OBJECTIVES: We describe the development of the primary-reported scar questionnaire (PR-SEQ) for measurement of scar-related distress and impairment in patients with severe psoriasis.

METHODS: The PR-SEQ was developed through a 5-step process: 1) open item collection on non-cosmetic scar below the neck; 2) item development by an expert panel including patients; 3) double forward and backward translation with subsequent translators' and developers' conferences; 4) feasibility testing of the pilot questionnaire in n=55 patients in 4 countries (D, USA, Canada, UK) with subsequent questionnaire refinement; 5) longitudinal feasibility and validation study in n=205 patients, respectively.

RESULTS: A total of 43 interviews across five surgery types were conducted to elicit information regarding their experiences with their disfiguring scar. During the CE interviews, the most important and relevant concepts patients used to describe scar appearance were color, size (height, width, thickness), and texture. The most important and relevant scar symptom concepts reported were itchiness, pain, swelling, and oozing. Psychological impact concepts were limitations of wearing certain clothing and feeling self-conscious, sad, and less attractive because of the scar. CONCLUSIONS: The CE interviews provided rich information about how patients perceive and experience their scars which extends beyond the typical appearance dimensions. This work is fundamental in providing the conceptual framework of the scar experience and the first steps in the development of the PR-SEQ.

PSS28
LONG-TERM IMPROVEMENT IN PATIENT-REPORTED OUTCOMES AFTER TRANSITION FROM METHOTREXATE TO USTEKINUMAB IN MODERATE TO SEVERE PSORIASIS: TRANSITION WEEK 52 RESULTS

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PSS29
DO SCARS IMPACT BEYOND JUST APPEARANCE? A REPORT OF THE CONTENT ELICITATION (CE) PHASE IN THE DEVELOPMENT OF THE PATIENT REPORTED SCAR EVALUATION QUESTIONNAIRE (PR-SEQ)

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OBJECTIVES: To investigate whether a 1-line (5 letters) average change in best corrected visual acuity (BCVA) was associated with changes in health-related quality of life (HRQoL) in patients with diabetic macular edema (DME).

METHODS: We conducted a 12-month randomized trial of dexamethasone intravitreal implant plus laser or laser alone for DME were analyzed. HRQoL was assessed by the National Eye Institute 25-item Visual Function Questionnaire (VFQ-25). Patients were categorized into groups based on time-weighted average BCVA change from baseline: worsened (ABBCVA $<$ 5), no change (5 $\leq$ ABBCVA $<$ 10) and improved (10 $\leq$ ABBCVA).

RESULTS: A total of 244 patients were treated in Arm1 and 245 in Arm2; 92% and 90%, respectively, completed 52 weeks’ therapy. Median baseline Dermatology Life Quality Index (DLQI) was 8 and 9 in Arm1 and 2, respectively, decreasing to 1 baseline value at Week 16 and 52. At Week 52 in Arm1 and 2, respectively, 54% and 52% of patients had a DLQI reduction $\geq$5 points; 62% and 67% had DLQI 0 or 1. Median DLQI scores were low at Week 28 among patients who dose escalated; further improvements were seen by Week 52. Median EuroQol-5D Visual Analogue Scale improved from baseline to Week 52; respectively, 7.0 (IQR 5.0–8.0) to 8.0 (IQR 7.0–9.0) in Arm1, and 7.0 (IQR 5.0–8.0) to 8.5 (IQR 7.9–9.5) in Arm2. Median Hospital Anxiety and Depression Scale (HADS) Anxiety and Depression scores also improved from baseline to Week 52.

CONCLUSIONS: In patients with moderate-to-severe psoriasis, ustekinumab use was associated with clinically relevant improvements in patient-reported outcomes, irrespective of whether patients were previously treated with biologic or conventional systemic therapies. Improvements at Week 16 were sustained to 52 weeks of ustekinumab therapy.

PSS25
NAIL ASSESSMENT IN PSORIASIS AND PSORIATIC ARTHRITIS (NAPPA): AN INTEGRATED APPROACH OF OUTCOMES MEASUREMENT IN NAIL PSORIASIS

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OBJECTIVES: To determine whether a range of established outcomes measures for psoriasis in general, there has been a lack of valid instruments for nail psoriasis (NPs). Therefore, we developed and validated the three-component tool “Nail Assessment in Psoriasis and Psoriatic Arthritis” (NAPPA) including health-related quality of life (NAPPA-Qol), patient-relevant treatment benefit (NAPPA-FB) and clinical severity (NAPPA-CLIN). The NAPPA tool was developed by a multinational expert group involving dermatologists, psychologists, statisticians, and patients.

RESULTS: Development included the following steps: 1) Open item collection on patient-relevant impairments and needs in n=120 patients in 2 countries (D, USA); 2) item development by an expert panel including patients; 3) double forward and backward translations with subsequent translators' and developers' conferences; 4) feasibility testing of the pilot questionnaire in n=55 patients in 4 countries (D, USA, Canada, UK) with subsequent questionnaire refinement; 5) longitudinal feasibility and validation study in n=205 patients from 6 countries (Germany, USA, Denmark, Japan, Italy, Spain).

RESULTS: Open item collection generated 692 single items with redundant content which could be condensed to 20 items for the NAPPA-Qol and 24 items for the NAPPA-FB. Most patients rated the final questionnaires as feasible, i.e. the purpose was clear to them (95.0%), instructions and questions were comprehensible (83.6% / 89.1%), and all relevant areas were covered (87.1%). NAPPA-Qol and -FB correlated moderately with clinical outcomes (PASI, NAPPA-FB) and well with other QoL questionnaires (EQ5D-SD, DLQI). Sensitivity to change and internal consistency were good. Clinical severity (NAPPA-CLIN) measured with a two-digit solution which correlated highly (r>0.9) with NAPISI but which can be assessed much more time-efficiently.

CONCLUSIONS: With the modular NAPPA outcomes tool, clinical and patient-reported outcomes in nail psoriasis can be measured validly and reliably. Thus, it can be recommended for usage in international clinical studies and daily practice.