Assessing Patient Concerns Regarding Seborrheic Keratoses on the Face: Comparison Against Other Cosmetic Concerns

Shuai Xu, MD, MSc,¹ Stacy Wang, PharmD²

¹Northwestern University Feinberg School of Medicine, Chicago, IL; ²Aclaris Therapeutics, Inc., Wayne, PA

CONCLUSIONS

The majority of survey participants were very bothered or extremely bothered by their SKs

Highly visible SKs on the face and hairline were of significant aesthetic concern to patients, and comparable to excess body fat and facial wrinkles

A majority of survey participants (85%) expressed that a blinded profile of HP40 was very appealing or extremely appealing, suggesting a strong interest in noninvasive treatment modalities for SK lesions

SYNOPSIS

- Seborrheic keratoses (SKs) are among the most common benign cutaneous lesions, affecting approximately 84 million individuals in the United States¹
- Typically, SKs do not require removal for medical reasons unless histologic confirmation is required (irritated or inflamed); however, these lesions are often a cosmetic concern to patients, especially if located on the face²

RESULTS

Demographics

• A total of 702 survey participants were enrolled; the study population was consistent with the sample recruitment quotas (**Table 2**)

Table 2. Demographics and Characteristics of Survey Participants

• The primary aesthetic concerns of survey participants were excess body fat, SKs on the face or hairline, and wrinkles on the face (**Figures 3A, 3B**)

Figure 3. Question: If you were going to get a treatment to improve your appearance, which issue would you address first, second, and third? (N=702)

A. Ranked First

- Removal of SKs by dermatologists often requires invasive procedures, including cryosurgery, shave excision, electrosurgery, curettage, and laser- or light-based treatment²
- Given the lack of clinical data supporting the efficacy and safety of these invasive techniques, a substantial unmet need exists for a safe, noninvasive, effective treatment for removal of SKs³
- Eskata (hydrogen peroxide topical solution 40% [w/w]; HP40; Aclaris Therapeutics, Inc., Wayne, PA) is a proprietary, stabilized, noninvasive therapy with demonstrated safety and efficacy in removal of SK lesions of the face, trunk, and extremities, and low risk of skin pigmentation changes or scarring³⁻⁵
 - HP40 is the first US Food and Drug Administration (FDA)-approved topical treatment for individuals with SKs that are raised⁵

OBJECTIVE

• To identify segments of consumers with raised facial SKs who are interested in a noninvasive treatment (ie, HP40) and describe these consumers in terms of demographics, lifestyle, attitudes, and behaviors



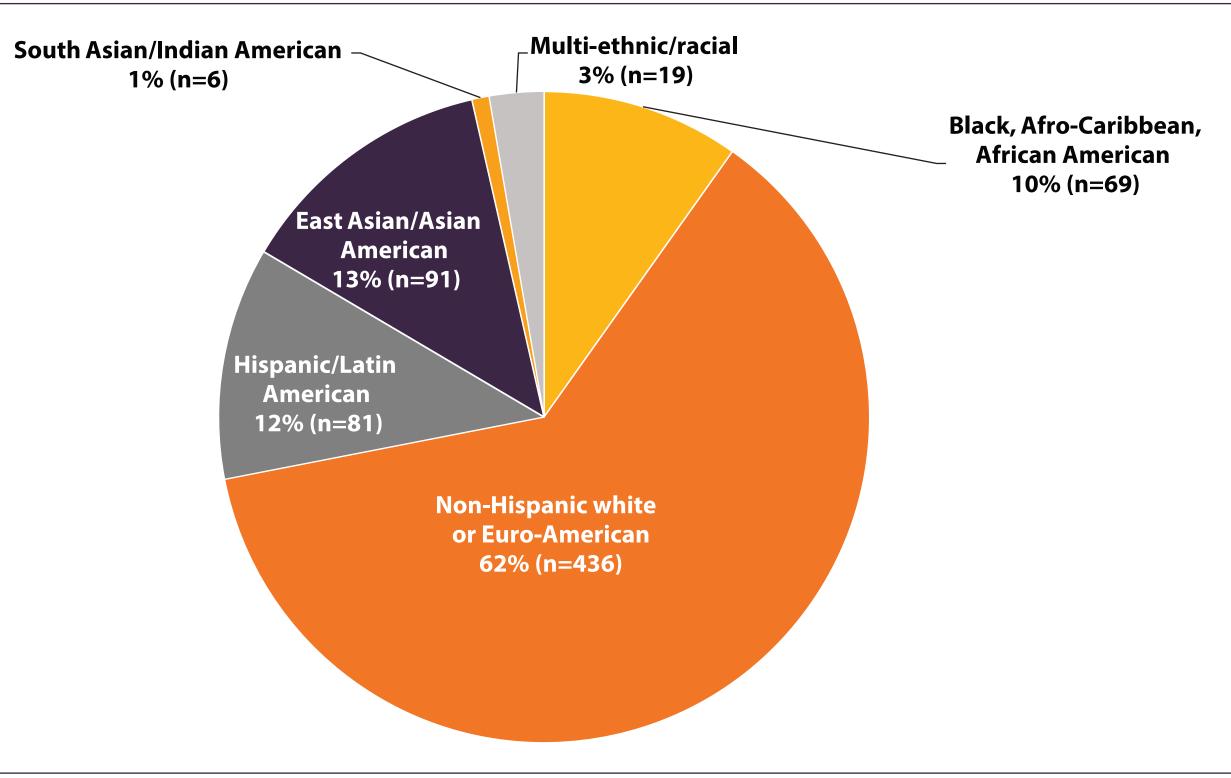
Study Design

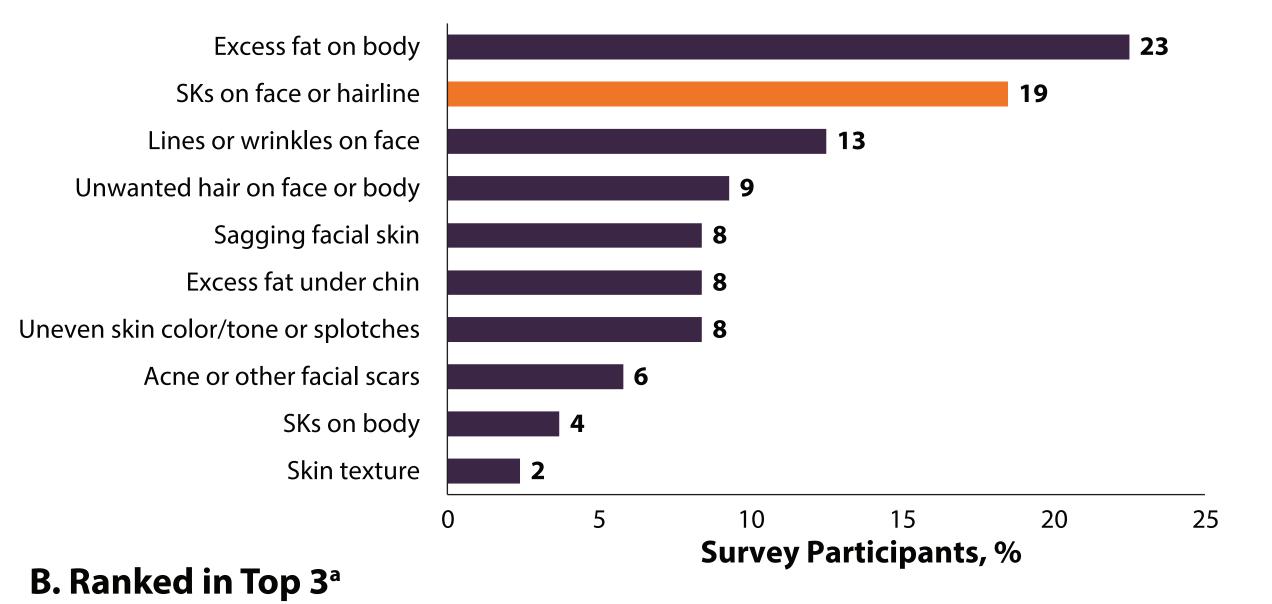
• An online survey was conducted between September 28 and October 13, 2017 among 702 eligible participants aged 35–65 years

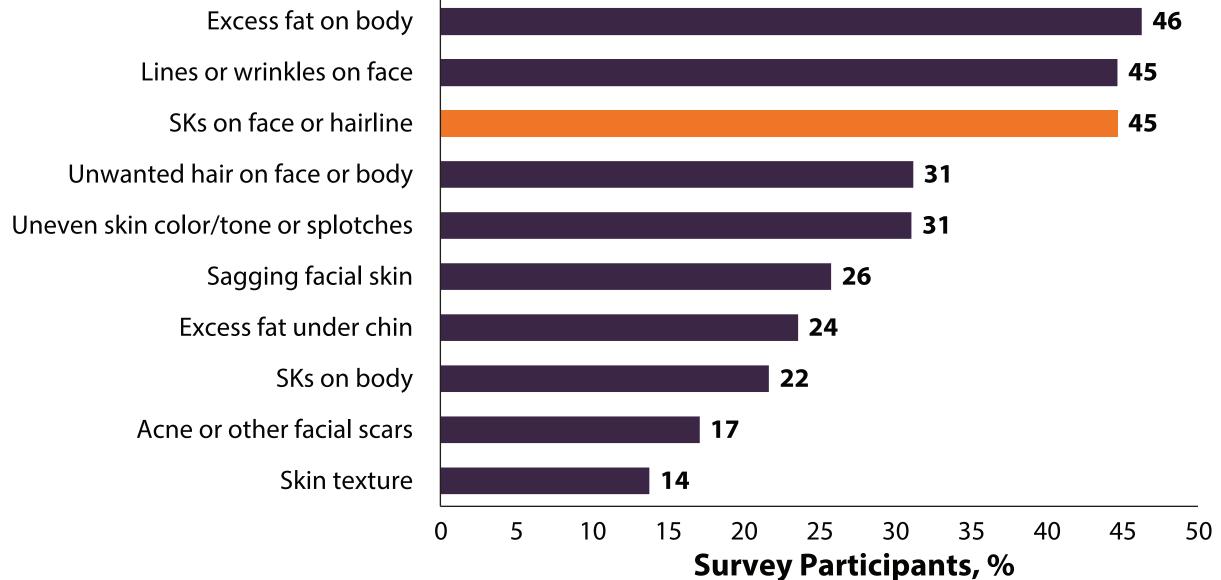
Male	142 (20)
Age category	
35–39	70 (10)
40–49	281 (40)
50–59	281 (40)
60–65	70 (10)
Visited dermatologist in previous 2 years	290 (41)
Mean (SD) household income, US dollars	120,566 (24,252)
Residing in a suburban area	547 (78)
Values are n (%) unless indicated otherwise.	

The racial and ethnic demographics of enrolled survey participants are summarized in Figure 1

Figure 1. Racial and Ethnic Background of Population Sample^a







— The sponsor was not identified to survey participants

Inclusion Criteria

- Eligible participants were diagnosed with SKs by a health care provider or had self-confirmed the presence of SKs using the definition and example images provided for the survey
- In addition, participants were required to meet the following criteria
- Bothered by appearance of SKs located on the face or hairline (\geq 3 on a 5-point Likert scale [1 = not at all bothered; 2 = slightly bothered; 3 = somewhat bothered; 4 = moderately bothered; 5 = extremely bothered])
- At least somewhat interested in an FDA-approved topical treatment to remove SKs on the face or hairline
- Annual income \geq \$75,000 and residing in an urban or suburban area

Exclusion Criteria

Survey participant or immediate family member was an employee or consultant for any pharmaceutical, advertising, marketing, market research, or public relations company at the time of survey completion

Sample Recruitment Quotas

- The sample population was estimated to include 140 males (20%) and 560 females (80%), and \geq 210 participants (30%) who had visited a dermatologist in the past 2 years
- Estimated population by age was categorized as 35–39 years (10%), 40–49 years (40%), 50–59 years (40%), and 60–65 years (10%)

Survey Questions

^aThe sum of the percentages is greater than 100% due to rounding.

- Survey participants self-reported a Fitzpatrick skin type of I or II (33%), III (42%), IV (16%), and V or VI (9%)
- Among survey participants who had visited a dermatologist in the past 2 years, the most common reasons for doing so were routine skin cancer check (66%), removal of noncancerous skin growths, marks, or spots (52%), or to have a suspicious mole or spot checked (47%)
- A total of 39% of participants reported that they were previously diagnosed with SKs by a health care provider
 - A total of 99% of participants self-confirmed the presence of spots, growths, or marks similar to SKs shown in the images provided

Aesthetic Concerns

- A total of 62% of survey participants reported being extremely or very bothered by SKs in highly visible areas, including the face and hairline (**Figure 2**)
- The mean (SD) score for this question was 3.8 (0.8), between the Likert scale scores of 3 (somewhat bothered) and 4 (very bothered)

Figure 2. Question: How bothered are you with the appearance of the SKs in

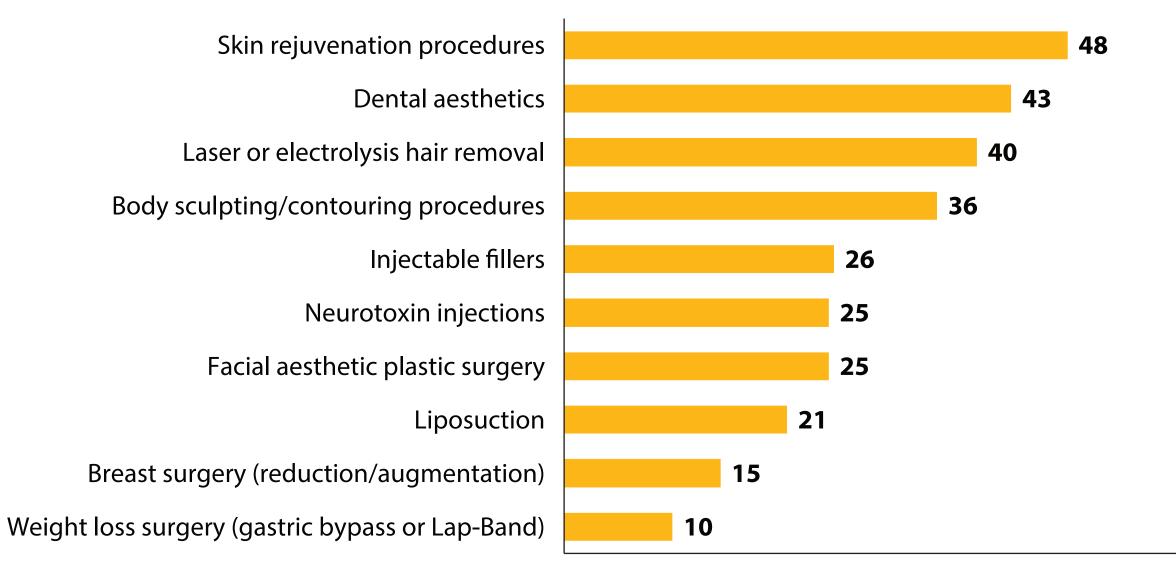
your highly visible areas such as the face and hairline?^{a,b,c}

SKs, seborrheic keratoses ^aParticipants gave 3 responses each

Interest in Aesthetic Procedures

- Many survey participants were extremely interested or very interested in skin rejuvenation procedures (48%) or dental aesthetics (43%; **Figure 4**)
- A total of 597/702 survey participants (85%) found the blinded product X consisting of highconcentration hydrogen peroxide (HP40) for the in-office treatment of SKs by a dermatologist to be extremely appealing or very appealing

Figure 4. Question: How interested are you in getting the following treatments whether you have had them or not?^a: Participants who responded "extremely interested" or "very interested" (N=702)



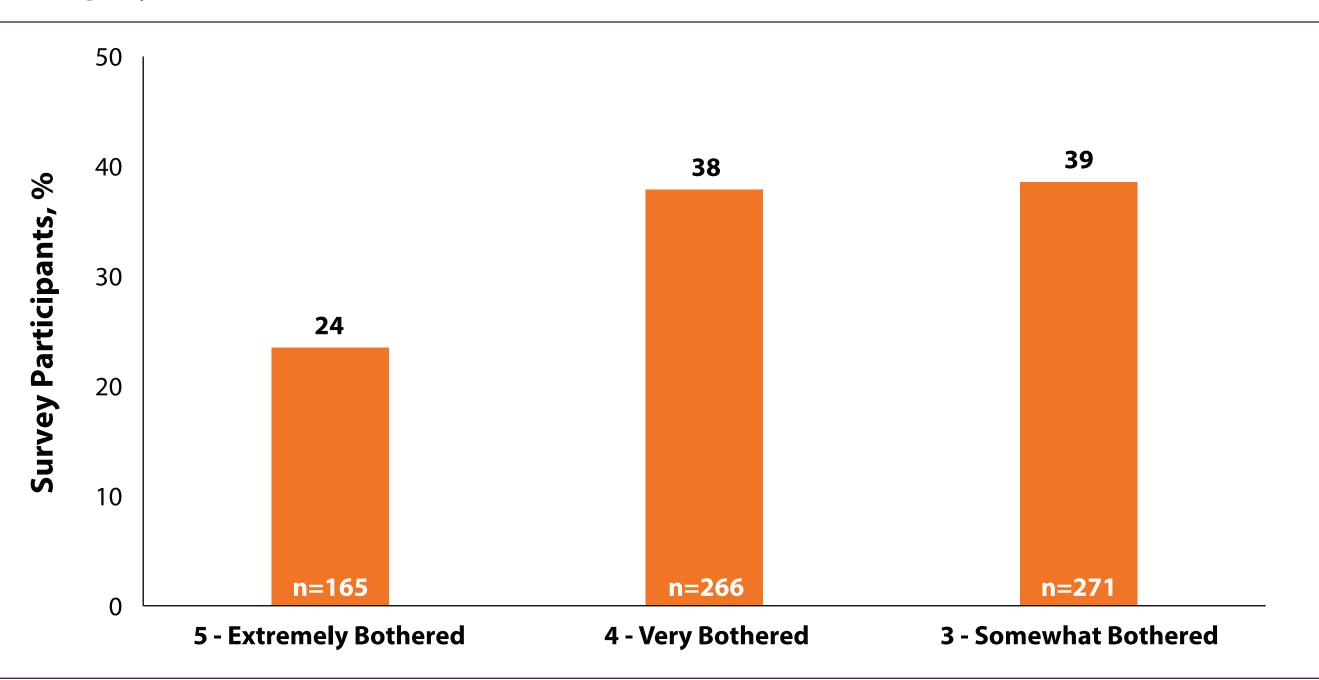
• A summary of survey questions is provided in **Table 1**

Table 1. Number of Survey Questions Included by Category^a

1. Screening	17 questions
2. Demographics and media habits	4 questions
3. Lifestyle, personality, skin care attitudes and behaviors, and relationship with a dermatologist	24 questions
4. Experience with SKs	26 questions
5. Profile of a product for treatment of SKs	14 questions
SKs, seborrheic keratoses. ªThe inclusion of some questions was conditional based on previous participant responses.	

Statistics

• Categorical data were presented as frequency and percentage and continuous variables were presented as mean (SD)



SKs, seborrheic keratoses

^aResponses on the Likert scale of 1 (not at all bothered) or 2 (slightly bothered) were excluded per the study protocol. ^bN=702. °The sum of the percentages is greater than 100% due to rounding.

20 30 40 50 10 60

Survey Participants, %

^aSurvey participants ranked treatments on a 5-point Likert scale (5 = extremely interested; 1 = not at all interested). Note that the data presented show the combined percentage of patients who responded "extremely interested" or "very interested." Participants could choose more than one response.

References

Bickers DR, et al. JAm Acad Dermatol. 2006;55:490-500.

- 2. Jackson JM, et al. J Drugs Dermatol. 2015;14:1119-25.
- Baumann LS, et al. J Am Acad Dermatol. 2018 Jun 1 [Epub ahead of print].
- 4. DuBois JC, et al. *Dermatol Surg*. 2018;44:330-40.
- 5. Eskata [package insert]. Wayne, PA: Aclaris Therapeutics, Inc; 2017.

Acknowledgments

This study was sponsored by Aclaris Therapeutics, Inc., Wayne, PA. Medical writing support was provided by Peloton Advantage, Parsippany, NJ, and funded by Aclaris Therapeutics, Inc.

Disclosures

Shuai Xu, MD, MSc, reports consulting for Aclaris Therapeutics. He also reports grant support from Pfizer Inc, Leo Pharma, and Novartis. Stacy Wang, PharmD, is an employee of Aclaris Therapeutics, Inc.

Email address for questions or comments: stevexumd@gmail.com