

# Efficacy of a Targeted Pigment-Correcting Spot Treatment Cream for Post-inflammatory Hyperpigmentation and Solar Lentigines in a 12-Week, Single-Center Clinical Study

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## OBJECTIVE

To assess the efficacy and tolerance of a novel targeted pigment-correcting spot treatment gel suspension cream (Spot Tx) when used over the course of 12 weeks by women with mild to moderate dark spots (ie, post-inflammatory hyperpigmentation [PIH]/acne marks and/or age spots/solar lentigines) on the face

## CONCLUSIONS

Spot Tx, a novel targeted pigment-correcting spot treatment cream, provided significant improvement in dark spots from PIH/acne marks and age spots/solar lentigines as early as week 2, with continued improvement through week 12 in a broad range of participant races, ethnicities, and skin types

Spot Tx was well tolerated, with mean tolerability scores less than 0.25 at all study visits

Participants reported an 85% overall satisfaction rate with Spot Tx at week 12

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### References

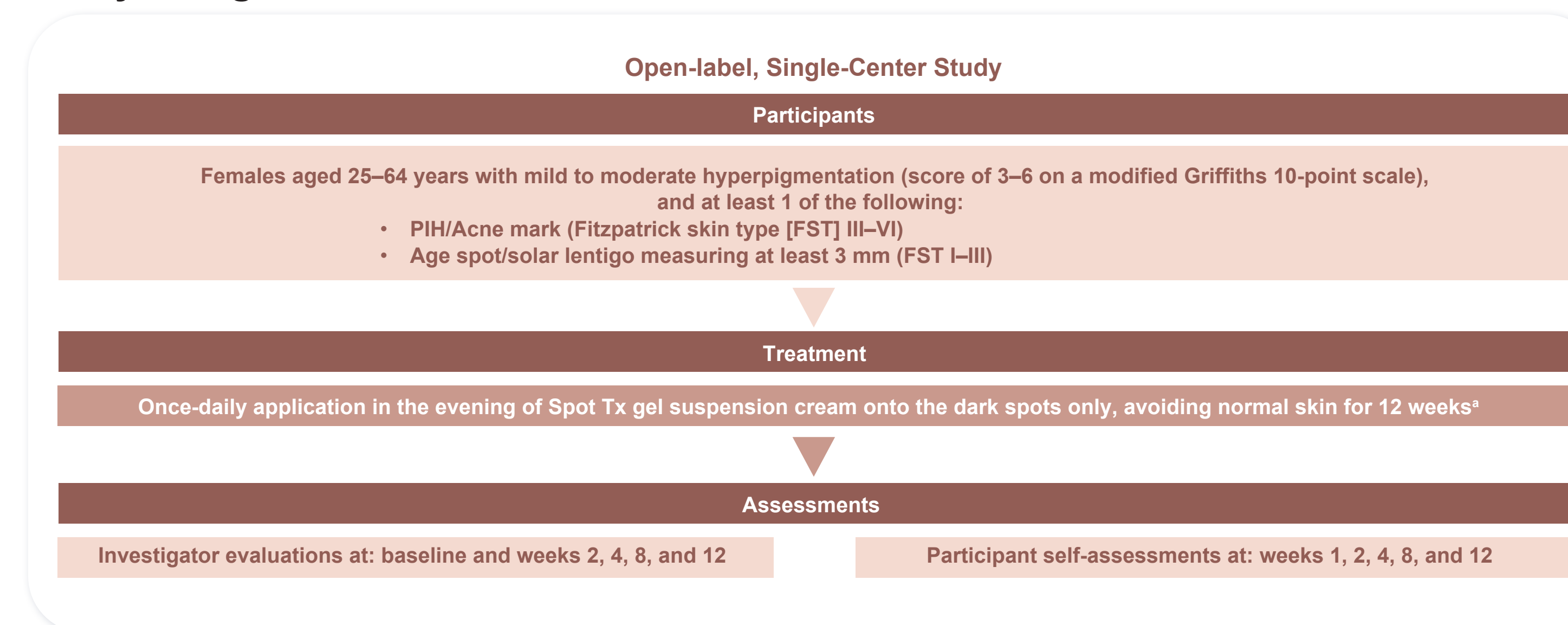
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## SYNOPSIS

- Hyperpigmentation (darkening of the skin) occurs when excess melanin deposits form, resulting in uneven skin color or tone<sup>1</sup>
- Facial hyperpigmentation types include post-inflammatory hyperpigmentation (PIH)/acne marks (acquired after cutaneous inflammation or injury) and age spots/solar lentigines (well-circumscribed lesions on sun-exposed surfaces of the skin)<sup>1,2</sup>
- Facial hyperpigmentation can have a negative impact on quality of life, affecting psychological and emotional well-being<sup>1,3</sup>
- We conducted a 12-week, single-center clinical trial in females aged 25 to 64 years with mild to moderate hyperpigmentation who had at least 1 PIH/acne mark or at least 1 age spot/solar lentigo

## METHODS

### Study Design



\*All participants were additionally instructed to wash their face twice daily using the SkinMedica Facial Cleanser and apply the SkinMedica Ultra Sheer Moisturizer (AM/PM) and SkinMedica Essential Defense Mineral Shield SPF 35 (AM and reapply as needed throughout the day) to the entire face.

### Study Assessments

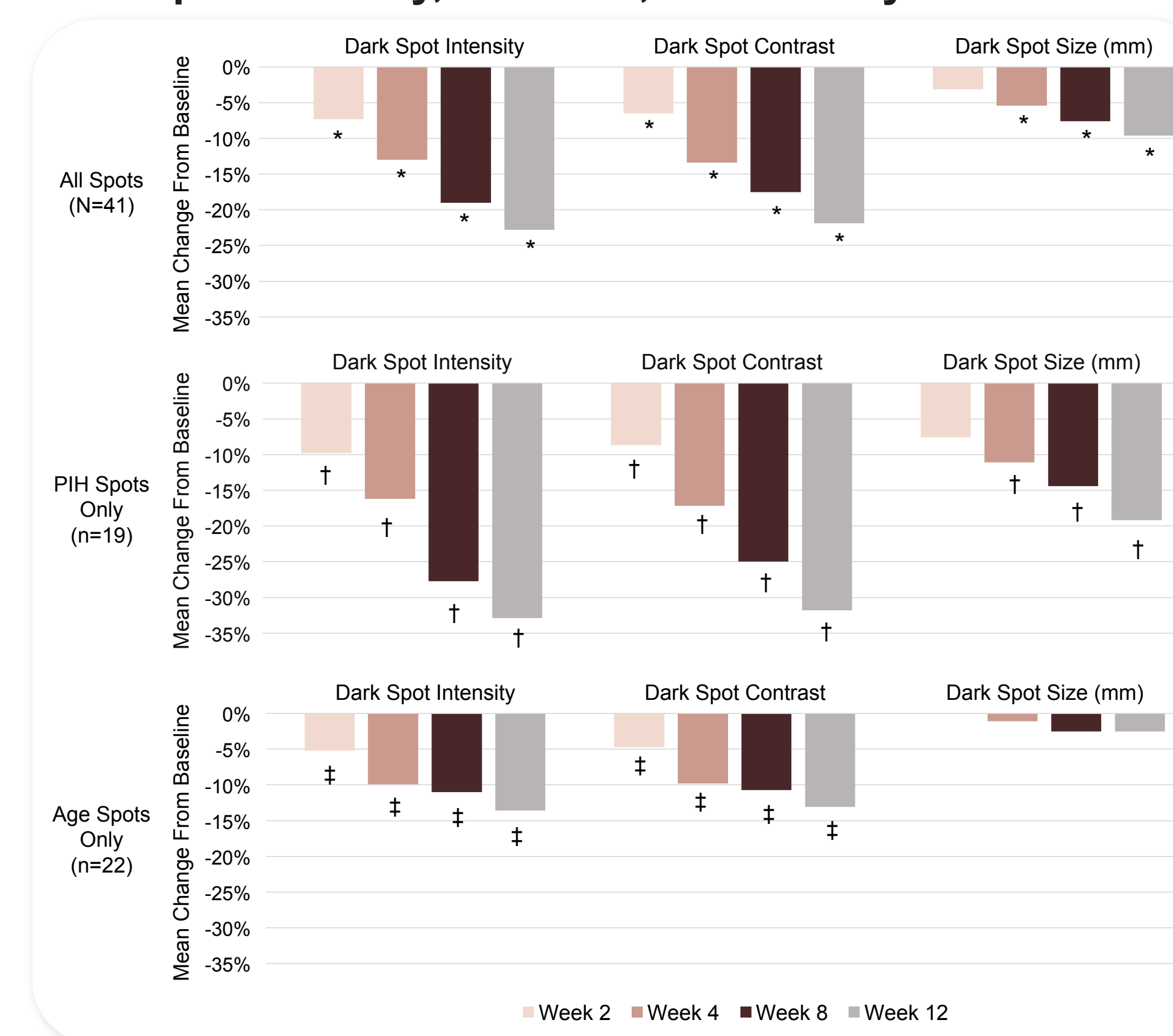
- Investigator assessments (clinical grading on a modified Griffiths scale: 0 [none], 1-3 [mild], 4-6 [moderate], 7-9 [severe]): overall hyperpigmentation, skin tone evenness, dark spot size, dark spot intensity, dark spot contrast
- Digital photography: VISIA-CR imaging
- Clinical grading of tolerability parameters (0 [none], 1 [mild], 2 [moderate], 3 [severe]): erythema, edema, dryness, burning, stinging, itching, peeling
- Participant self-assessment questionnaire: treatment satisfaction, effects of immediate and continued use, texture, application experience

## RESULTS

### Participants and Treatment Characteristics

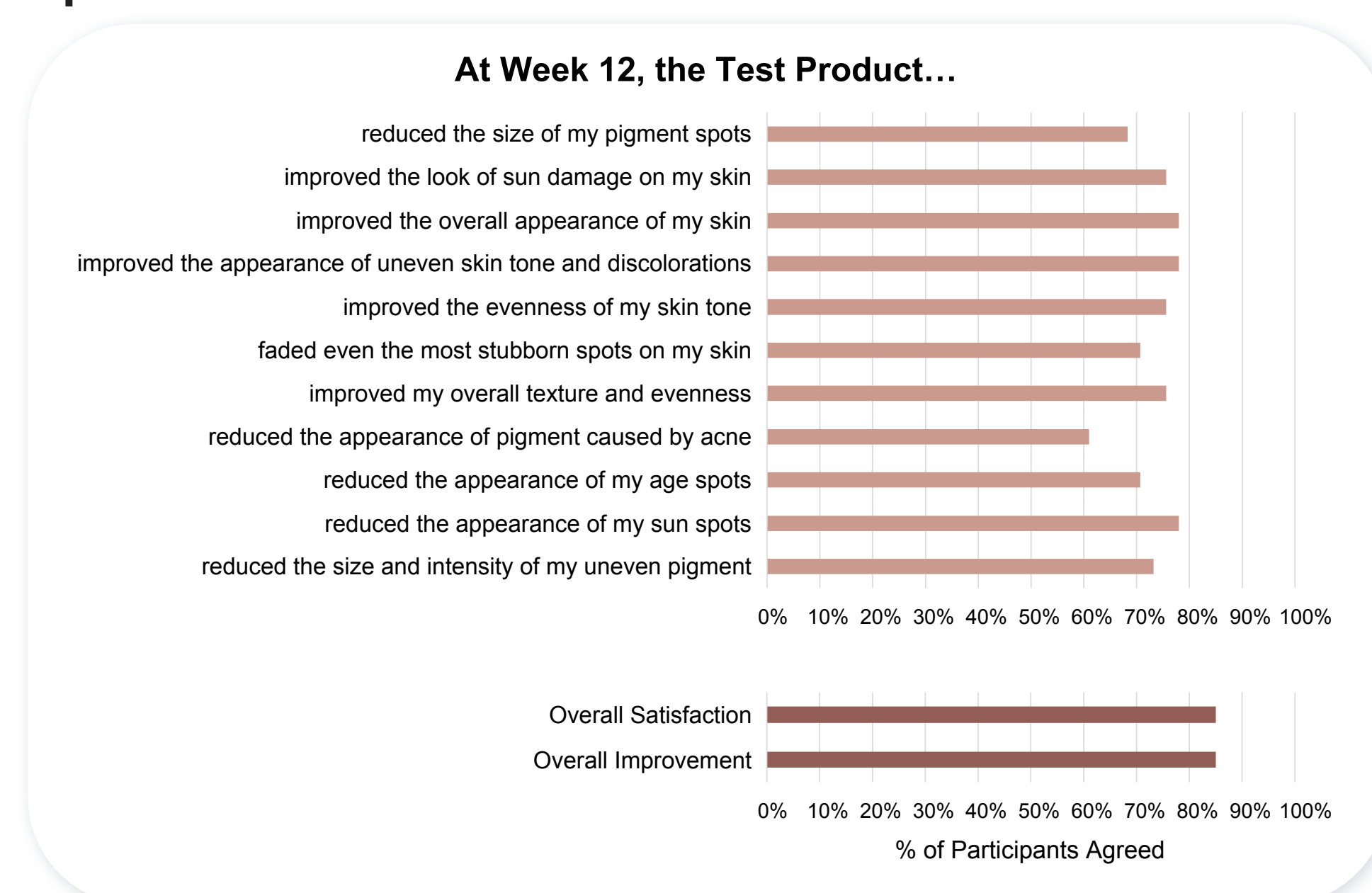
	PIH (n=19)	Age Spots (n=22)	All Participants (N=41)
Race/Ethnicity, n (%)			
White/Caucasian	1 (5.3)	11 (50.0)	12 (29.3)
Hispanic	7 (36.8)	5 (22.7)	12 (29.3)
Black/African American	10 (52.6)	0	10 (24.4)
Asian	1 (5.3)	4 (18.2)	5 (12.2)
Native American/Alaska Native	0	1 (4.5)	1 (2.4)
Asian/Caucasian	0	1 (4.5)	1 (2.4)
Fitzpatrick skin type, n (%)			
I	0	1 (4.5)	1 (2.4)
II	0	9 (40.9)	9 (22.0)
III	0	10 (45.5)	10 (24.4)
IV	10 (52.6)	2 (9.1)	12 (29.3)
V	9 (47.4)	0	9 (22.0)

### Significant Improvements in Investigator-Assessed Dark Spot Intensity, Contrast, and Size by Week 12

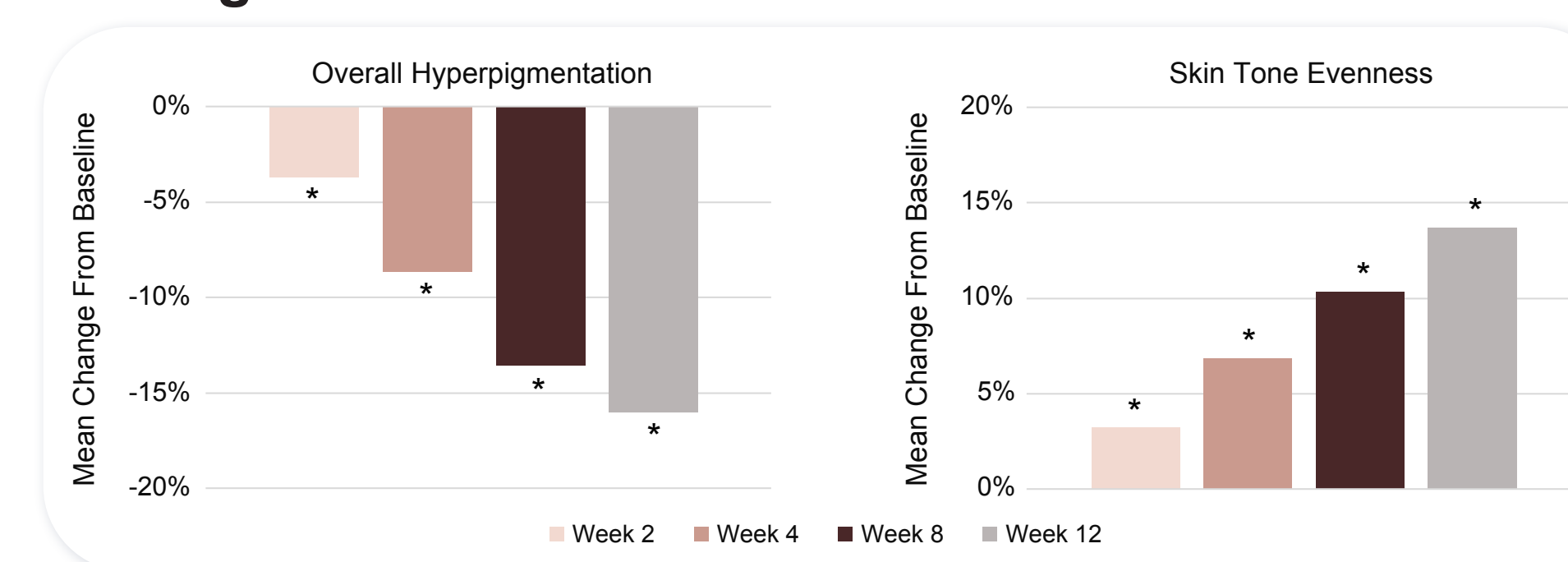


\*P<0.008, †P<0.031, ‡P<0.016 vs baseline (Wilcoxon signed-rank test).

### High Levels of Self-perceived Effectiveness and Overall Improvement and Satisfaction With Continued Use of Spot Tx at Week 12



### Significant Improvements in Investigator-Assessed Overall Hyperpigmentation and Skin Tone Evenness Through Week 12



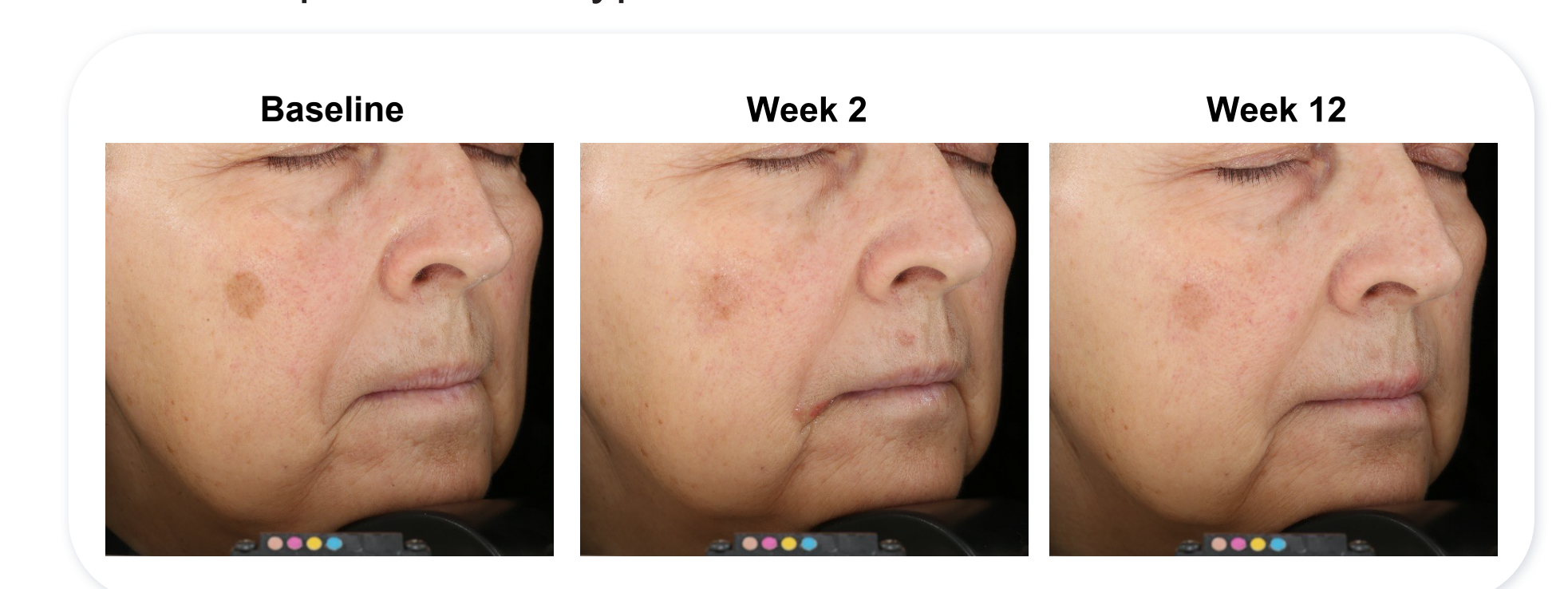
Graph inverted to show positive mean values for clarity in indicating improvement. \*P<0.018 vs baseline (Wilcoxon signed-rank test).

### Improvement From Baseline Shown on Digital Photography at Week 12

- Improvement in PIH in a 25-year-old African American female with Fitzpatrick skin type V



- Improvement in age spots in a 64-year-old Hispanic female with Fitzpatrick skin type II



### Spot Tx Was Well Tolerated

- Mean scores for all tolerability parameters were less than 0.25 at all study visits