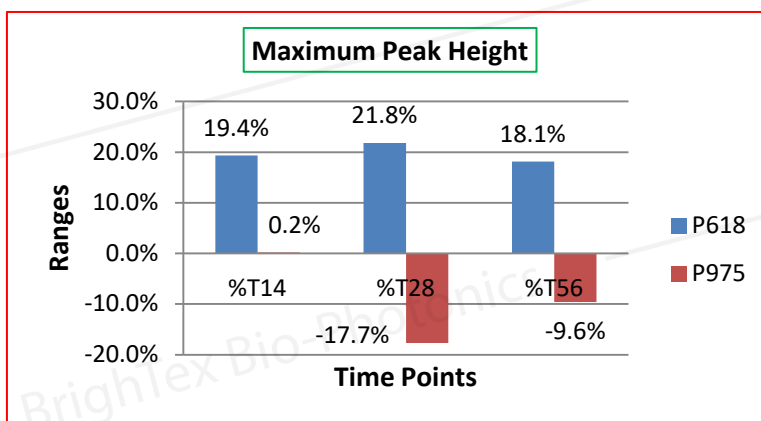
**Improvements Observed:** Decrease in Maximum Peak Height from visit 1 to visit 4



## Texture 3D Test Results and Statistical Summary

Clarity™ Mini3D System-Texture 3D				
Parameter	Treatment	Visit	Number of subjects showed improvement who has baseline out of 12 subjects	% of Subject showed improvement
Maximum Peak Height	Product 975	Day 7	7	58.3%
		Day 28	7	58.3%
		Day 56	7	58.3%

### Overall Comparison Trends:



## 2. Skin Color

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, Astar

**Astar:** Decrease in redness

**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  $L^* = 100$ .

**Right Profile, Product: 618**

**T0**



**T1**



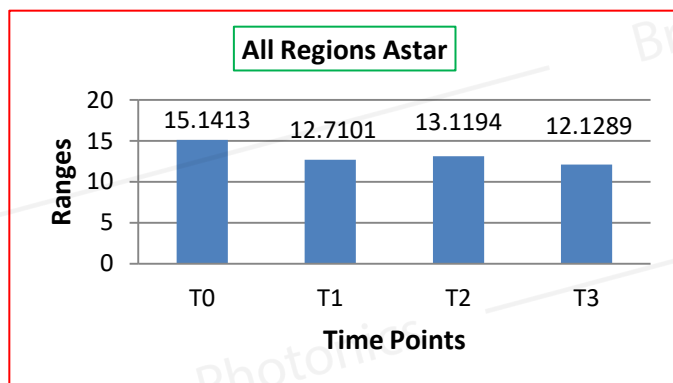
**T2**



**T3**

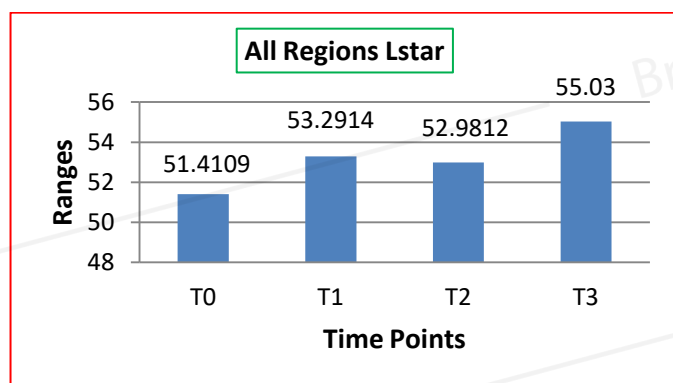


Subject 19 results



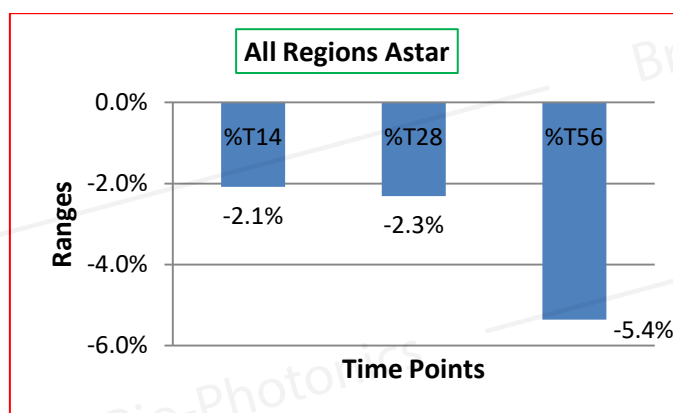
**Improvements Observed:** Decrease in Astar from visit 1 to visit 4

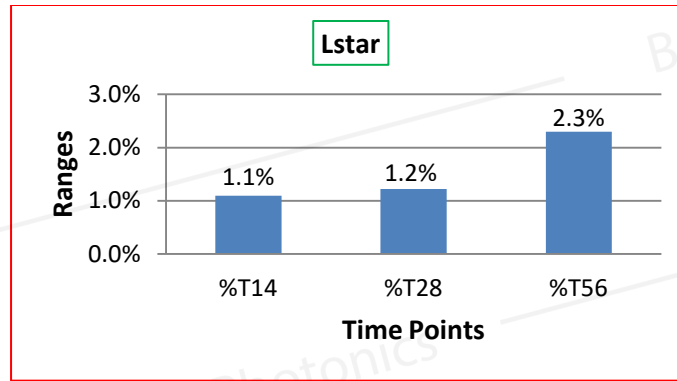
Subject 19 results



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

**Overall Study Trends:**





### Skin Color Test Results and Statistical Summary

Clarity™ Mini3D System-Skin Color				
Parameter	Treatment	Visit	Number of subjects showed improvement who has baseline out of 12 subjects	% of Subject showed improvement
Lstar	Product 618	Day 7	9	75.0%
		Day 28	9	75.0%
		Day 56	12	100.0%
Astar	Product 975	Day 7	7	58.3 %
		Day 28	9	75.0 %
		Day 56	12	100.0 %

Left Profile, Product: 975

T0



T1



T3

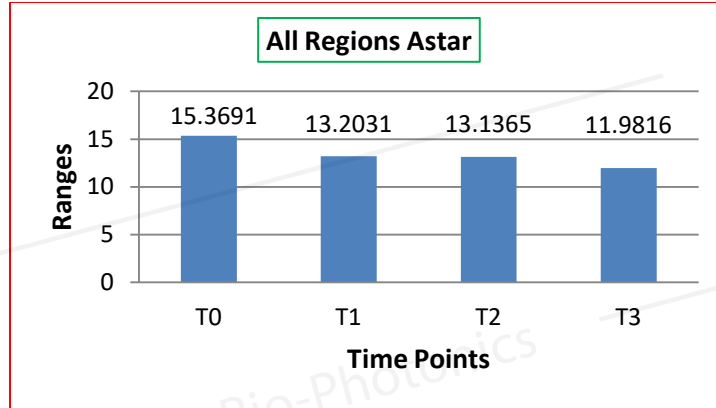


T4



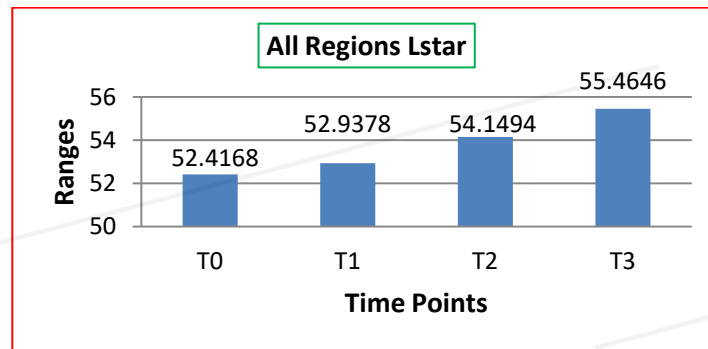


Subject 19 results



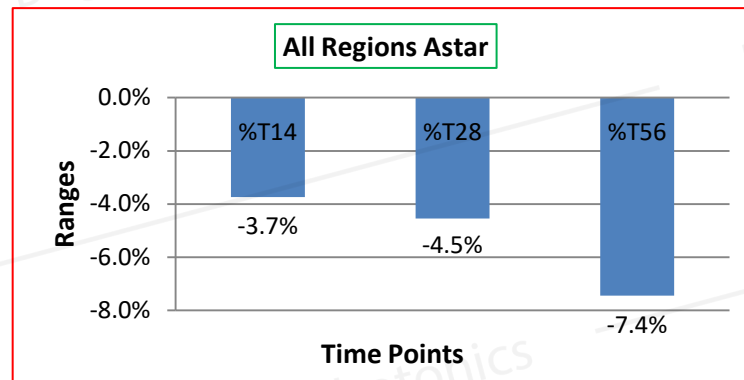
**Improvements Observed:** Decrease in Astar from visit 1 to visit 4

Subject 19 results

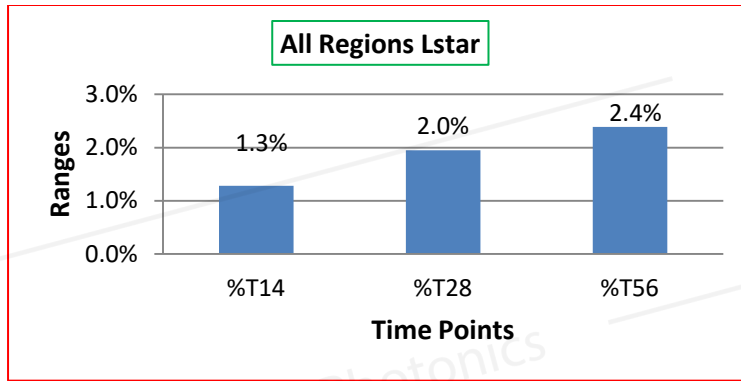


**Improvements Observed:** Increase in Lstar from visit 1 to visit 4

**Overall Study Trends:**



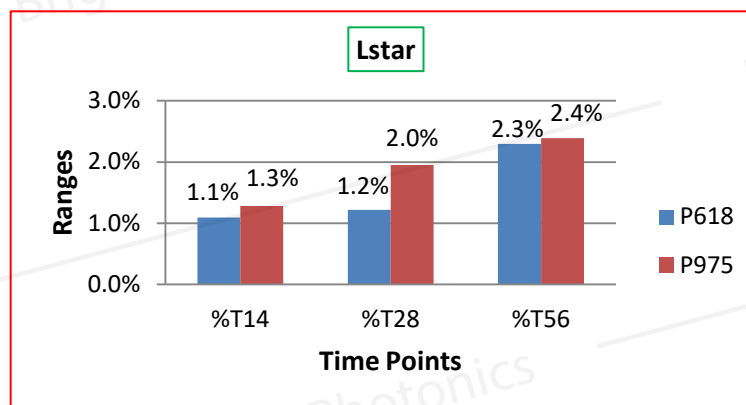


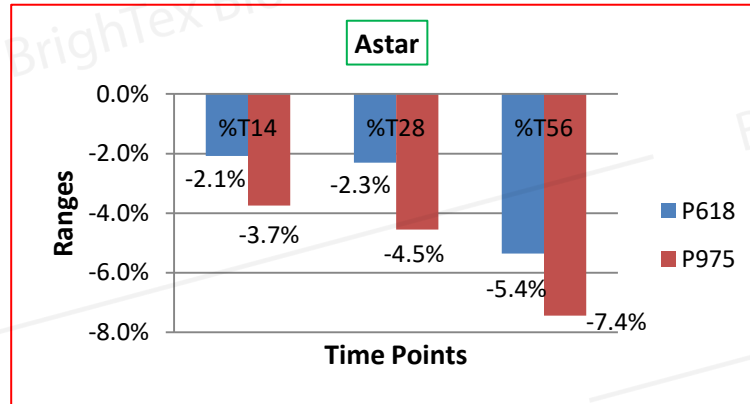


### Skin Color Test Results and Statistical Summary

Clarity™ Mini3D System-Skin Color				
Parameter	Treatment	Visit	Number of subjects showed improvement who has baseline out of 12 subjects	% of Subject showed improvement
Lstar	Product 975	Day 7	9	75.0%
		Day 28	11	91.7%
		Day 56	12	100.0%

### Overall comparison Trends:





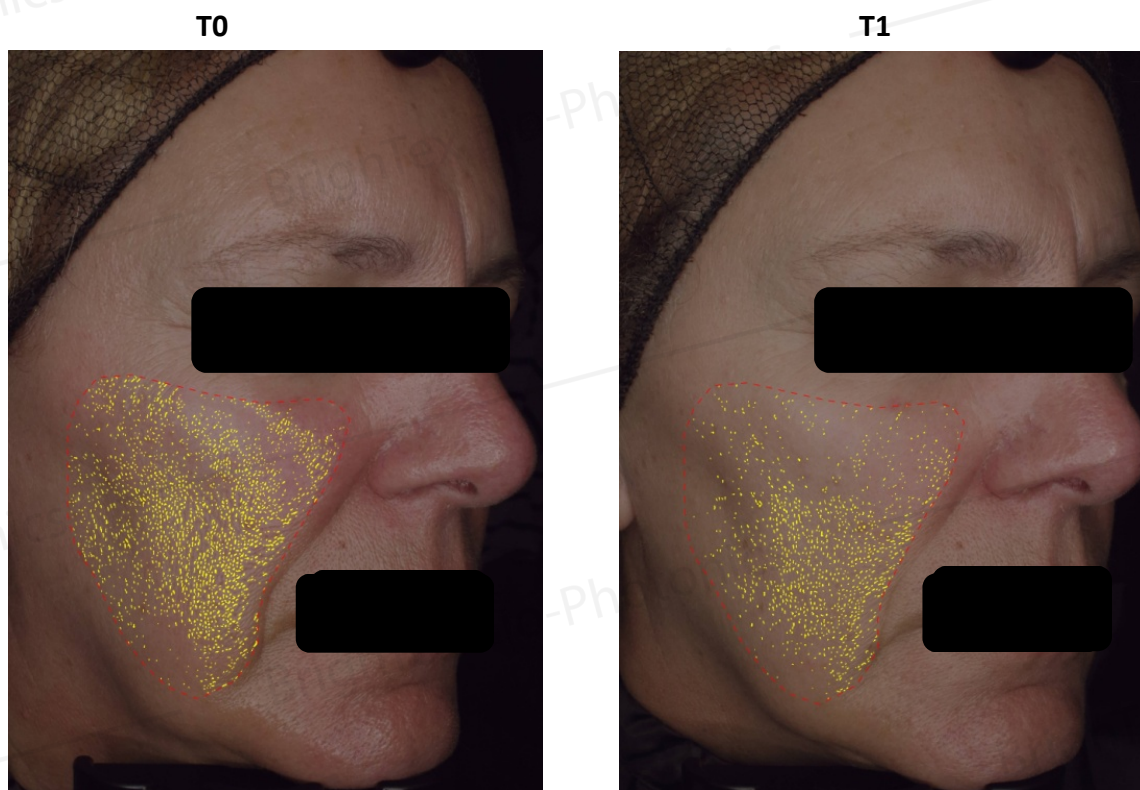
### 3. Pores

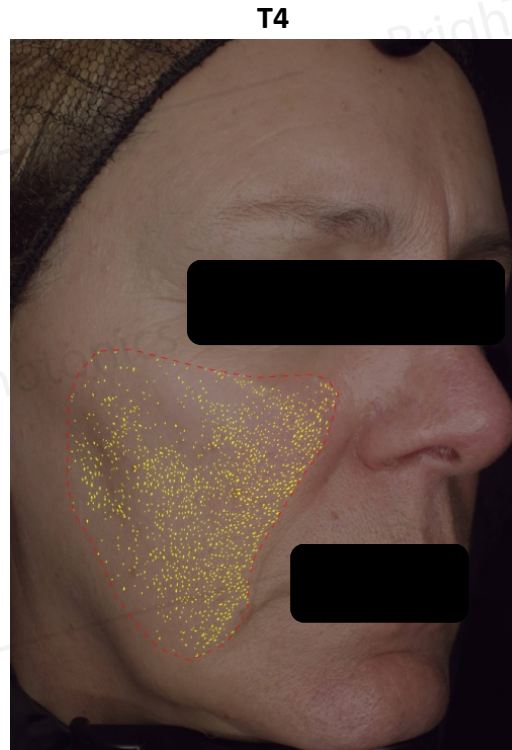
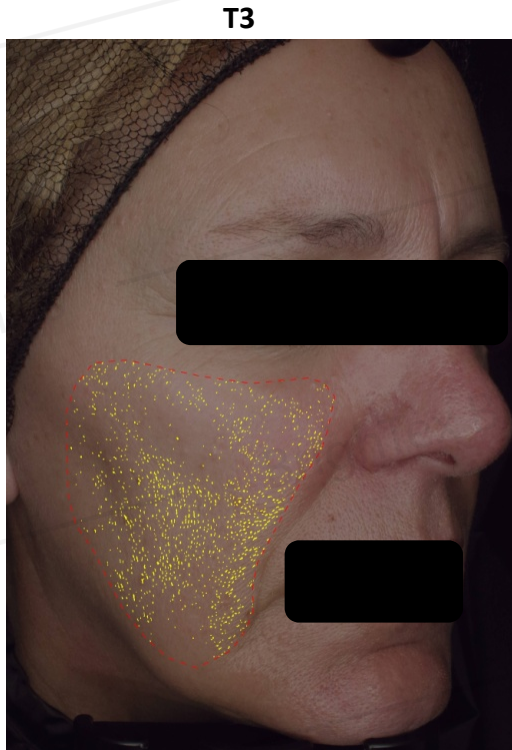
Pores are the tiny holes on the skin that shed or secrete the sebum (oil) produced by the sebaceous glands and are invisible to the naked eye. Enlarged pores grow in size because of the excessive sebum (or sluggish oil flow) production.

**Measured Parameters: Pore Average Intensity**

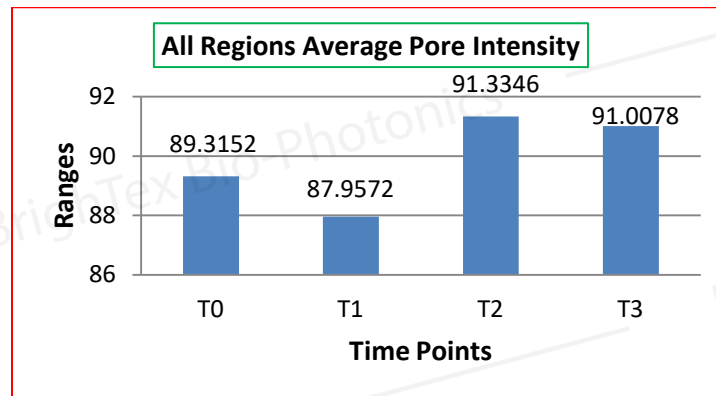
**Pore Average Intensity:** Decrease in pore visibility

**Right Profile, Product: 618**

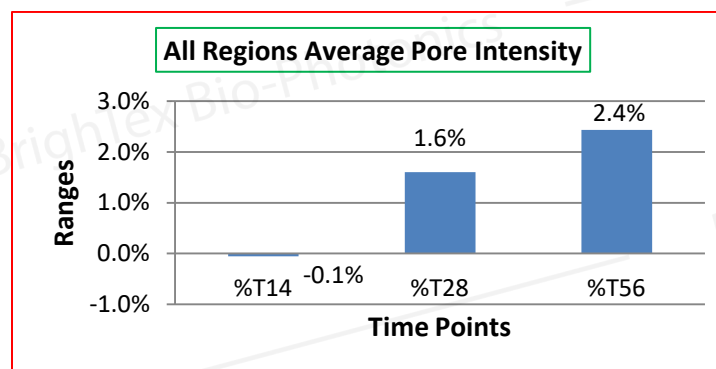




Subject 9 results



Overall Study Trends:



**Improvements Observed:** Increase in Average pore intensity from visit 1 to visit 4

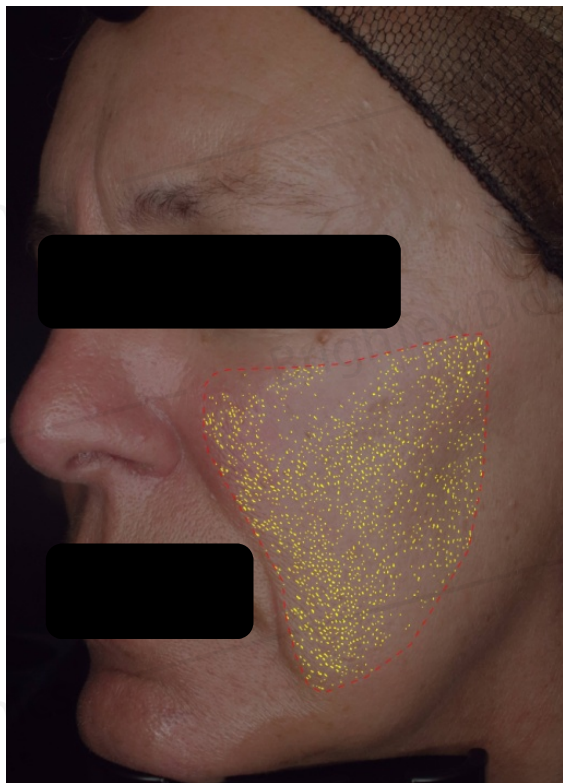
**Pores Test Results and Statistical Summary**

Clarity™ Mini 3D System- Pores				
Parameter	Treatment	Visit	Number of subjects showed improvement who has baseline out of 12 subjects	% of Subject showed improvement
Average Pore Intensity	Product 618	Day 7	7	58.3%
		Day 28	1	8.3%
		Day 56	2	16.7%

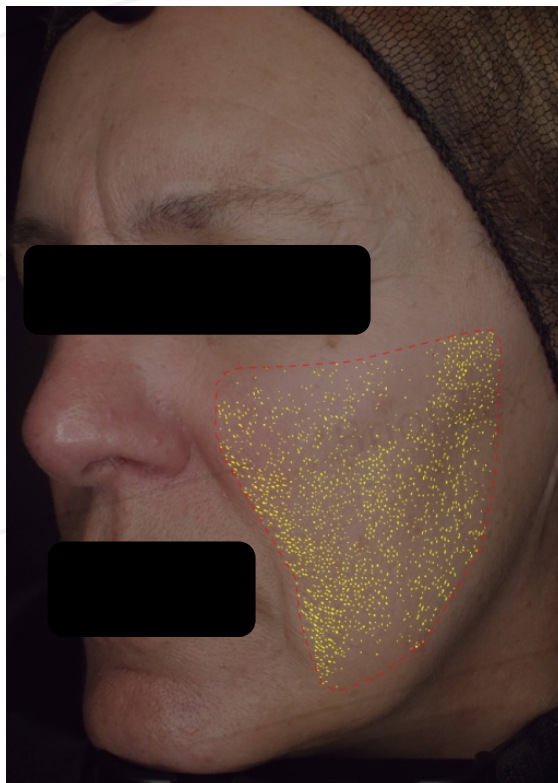


Left Profile, Product: 975

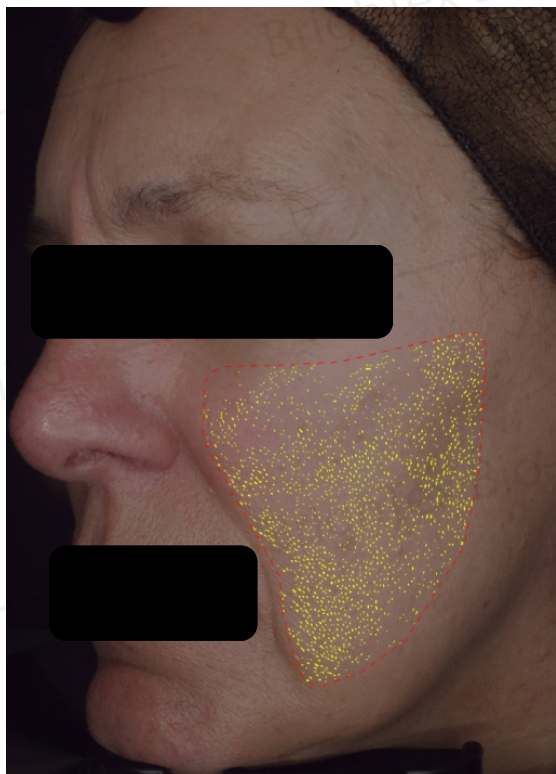
T0



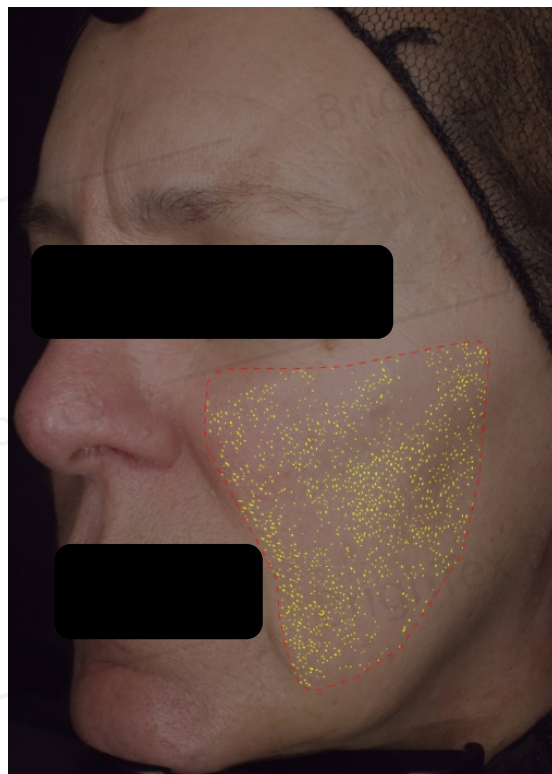
T1



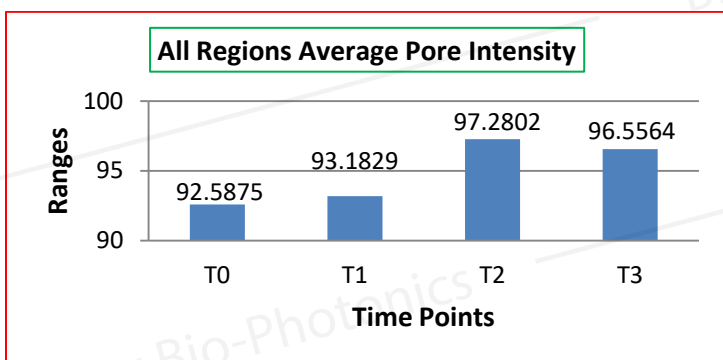
T3



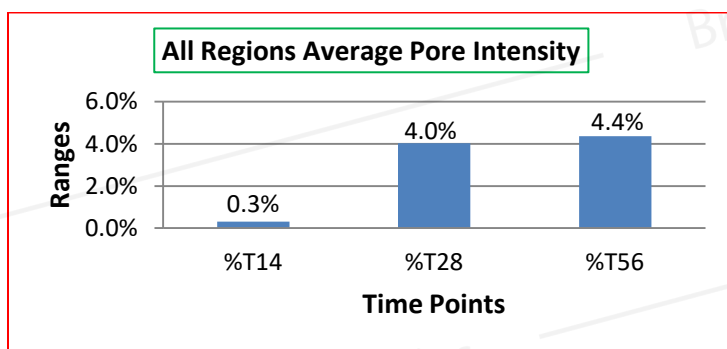
T4



Subject 9 results



Overall Study Trends:



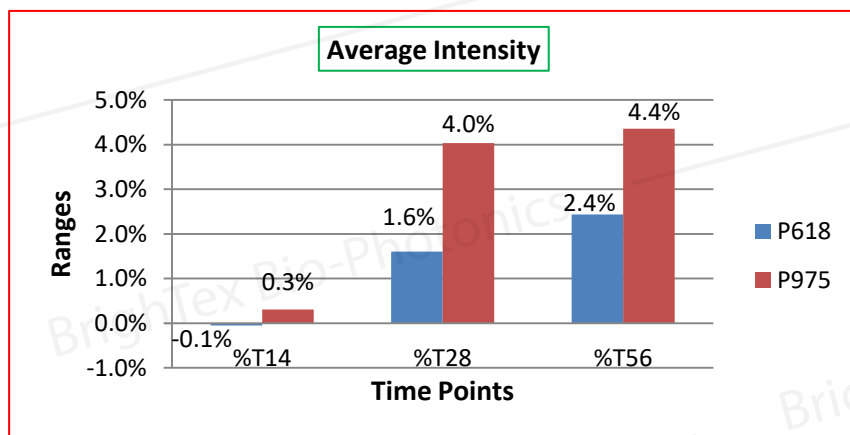
**Improvements Observed:** Increase in average pore intensity from visit 1 to visit 4

**Pores Test Results and Statistical Summary**

Clarity™ Mini 3D System- Pores				
Parameter	Treatment	Visit	Number of subjects showed improvement who has baseline out of 12 subjects	% of Subject showed improvement
Average Pore Intensity	Product 975	Day 7	6	50.0%
		Day 28	1	8.3%
		Day 56	0	0.0%



### Overall Comparison Trends:



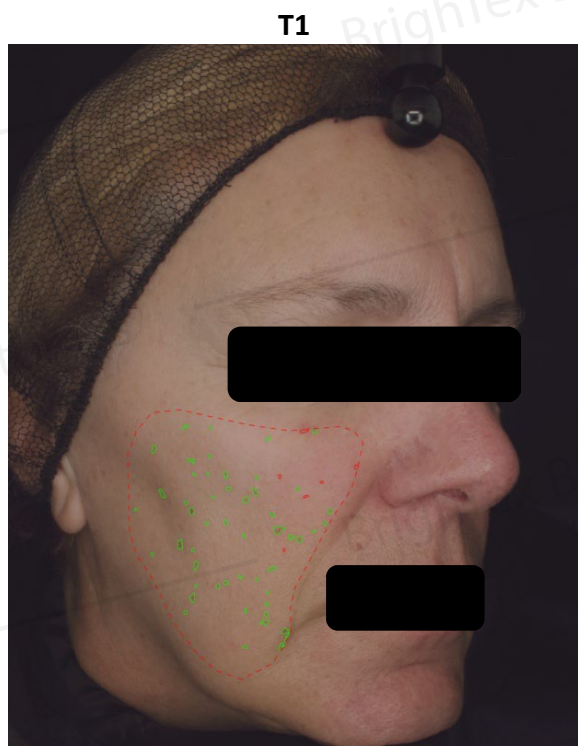
## 4. Surface Spots

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.

**Measured Parameters: Average Pigment Intensity**

**Average Pigment intensity:** Decrease in pigment darkness

**Right Profile, Product:618**



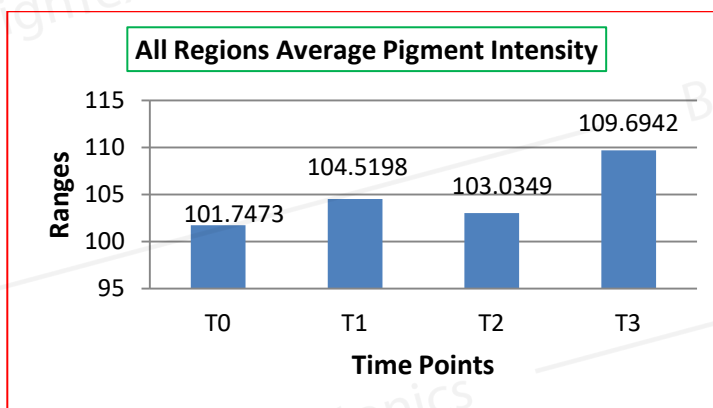
T2



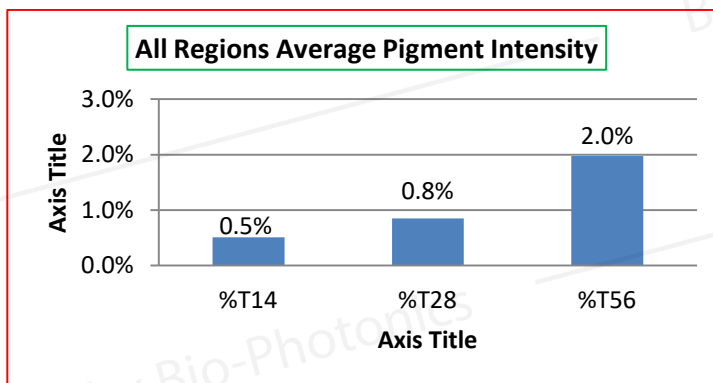
T3



Subject 19 results



## Overall Study Trends:



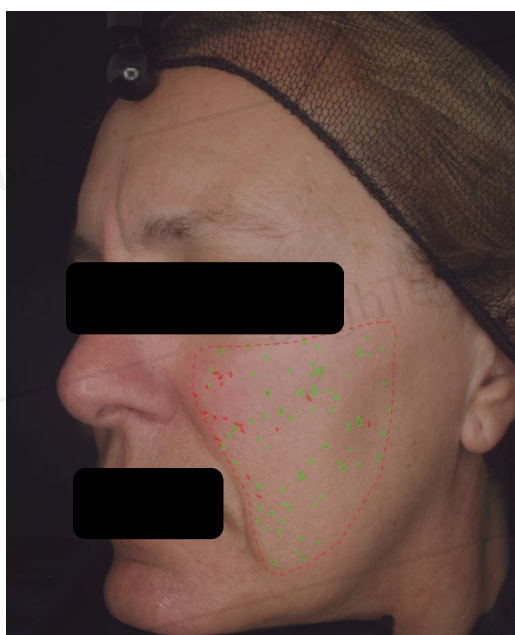
**Improvements Observed:** Increase in Average Pigment Intensity from Visit 1 to Visit 4

## Surface Spots Test Results and Statistical Summary

Clarity™ Mini 3D System- Surface Spots				
Parameter	Treatment	Visit	Number of subjects showed improvement who has baseline out of 12 subjects	% of Subject showed improvement
Average Pigment Intensity	Product 618	Day 7	8	66.7%
		Day 28	8	66.7%
		Day 56	9	75.0%

**Left Profile, Product: 975**

**T0**

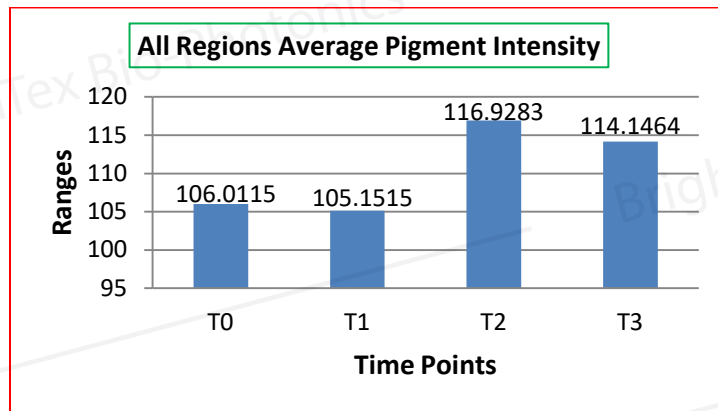


**T1**

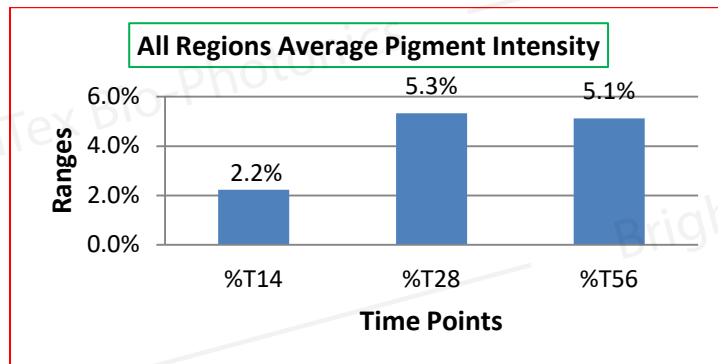




Subject 19 results



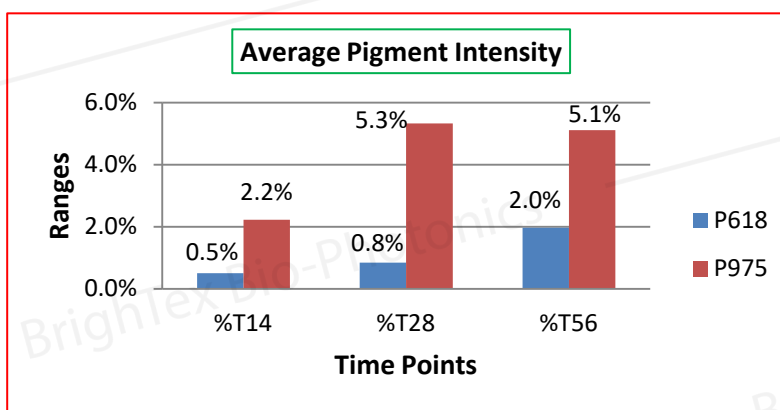
Overall Study Trends:



## Surface Spots Test Results and Statistical Summary

Clarity™ Mini 3D System- Surface Spots				
Parameter	Treatment	Visit	Number of subjects showed improvement who has baseline out of 12 subjects	% of Subject showed improvement
Average Pigment Intensity	Product 975	Day 7	7	58.3%
		Day 28	9	75.0%
		Day 56	10	83.3%

### Overall Comparison Trends:



## 5. CP Spots

Pigmentation not visible on the surface that lies underneath the skin is subsurface pigmentation. Generally, it is an indication of an internal damage caused by the sun.

### Measured Parameters: Size Category2 Spots

**Size Category2 Spots:** Decrease in spots count which are  $> 2 \text{ mm}^2$  &  $\leq 4 \text{ mm}^2$

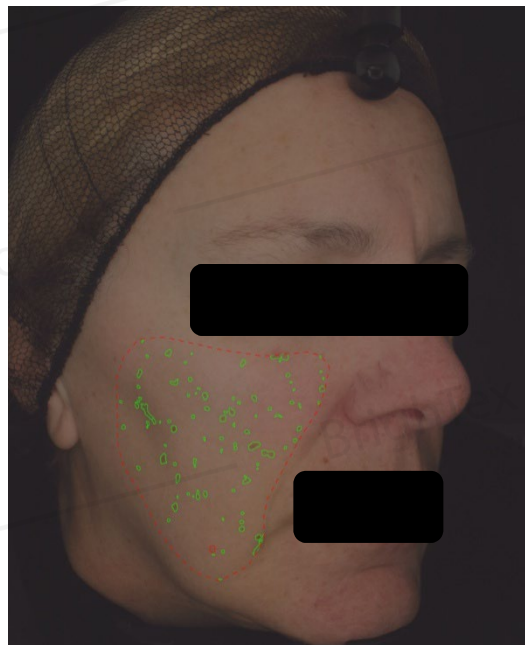


**Right Profile, Product: 618**

**T0**



**T1**



**T2**

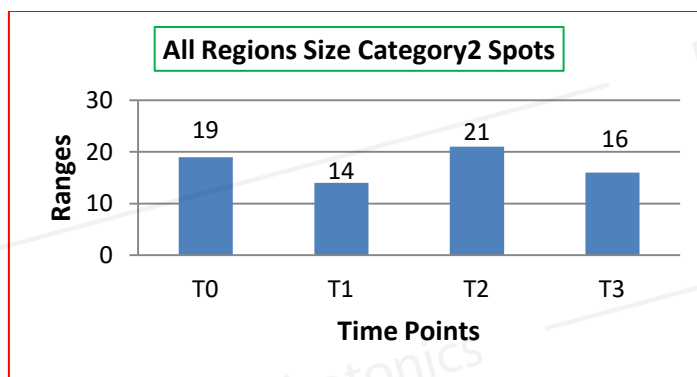


**T3**

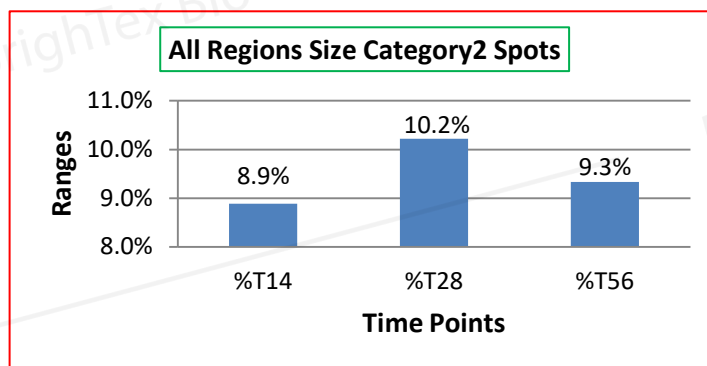




Subject 19 results



Overall Study Trends:



**Improvements Observed:** Decrease in Size Category2 Spots from visit1 to visit4

#### CP SpotsTest Results and Statistical Summary

Clarity™ Mini 3D System- CP Spots				
Parameter	Treatment	Visit	Number of subjects showed improvement who has baseline out of 12 subjects	% of Subject showed improvement
Size Category2 Spots	Product 618	Day 7	4	33.3%
		Day 28	4	33.3%
		Day 56	5	41.7%

Left Profile, Product: 975

T0



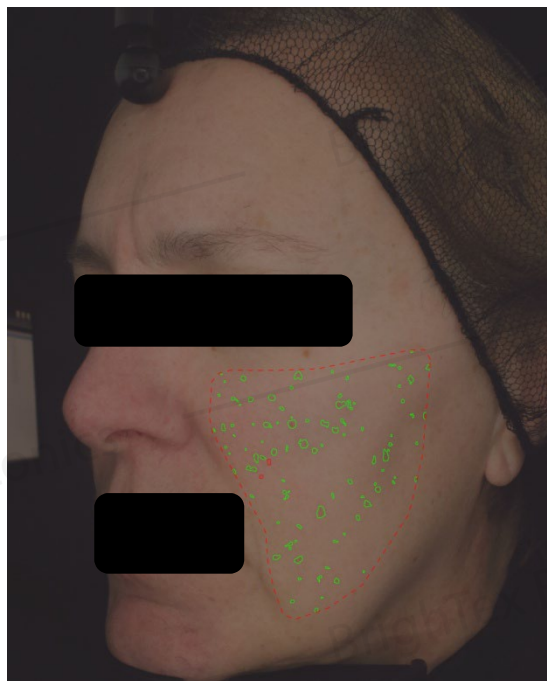
T1



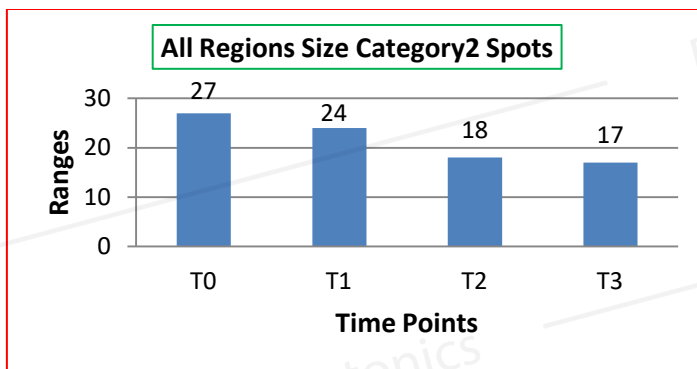
T3



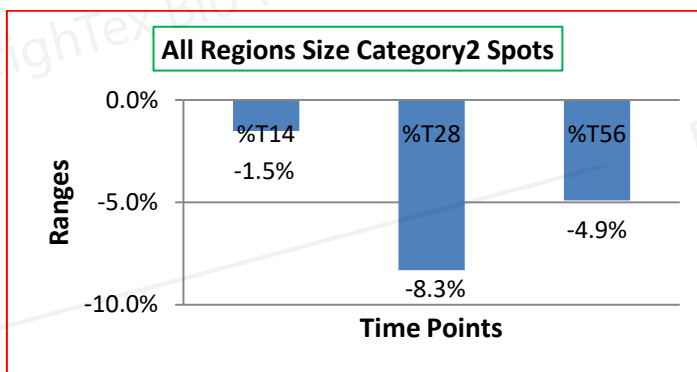
T4



Subject 19 results



Overall Study Trends:

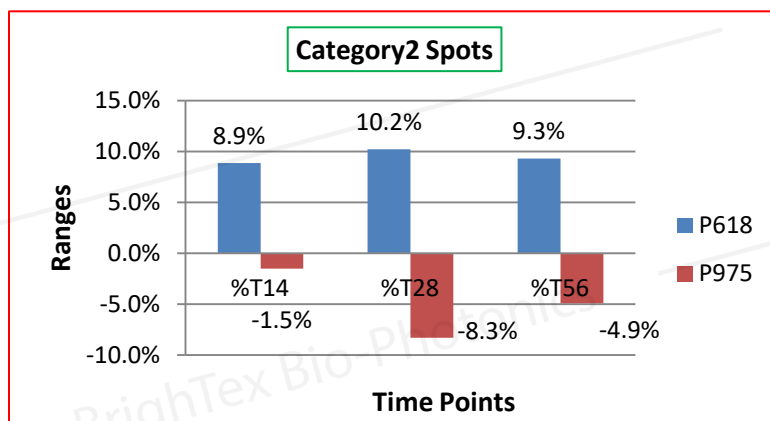


**Improvements Observed:** Decrease in Size Category2 Spots from visit 1 to visit 4

**CP Spots Test Results and Statistical Summary**

Clarity™ Mini 3D System- CP Spots				
Parameter	Treatment	Visit	Number of subjects showed improvement who has baseline out of 12 subjects	% of Subject showed improvement
Size Category2 Spots	Product 975	Day 7	5	41.7%
		Day 28	5	41.7%
		Day 56	6	50.0%

## Overall Comparison Trends:



## 6. Nasolabial 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

**Measured Parameters: Fine Wrinkles Surface Area (%), Emerging Wrinkles Average Severity**

**Fine Wrinkles Surface Area (%):** Decrease in (total number of fine wrinkle pixels / total number of ROI pixels) \* 100

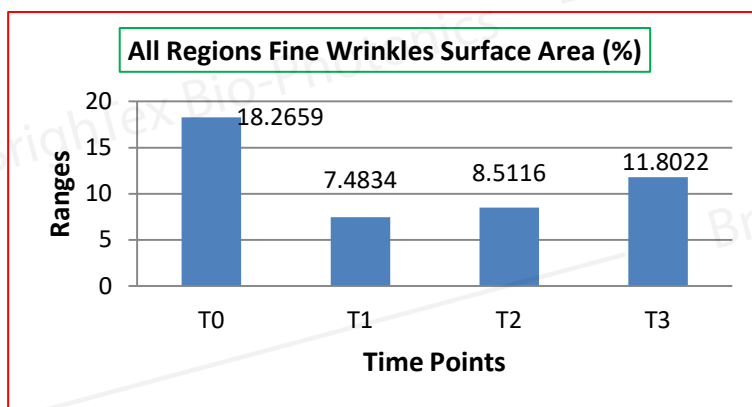
**Emerging Wrinkles Average Severity:** Decrease in the average of intensity difference of each wrinkle pixel from its start to the end point

**Right Profile, Product: 618**





Subject 19 results

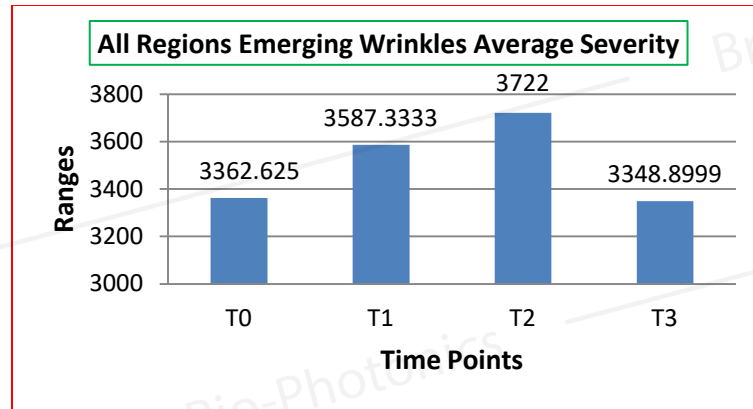


**Improvements Observed:** Decrease in Fine Wrinkles Surface Area (%) from visit 1 to visit 4

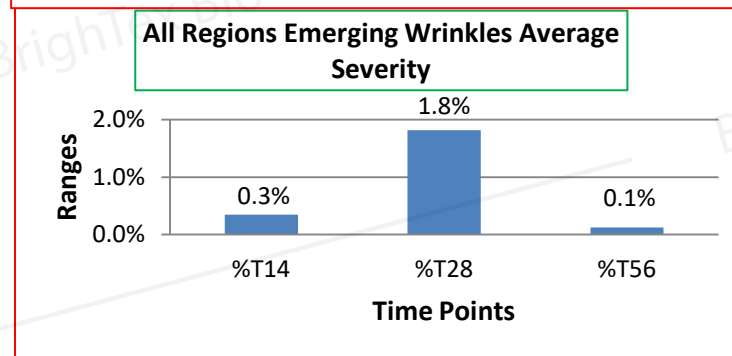
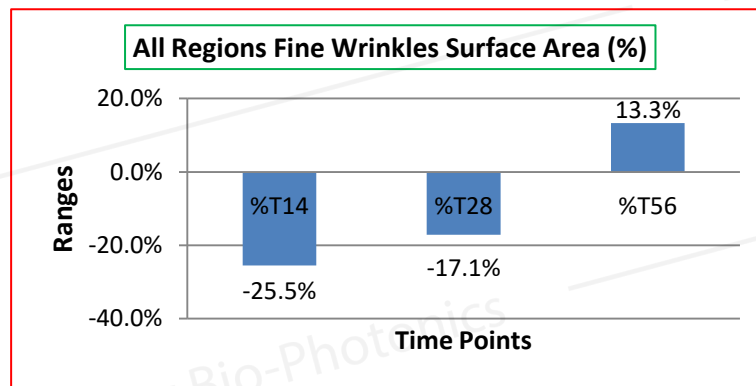
**Overall Study Trends:**



Subject 19 results



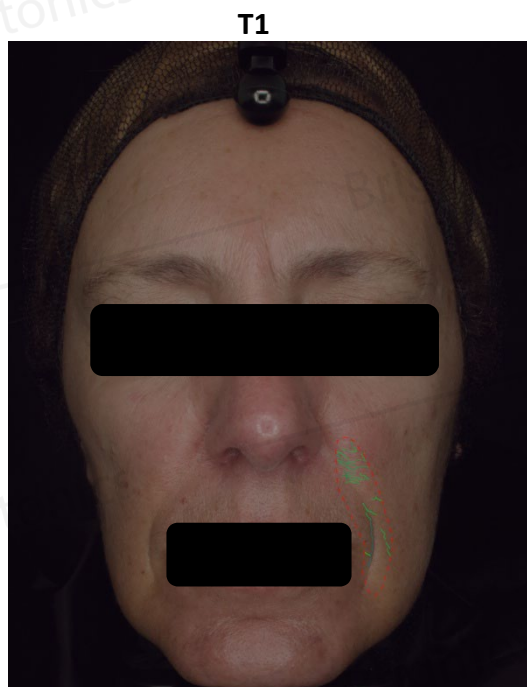
**Improvements Observed:** Decrease in Emerging Wrinkles Average Severity from visit 1 to visit 4  
**Overall Study Trends:**

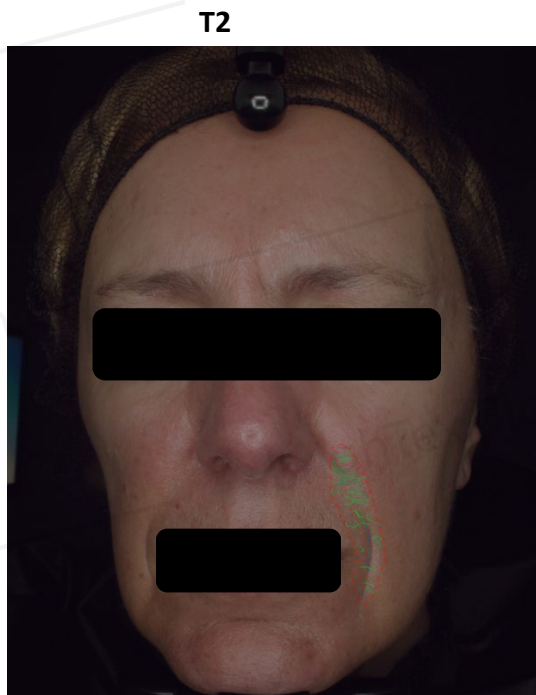


## Nasolabial Wrinkles Test Results and Statistical Summary

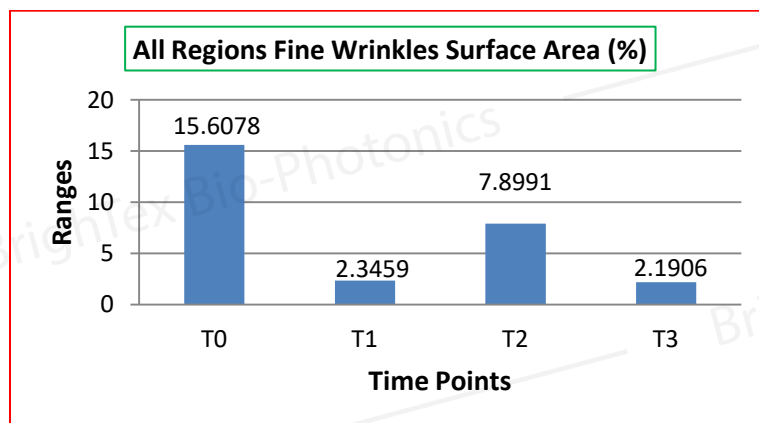
Clarity™ Mini 3D System- Nasolabial Wrinkles				
Parameter	Treatment	Visit	Number of subjects showed improvement who has baseline out of 12 subjects	% of Subject showed improvement
Fine Wrinkles Surface Area (%)	Product 618	Day 7	5	41.7%
		Day 28	7	58.3%
		Day 56	7	58.3%
Emerging Wrinkles Average Severity	Product 618	Day 7	4	33.3%
		Day 28	6	50.0%
		Day 56	6	50.0%

### Left Profile, Product: 975



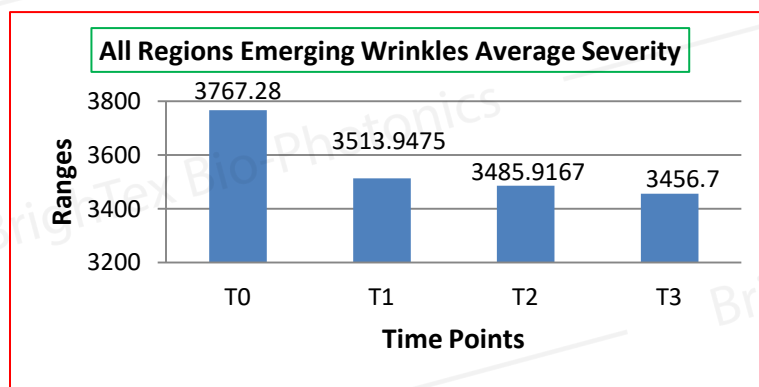


Subject 19 results



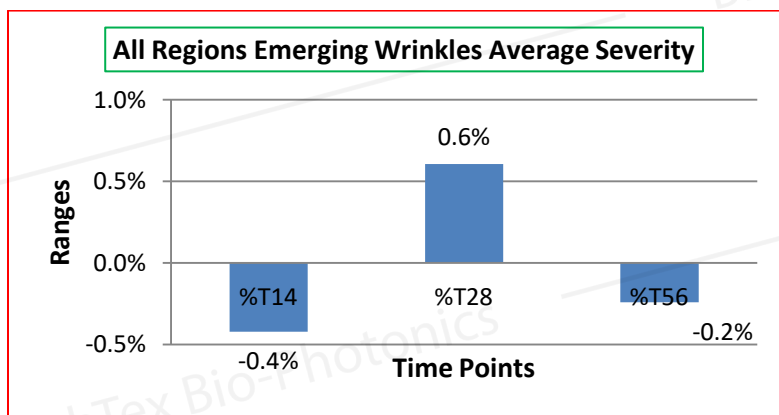
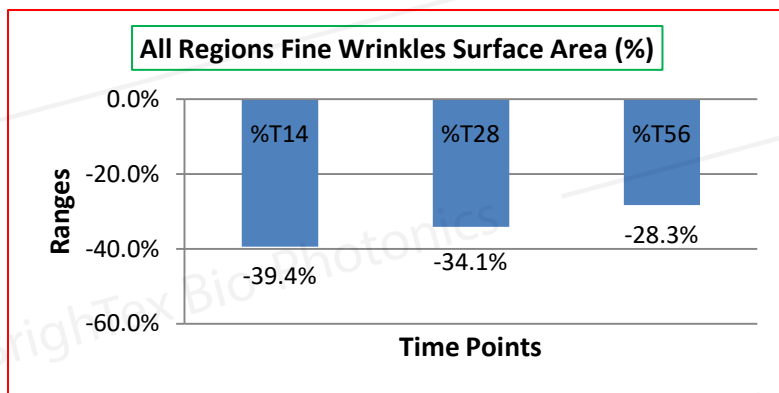
**Improvements Observed:** Decrease in Fine Wrinkles Surface Area (%) from Visit 1 to Visit 4

Subject 19 results



**Improvements Observed:** Decrease in Emerging Wrinkles Average Severity from visit 1 to visit 4

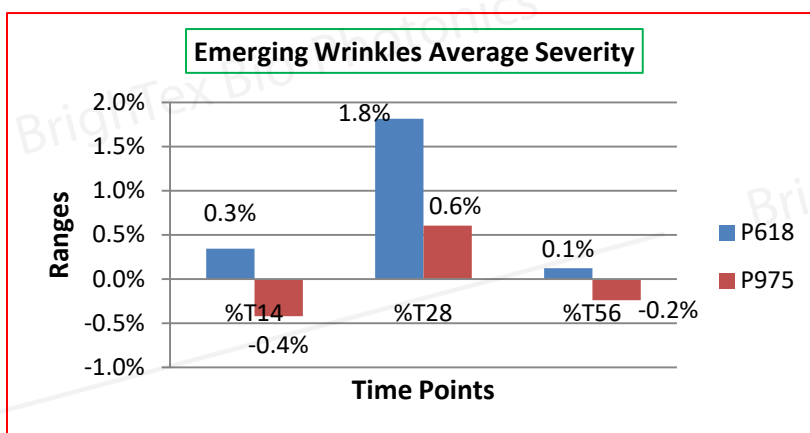
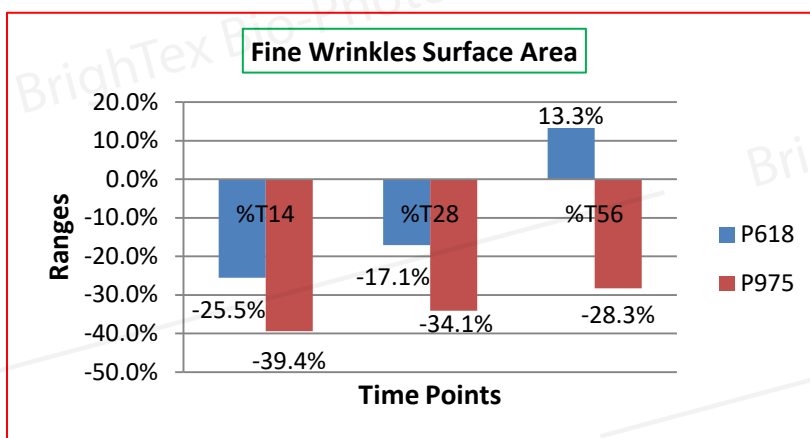
**Overall Study Trends:**



## Nasolabial Wrinkles Test Results and Statistical Summary

Clarity™ Mini 3D System- Nasolabial Wrinkles				
Parameter	Treatment	Visit	Number of subjects showed improvement who has baseline out of 12 subjects	% of Subject showed improvement
Fine Wrinkles Surface Area (%)	Product 975	Day 7	9	75.0%
		Day 28	9	75.0%
		Day 56	7	58.3%
Emerging Wrinkles Average Severity	Product 975	Day 7	6	50.0%
		Day 28	5	41.7%
		Day 56	4	33.3%

### Overall Comparison Trends:





## 7. Crowfeet 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

**Measured Parameters: Deep Wrinkles Surface Area, Deep Wrinkles Average Length**

**Deep Wrinkles Surface Area:** Decrease in (total number of deep wrinkle pixels / total number of ROI pixels) \* 100

**Deep Wrinkles Average Length:** Decrease in deep wrinkles average length

**Left Profile, Product: 618**

T0

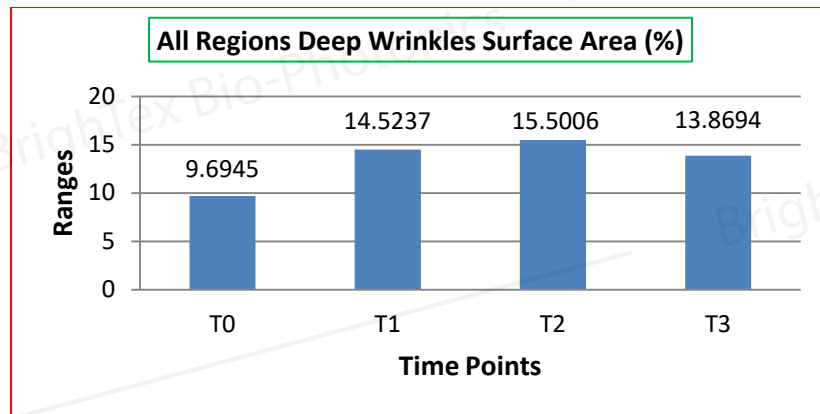


T1



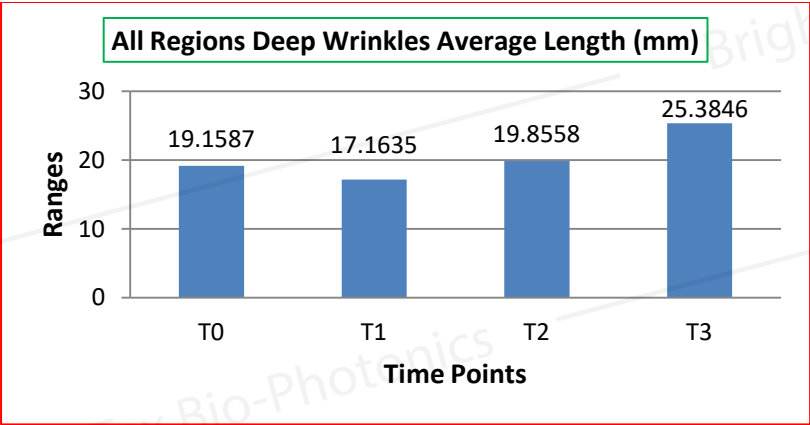


Subject 9 results



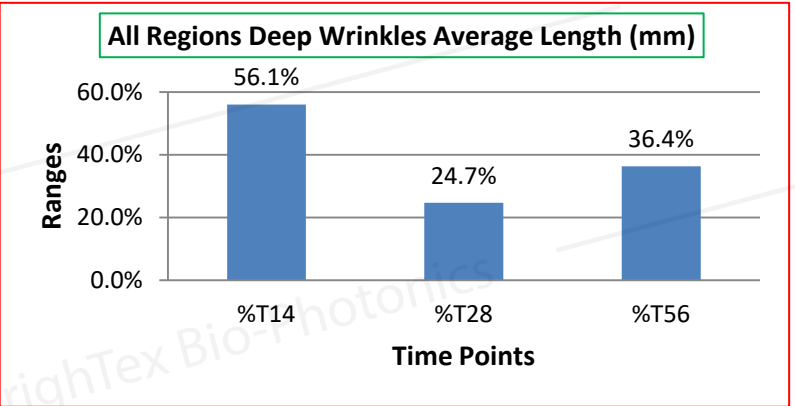
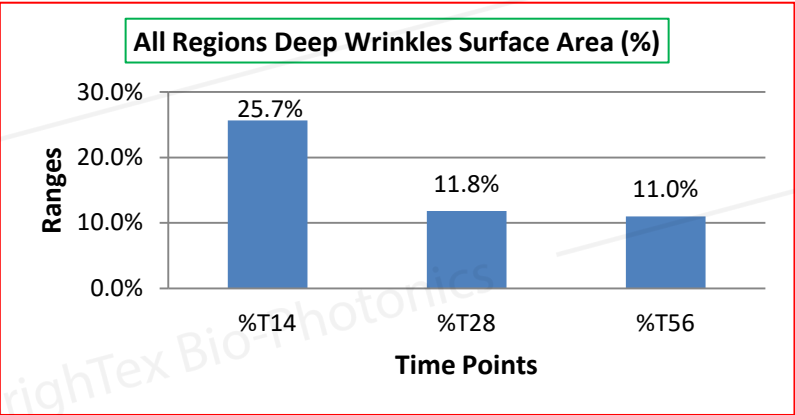
**Improvements Observed:** Decrease in Deep Wrinkles Surface Area (%) from visit 1 to visit 4

Subject 9 results



**Improvements Observed:** Decrease in Deep Wrinkles Average Length(mm) from visit 1 to visit 4

**Overall study Trends:**



## Crowfeet Wrinkles Test Results and Statistical Summary

Clarity™ Mini 3D System- Crowfeet Wrinkles				
Parameter	Treatment	Visit	Number of subjects showed improvement who has baseline out of 12 subjects	% of Subject showed improvement
Deep Wrinkles Surface Area (%)	Product 618	Day 7	5	41.7%
		Day 28	3	25.0%
		Day 56	5	41.7%
Deep Wrinkles Average Length (mm)	Product 618	Day 7	3	25.0%
		Day 28	2	16.7%
		Day 56	3	25.0%

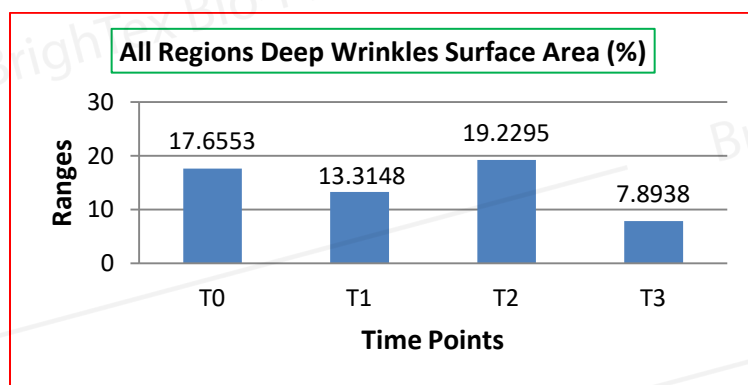
## Right Profile, Product: 975







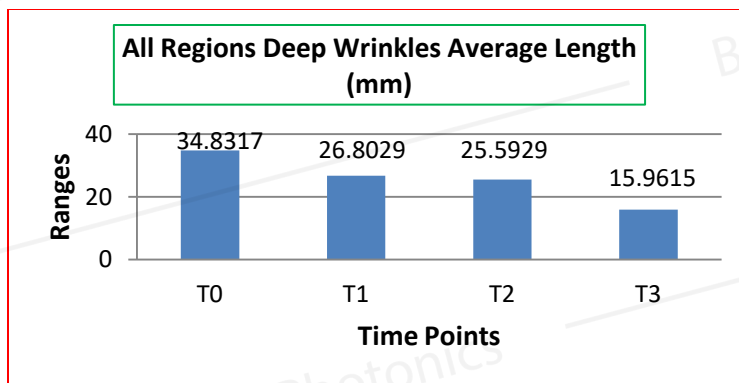
Subject 9 results



**Improvements Observed:** Decrease in Deep Wrinkles Surface Area (%) from visit 1 to visit 4

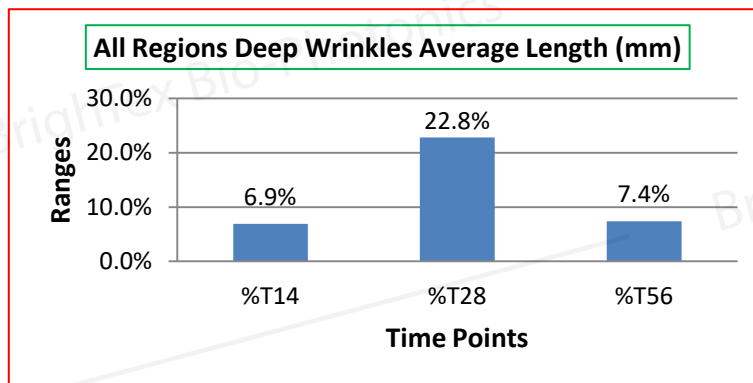
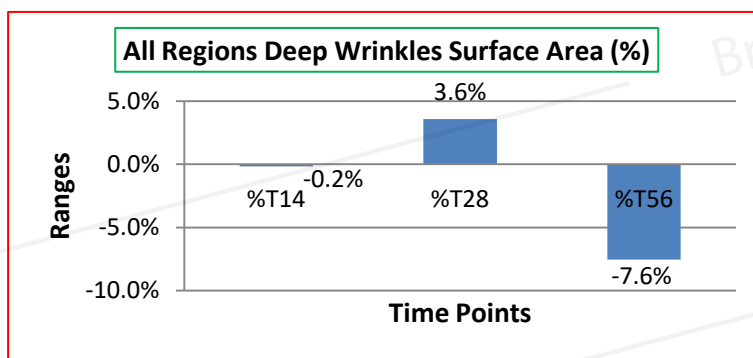


Subject 9 results



**Improvements Observed:** Decrease in Deep Wrinkle Average Length (mm) from visit 1 to visit 4

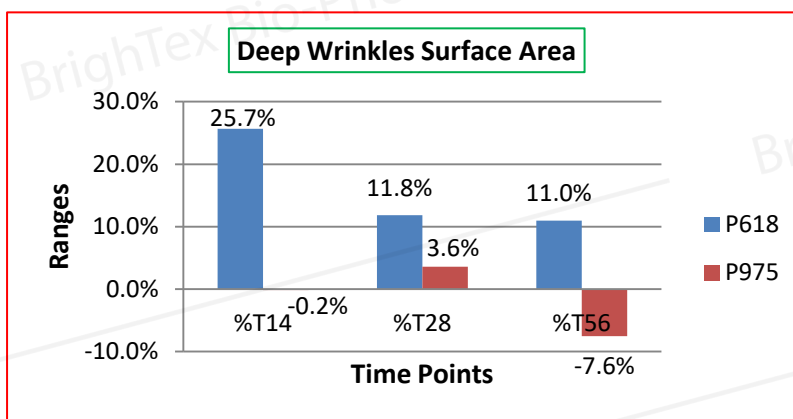
**Overall Study Trends:**

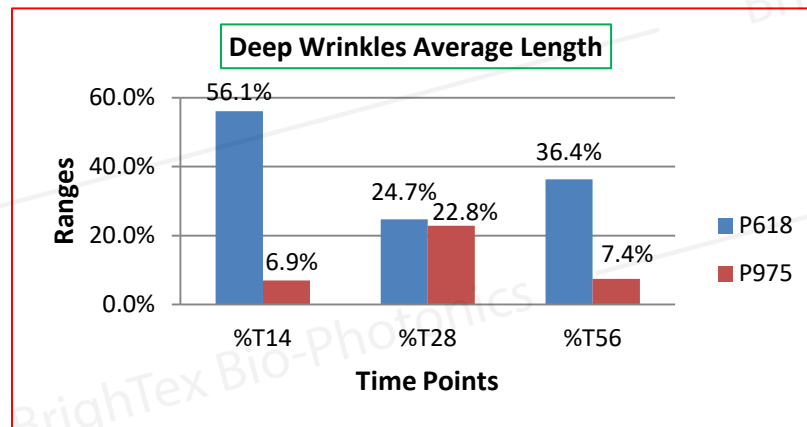


## Crowfeet Wrinkles Test Results and Statistical Summary

Clarity™ Mini 3D System- Crowfeet Wrinkles				
Parameter	Treatment	Visit	Number of subjects showed improvement who has baseline out of 12 subjects	% of Subject showed improvement
Deep Wrinkles Surface Area (%)	Product 975	Day 7	6	50.0%
		Day 28	5	41.7%
		Day 56	4	33.3%
Deep Wrinkles Average Length (mm)	Product 975	Day 7	5	41.7%
		Day 28	3	25.0%
		Day 56	4	33.3%

### Overall Comparison Trends:





## 8. Wrinkles3D Overall

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 Parameter: Total Volume, Average Depth**

**Total Volume:** Decrease in total Intensity of wrinkle recognized pixels

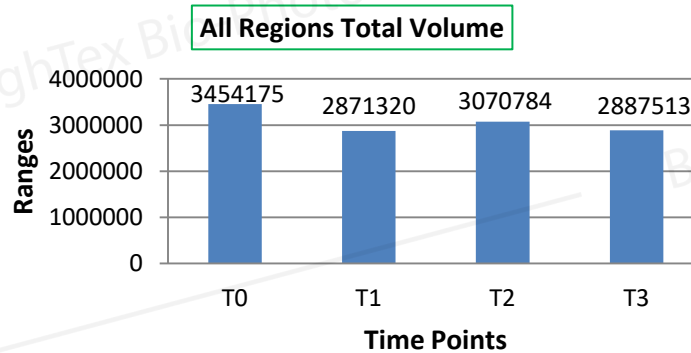
**Average Depth:** Decrease in average intensity of wrinkle recognized pixels

**Right Profile, Product: 618**



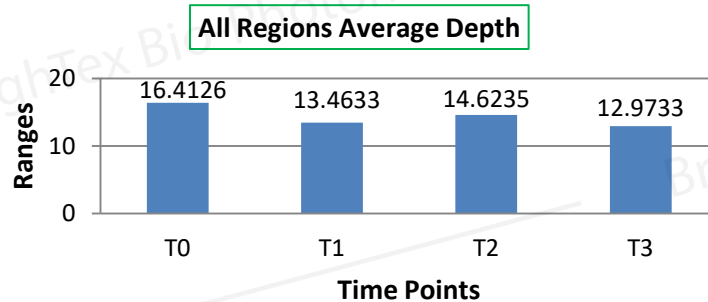


Subject 19 results



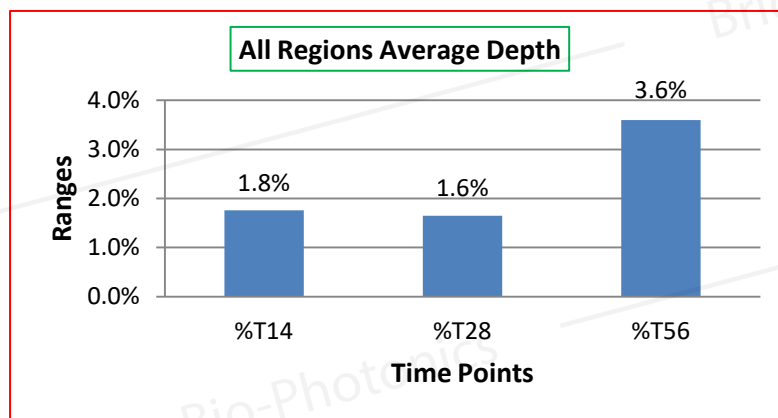
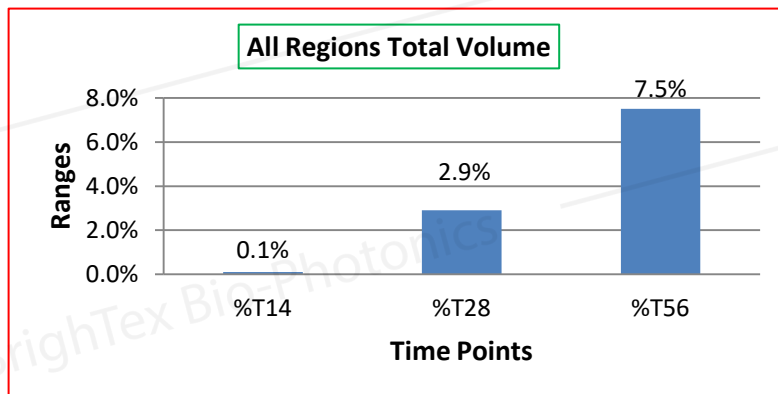
**Improvements Observed:** Decrease in Total Volume from Visit 1 to Visit 4.

Subject 19 results



**Improvements Observed:** Decrease in Average Depth from Visit 1 to Visit 4.

**Overall Study Trends:**



**Wrinkles 3D Overall Test Results and Statistical Summary**

Clarity™ Mini 3D System- Wrinkles3D Overall				
Parameter	Treatment	Visit	Number of subjects showed improvement who has baseline out of 12 subjects	% of Subject showed improvement
Total Volume	Product 618	Day 7	4	33.3%
		Day 28	5	41.7%
		Day 56	5	25.0%
Average Depth	Product 618	Day 7	5	41.7%
		Day 28	5	41.7%
		Day 56	5	41.7%



**Improvements Observed:** Decrease in Wrinkle count from visit 1 to visit 4

**Left Profile, Product: 975**

**T0**



**T1**



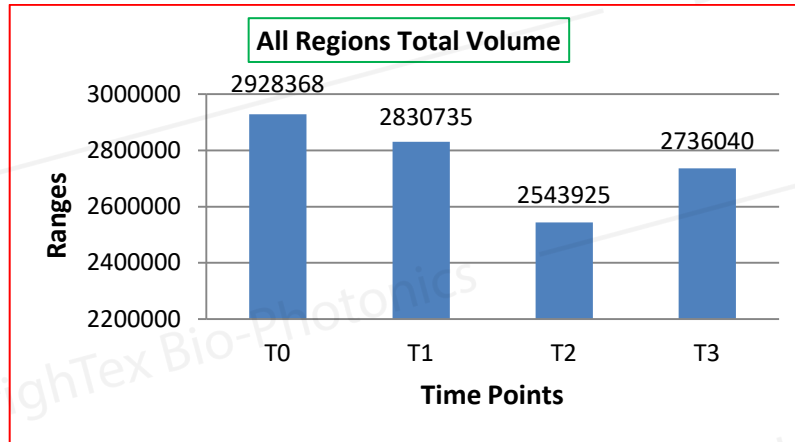
**T3**



**T4**

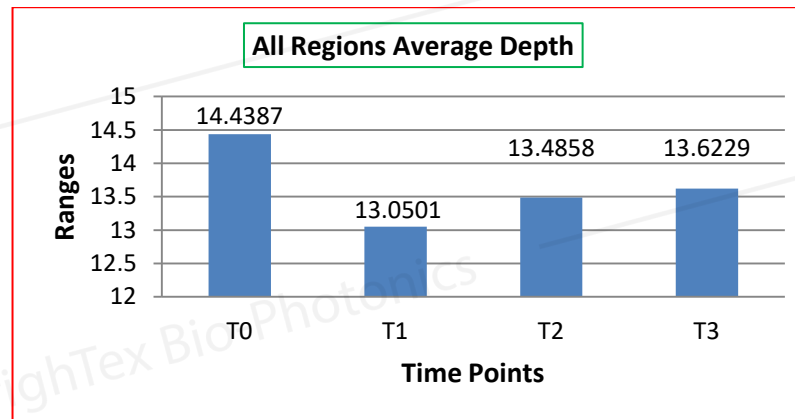


Subject 19 results



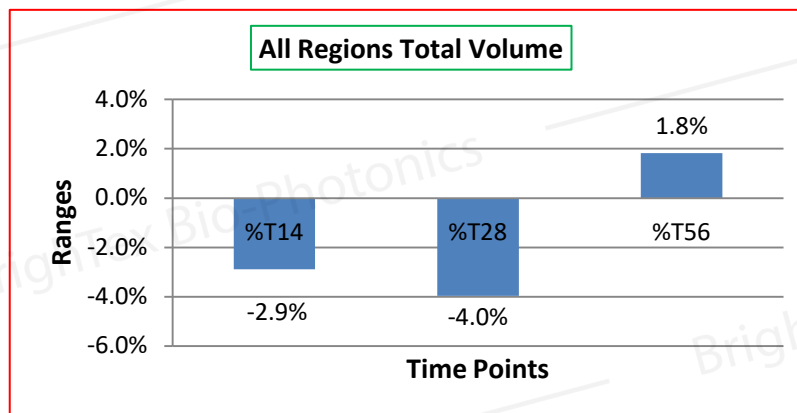
**Improvements Observed:** Decrease in Total Volume from visit 1 to visit 4.

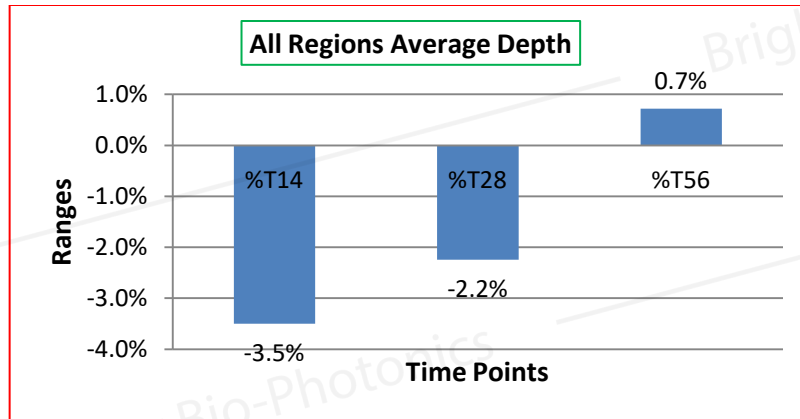
Subject 19 results



**Improvements Observed:** Decrease in Average Depth from visit 1 to visit 4.

**Overall Study Trends:**

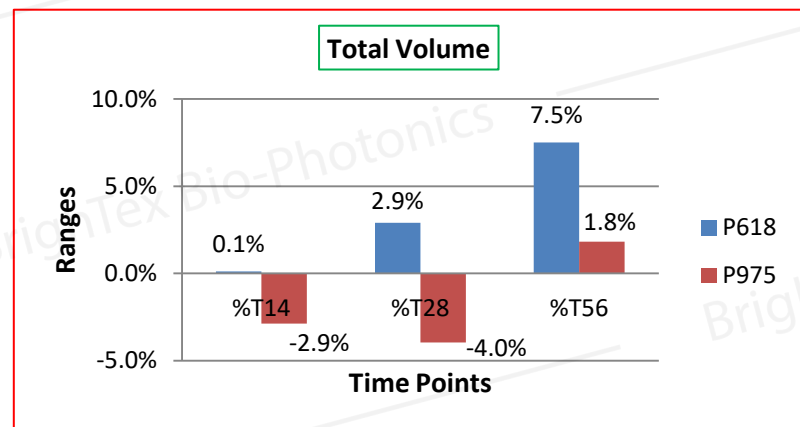


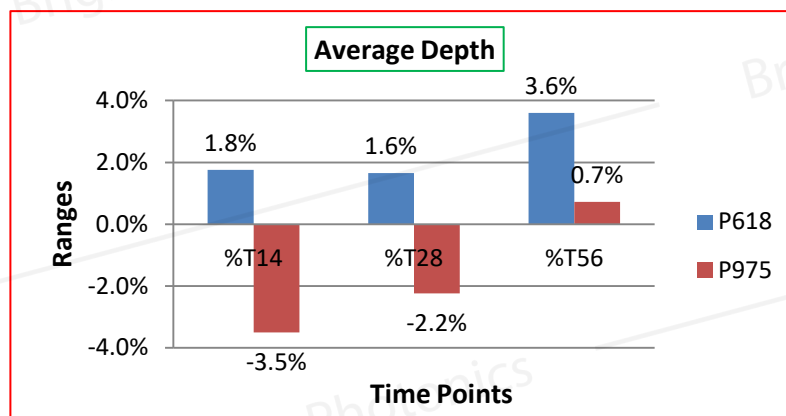


### Wrinkles 3D Overall Test Results and Statistical Summary

Clarity™ Mini 3D System- Wrinkles3D Overall				
Parameter	Treatment	Visit	Number of subjects showed improvement who has baseline out of 12 subjects	% of Subject showed improvement
Total Volume	Product 975	Day 7	8	66.7%
		Day 28	8	66.7%
		Day 56	6	50.0%
Average Depth	Product 975	Day 7	6	50.0%
		Day 28	7	58.3%
		Day 56	5	41.7%

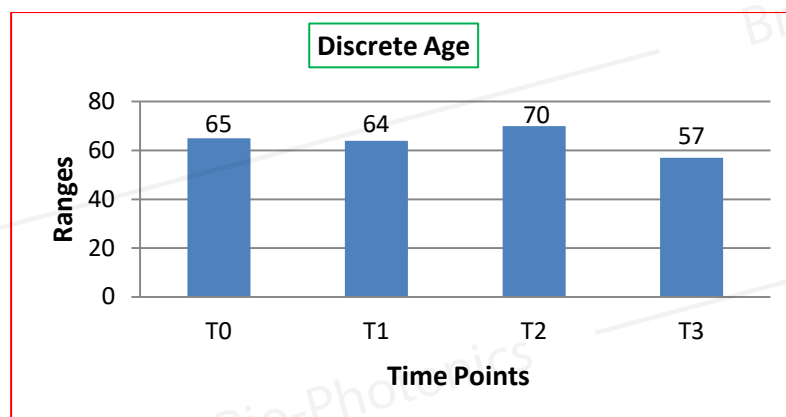
### Overall Comparison Trends:





## 9. Discrete Age

Subject 9 results

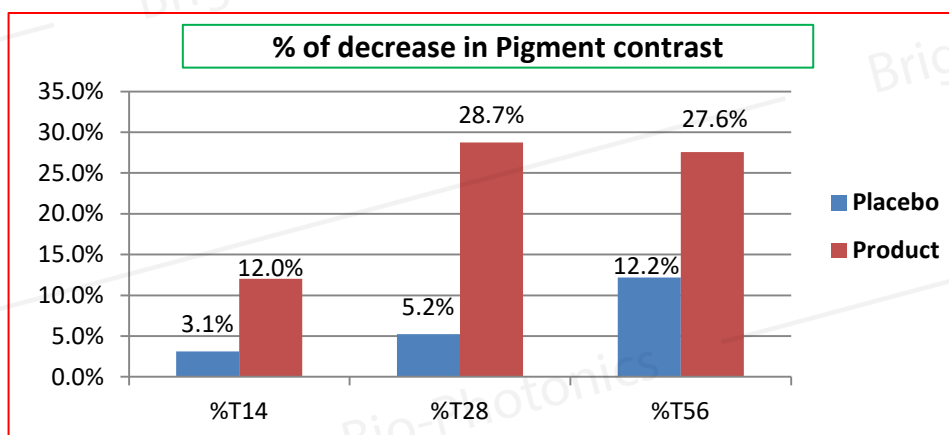
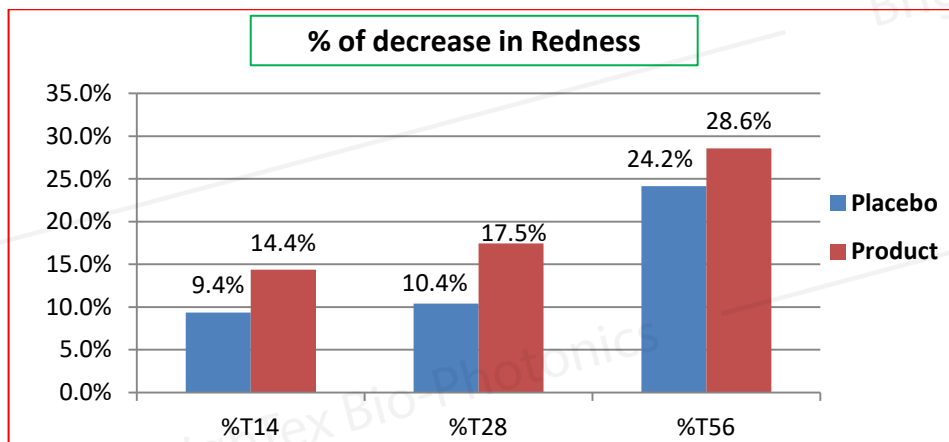
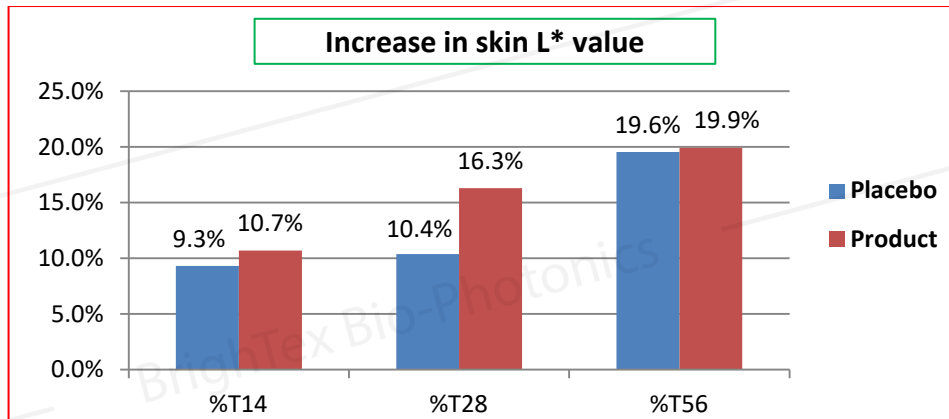


**Improvements Observed:** Decrease in Skin Age from visit1 to visit4

### Discrete Age Test Results and Statistical Summary

Clarity™ Mini 3D System- Discrete Age			
Parameter	Visit	Number of subjects showed improvement who has baseline out of 12 subjects	% of Subject showed improvement
Discrete Age	Day 7	3	21.4%
	Day 28	6	42.9%
	Day 56	6	42.9%

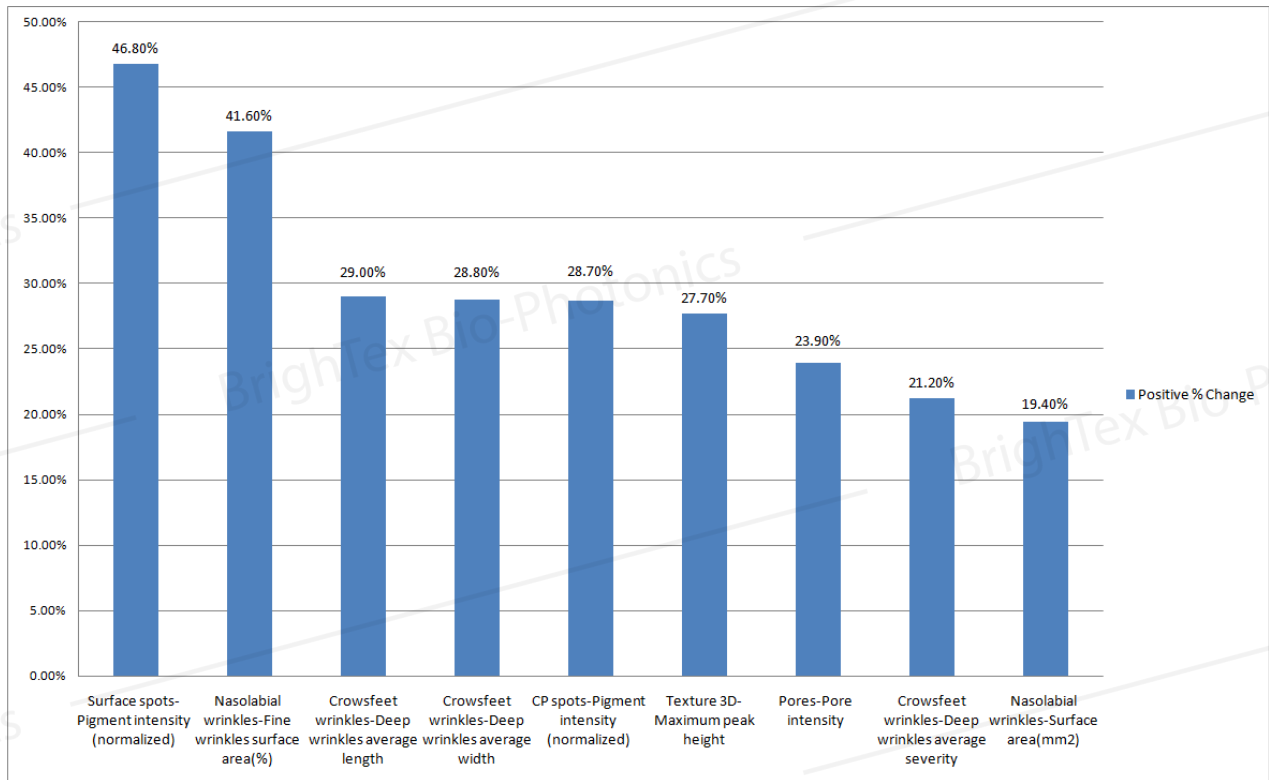
## Section 6: Study Conclusion



- Given Parameters showed positive % change at all time points T14,T28,T56 with Active product
- Most of the other Parameters showed positive % change at final time point T56 with Active Product



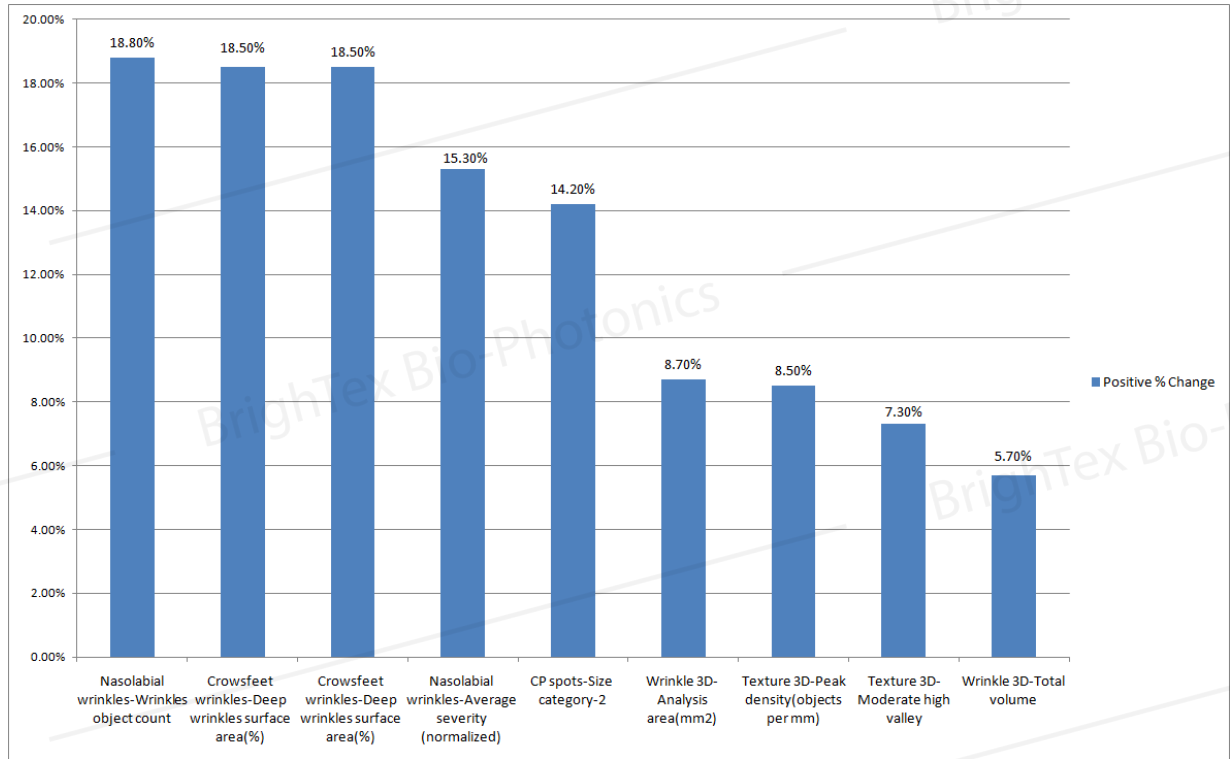
- Parameters having positive % change at T56 w.r.t T0 with Active Product in comparison to Placebo



- Parameters having positive % change at T56 w.r.t T0 with Active Product in comparison to Placebo

S.No	Parameter	Positive change (%)	Description
1	<b>Surface spots</b> -Pigment intensity (normalized)	46.80%	Decrease in pigment darkness
2	<b>Nasolabial wrinkles</b> -Fine wrinkles surface area (%)	41.60%	Decrease in (total number of fine wrinkle pixels / total number of ROI pixels) * 100
3	<b>Crowfeet wrinkles</b> -Deep wrinkles average length	29.00%	Decrease in deep wrinkles average length
4	<b>Crowfeet wrinkles</b> -Deep wrinkles average width	28.80%	Decrease in deep wrinkles average width
5	<b>CP spots</b> -Pigment intensity (normalized)	28.70%	Decrease in pigment darkness
6	<b>Texture 3D</b> -Maximum peak height	27.70%	Decrease in highest peak (bump/height) in the ROI
7	<b>Pores</b> -Pore intensity (normalized)	23.90%	Decrease in pore visibility
8	<b>Crowfeet wrinkles</b> -Deep wrinkles average severity	21.20%	Decrease in the average of intensity difference of each wrinkle pixel from its start to the end point
9	<b>Nasolabial wrinkles</b> -Surface area(mm <sup>2</sup> )	19.40%	Decrease in total surface area of wrinkles in mm <sup>2</sup>

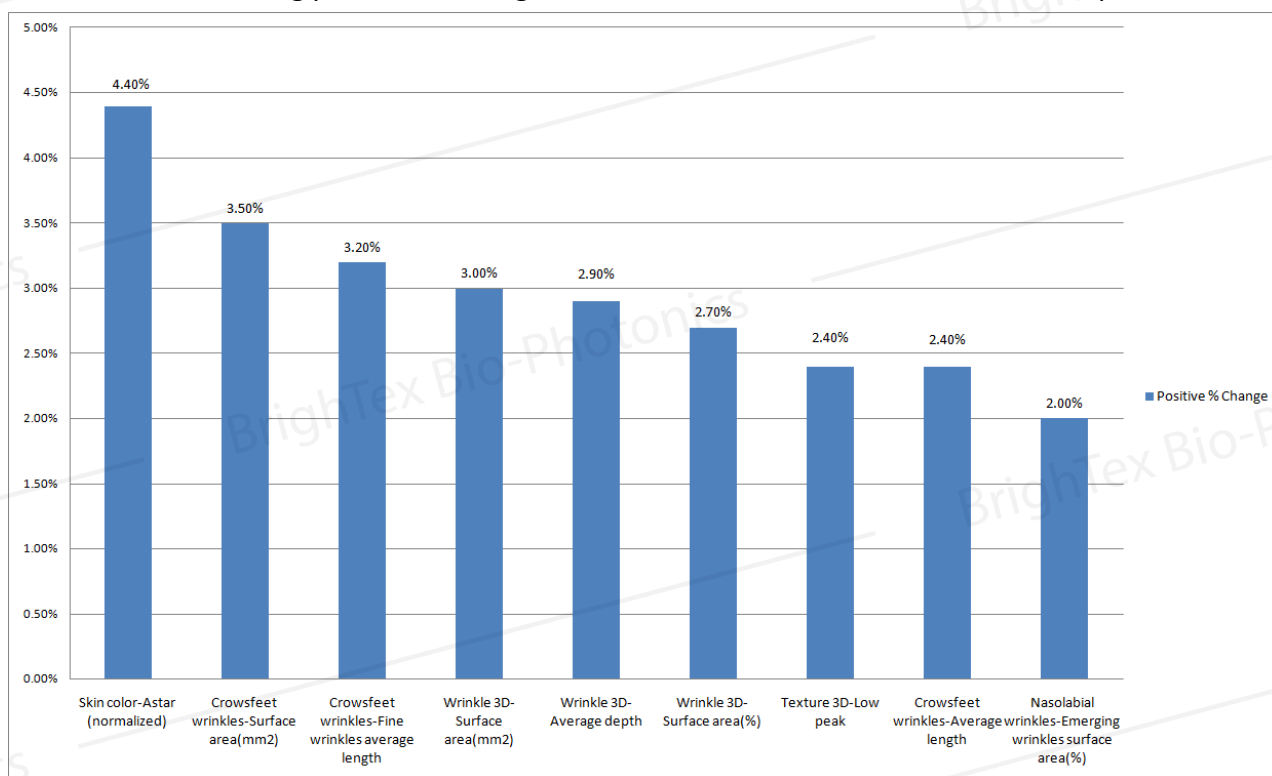
- Parameters having positive % change at T56 w.r.t T0 with Active Product in comparison to Placebo



- Parameters having positive % change at T56 w.r.t T0 with Active Product in comparison to Placebo

S. No	Parameter	Positive change (%)	Description
10	<b>Nasolabial wrinkles</b> -Wrinkles object count	18.80%	Decrease in total wrinkles count
11	<b>Crowfeet wrinkles</b> -Deep wrinkles surface area (%)	18.50%	Decrease in (total number of deep wrinkle pixels / total number of ROI pixels) * 100
12	<b>Crowfeet wrinkles</b> -Deep wrinkles surface area (%)	18.50%	Decrease in ( <b>total number of deep wrinkle pixels / total number of ROI pixels</b> ) * 100
13	<b>Nasolabial wrinkles</b> -Average severity (normalized)	15.30%	Decrease in the average of intensity difference of each wrinkle pixel from its start to the end point
14	<b>CP spots</b> -Size category-2	14.20%	Decrease in spots count which are > 2 mm <sup>2</sup> & <= 4 mm <sup>2</sup>
15	<b>Wrinkle 3D</b> -Analysis area(mm <sup>2</sup> )	8.70%	Decrease in total ROI area of wrinkles
16	<b>Texture 3D</b> -Peak density(objects per mm)	8.50%	Decrease in number of peak (bumps/heights) objects per mm <sup>2</sup> area
17	<b>Texture 3D</b> -Moderate high valley	7.30%	Decrease in percentage area of pixels whose depth range is between >=10 & < 20
18	<b>Wrinkle 3D</b> -Total volume	5.70%	Decrease in total Intensity of wrinkle recognized pixels

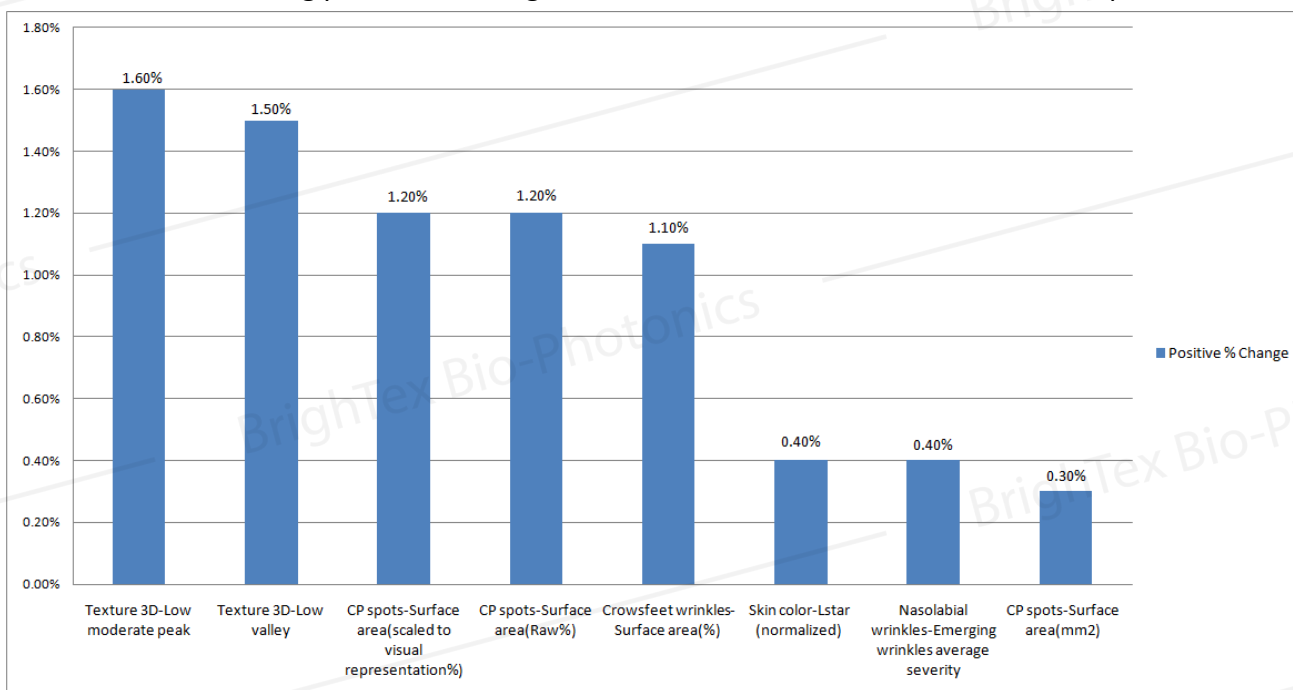
- Parameters having positive % change at T56 w.r.t T0 with Active Product in comparison to Placebo



- Parameters having positive % change at T56 w.r.t T0 with Active Product in comparison to Placebo

S.No	Parameter	Positive change (%)	Description
19	<b>Skin color-Astar (normalized)</b>	4.40%	Decrease in redness
20	<b>Crowfeet wrinkles-Surface area(mm<sup>2</sup>)</b>	3.50%	Decrease in total number of wrinkle pixels in mm <sup>2</sup>
21	<b>Crowfeet wrinkles-Fine wrinkles average length</b>	3.20%	Decrease in the average length of fine wrinkles
22	<b>Wrinkle 3D-Surface area(mm<sup>2</sup>)</b>	3.00%	Decrease in total number of wrinkle pixels in mm <sup>2</sup>
23	<b>Wrinkle 3D-Average depth</b>	2.90%	Decrease in average intensity of wrinkle recognized pixels
24	<b>Wrinkle 3D-Surface area (%)</b>	2.70%	Decrease in (total number of wrinkle pixels / total number of ROI pixels) * 100
25	<b>Texture 3D-Low peak</b>	2.40%	Decrease in percentage area of pixels whose height range is between > 0 and < 2
26	<b>Crowfeet wrinkles-Average length</b>	2.40%	Decrease in average length of wrinkle
27	<b>Nasolabial wrinkles-Emerging wrinkles surface area (%)</b>	2.00%	Decrease in (total number of emerging wrinkle pixels / total number of ROI pixels) * 100

- Parameters having positive % change at T56 w.r.t T0 with Active Product in comparison to Placebo



- Parameters having positive % change at T56 w.r.t T0 with Active Product in comparison to Placebo

S.No	Parameter	Positive change (%)	Description
28	<b>Texture 3D</b> -Low moderate peak	1.60%	Decrease in <b>percentage area of pixels whose height range is between <math>\geq 2</math> and <math>&lt; 4</math></b>
29	<b>Texture 3D</b> -Low valley	1.50%	Decrease in percentage area of pixels whose depth range is between $> 0$ and $< 2$
30	<b>CP spots</b> -Surface area (scaled to visual representation %)	1.20%	Decrease in raw percentage value, scaled to reach visual representation(internal scale min=0, max=45)
31	<b>CP spots</b> -Surface area (Raw %)	1.20%	Decrease in (total number of Pigmented pixels / total number of ROI pixels) * 100
32	<b>Crowfeet wrinkles</b> -Surface area (%)	1.10%	Decrease in (total number of wrinkle pixels / total number of ROI pixels) * 100
33	<b>Skin color</b> -Lstar (normalized)	0.40%	As $L^*$ increases the brightness in Skin color is increasing
34	<b>Nasolabial wrinkles</b> -Emerging wrinkles average severity	0.40%	Decrease in the average of intensity difference of each wrinkle pixel from its start to the end point
35	<b>CP spots</b> -Surface area(mm <sup>2</sup> )	0.30%	Decrease in total number of pigmented pixels in mm <sup>2</sup>

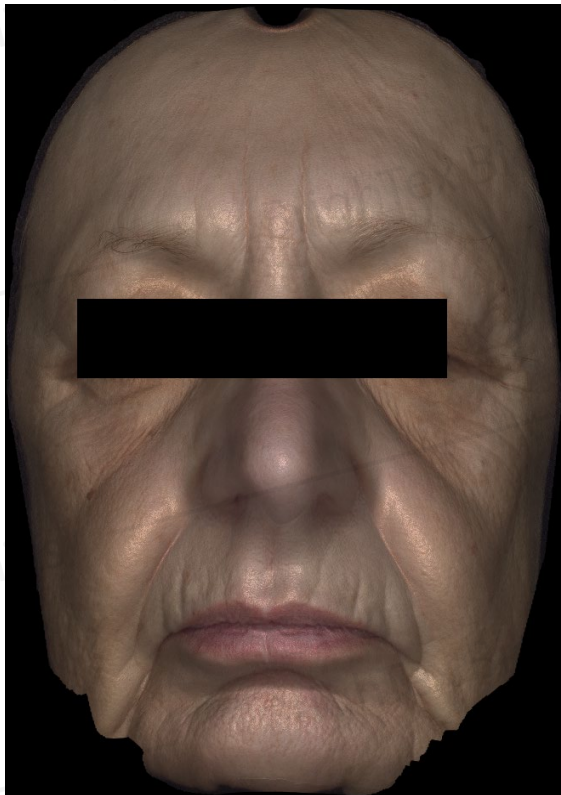
**Normalized:** Intensity measurements are normalized using its respective minimum value of the entire report and then calculated % change

- Statistically significant improvements were seen in the size and visibility of both crows-feet and nasolabial wrinkles
- Pigmented spots has a decrease in visibility
- Reduction in skin redness
- Decrease in pore visibility
- Skin texture was also found to be smoother

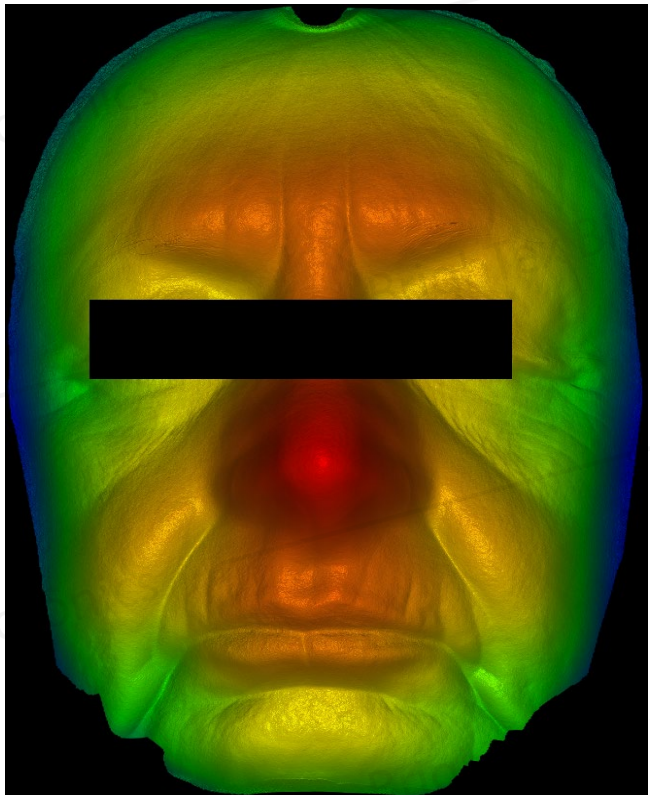
From the above improvements we conclude that there is a positive visible impact on skin with Product in comparison to Placebo

## 6.1 3DModel Front View

**Skin Texture**

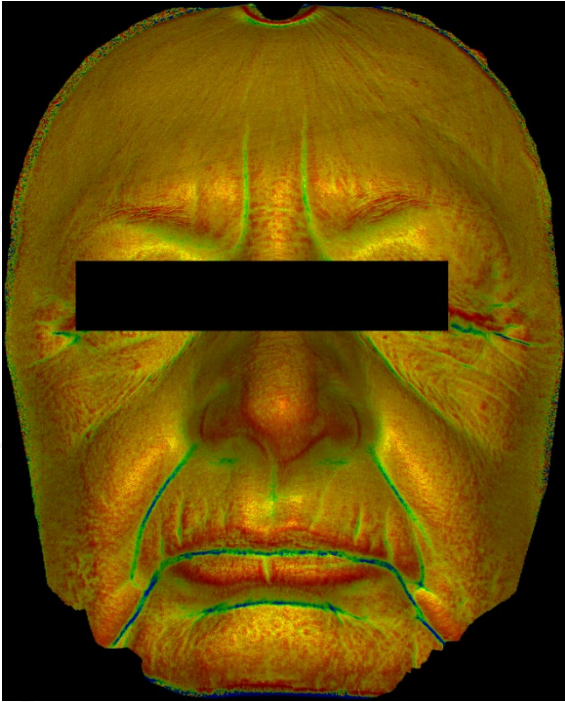


**Global Color Map**

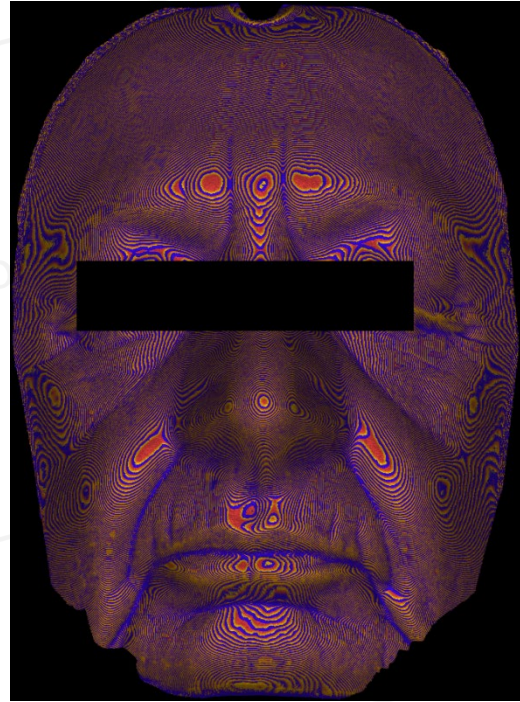




**Localized Color Map**

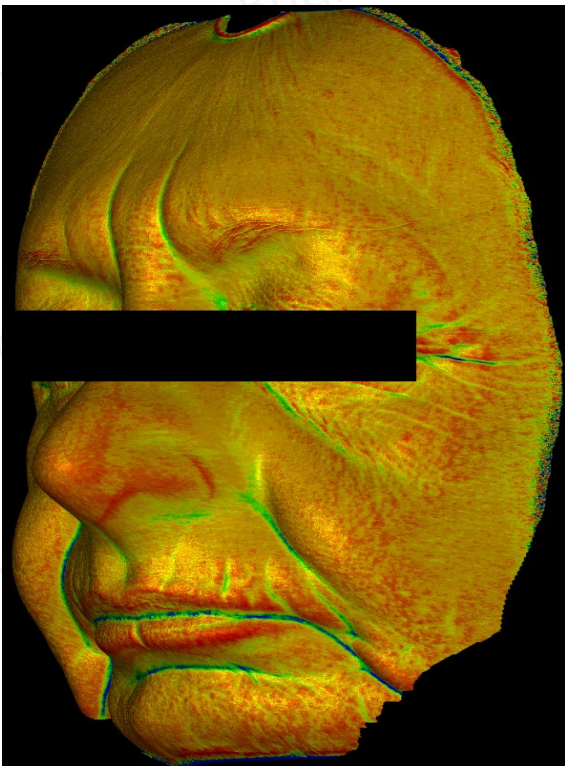


**Localized Contour Map**

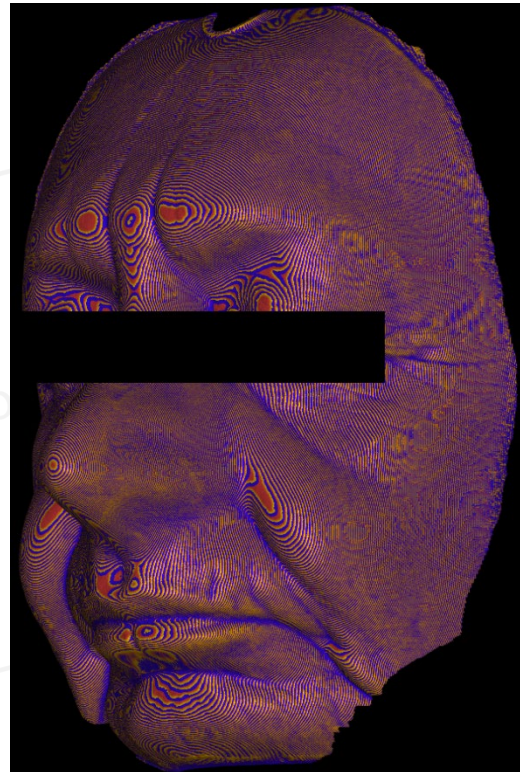


## 6.2 3DModel Side View

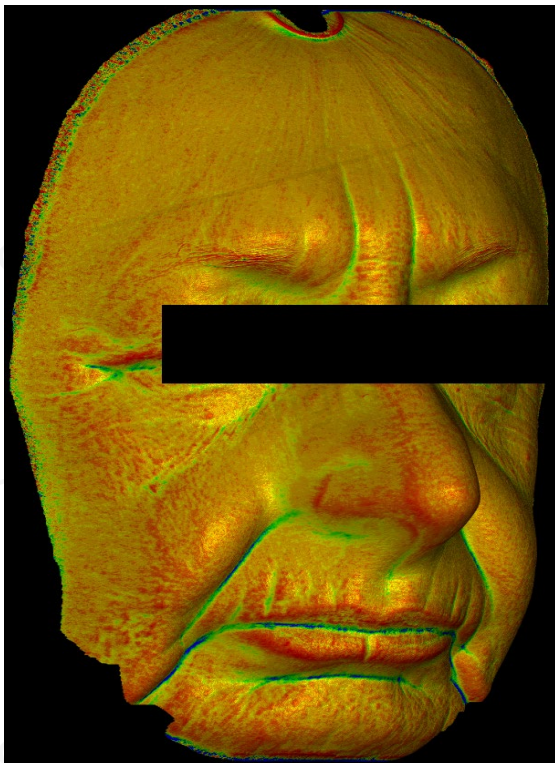
**Localized Color Map**



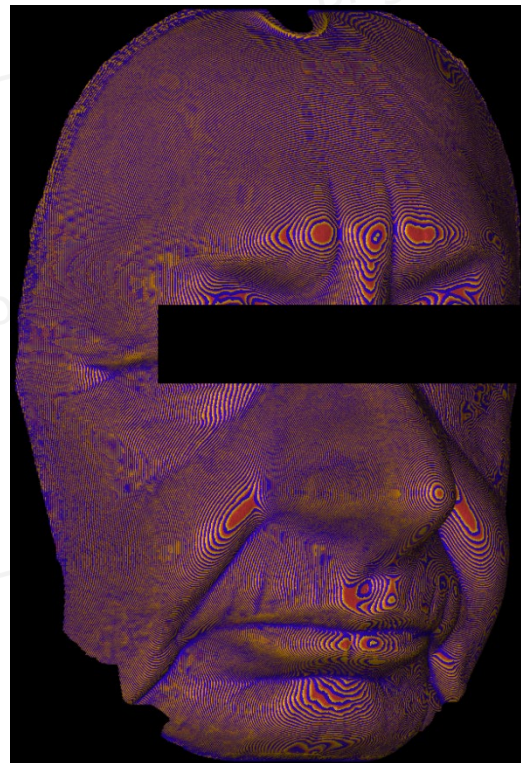
**Localized Contour Map**



Localized Color Map



Localized Contour Map



## Section 7: Product Usage/Application Instructions

As per the product usage instructions provided by the BIO-EC laboratory instructors, From **Day 0 to Day 56** Application of the products on each hemi-face twice Daily.