

## 1863 - Development and Content Validity of the Hand Disability in Systemic Sclerosis—Digital Ulcers (HDISS-DU) Scale

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*Hall F2 - Poster Hall (McCormick Place West)*

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**Background/Purpose:** Digital ulcers (DU) are common, painful, debilitating manifestations of systemic sclerosis (SSc); they adversely affect hand function in daily activities. The Cochin Hand Function Scale (CHFS), originally developed for use in rheumatoid arthritis, is a self-administered hand functional disability questionnaire, containing 18 items related to daily activities. The objective of this research was to evaluate the content validity of the CHFS in patients with SSc and active DU, and to modify the instrument as needed.

**Method:** A cross-sectional qualitative interview study was conducted in the US. Eligibility included a diagnosis of SSc and at least one recent, visible, active ischemic DU, for which the patient had seen a physician within the past 8 weeks. The study had 2 phases: Phase I consisted of 20 face-to-face semi-structured interviews, which focused on 2 parts: a) elicitation of emergent concepts relevant and important to DU-related hand function and b) cognitive debriefing of the CHFS. Based on findings and after having reached saturation of concepts, the original CHFS was modified and then cognitively debriefed in further qualitative interviews (Phase II, n=16) to confirm changes and the content validity of the modified instrument. IRB approval was obtained and all participants provided written informed consent. Interviews were recorded, transcribed, and analyzed using Atlas.ti (qualitative analysis software).

**Result:** The 36 patients had a mean age of 52.5 years (range: 18-73); 81% were female, and 83% Caucasian. Among the 35 participants with clinician-documented data, the mean number of active ulcers was 2.7; 89% and 71% had DU(s) on the dominant hand and submissive hand, respectively. Examples of commonly reported limitations due to DUs (in Phase I) included: activities using fingertips (e.g., using keyboard), washing dishes, cleaning, dressing, fitness activities, bathing/ showering, and grooming. Items in the original CHFS were modified and new items were added to cover the types of limitations patients reported in Phase I; specifically, 13 items were added, 4 items were deleted, and 12 items were modified and/or clarified to be more relevant to DU-related hand functioning. The revised instrument was called the Hand Disability in Systemic Sclerosis – Digital Ulcers (HDISS-DU) questionnaire. In Phase II, in which the HDISS-DU was cognitively debriefed, participants confirmed the clarity and relevance of the items, and the appropriateness of the recall period and response scales of the revised instrument. Only limited additional modifications to the instructions and response options were required; one item was deleted. The current version of the HDISS-DU assesses the impact of DUs on hand functioning through 26-items; patients are asked to rate their ability to complete common activities over the past 7 days.

**Conclusion:** The qualitative interview study suggests that the draft version of the HDISS-DU is a comprehensive, content valid instrument assessing the impact of DUs on hand functioning in patients with SSc. Future studies will be conducted for additional item reduction (if required) and assessment of psychometric properties of the HDISS-DU.

**Keywords:** disability, hand disorders, patient questionnaires and systemic sclerosis

**Disclosure:** **D. Khanna**, Actelion Pharmaceuticals; United Therapeutics; Pfizer; Novartis, 5, Actelion, Allschwil, Switzerland; , 8 ; **S. Poiraudau**, Actelion, Allschwil, Switzerland, 5 ; **H. Gelhorn**, Actelion, Allschwil, Switzerland, 5, United BioSource Corporation, 3 ; **E. Hunsche**, Actelion, Allschwil, Switzerland, 1, Actelion, Allschwil, Switzerland, 3 ; **K. Papadakis**, Actelion, Allschwil, Switzerland, 3 ; **L. Perchenet**, Actelion, Allschwil, Switzerland, 3 ; **M. S. Mattera**, Actelion, Allschwil, Switzerland, 5 ; **M. Vernon**, Actelion, Allschwil, Switzerland, 5 ; **L. Mouthon**, Actelion, Allschwil, Switzerland; Actelion France; Pfizer, 5, Actelion France; Pfizer, 2, Actelion France; GSK; Lilly, 6 .