assessed using Cronbach's alpha and inter-class correlation. RESULTS: The mean age was 76.3 (8.9) years, majority of the subjects were female (55.1%), residing in the United States (77.5%) and Caucasian (92.8%). The mean utility value calculated with the VQ-UI was 0.68 (0.11), compared to the EQ-5D 0.88 (0.12), HUI2 0.81 (0.13), and HUI3 0.77 (0.14). The VQ-UI is associated with HUI2 (r = 0.22, p < 0.001) and not significantly associated with the EQ-5D or the HUI3. There was no significance in the correlation between VQ-UI and visual acuity in the study eye. The VQ-UI varied by known groups using a combination of study and fellow eye visual acuity; the more impaired visual acuity lower the utility value (more disability of quality functioning). Internal consistency reliability for the VQ-UI was 0.76 and the intra-class correlation was 0.84. CONCLUSIONS: Utility values calculated from the VQ-UI demonstrated greater visual functioning impairment compared to the HUI and VQ-UI showed good convergent validity with the HUI2; good discriminant validity with visual acuity known groups and good internal consistency and test-retest reliability in individuals with AMD.

**PSS14**

**VALIDATION OF THE EYELASH SATISFACTION FOLLOW-UP QUESTIONNAIRE FOR FOLLOW-UP SELF-ASSESSMENT OF EYELASH SATISFACTION**

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OBJECTIVES: The Eyelash Satisfaction Questionnaire (ESQ), a static measure, has been previously validated for the assessment of eyelash-specific patient-reported outcome (PRO) measures. The PROs were designed to assess patients receiving a therapeutic agent to treat hypotrichosis of eyelashes. The current study aimed to validate a similar questionnaire, the Eyelash Satisfaction Follow-up Questionnaire (ESFQ), a 39-item dynamic measure designed specifically to self-assess eyelash-specific PROs.

**METHODS:** The ESQ was initially examined using a "challenge validation" sample consisting of online respondents. Confirmatory factor analysis (CFA) was initially used to test the measurement structure of the questionnaire. Item- and scale-level psychometric properties such as item-total correlations, internal consistency, and convergent and discriminant validities were reviewed. The ESFQ was then used in a clinical population receiving bimatoprost ophthalmic solution 0.03%, a product that improves eyelash prominence, during a 16-week randomized, controlled, masked, clinical trial. **RESULTS:** Initial CFA results revealed a "good fit" based on hypothesized similarity with the factor structure identified in the ESQ. A model using 9 indicators (3 per factor), similar to the structure of the ESQ, was chosen as the optimal method. The final model showed good internal consistency along with convergent and discriminant validities. However, the alpha-removed statistic for the length, fullness, and overall satisfaction (LFOS) construct showed a significant increase in scale consistency with the removal of item 8 (Compared to your first visit, overall, how satisfied are you with your eyelashes now?). Despite this, the model structure was retained to better facilitate comparisons between the ESQ and ESFQ and to provide sufficient measures to properly evaluate the construct. **CONCLUSIONS:** The 9-item ESFQ appears to be a valid measure to assess changes in eyelash-specific PROs. The factor structure showed near equivalence with the ESQ. Future research will involve further validation of the ESFQ in response to variations in hypotrichosis etiologies and clinical treatment paradigms.

**PSS15**

**COMPARISON OF THE PRO ENDPOINTS FOUND IN LABELING CLAIMS OF PRODUCTS FOR THE TREATMENT OF PсорIASIS WITH THOSE RECOMMENDED BY THE CORRESPONDING EMEA GUIDANCE**

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OBJECTIVES: Our objective was to compare the PRO endpoints recommended by the EMEA for guidance on the clinical investigation of medicinal products indicated for the treatment of psoriasis (CHMP/EWP/2454/02) published in November 2004, with those used for the approval of medicinal products for psoriasis.

**METHODS:** The EMEA website was searched to identify all medicinal products approved specifically for psoriasis since 1995. PROlabels was searched to identify the products with a PRO labeling claim. **RESULTS:** The EMEA guidance specifies that “Patient-assessed drug efficacy may be a secondary or tertiary endpoint in pivotal clinical trials. These measures correspond both to efficacy evaluated by patients and to health-related quality of life (HRQoL) scales validated in dermatology.” The guidance quotes simple measures such as symptom improvement, tolerability, cosmetic acceptability, ease of use, patient’s assessment of global improvement and of the products' efficacy and of the products' acceptability. The guidance has only endorsed the use of PRO endpoints. However, comparison of the dates of the guidance publication and of the products' approval suggest that the guidance has only endorsed the use of PRO endpoints. These measures correspond both to efficacy evaluated by patients and to health-related quality of life (HRQoL) scales validated in dermatology. The PROmeasure for psorisis was failed to respond to, or were intolerant of, prior therapies (phototherapy, cyclosporine, methotrexate, and/or oral retinoids) received adalimumab (80 mg) at Week 0 followed by adalimumab (40 mg) every other week starting at Week 1. Changes in the Dermatology Life Quality Index (DLQI), Beck Depression Inventory-II (BDI) and EQ-SD at baseline, Week 16 and Week 24 were evaluated. **RESULTS:** A total of 203 patients (male, 61%; mean age, 46 years; mean PASI score, 20) were enrolled at 26 sites. At baseline, mean DLQI, BDI and EQ-SD were 12.9, 9.3, and 0.79, respectively. At Week 16, the mean DLQI score improved to 2.9 (change = -10.0); p < 0.0001, and the BDI was reduced to 3.2 (change = -4.2; p < 0.0001), and the EQ-SD had improved to 0.89 (change = 0.10; p < 0.0001). A 16-week results were sustained to 24-weeks, and all outcomes showed statistically significant improvements from baseline. Improvements were even greater in patients with a baseline DLQI score ≥10. **CONCLUSIONS:** Adalimumab treatment was associated with statistically significant improvements in PROs of psoriasis patients in Canada, including depression. The results of this open-label study were consistent with outcomes observed in randomized placebo controlled clinical trials of adalimumab, confirming that adalimumab has a substantial impact on patient health-related quality of life.