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# Development of a Photonumeric Lip Health Scale

Zoe Diana Draelos MD,[a] Darrell Rigel MD,[b] Adam J. Friedman MD[c]
[a]Dermatology Consulting Services, PLLC, High Point, NC
[b]NYU Langone Health, New York, NY
[c]George Washington School of Medicine and Health Sciences, Washington, DC

## ABSTRACT

**Background:** The lips are important facial anatomic features with particular vulnerability to environmental damage, yet they have received little attention in the dermatologic literature. A photonumeric rating scale for clinically assessing lip heath is needed to advance lip research.

**Objective:** To develop a photonumeric lip health assessment scale for clinical use that can evaluate the efficacy of products for improving lip health.

**Methods:** The VISIA®-CR 4.3 system was used to photograph the frontal face of 103 subjects with Fitzpatrick skin types I–III exhibiting a range of lip health status based on the key characteristics of lip shine, texture, and vermilion border. An expert panel comprising 3 dermatologists independently rated the images based on the proposed rating scale. Images with ≥75% rater agreement were redistributed to the panel for selecting the final images and verification of the final scale.

**Results:** The panel selected 15 images for the final scale: 5 for each of the key characteristics (lip shine, texture, and vermilion border) and 1 for each ordinal rating of 0–5 within a characteristic (eg, 0=very shiny, 5=very dull). All of these images achieved 100% agreement among the raters.

**Conclusion:** This scale provides healthcare professionals and researchers a way to evaluate current lip health, track improvement, and evaluate the efficacy of treatments. It can be used to communicate with patients during discussions about lip conditions, recommending treatments, and setting goals. The scale also provides a research tool to evaluate different formulations for developing lip care products.

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## INTRODUCTION

The lips are central to many critical human functions, for example, by facilitating breathing, speech, eating, and intimacy.[1-4] The lips are also a common characteristic defining facial aesthetics. Full lips are associated with youth and beauty, while the loss of exposed vermilion and vermilion bulk during aging is considered less attractive.[5] The lips may be secondary only to the eyes[6,7] in terms of facial visual importance.

Anatomically, the lips act as the transitional junction between the keratinized skin of the face and mucosa of the oral cavity.[3] The skin of the lips generally has the same basic features as the skin in other areas of the body [8]: it serves as a protective barrier between the human body and the external environment, and it plays a role in metabolic processes, resorptive and thermoregulatory functions, and immune defense.[9] But just as specific characteristics differentiate the facial skin from skin elsewhere on the body, the lip vermilion differs from the skin that surrounds it.[8] While both facial and lip skin are stratified squamous epithelium,[10] lip skin is non-keratinized.[3] Keratins are strong fibrous proteins that provide strength and resilience to skin cells.[11] Additionally, the lips have far fewer layers than facial skin, so lip skin has comparatively less barrier function.[3,12] Other characteristics of the lips that make them particularly vulnerable to environmental damage from wind, sun, temperature, and smoking include low-hydration state and low moisture-retaining capacity.[8,12] For example, hydration is significantly higher on the cheek compared with lip skin.[8] Furthermore, the lips have fewer natural moisturizing factors (eg, lipids)[13] and lower levels of natural ultraviolet protectants (eg, melanin, urocanic acid).[14] These characteristics make the lips prone to conditions such as cheilitis simplex, perleche, actinic cheilitis, which can carry malignant potential, and eczematous dermatoses (eg, allergic and irritant contact dermatitis).[15] Other lip conditions can be caused by nutritional deficiencies, systemic diseases, psychiatric disorders, certain medications, and irritating products.[15]

Despite the importance of the lips and their vulnerability to environmental damage, there are no established clinical measures of lip health. Photonumeric scales can counterbalance

the lack of reliable validated outcome measures in dermatology.[16] They have been shown to provide superior interobserver agreement when compared with purely descriptive scales,[17,18] and they have demonstrated consistency, precision, and reproducibility.[16] A photonumeric scale assigns numbers to images that represent diversity of appearance to facilitate a rating or grading process, usually from good to poor. Current validated photonumeric scales are based on lip shape and contour and are designed to standardize evaluations, quantify results, and measure the longevity of dermal fillers and other procedures for lip rejuvenation in clinical trials.[16] Additionally, these scales are used to evaluate the effectiveness of lip augmentation in clinical trials of hyaluronic acid gel (a type of dermal filler) injection[19] and to objectively quantify lip volume in clinical practice relative to aesthetic procedures.[20] These scales focus on technologies and applications that are designed to enhance and beautify the lips; therefore, they do not directly assess lip health. Dermal fillers are cosmetic tools for "anti-aging" and "rejuvenation"[21] that have the same goals as lip peels,[22] implants,[23] lifts,[24] and related procedures. Current scales are associated with cosmetic terms such as "augmentation" and "renewal."[12,20] Therefore, this article describes the methodology that was used to develop a photonumeric lip health assessment scale for clinical use and evaluating the efficacy of lip care products in improving lip health.

## METHODS

### Study Design, Setting, and Subjects

This was a single-site study conducted at Dermatology Consulting Services, High Point, North Carolina, that utilized a research team comprising the primary dermatologist investigator (ZDD) and 2 external dermatologists who also formed the panel that reviewed the photographs and used the proposed ordinal rating scale to assess lip health. The study protocol was submitted to a sponsor-approved Institutional Review Board (Allendale Institutional Review Board, Lyme, Connecticut). To protect confidentiality, subject data were identified by number and subject initials only. The principles of Informed Consent according to US Food and Drug Administration regulations and the International Council for Harmonisation Guideline for Good Clinical Practice were followed. One hundred subjects were planned to be enrolled to obtain 100 evaluable lip images. An additional 3 subjects were enrolled to obtain images for correcting any deficiencies in the dataset. This sample size was based on the primary investigator's previous experience with developing photonumeric scales.

Prescreening involved selection of candidates from the research center database. These candidates were contacted and asked to provide a current photograph of their lips for the research site to determine if they were suitable for study imaging. Those found to be initially suitable and those who did not provide a photograph were invited to the research site for in-person qualification via a dermatologic lip examination performed by the primary investigator. Screening involved the primary investigator assessing potential subjects according to the inclusion and exclusion criteria (Table 1). No specific lip conditions or diseases were excluded from the study. The goal of screening was to include a wide variety of lip conditions within Fitzpatrick skin types I–III. Other Fitzpatrick skin types were excluded because the lip architecture is different among individuals with higher Fitzpatrick ratings.[25]

**TABLE 1.**

| Study Inclusion and Exclusion Criteria | |
|---|---|
| **Eligible subjects were** | **Ineligible subjects were** |
| • Aged 18+ years with Fitzpatrick skin types I–III<br>• Able to understand the study and cooperate with the protocol procedures<br>• In general good health as determined by the investigator<br>• Able to read and sign the informed consent form after the nature of the study had been fully explained<br>• Willing to present at the research facility with nothing on their lips<br>• Willing to discontinue all lip products, to include cosmetics, lipsticks, lip balms, lip gloss, for 24 hours prior to enrollment | • Viewed by the investigator as not being able to complete the study<br>• Employees of the research center or a manufacturer of personal care products<br>• Not willing to follow the study requirements |

Subjects were selected to participate based on whether their lip features met any of the predetermined ordinal ratings for health on the 3 key lip characteristics: shine, texture, and vermilion border. After being fully informed of the study objectives and procedures, eligible subjects signed an informed consent form that included photography consent. At the conclusion of photography, subject participation in the study was complete.

### Concomitant Medications

Subjects were allowed to continue all oral and topical medications, which remained unchanged during the study, and no medications were prohibited. However, subjects were required to discontinue use of all lip cosmetics, lip balms, lipsticks, and lip gloss 24 hours prior to study enrollment and were restricted from using any of these products until their study participation was complete. In addition, no skincare products or topical medications of any kind were used on the face or lips on the day of photography. Subjects were advised to present to the research facility with nothing on their lips.

### Procedure

All enrolled subjects underwent VISIA®-CR 4.3 photography of

**TABLE 2.**

| Photometric Lip Scale Ordinals | | |
|---|---|---|
| **Shine** | **Texture** | **Vermilion border** |
| 0: Very shiny<br>1: Shiny<br>2: Somewhat shiny<br>3: Dull<br>4: Very dull | 0: Very smooth texture<br>1: Smooth texture<br>2: Somewhat smooth texture<br>3: Rough texture<br>4: Very rough texture | 0: Very well-defined<br>1: Well-defined<br>2: Somewhat well-defined<br>3: Poorly defined<br>4: Very poorly defined |

the full face, including the lips, on study day 1. The primary investigator rated the 3 lip characteristics in real time to ensure that a sufficient number of diverse images were obtained to represent the entire spectrum of the lip scale ordinal ratings (Table 2). When a sufficient number of images were obtained to illustrate a specific characteristic and ordinal rating of the photonumeric scale, enrollment for that characteristic/rating was closed.

### VISIA Facial Imaging System for Clinical Research

Photography was conducted with the VISIA-CR 4.3 system for repeatable clinical imaging and skin analysis.[26] It allowed rapid attainment of high-resolution images, and the booth-like device ensured that subjects maintained the proper position for the duration of the capture set. The frontal face was captured with "standard light 1" modality.

### Training of Dermatologist Raters

The primary investigator conducted 2 sessions to educate the raters and facilitate discussion about lip characteristics, issues, and potential rating terminology. During training session 1, the primary investigator presented to the raters the qualities of lip texture, lip shine, and lip vermilion border to establish an overall lip health score. The panel then reviewed stock images to arrive at a rating consensus. When the primary investigator determined that the expert panel was familiar with the rating scale and concepts, training was concluded. After training, selected VISIA-CR 4.3 images from the study dataset were evaluated collectively by the expert panel to further define the ordinal scoring system. The primary investigator also conducted training for another staff member of the research center.

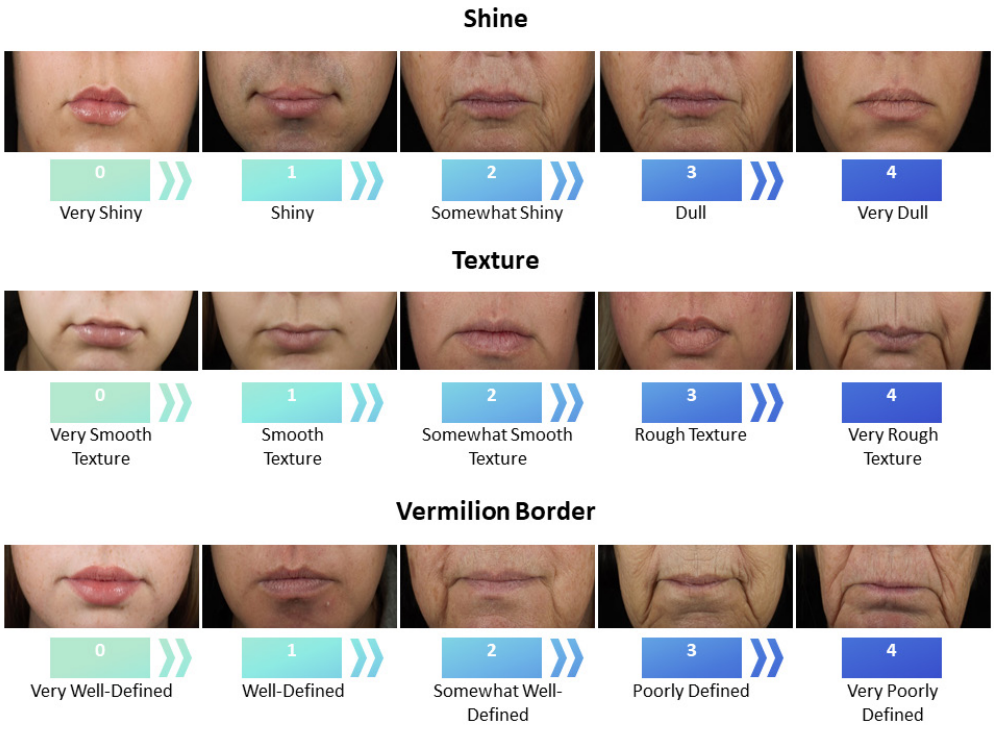
### Proposed Rating Scale

The 3 key lip characteristics—texture, shine, and vermilion border—were selected because of their importance to the appearance attributes of lip health that can be affected by lip products.[12,27,28] For example, healthy lips have a distinct vermilion border.[27,28] In addition, the characteristics were selected because they represent healthy lips and are easily photographable.

## RESULTS

The photography session produced 103 images, that were then processed and archived for distribution to the expert dermatologist panel. Distribution entailed random loading of the images to flash drives, which were mailed to each panel member. An email provided instructions and an Excel scoring sheet for data collection.

**FIGURE 1.** Proposed photonumeric lip rating scale.



A total of 15 images were thought to be necessary for the final scale. Panel evaluations occurred in 2 phases. During evaluation 1, the images were rated independently based on the proposed rating scale (Table 2) by each of the 3 experts. The ordinal scores for each characteristic were summed to arrive at an overall lip health score for each image. During evaluation 2, the images with the greatest rater agreement (ie, ≥75% of experts agreed on the image rating) during evaluation 1 were redistributed to the expert panel for selection of the final images and verification of the final scale. This evaluation session was repeated until 15 images (ie, 5 for each of the key characteristics and 1 for each ordinal rating within a characteristic) were obtained. All 15 images included in the final photonumeric scale (Figure 1) achieved 100% agreement among the raters.

## DISCUSSION

This dermatologic study evaluated the lips of 103 subjects to produce a photonumeric lip assessment scale that allows rating of health issues associated with 3 key lip characteristics: shine, texture, and vermilion border. The scale is designed for clinical use to evaluate the efficacy of lip care products in achieving or sustaining lip health. It comprises 15 images, 5 for each of the key characteristics and 1 for each ordinal rating within a characteristic. The study aimed to achieve ≥75% agreement among the 3 expert panel members on all images selected for the final photonumeric lip health scale. In fact, all 15 images included in the final scale achieved 100% rater agreement.

Photonumeric scales are user-friendly, helpful skin assessment tools.[18] A 1992 study developed a photonumeric scale for the evaluation of facial cutaneous photodamage. Those researchers conducted a side-by-side comparison of their photonumeric scale and a conventional, widely used descriptive scale, also for assessing cutaneous photodamage.[17] Use of a photonumeric scale was found to be superior to use of purely descriptive, written scales in the assessment of facial skin. Today, numerous photonumeric scales for skin conditions have been published.[18,29-31]

Extrinsic skin aging stemming from ultraviolet radiation, cigarette smoking, air pollution, and other factors is both preventable and treatable and can be distinguished from chronologic or intrinsic aging.[17,32] Three types of cheilitis that commonly occur (ie, cheilitis simplex, angular/infective cheilitis, and contact/eczematous cheilitis) are reversible with emollients and other treatments.[15] Nevertheless, and even though cheilitis may be associated with numerous diseases (eg, diabetes, iron-deficiency anemia), a clear classification system for cheilitis had not been established as of 2018.[15] Similarly, it appears that few studies have investigated sun protection for the lips, despite the fact that the lips are a high-risk location for squamous cell carcinoma. In fact, the first European study of lip photoprotection in patients with actinic cheilitis was published in 2019.[33] As an anatomic structure central to many critical human functions, the lips deserve more attention from dermatologists. Other treatable lip conditions include dryness, chapping, and dull color,[12] and unhealthy lips have a less distinct vermilion border, rough texture, and reduced shine.[12,27,28] Age- and sun-related changes to the skin include wrinkles (increased quantity and visibility)[17] and degeneration of elastic and collagen fibers,[12] and the lips also are a common site for eczematous dermatitis.[15]

Damage to the lip skin barrier is treatable by a variety of externally applied substances, such as ceramides, hyaluronic acid, licorice extracts, dimethicone, petrolatum, and paraffin wax.[34] Moisturizers are important to basic skin care because they help protect the skin by stimulating its natural barrier function, and they respond to the skin's continual need for moisture.[35] Studies support the use of lip creams in the winter, when conditions are dry and cold.[8] The application of lip balms, petroleum jelly, emollients, and topical corticosteroids can help cheilitis simplex.[15]

The present study has produced the only photonumeric rating scale for assessing lip health. Technical expertise is required to attain high-quality photographs for dermatologic rating purposes.[17] The VISIA-CR 4.3 system employed in the present study uses digital technology to produce high-resolution images for clinical research, which is a strength of this study.[26] A limitation of this research was the exclusion of subjects with Fitzpatrick skin types IV–VI. In addition, this photonumeric scale was developed for use only in Caucasian subjects. Future studies can develop additional photonumeric lip health scales for other populations with different skin types, as well as to validate the present scale.

Despite these limitations, this scale provides healthcare professionals a way to evaluate lip health, track improvement, and establish the efficacy of lip care products. It can also serve as a visual source of information that can be used during discussions with patients about lip conditions and when making treatment recommendations. In addition, the scale provides a research tool to evaluate different formulations in the development of lip products.

## DISCLOSURES

Zoe Diana Draelos MD received an educational grant from Pfizer to develop the lip health photonumeric scale. Darrell Rigel MD received an educational grant from Pfizer to develop the lip health photonumeric scale. Adam Friedman MD received an educational grant from Pfizer to develop the lip health photonumeric scale.

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*Data Sharing Statement:* Upon request, and subject to certain criteria, conditions and exceptions (see https://www.pfizer.com/science/clinical-trials/trial-data-and-results for more information), Pfizer will provide access to individual de-identified participant data from Pfizer-sponsored global interventional clinical studies conducted for medicines, vaccines and medical devices (1) for indications that have been approved in the US and/or EU or (2) in programs that have been terminated (ie, development for all indications has been discontinued). Pfizer will also consider requests for the protocol, data dictionary, and statistical analysis plan. Data may be requested from Pfizer trials 24 months after study completion. The de-identified participant data will be made available to researchers whose proposals meet the research criteria and other conditions, and for which an exception does not apply, via a secure portal. To gain access, data requestors must enter into a data access agreement with Pfizer. On August 1, 2019, Pfizer Consumer Healthcare became part of GSK Consumer Healthcare.

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## AUTHOR CORRESPONDENCE

**Zoe Diana Draelos MD**

E-mail:..... zdraelos@northstate.net