VELLUS HAIR

STUDY TEMPLATE

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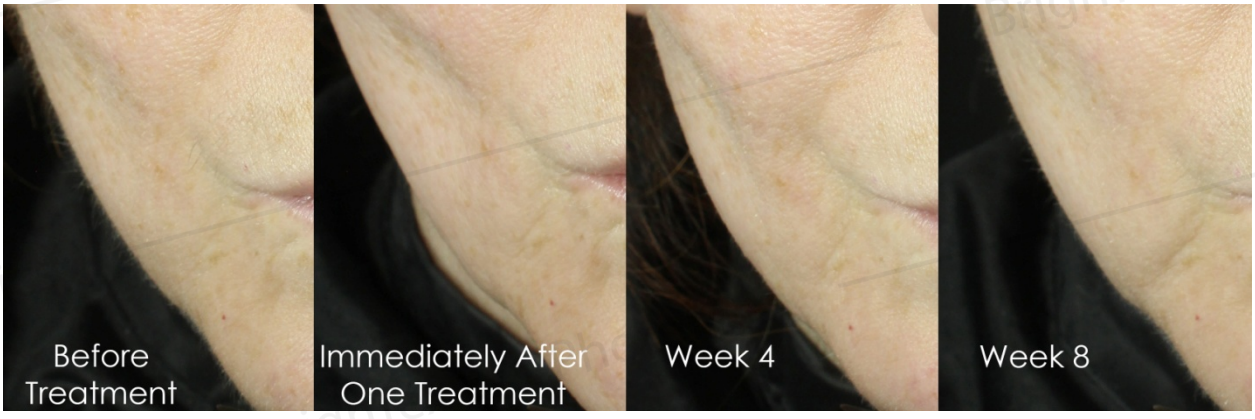
ABSTRACT

The objective of this clinical study is to assess the re-growth of Vellus hair in four weeks after single use of the Vellus Hair removal device by Group A and efficacy of the Vellus Hair removal device to reduce the appearance of fine lines and wrinkles, brighten dark spots and correct uneven skin tone following four weeks and eight weeks of continued use, as once in a week by Group B.

Measurements for Group A and B are assessed at Baseline (Before use of Vellus hair removal device), Immediate (Immediately after use of Vellus hair removal device), and Week 4 and at Week 8 only for Group B by BrighTex Bio Photonics Clarity Research 3D system and D – Squame measurements are recorded.

Subjects in Group A will use the Vellus Hair removal device once in the laboratory and will return after 4 weeks to assess the regrowth of Vellus hair. It was concluded that there was no increase in the hair pixels and surface area at Week 4 compared to baseline. Hence, the density of the Vellus hair did not increase from baseline for Group A.

Subjects in Group B will return after 4 weeks and 8 weeks of once in a week device use to assess changes in fine lines, wrinkles, dark spots, and uneven skin tone. It was concluded that the Hair Pixels and Surface Area at Immediate, Week 4 and Week 8, % of subjects showed improvement from range 74.10% - 84.70% whereas for Wrinkles - 2D Fine wrinkles average length showed improvement at Week 4 and Week 8 for Group B, % of subjects showed improvement from range 48.30% - 51.90%.



Section 1: OBJECTIVE

The objective of this clinical study is to assess the efficacy of the Vellus Hair removal device to reduce the appearance of fine lines and wrinkles, brighten dark spots and correct uneven skin tone following four weeks and eight weeks of continued use by Group B.

The secondary objective of this clinical study is to test the efficacy of the device to

- Exfoliate
- Remove facial Vellus hair after one use in the lab, and
- Assess the re-growth thickness and length of Vellus hair four weeks after use of the device by Group A.

Section 2: STUDYDESIGN

Approximately 30-35 female subjects will be enrolled in this clinical study to assess the efficacy of the Vellus Hair removal device to,

1) Exfoliate and

2) Remove facial Vellus hair and to assess the efficacy of the Vellus Hair removal device to reduce the appearance of fine lines and wrinkles, brighten dark spots and correct uneven skin tone following four weeks and eight weeks of use (Group B).

Approximately 5 female subjects will be enrolled in this clinical study to assess the efficacy of the Vellus Hair removal device to

1) Exfoliate,

2) Remove facial Vellus hair after one use in the lab, and

3) Assess the regrowth of Vellus hair four weeks after use of the device (Group A)

A Research Laboratory technician will assign the subjects to Group A or Group B respectively. Subject in Group A will use the Vellus Hair removal device once in the laboratory and will return after 4 weeks to assess regrowth of Vellus hair. Subjects in Group B will return after 4 weeks and 8 weeks of once weekly device use to assess changes in fine lines, wrinkles, dark spots, and uneven skin tone.

Procedures	Screening (Day -7 +/- 2 Days)	Baseline	Immediate (Approximately 15 Minutes Post-Use)	Week 4	Week 8*
Informed Consent Obtained	✓				
Inclusion and Exclusion Criteria Verified	✓				
Clarity Research 3D System Imaging		✓	✓	✓	✓*
Device Used in Laboratory (by Group A & B)		✓+			
Device Used at home (once in a week by Group B)				✓	✓
Test Materials, Use Instructions, and Daily Diaries Distributed (Group B only)			✓		
Test Materials, Use Instructions, and Daily Diaries Collected (Group B only)					✓*

+ indicates device used in laboratory following Baseline measurements.

* Group B only

Section 3: STUDY POPULATION

Each study's protocol has guidelines for who can or cannot (inclusion and exclusion criteria) participate in the study. These guidelines, called eligibility criteria, describe characteristics that must be shared by all participants as part of the informed consent. The criteria differ from study to study. They may include age, gender, medical history, and current health status.

A total of 30-35 female participants will be enrolled. Participants are recruited from the Research centre panellist database. Interested candidates will report to the program coordinator at the summit for screening and participants who meet all of the inclusion criteria and none of the exclusion criteria will be enrolled.

3.1 INCLUSION CRITERIA

Approximately 30-35 subjects will be enrolled in this study
Inclusion Criteria:
A subject may be eligible for study participation if all of the following criteria are met:
1) Subject is female between 18 and 65 years of age (Group A only) or between 40 and 65 years of age (Group B)
2) Subject exhibits mild to moderate fine lines and wrinkles in the crow's feet area
3) Subject exhibits mild to moderate facial dark spots;
4) Subject exhibits mild to moderate amount of facial Vellus hair
5) Subject agrees not to introduce any new cosmetic or toiletry products during the study
6) Subject is dependable and able to follow directions as outlined in the protocol
7) Subject agrees to discontinue use of any products that contain anti-aging/lightening /facial hair removal ingredients/benefits for the conditioning phase and for the duration of the study
8) Subject agrees not to wax/thread/shave/laser/tweeze or uses any hair removal products for the duration of the study (Vellus hair should be in its natural state)
9) Subjects should not use any other methods of exfoliation including microdermabrasion or scrubs
10) Subject is willing to participant in all study evaluations
11) Subject is in generally good health and has a current Panellist Profile Form on file at Clarity Research 3D Laboratory
12) Subject agrees to sign a Photography Release Form, providing consent for the capture of digital images for use in relation to this clinical study
13) Subject has completed a HIPAA Authorization Form in conformance with 45 CFR Parts 160 and 164
14) Subject understands and is willing to sign an Informed Consent Form in accordance with 21 CFR Part 50: "Protection of Human Subjects."

3.2 EXCLUSION CRITERIA

A subject is not eligible for study participation if any of the following criteria are met:
a) Subject is pregnant, nursing, planning a pregnancy, or not using adequate birth control;
b) Subject has received treatment with sympathomimetic, antihistamines, vasoconstrictors, non-steroidal anti-inflammatory agents, and/or systemic or topical corticosteroids within one week prior to initiation of the study;
c) Subject 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;
d) Subject is currently taking certain medications (including Retin - A, Tretinoin or similar) which, in the opinion of the Principal Investigator, may interfere with the study;
e) Subject has known allergies to skin treatment products or cosmetics, toiletries, and/or topical drugs;
f) Subject has active acne, open sore, sunburn, distressed skin, cuts, and abrasions;
g) Subject has been recently treated with a laser or has been recently chemically treated.

3.3 SUBJECT TERMINATION AND WITHDRAWAL

A subject may be discontinued from study participation at any time if the Principal Investigator or designated medical staffs feels that it is not in the subject's best interest to continue.

All subjects 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 subject withdrawals. The reason for the subject's withdrawal from the study will be specified in the subject's source documents and included in the final report.

Section 4: TEST METHOD

4.1 SUBJECT IDENTIFICATION

All subjects will be initially identified by a permanent Research centre panellist database identification number. Once the subject meets the qualification criteria, a study subject number will be assigned. This permanent subject number will be assigned in sequence as subjects are enrolled in the study.

4.2 SCREENING VISIT

Subjects will report to the testing facility with bare faces, free from makeup or skin products. Informed consent will be obtained. Inclusion and exclusion criteria will be verified. Subjects will be assigned to Group A or Group B at the discretion of the Clarity Research Laboratory technician. Subjects will be instructed to refrain from using any facial products such as anti-aging, lightening, and/or facial hair removal products on the face for the conditioning phase.

4.3 BASELINE VISIT

Subjects will return to the testing facility following the 7-day (±2days) conditioning phase with bare faces, free from makeup or skin products. Subjects will acclimate to ambient laboratory conditions for approximately 15 minutes.

4.3.1 Group A (approximately 5 subjects): Clarity Research 3D System images (eyes closed) will be captured to assess Vellus hair. D Squame measurements will be taken. A technician will perform the first use of the device in the lab and instruct the subjects in its use. Subjects will acclimate for 15 minutes post device use. Immediately/15 minutes post use, Clarity Research 3D System images (eyes closed) will be captured to assess Vellus hair. D-Squame measurements will be taken. Subjects will be instructed to continue using their regular facial cleansers and products that do not contain anti-aging/lightening/hair removal ingredients/benefits for the duration of the study. Subjects will be instructed to return after 4 weeks to assess regrowth of Vellus hair. Subjects in Group A will be instructed not to use any hair removal products on the face for the duration of the study.

4.3.2 Group B (approximately 25-30 subjects): Clarity Research 3D System images (eyes closed) will be captured to assess Vellus hair, fine lines and wrinkles, dark spots and uneven skin tone. D-Squame measurements will be taken. A technician will perform the first use of the device in the lab and instruct the subjects in its use. Subjects will acclimate for 15 minutes post device use. Immediately 15 minutes post use, Clarity Research 3D System images (eyes closed) will be captured to assess Vellus hair, fine lines and wrinkles, dark spots and uneven skin tone. D-Squame measurements will be taken. Subjects will be provided with the Vellus Hair removal device, pre removal cleanser, and post removal moisturizer to be used once per week for the duration of the study. Subjects would apply SPF cream daily throughout the duration of the study. Subjects will be provided with a diary to record uses of the Vellus Hair removal device. Subjects will be instructed to continue using their regular facial cleansers and products that do not contain anti-aging/lightening/hair removal ingredients/benefits for the duration of the study. Subjects will be instructed to return after 4 and 8 weeks to assess changes in fine lines, wrinkles, dark spots, and uneven skin tone.

Subjects will be instructed to rinse their face with water post device use and before the post removal moisturizer.

4.4 WEEK 4

Subjects will return to the testing facility approximately 4 weeks after Baseline with bare faces, free from makeup or skin products. Subjects will acclimate to ambient laboratory conditions for approximately 15 minutes. Daily diaries will be reviewed by clinical study staff to confirm study compliance.

Clarity Research 3D System images will be captured of subjects in Group A to assess regrowth of Vellus hair. Following study evaluations, subjects in Group A will be dismissed from study participation.

Clarity Research 3D System images will be captured of subjects in Group B to assess changes in fine lines, wrinkles, dark spots, and uneven skin tone. Following study evaluations, subjects in Group B will be instructed to continue use of the device and accessory products, and to return to the testing facility in four weeks.

4.5 WEEK 8

Subjects in Group B will return to the testing facility approximately 8 weeks after Baseline with bare faces, free from makeup or skin products. Subjects will acclimate to ambient laboratory conditions for approximately 15 minutes. Daily diaries will be reviewed for compliance and collected.

Clarity Research 3D System images will be captured for the subjects in Group B to assess changes in fine lines, wrinkles, dark spots, and uneven skin tone. Following study evaluations, subjects in Group B will be dismissed from study participation.

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. The Clarity Research 3D System features 3 cameras, each with 25 megapixels and SLR image capture in 16-bit. The Automated image recognition includes artificial intelligence for facial and skin area recognition, high precision facial detection, automation for facial zoning and zoning by area of interest, and data tracking by region of interest. The Clarity Research 3D System captures 6 types of skin images, including diffuse white light, melanin, haemoglobin, texture, 3D

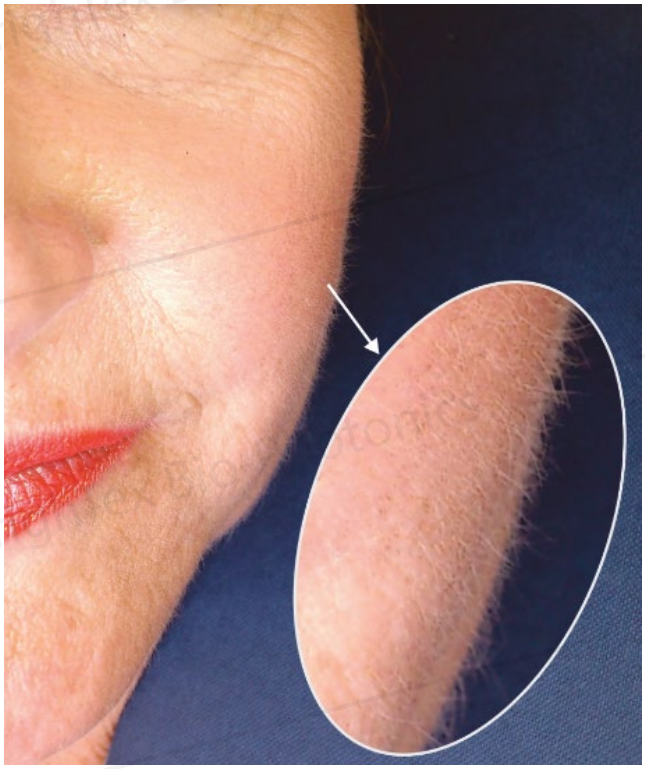
macro structure, and 3D micro structure. The system also allows for simultaneous front, left and right profile capture with no repositioning requirements.
The following parameters will be assessed:
•Surface spots: spot count, size distribution, and pigment intensity
•Evenness of skin tone
•Fine lines and wrinkles crow's feet area: surface area, average severity, average length, and average width of emerging lines, fine lines, and deep lines and wrinkle object count.
• Density and length of Vellus hair
Clarity Research 3D System photography (eyes closed) will be captured at Baseline, Immediate, and Week 4 for Group A. Clarity Research 3D System photography will be captured at Baseline, Immediate, Week 4, and Week 8 for Group B.

5.2 SKIN FEATURE TO BE STUDIED

5.2.1 Vellus Hair

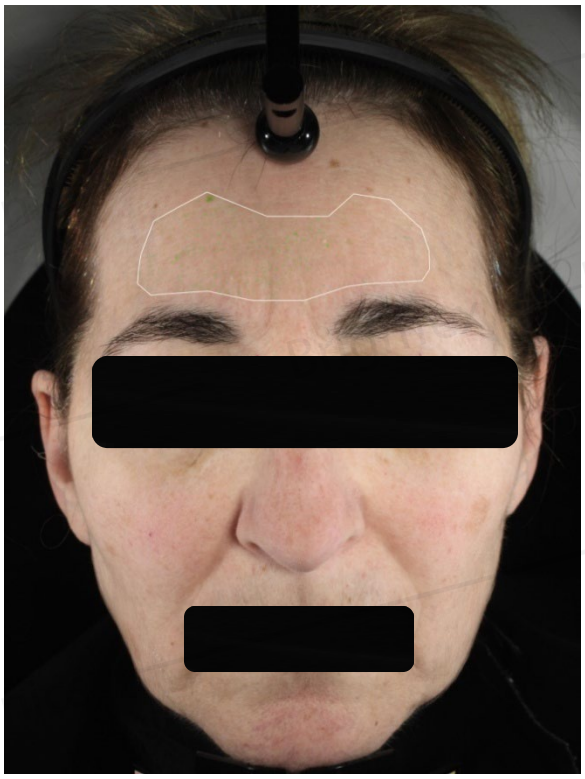
Vellus hair is short, thin, slight-colored, and barely noticeable thin hair that develops on most of a person's body during childhood. Exceptions include the lips, the back of the ear, the palm of the hand, the sole of the foot, some external genital areas, the navel, and scar tissue. The density of hair – the number of hair follicles per area of skin – varies from person to person. Each strand of Vellus hair is usually less than 2 mm (1/13 inch) long and the follicle are not connected to a sebaceous gland.

Sample Image:

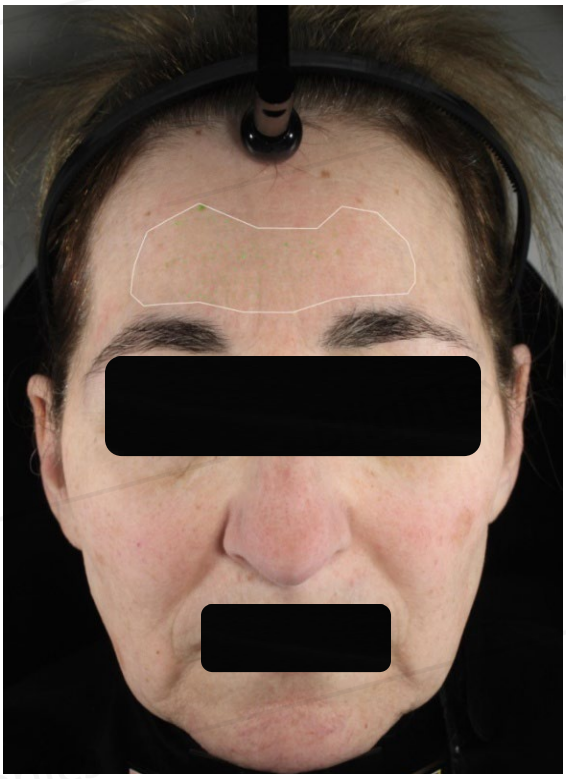


Sample Result Images:

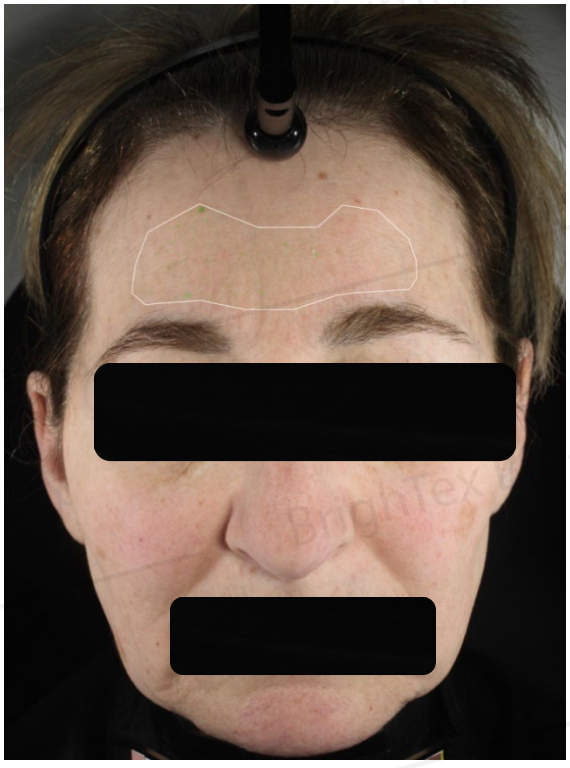
T0 – Front



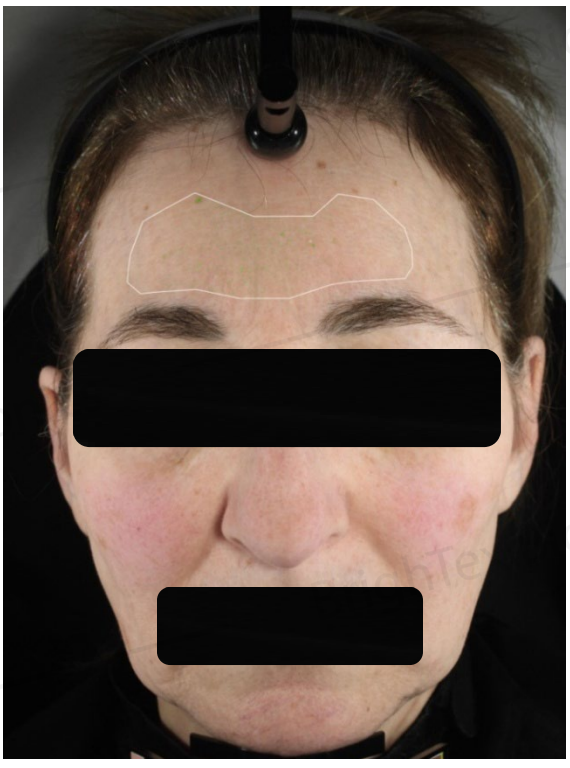
T1-Front



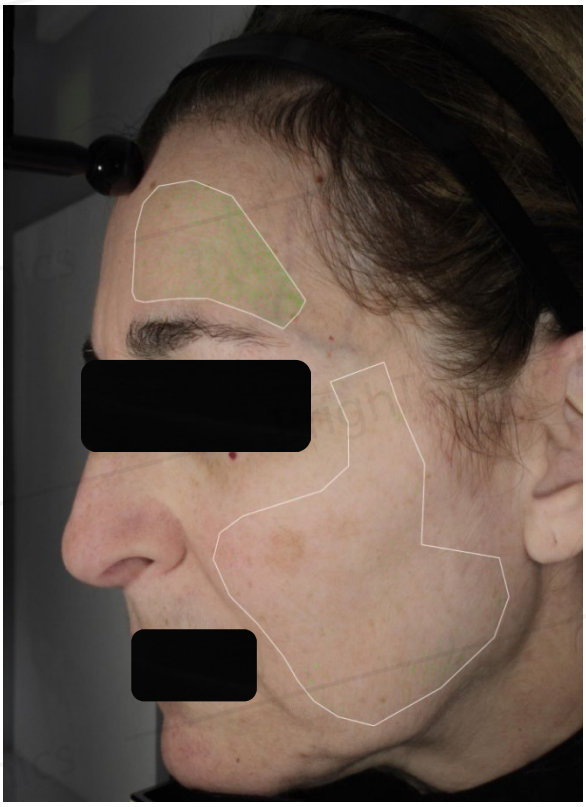
T2-Front



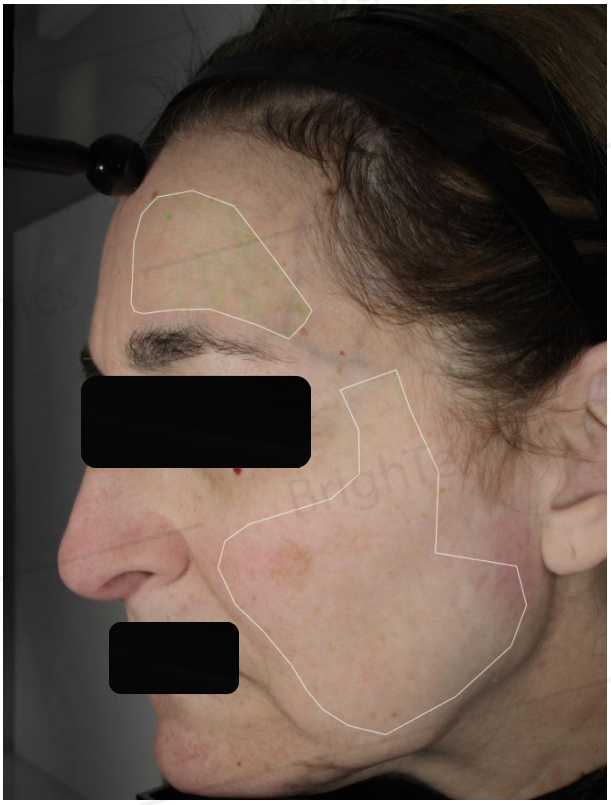
T3-Front



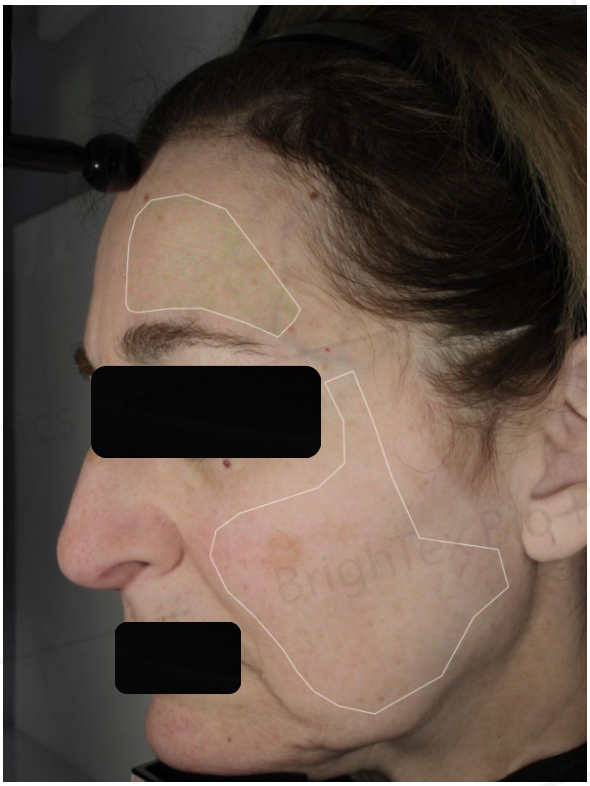
T0 – Left



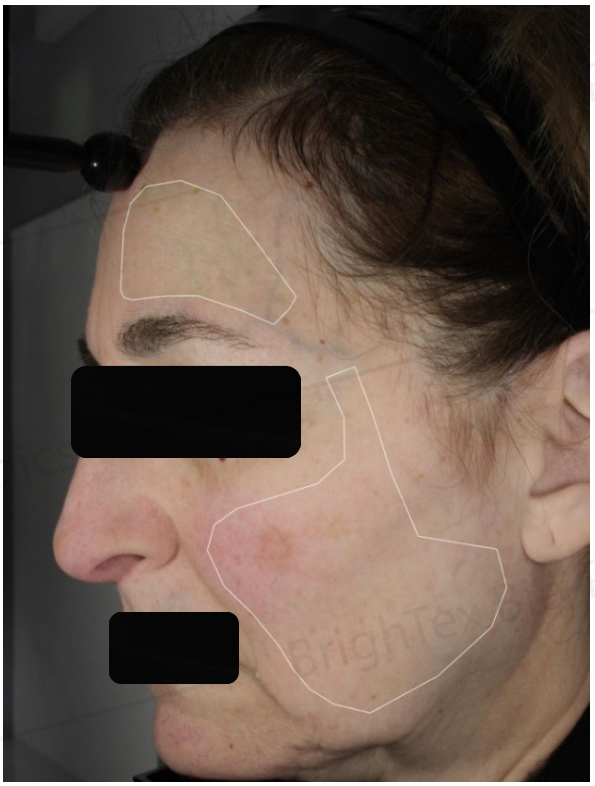
T1-Left



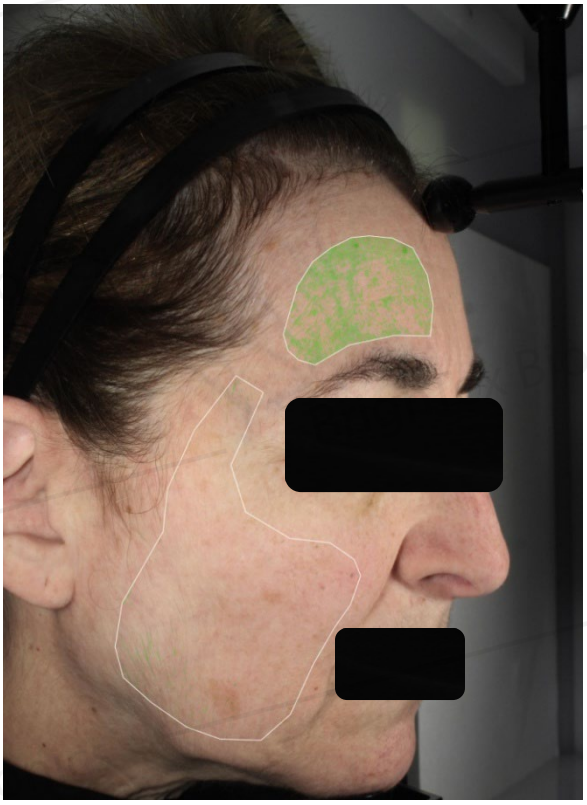
T2-Left



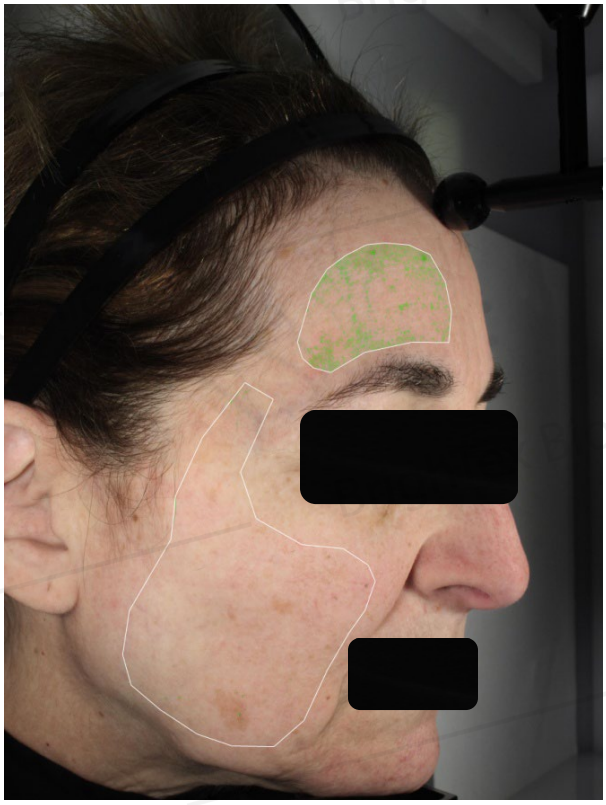
T3-Left



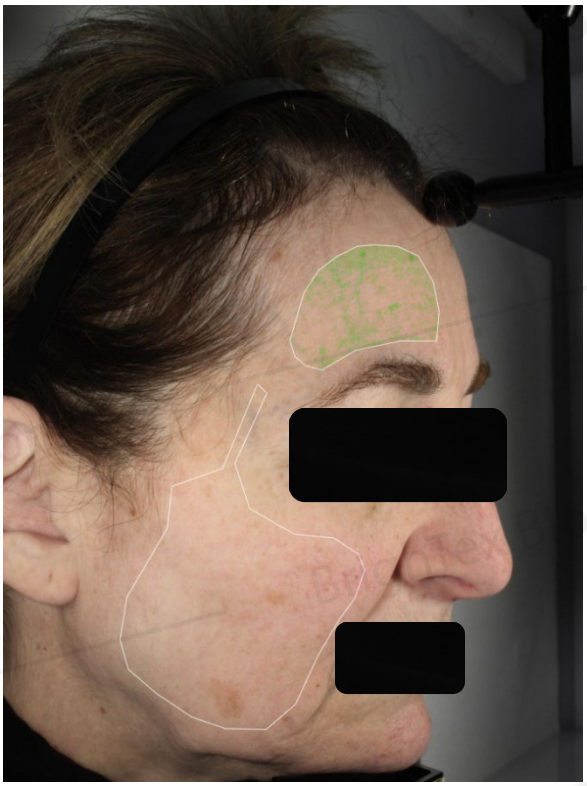
T0 – Right



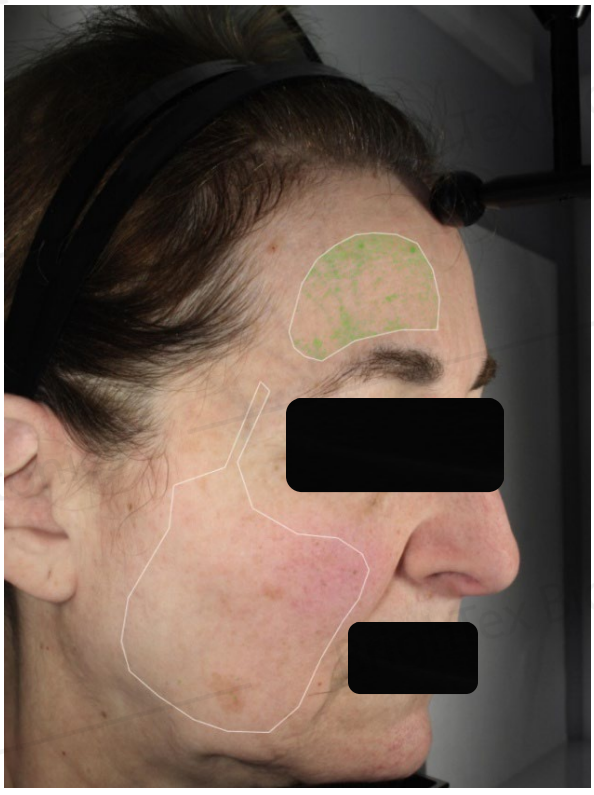
T1-Right



T2-Right



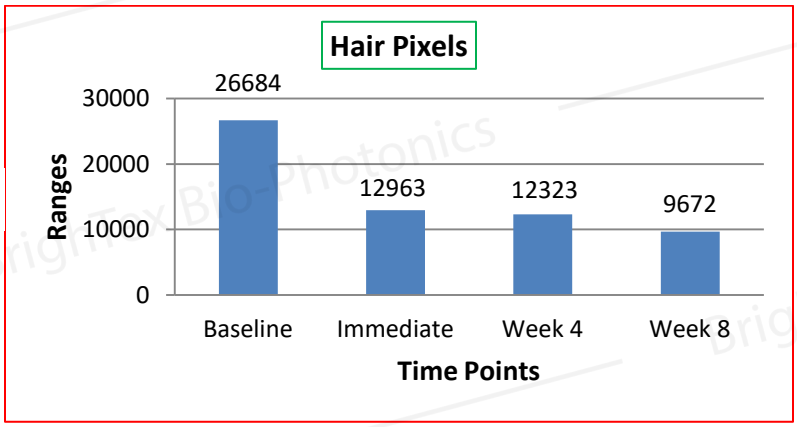
T3-Right



Measured Parameters: Hair Pixels, surface Area (%)

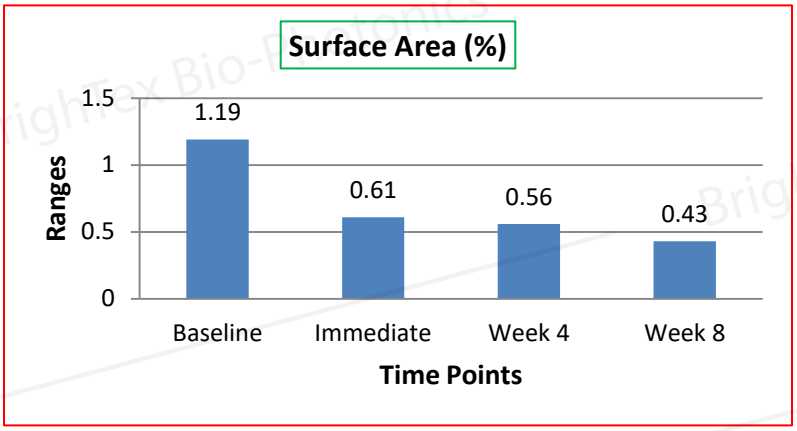
Hair Pixels: Total number of Hair pixel count.

Subject 08 Results

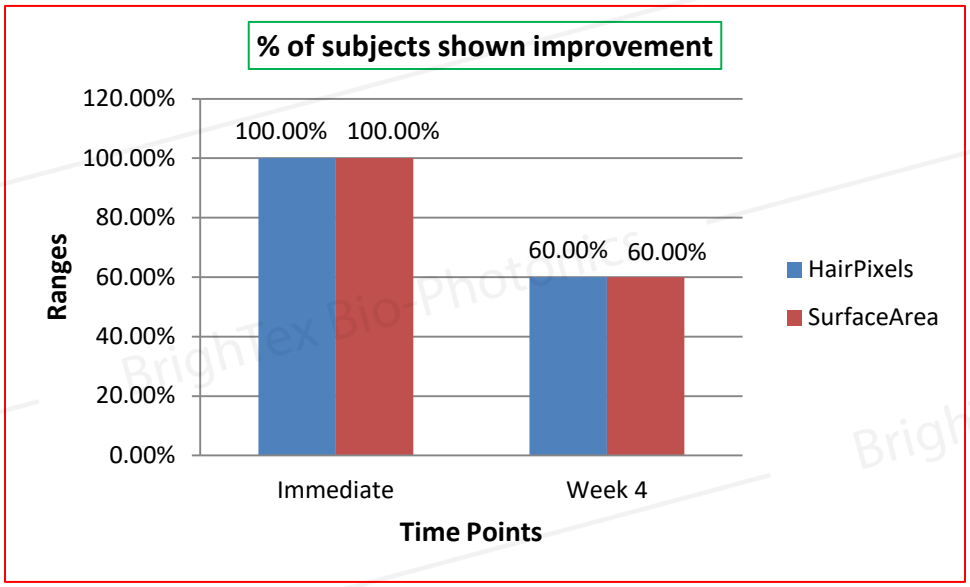


Surface Area (%): This measures the area affected by the Hair pixels.

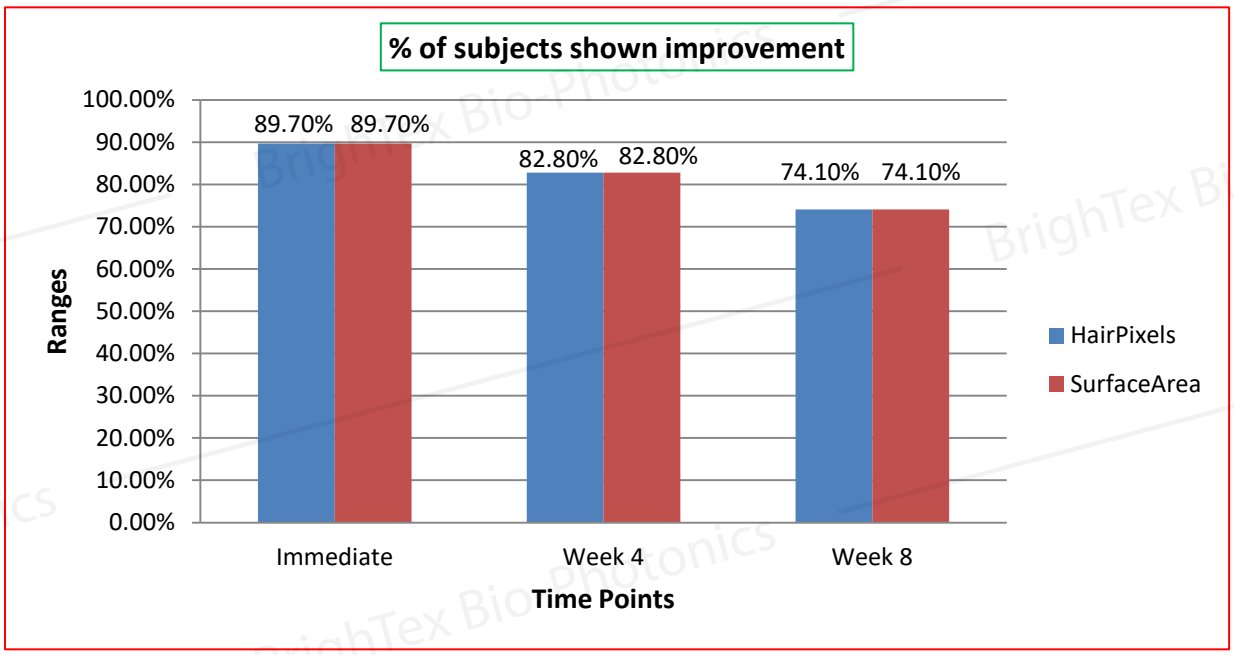
Subject 08 Results



Vellus Hair Group A Statistical Summary:



Vellus Hair Group B Statistical Summary:



5.2.2 Surface Spots

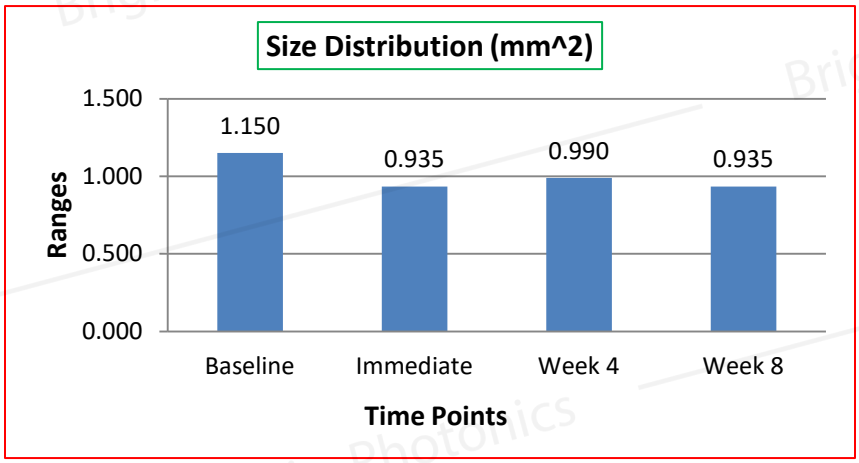
Pigmentation or spots is a localized change in skin color caused by the variation in the amount and type of melanin production underneath the skin.

Measured Parameters: Size Distribution (mm^2), Spot Count

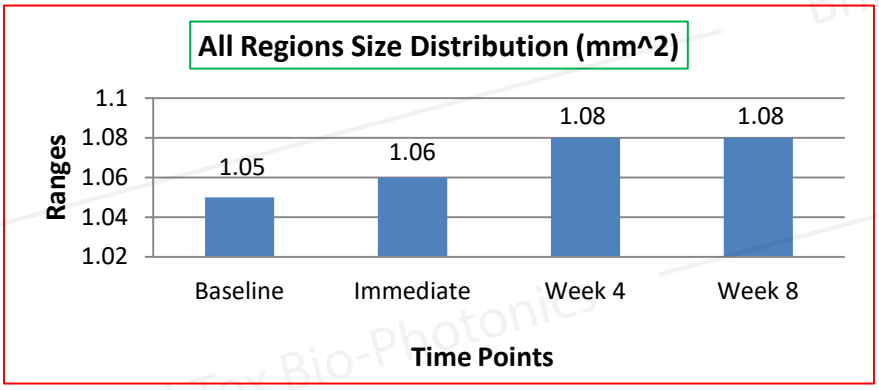
a. Size Distribution (mm^2):

It means the Standard deviation of the recognized spots size. If there is a decrease in size of the recognized spots from baseline to subsequent sessions then it is a positive improvement.

Subject 16 Results



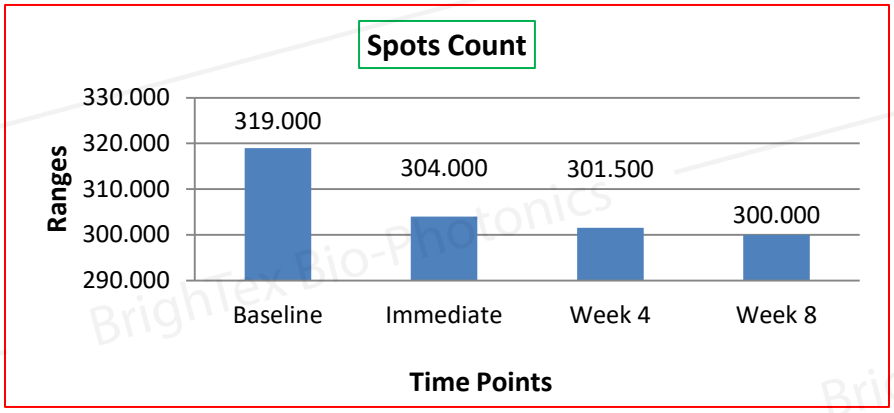
Overall Study Trends:



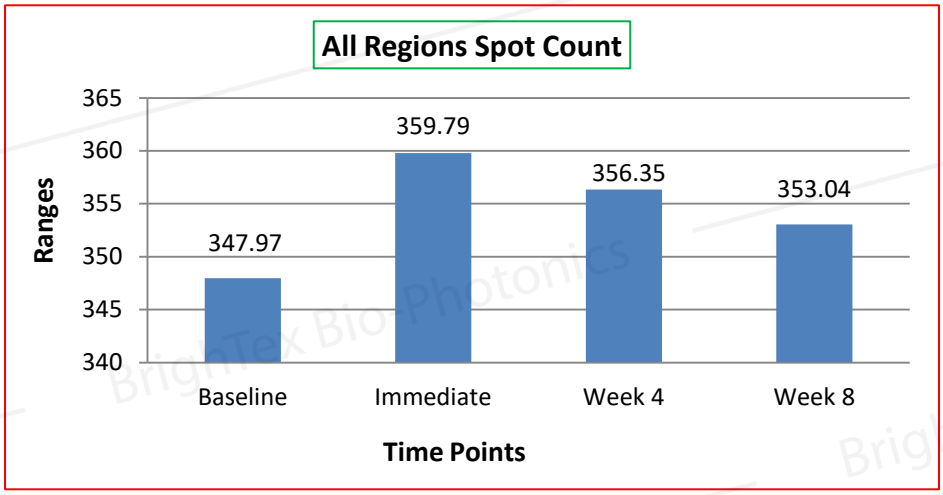
b. Spots Count:

Total number of spots recognized. If there is a decrease in the count of recognized spots from baseline to subsequent sessions then it is a positive improvement.

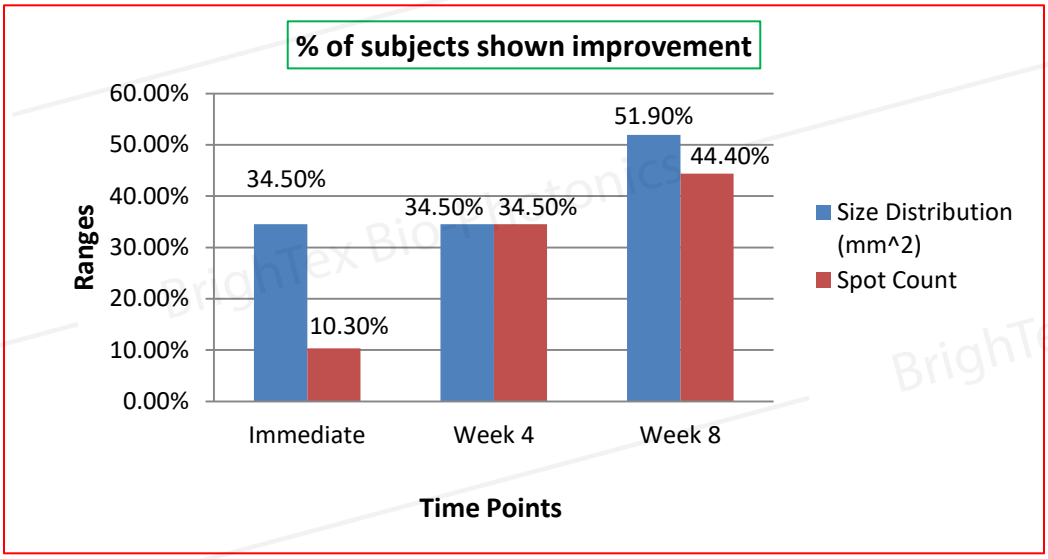
Subject 21 Results



Overall Study Trends:



SurfaceSpots_2D Statistical Summary (Group B):



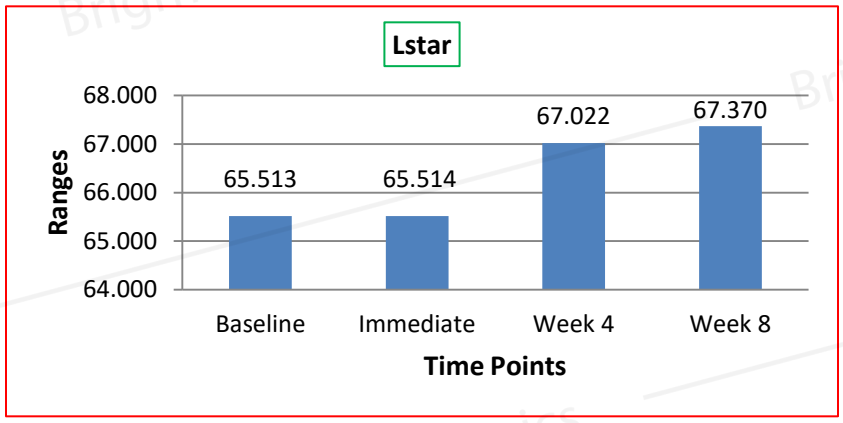
5.2.3 Evenness of skin tone

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.

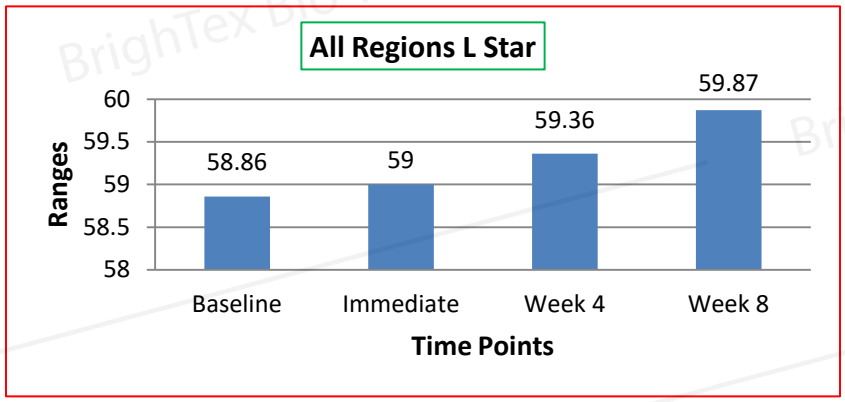
Measured Parameters: Lstar

Lstar: As L* increases the brightness in Skin color increases

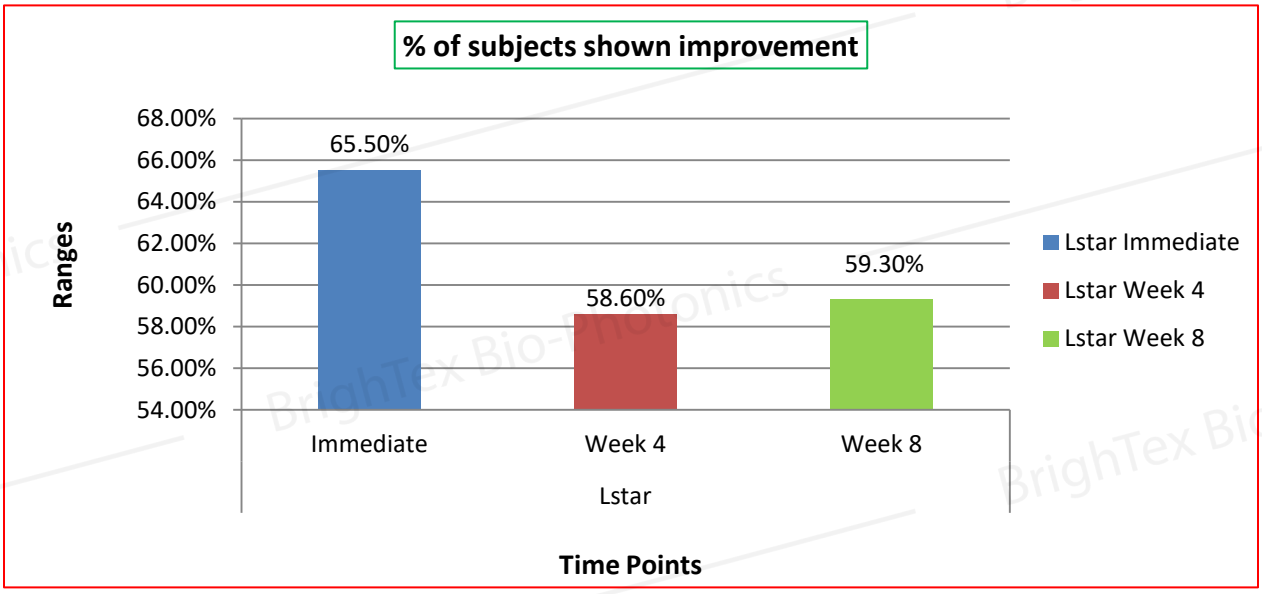
Subject 14 Results



Overall Study Trends:



Skin Color_2D Group B Statistical Summary:



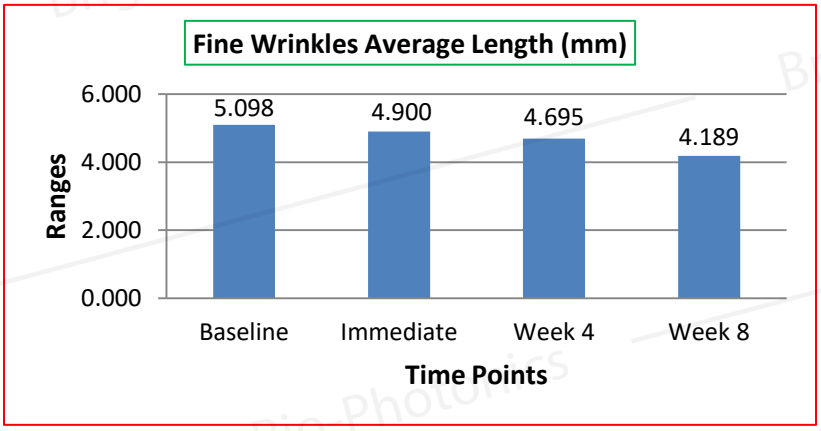
5.2.4 Fine lines and wrinkles crow's feet area

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.

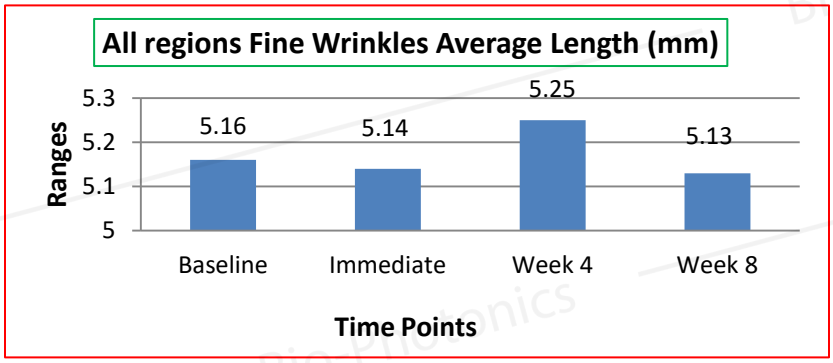
Measured Parameters: Fine Wrinkles Average Length (mm

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

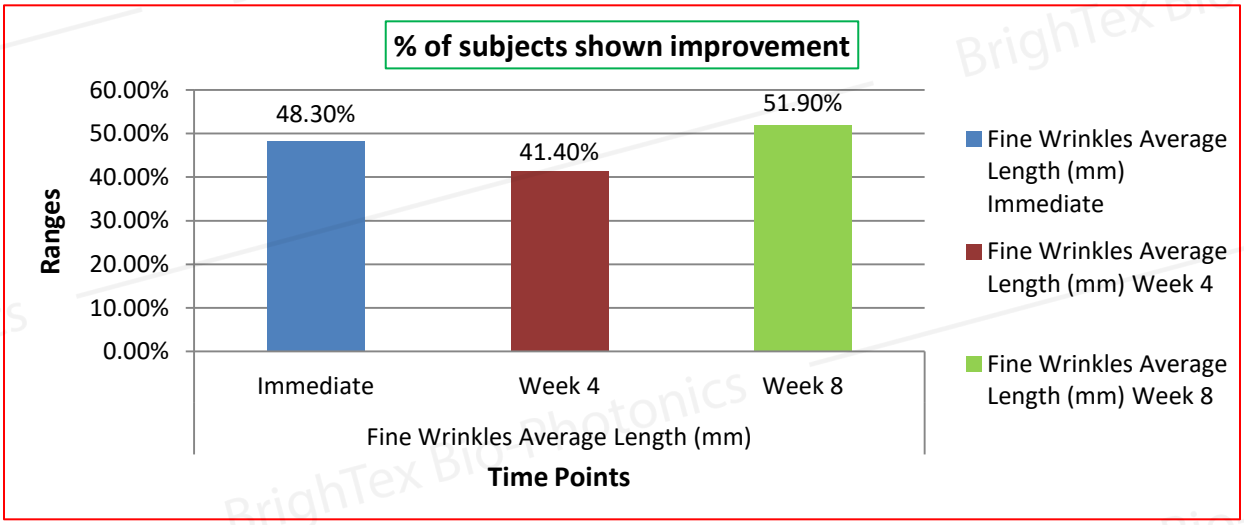
Subject 20 Results



Overall Study Trends:



Wrinkles 2D Statistical Summary:



Section 6: Product Use Instructions

PRE Removal, VELLUS HAIR REMOVAL, and POST Removal should be used once per week. Subjects will be instructed to rinse their faces with water post-device use and before the POST removal moisturizer.

DERMAPROTECT SPF50 should be applied each morning to participants face, daily, for the duration of the 8 weeks. Makeup may be applied following SPF application.

6.1 HOW TO USE VELLUS HAIR REMOVAL DEVICE

1. Wash face with pre removal cleanser. Rinse well and pat dry.

2. Load a new Edge, turn on device. Beginning in front of your ear at cheekbone, hold skin taut with finger from opposite hand. Using short feathery strokes glide VELLUS HAIR REMOVAL across entire face, avoiding surface of lips, nose, and eyelids

3. Press eject button to release Edge and dispose in waste basket. Massage a small amount of post removal moisturizer onto skin after treatment.

Section 7: CONCLUSION

7.1 D-Squame

There was 100% improvement across all subjects in the D-Squame measurements for Group A and Group B immediately post application.

Clarity Research 3D System

There was no increase in the hair pixels/surface area for Group A at Week 4 compared to baseline. Hence, the density of the Vellus hair did not increase from baseline in Group A.

The following parameters showed improvements in Group B for 2D Vellus Hair: Hair Pixels and Surface Area, for the Forehead and Cheek regions at Immediate, Week 4 and Week 8.

The following parameter showed improvements in Group B for Wrinkle 2D: Fine wrinkles average length at Week 4 and Week 8.