A Single-Center Clinical Study to Assess the Efficacy of Two Topical Products for Improving the Appearance of Moderate Dry, Persistently Rough, Bumpy Skin on the Body

Hypothesis: The Sponsor's test materials will produce a statistically significant improvement in efficacy parameter clinical grading scores, Corneometer, and Cutometer measurements, as well as image analysis of skin color and texture parameters over the course of 4 weeks of use when compared with baseline scores/values. The Sponsor's test material(s) will not produce a statistically significant worsening in Tewameter measurements over the course of 4 weeks when compared to baseline scores. Furthermore, the Sponsor's test material(s) will be well perceived by the subjects according to self-assessment questionnaires.

Key Results:

Summary

Sponsor's test product, "*Body Smoothing Lotion #2367-03"* had shown overall significant improvement in the clinical and global grading of efficacy parameters as compared to the marketed, '*Benchmark Body Treatment #883140023210'.* While the efficacy of both products were comparable in the arms of the test subjects, a marked difference in improvement was noted in the thigh with the sponsors test product, in regard to all parameters, except for dryness and scaling. In addition, significant improvement in skin moisture, as assessed by Corneometer was observed with the test product. There was no significant difference between the two products in terms of skin moisture or elasticity. Though the test product's performance in reducing transepidermal water loss, as assessed by Tewameter, was in the normal range, it was not equivalent to the comparator.

Detailed results of each parameter

Clinical Grading of Efficacy Attributes

1. Visual Bumpiness:
    - The test product caused significant reduction in bumpiness in arms and thighs of the subject population over a period of 4 weeks.
    - Average bumpiness in arms (left and right upper arm) at baseline as compared to week 4 in the test product and the comparator groups were, 1.83 ±0.64 vs. 0.98 ±0.73 ($p<0.001$) and 1.81 ±0.60 vs. 1.02 ±0.73 ($p<0.001$), respectively.
    - % of change in the mean visual bumpiness in arms for the test product vs. the comparator was -46 and -44.4%, respectively. No subject in either group had a worsening of visual bumpiness.
    - Average bumpiness in thigh (left and right thigh) at baseline as compared to week 4 in the test product group and the comparator groups were, 1.81 ±0.44 vs. 0.71 ±0.84 ($p=0.031$) and 2.10 ±0.22 vs. 1.31 ±0.13 ($p=0.125$), respectively.
    - % of change in the mean visual bumpiness in the thighs for the test product vs. the comparator was -61.4 and -38.2%, respectively. No subject in either group had a worsening of visual bumpiness.
    - Although, the improvement in visual bumpiness was comparable among the products

with no statistically significant difference, the test product showed greater improvement in more friction areas like, thighs.

2. Tactile Roughness:
    - The test product caused significant reduction in tactile roughness in arms and thighs of the subject population over a period of 4 weeks.
    - Average roughness in arms (left and right upper arm) at baseline as compared to week 4 in the test product and the comparator groups were, 1.86 ±0.65 vs. 0.82 ±0.63 ($p<0.001$) and 1.88 ±0.56 vs. 0.84 ±0.62 ($p<0.001$), respectively.
    - % of change in the mean tactile roughness in arms for the test product vs. the comparator was -56 and -55.8%, respectively. No subject in either group had a worsening of effects.
    - Average roughness in thigh (left and right thigh) at baseline as compared to week 4 in the test product group and the comparator groups were, 1.69 ±0.51 vs. 0.46 ±0.56 ($p=0.031$) and 2.10 ±0.22 vs. 0.94 ±0.66 ($p=0.125$), respectively.
    - % of change in the mean tactile roughness in the thighs for the test product vs. the comparator was -72.5 and -55.9%, respectively. No subject in either group had a worsening of effects.
    - Although, the improvement in tactile roughness was comparable among the products with no statistically significant difference, the test product showed greater improvement in more friction areas like, thighs.

3. Discoloration:
    - The test product caused significant reduction in discoloration in arms and thighs of the subject population over a period of 4 weeks.
    - Average discoloration in arms (left and right upper arm) at baseline as compared to week 4 in the test product and the comparator groups were, 1.65 ±0.79 vs. 0.82 ±70 ($p<0.001$) and 1.71 ±0.70 vs. 0.96 ±0.76 ($p<0.001$), respectively.
    - % of change in the mean discoloration in arms for the test product vs. the comparator was -49.2 and -43.8%, respectively. No subject in either group had a worsening of effects.
    - Average discoloration in thigh (left and right thigh) at baseline as compared to week 4 in the test product group and the comparator groups were, 1.47 ±0.66 vs. 0.58 ±0.80 ($p=0.031$) and 1.75 ±0.50 vs. 1.00 ±0.35 ($p=0.125$), respectively.
    - % of change in the mean discoloration in the thighs for the test product vs. the comparator was -62.2 and -40.7%, respectively. No subject in either group had a worsening of effects.
    - Although, the improvement in discoloration was comparable among the products with no statistically significant difference, the test product showed greater improvement in more friction areas like, thighs.

4. Dryness:

- The test product caused statistically significant reduction in dryness in the arms of the subject population over a period of 4 weeks. Although, a reduction in dryness was noticed in the thighs of the subjects, it did **not** reach statistical significance.

- Average dryness in arms (left and right upper arm) at baseline as compared to week 4 in the test product and comparator groups were, 1.05 ±0.61 vs. 0.16 ±0.42 ($p<0.001$) and 1.34 ±0.66 vs. 0.11 ±0.33 ($p<0.001$), respectively.

- % of change in the mean dryness in arms for the test product vs. the comparator was -84.3 and -91.5%, respectively.

- Out of 38 subjects finishing the study at week 4 in the test product group, 32 showed improvement in dryness in arms, 5 had no change and one showed worsened dryness of skin. While, no subject in the comparator group (out of 33) had a worsening of dryness in arms.

- Average dryness in thigh (left and right thigh) at baseline as compared to week 4 in the test product group and comparator groups were, 0.75 ±0.76 vs. 0.25 ±0.61 ($p=0.500$) and 1.10 ±0.82 vs. 0.13 ±0.25 ($p=0.250$), respectively.

- % of change in the mean dryness in the thighs for the test product vs. the comparator was -62.5 and -90.0%, respectively.

- Out of 6 subjects finishing the study at week 4 in the test product group, two showed improvement in dryness in thighs, three had no change and one showed worsened dryness of skin. While, no subject in the comparator group (out of 4) had a worsening of effects.

- The improvement in dryness was comparable among the products with no statistically significant difference between the groups.

5. Scaling:

    - The test product caused statistically significant reduction in scaling in the arms of the subject population over a period of 4 weeks. Although, a reduction in scaling was noticed in the thighs of the subjects, it did **not** reach statistical significance.

    - Average scaling in arms (left and right upper arm) at baseline as compared to week 4 in the test product and comparator groups were, 0.24 ±0.49 vs. 0.05 ±0.22 ($p<0.006$) and 0.47 ±0.54 vs. 0.00 ±0.00 ($p<0.001$), respectively.

    - % of change in the mean scaling in arms for the test product vs. the comparator group was -79.5 and -100.0%, respectively.

    - Out of 38 subjects finishing the study at week 4 in the test product group, 10 showed improvement in scaling in arms, 26 had no change and two showed worsened scaling. While, no subject in the comparator group (out of 33) had a worsening of effects.

    - Average scaling in thigh (left and right thigh) at baseline as compared to week 4 in the test product group and comparator groups were, 0.31 ±0.70 vs. 0.08 ±0.20 ($p=1.000$) and 0.60 ±0.89 vs. 0.00 ±0.00 ($p=0.500$), respectively.

    - % of change in the mean scaling of thighs in the test product vs. the comparator

group was -80.0 and -100.0%, respectively. No subject in either group had a worsening of effects in the thighs.

- The improvement in scaling was comparable among the products with no statistically significant difference between the groups.

6. Global efficacy:

    - The test product caused significant improvement in global efficacy in arms and thighs of the subject population over a period of 4 weeks.

    - Average global efficacy in arms (left and right upper arm) at baseline as compared to week 4 in the test product and the comparator groups were, 1.80 ±0.64 vs. 0.97 ±0.70 ($p<0.001$) and 1.86 ±0.59 vs. 1.01 ±0.74 ($p<0.001$), respectively.

    - % of change in the mean global efficacy in arms for the test product vs. the comparator was -46.0 and -46.2%, respectively. No subject in either group had a worsening of effects.

    - Average global efficacy in thigh (left and right thigh) at baseline as compared to week 4 in the test product and the comparator groups were, 1.81 ±0.44 vs. 0.71 ±0.84 ($p=0.031$) and 2.15 ±0.22 vs. 1.38 ±0.14 ($p=0.125$), respectively.

    - % of change in the mean global efficacy in the thighs of subjects for the test product vs. the comparator was -61.4 and -37.1%, respectively.

    - Although, the improvement in global efficacy was comparable among the products with no statistically significant difference, the test product showed greater improvement in more friction areas like, thighs.

Bioinstrumentation

1. Corneometer (Skin dryness/moisture):

    - The test product caused a significant improvement in skin moisture (upper arm) over a period of 4 weeks.

    - Average skin moisture at baseline as compared to week 4 in the test product and the comparator groups were, 25.08 ±9.76 vs. 32.29 ±11.87 ($p<0.001$) and 23.36 ±6.87 vs. 35.30 ±12.42 ($p<0.001$), respectively.

    - Out of 38 subjects finishing the study at week 4 in the test product group, 27 showed improvement of dryness in arms, zero had no change, and 11 showed worsening of skin dryness. While, in the comparator group, 33 subjects finished the study at week 4, 29 had improvement, zero no change and 4 showed worsening of dryness.

    - The improvement in skin moisture was comparable among the products with no statistically significant difference between the groups.

2. Cutometer-Pure Elasticity:

- The test product showed a slight improvement in pure elasticity in the upper arm over a period of 4 weeks, though it did **not** reach statistical significance.

- Average pure elasticity at baseline as compared to week 4 in the test product and the comparator groups were, 0.66 ±0.14 vs. 0.72 ±0.16 ($p<0.066$) and 0.64 ±0.14 vs. 0.70 ±0.12 ($p<0.029$), respectively.

- Out of 37 subjects finishing the study at week 4 in the test product group, 21 showed improvement, zero had no change, and 16 showed worsening of pure elasticity. While, in the comparator group, 33 subjects finished the study at week 4, 23 had improvement, zero no change and 10 showed worsening of pure elasticity.

- The improvement in pure elasticity was higher in the comparator group, though no statistically significant difference was observed between the groups.

3. Cutometer-Biological Elasticity:

    - The test product and the comparator showed a slight improvement in Biological elasticity in the upper arm over a period of 4 weeks. However, neither of the groups reached a statistically significant difference from the baseline.

    - Average biological elasticity at baseline as compared to week 4 in the test product and the comparator groups were, 0.48 ±0.13 vs. 0.53 ±0.15 ($p<0.055$) and 0.47 ±0.12 vs. 0.49 ±0.10 ($p<0.137$), respectively.

    - No statistically significant difference was observed between the groups.

    - Out of 37 subjects finishing the study at week 4 in the test product group, 24 showed improvement, one had no change and 12 showed worsening of biological elasticity. While, in the comparator group, 33 subjects finished the study at week 4, 21 had improvement, zero no change and 12 showed worsening of biological elasticity.

4. Cutometer-Extensibility and Resiliency:

    - The test product and the comparator did **not** show any improvement in the extensibility and resiliency of skin in the upper arm of subjects over a period of 4 weeks.

    - No statistically significant difference was observed between the groups.

    - Out of 37 subjects finishing the study at week 4 in the test product group, 20 showed improvement in extensibility, zero had no change, and 17 showed worsening of skin extensibility. While, in the comparator group, 33 subjects finished the study at week 4, 20 had improvement, zero no change and 13 showed worsening of skin extensibility.

    - Out of 37 subjects finishing the study at week 4 in the test product group, 22 showed improvement in resiliency, zero had no change and 15 showed worsening of skin resiliency. While, in the comparator group, 33 subjects finished the study at week 4, 20 had improvement, one had no change and 12 showed worsening of skin resiliency.

5. Tewameter (transepidermal water loss):

    - The test product showed a slight improvement in reducing the transepidermal water loss in the upper arm over a period of 4 weeks, though it did **not** reach statistical significance.

    - Average transepidermal water loss at baseline as compared to week 4 in the test product and the comparator groups were, 5.33 ±1.59 vs. 5.76 ±1.65 ($p<0.066$) and 6.31 ±6.45 vs. 4.54 ±3.28 ($p<0.005$), respectively.

    - Out of 38 subjects finishing the study at week 4 in the test product group, 17 showed improvement in water loss, zero had no change and 21 showed increased water loss. While, in the comparator group, 33 subjects finished the study at week 4, 22 had improvement, zero had no change and 11 showed worsening of water loss.

    - The improvement in transepidermal water loss was higher in the comparator group, as compared to the test product group. ($p= 0.003$, as calculated by Wilcoxon Rank Sum test)

Self-assessment Questionnaires

- The test product showed a marked improvement in the way subject feels confident and comfortable about how their skin looks and feels.

- % of subjects whose response ranged from ‘somewhat agree to strongly agree’ for how comfortable they are in their own skin at baseline vs. week 4 was 46.3% and 68.4 %, respectively.

- % of subjects whose response ranged from ‘somewhat agree to strongly agree’ for how confident they are in their own skin at baseline vs. week 4 was 41.5% and 65.8%, respectively.

- % of subjects whose response ranged from ‘somewhat agree to strongly agree’ for how much they love their skin looks and feels at baseline vs. week 4 was 14.6% and 55.3%, respectively.

Patient 5 Arms Baseline Visable Light

Left arm

Right arm

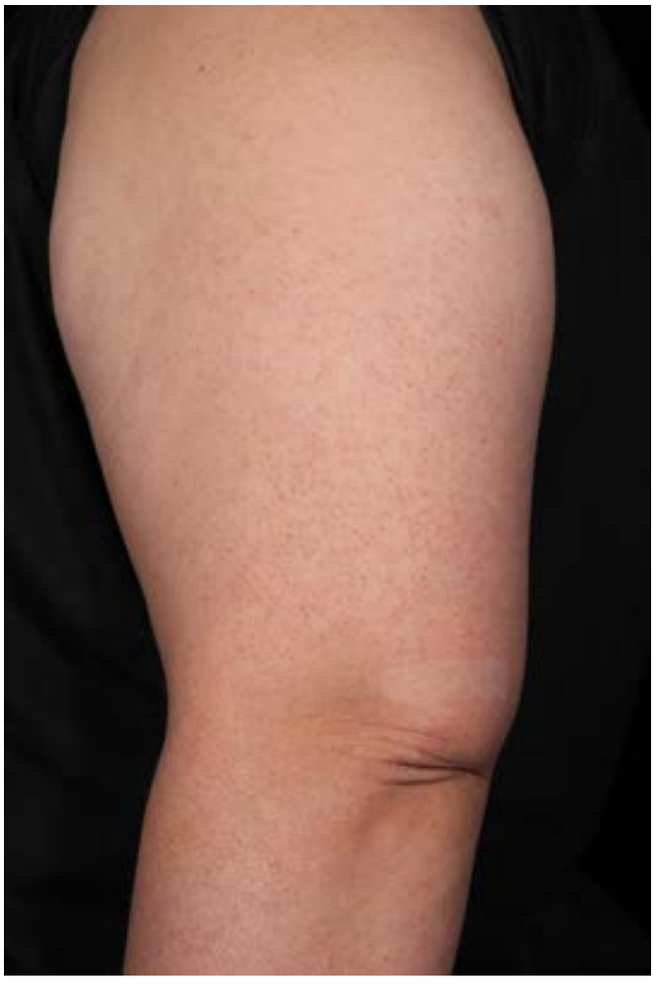
Patient 5 Arms 4 week Visable Light

Left arm

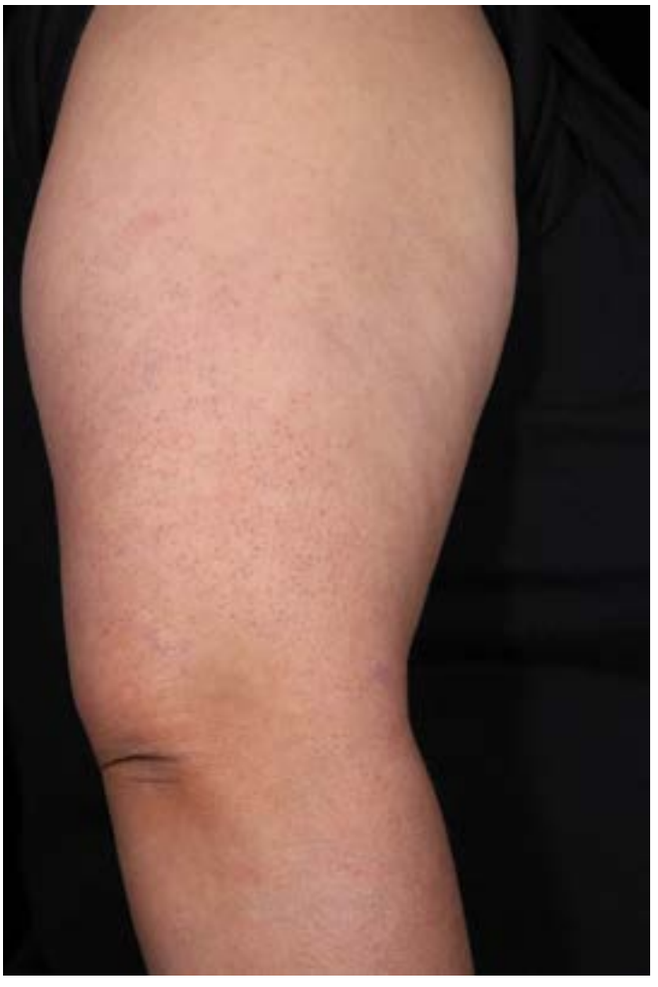
Right arm

Patient 10 Arms Baseline Visable Light

Left arm

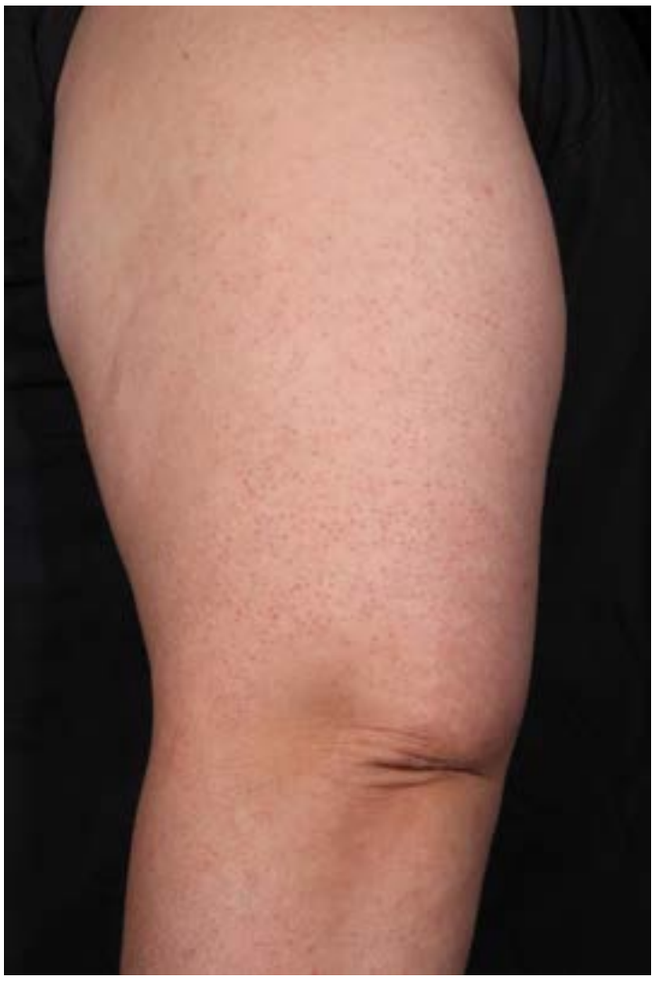


Right arm

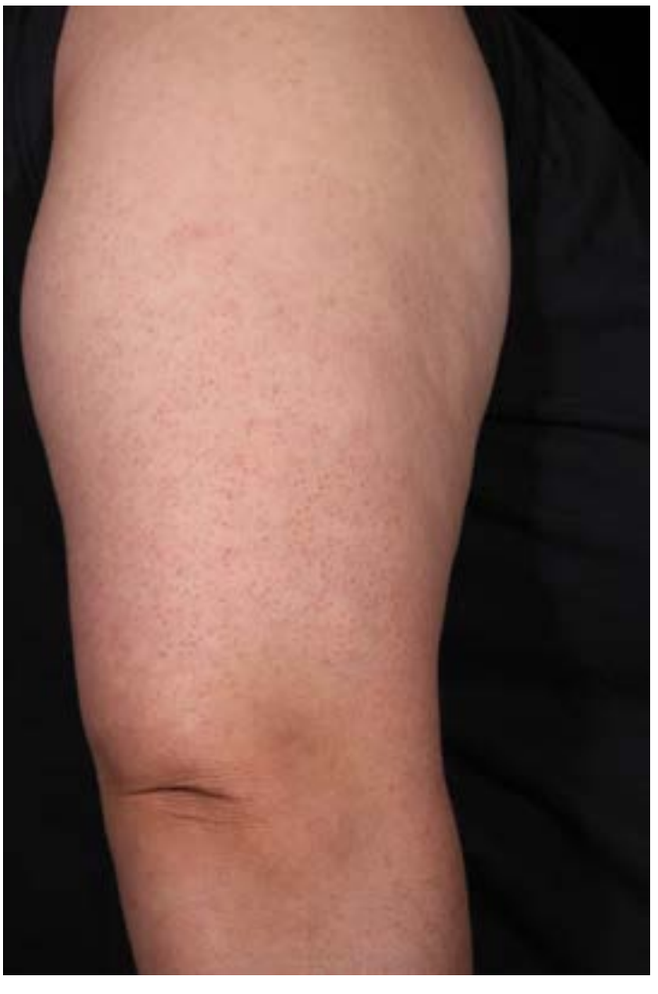


Patient 10 Arms 4 week Visable Light

Left arm

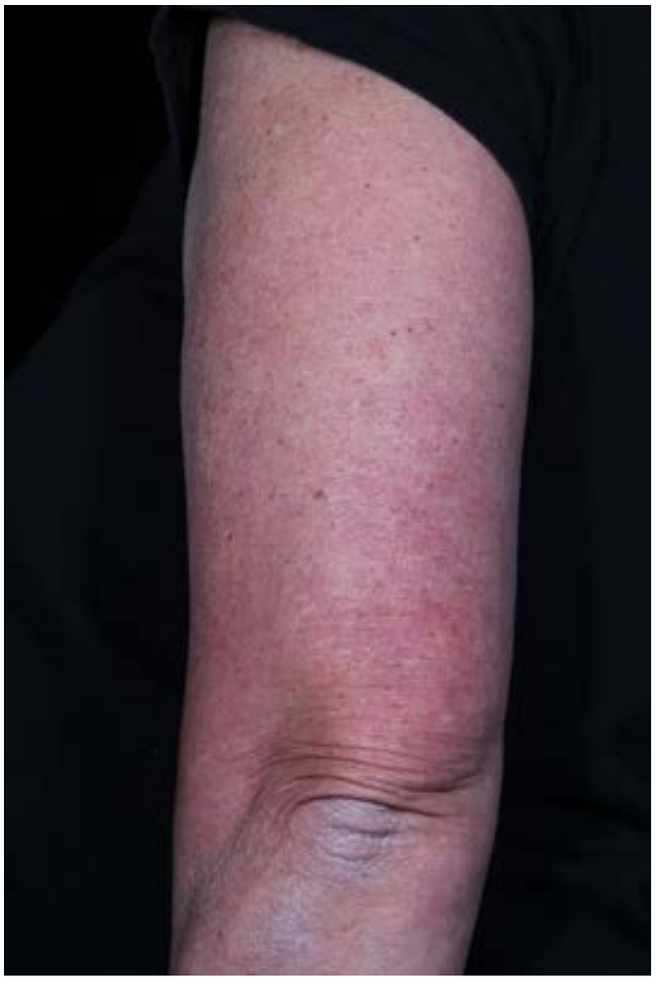


Right arm

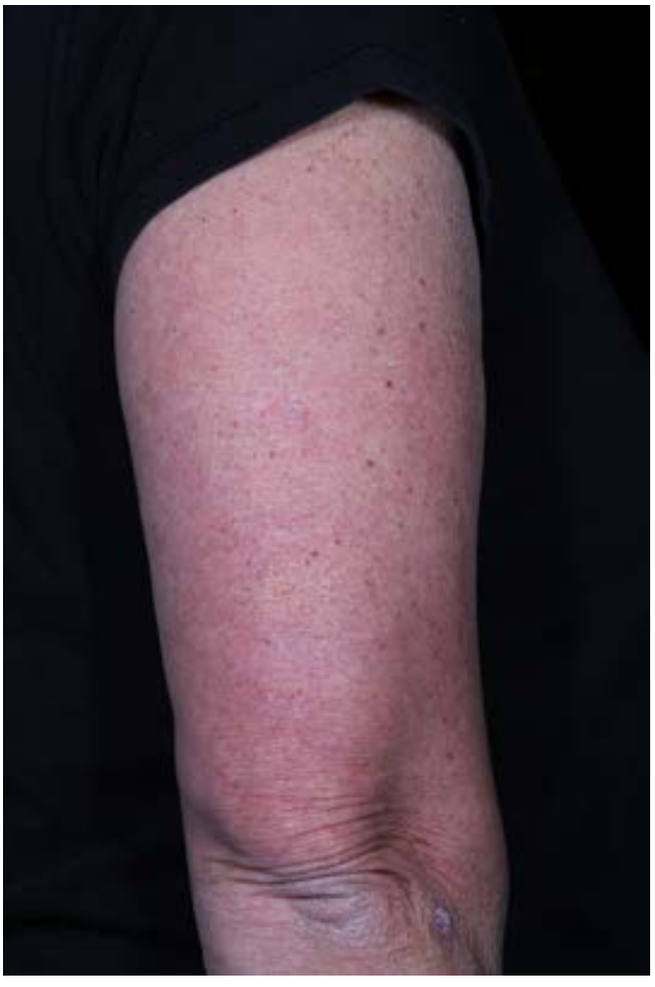


Patient 20 Arms Baseline Visable Light

Left arm



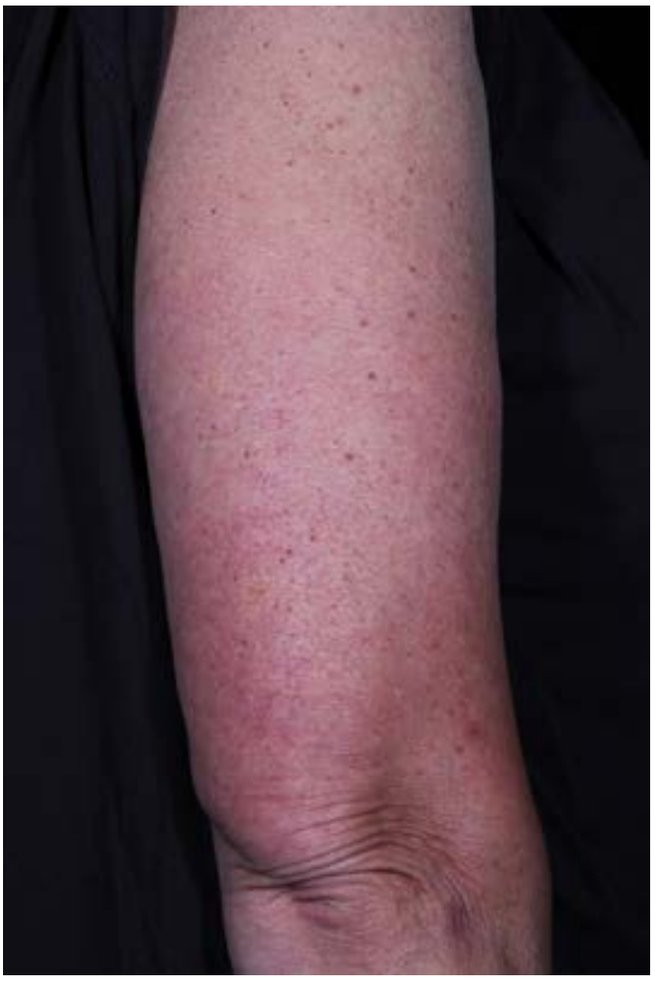
Right arm



Patient 20 Arms 4 week Visable Light

Left arm

Right arm



Patient 52 Arms Baseline Visable Light

Left arm

Right arm

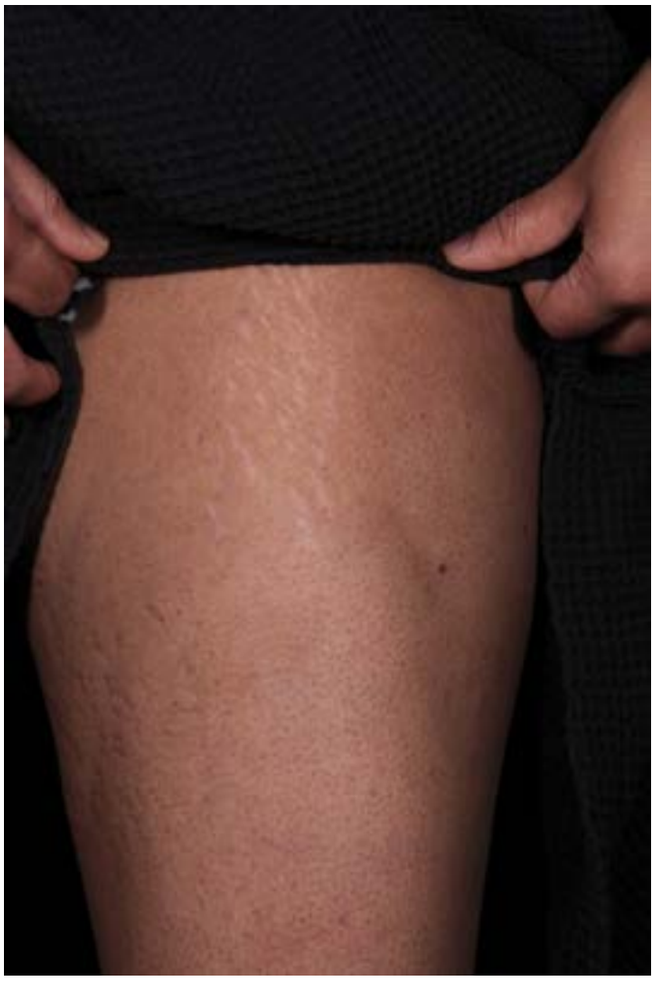
Patient 52 Arms 4 week Visable Light

Left arm

Right arm

Patient 19 Legs Baseline Visable Light

Left leg



Right leg

Patient 19 Legs 4 week Visable Light

Left leg

Right leg

Patient 35 Legs Baseline Visable Light

Left leg

Right leg

Patient 35 Legs 4 week Visable Light

Left leg

Right leg