

Provisional American College of Rheumatology (ACR) Combined Response Index in diffuse cutaneous Systemic Sclerosis (CRISS) Score Correlates with Changes (Δ) in Patient-reported Outcomes (PROs)

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Disclosures

- Grants/Research Support
 - Roche-Genetech
 - GSK
 - BMS
 - Boehringer Ingelheim
 - Cytori
 - Chemocentryx
 - Corbus
 - Formation Biologics
 - Sanofi
 - Inflarx

- Consulting
 - Roche-Genetech
 - GSK
 - CSL Behring
 - Sanofi
 - Janssen
 - Chemocentryx
 - Formation Biologics

Background

- ACR CRISS score is a composite outcome developed to assess the likelihood of improvement from baseline in clinical trials in subjects with dcSSc
- Several trials have reported positive outcomes using ACR CRISS score as a primary, secondary, or post-hoc efficacy outcome
- Primary efficacy outcomes should reflect clinical benefit, that is how the patient feels, functions, or survives

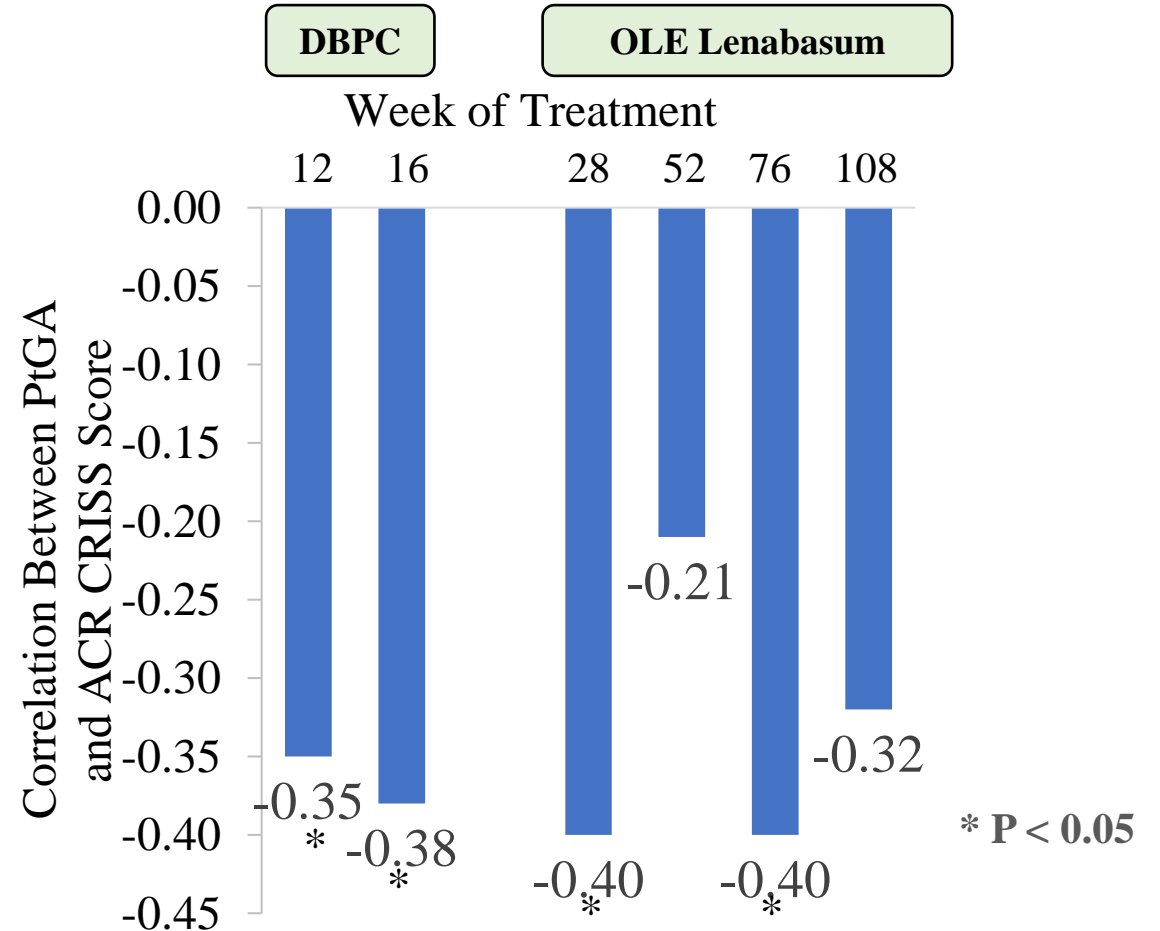
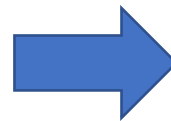
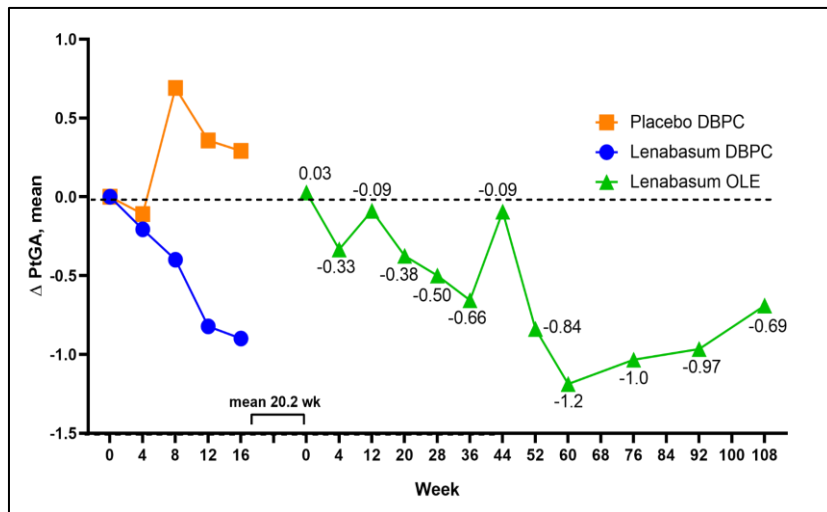
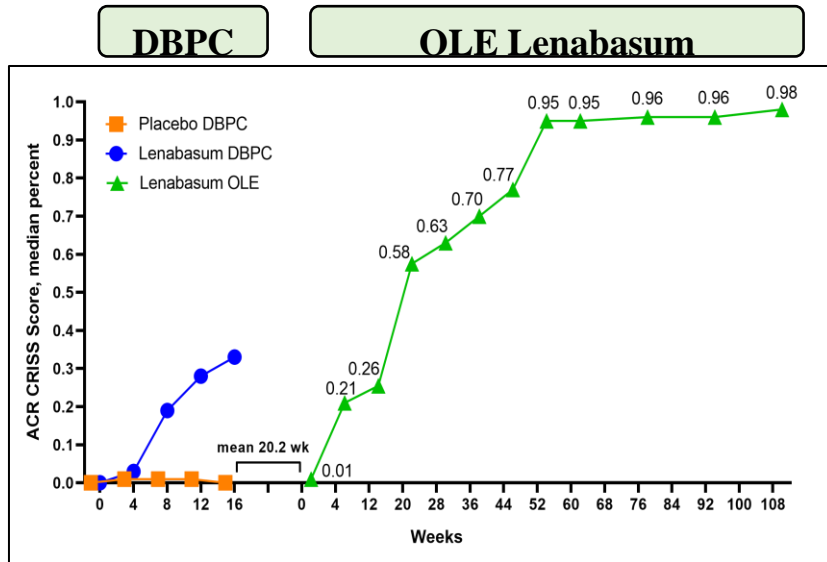
Objective

Determine whether ACR CRISS score reflects patient-reported outcomes, including two that are part of the ACR CRISS score itself (HAQ-DI and PtGA), Systemic Sclerosis Skin Symptoms Patient-reported Outcome¹ (SSPRO) and PROMIS-29 domain scores over 12 months

Methods

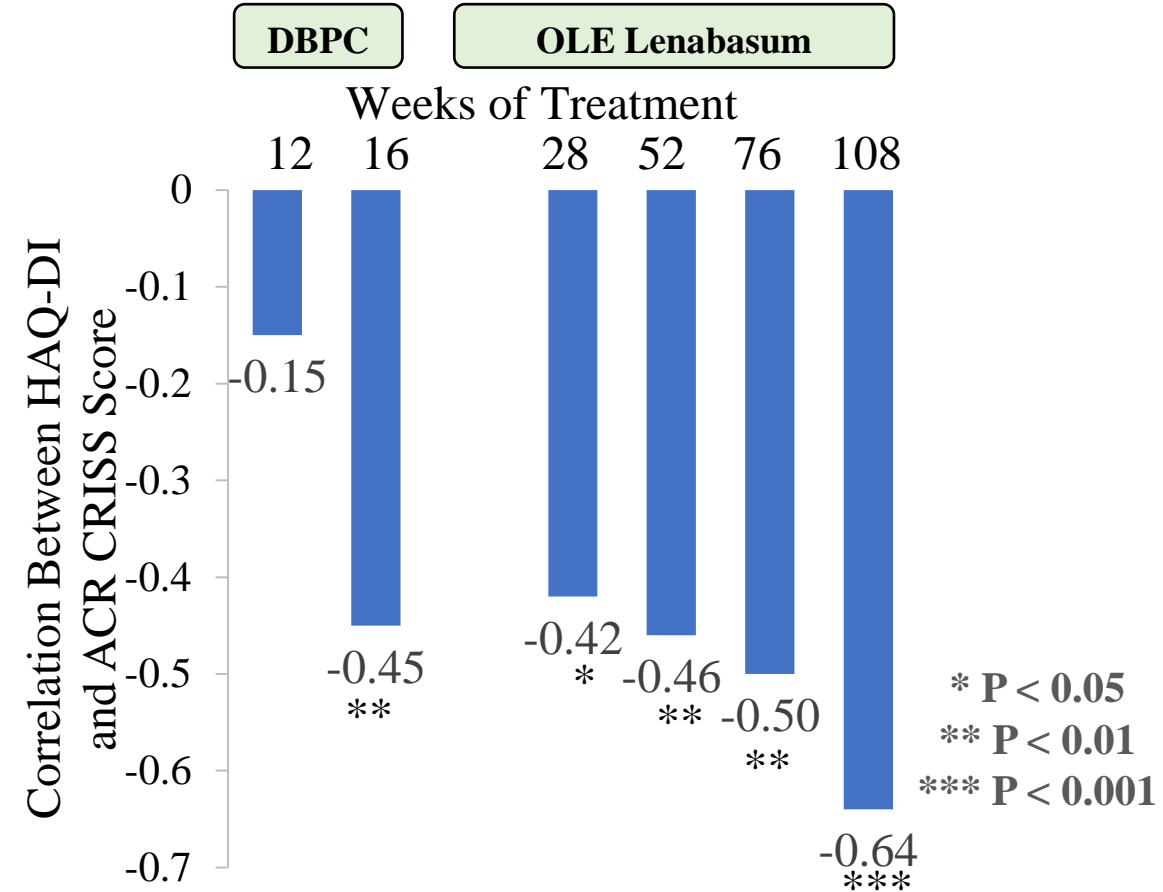
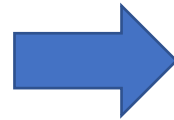
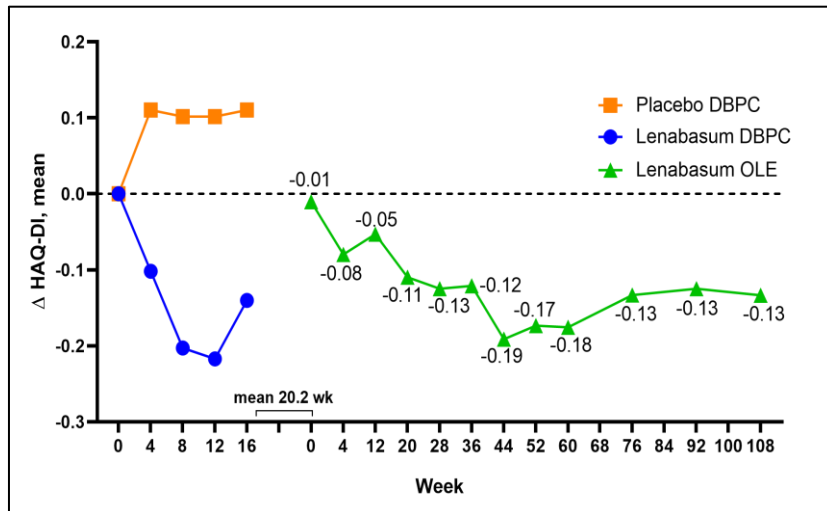
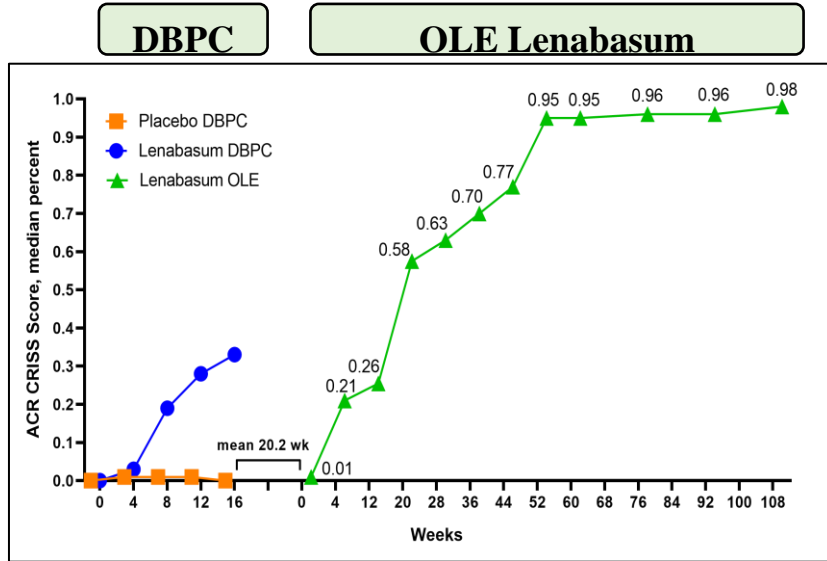
- Determine Spearman correlation coefficients between ACR CRISS score and change in PROs in a phase 2 study of lenabasum in dcSSc
 - Months 3 and 4 in double-blind placebo control Part A of study (n = 38 each) and months 6, 12, 18, and 24 in open-label extension of study (N = 36, 31, 30, and 29, respectively)
- Baseline was time of the first dose in Part A or the first dose in the OLE
- For description purposes, correlations coefficients (r) are categorized as:
 - no (0 to 0.19)
 - low (0.20 to 0.34)
 - moderate (0.35 to 0.59)
 - strong (0.60 to 0.79)

Results: ACR CRISS Score and Change in PtGA (Overall Health)



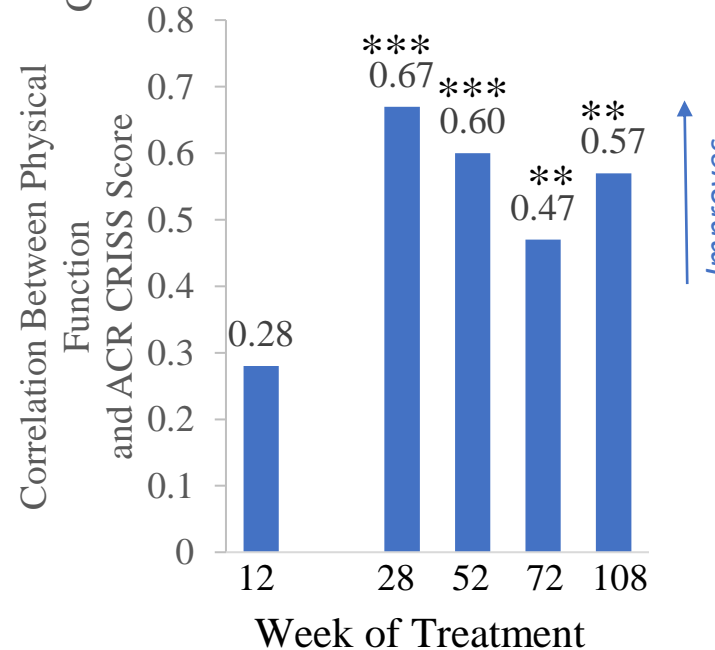
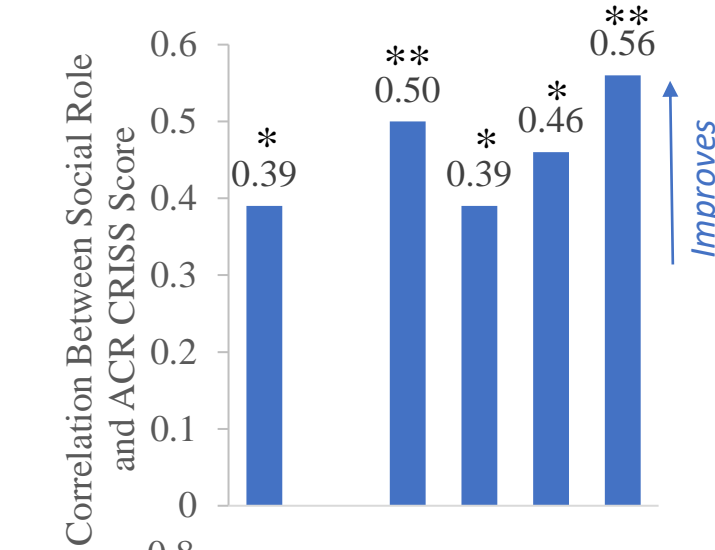
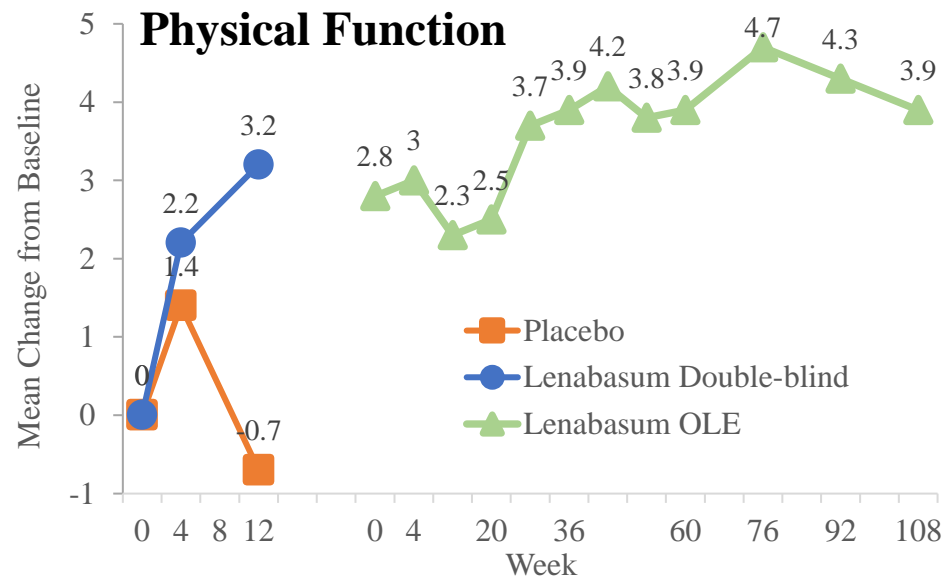
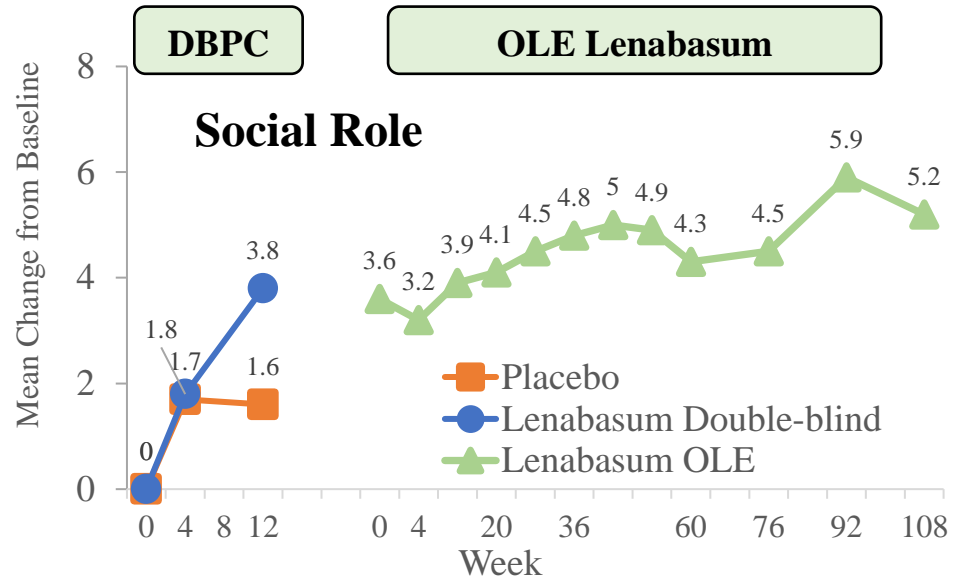
Low to moderate correlations

Results: ACR CRISS Score and Change in HAQ-DI (Function)



Moderate to strong correlations after week 16

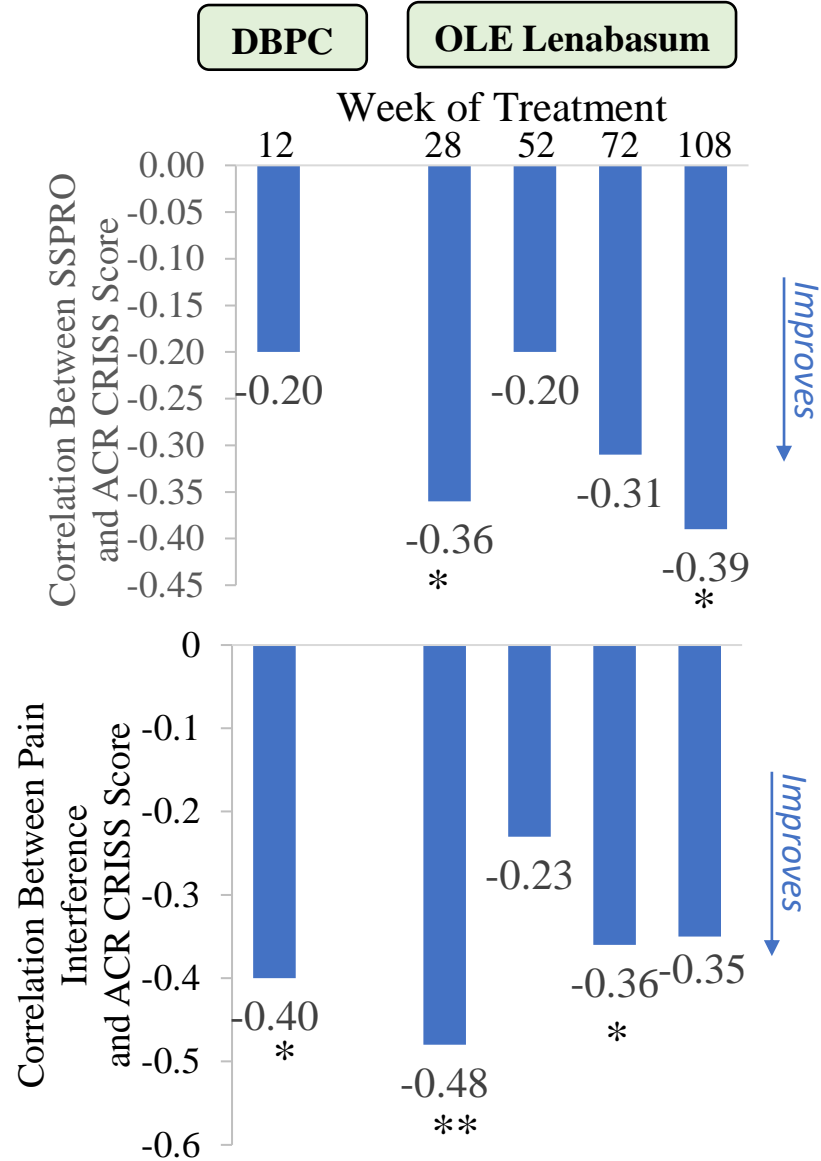
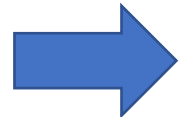
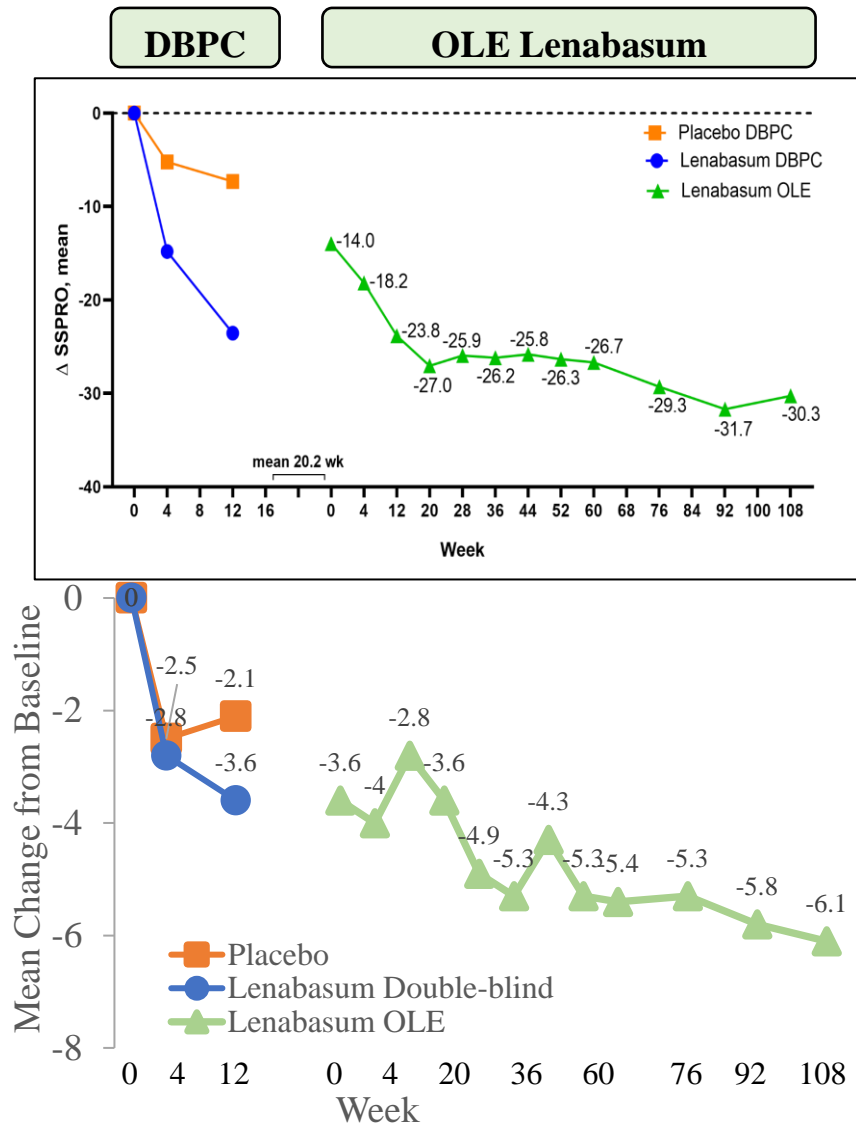
Results: ACR CRISS Score and Change in PROMIS-29 Social Role and Physical Function Domains (Function)



Moderate to strong correlations

* P < 0.05
 ** P < 0.01
 *** P < 0.001

Results: ACR CRISS Score and Change in SSPRO and PROMIS-29 Pain Interference Domains (Symptoms)



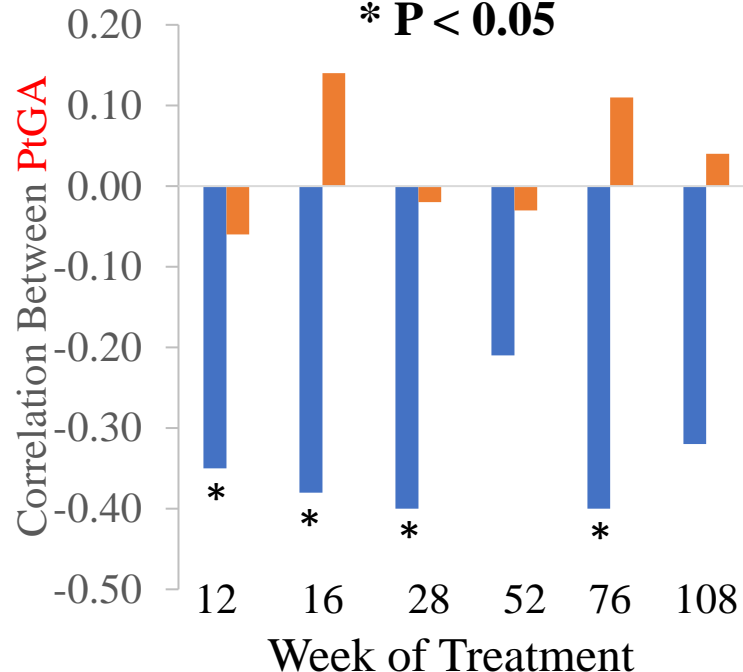
Low to moderate correlations

* P < 0.05
** P < 0.01

Correlations of ACR CRISS Score vs. Change in mRSS with Change in PRO

Overall

* P < 0.05

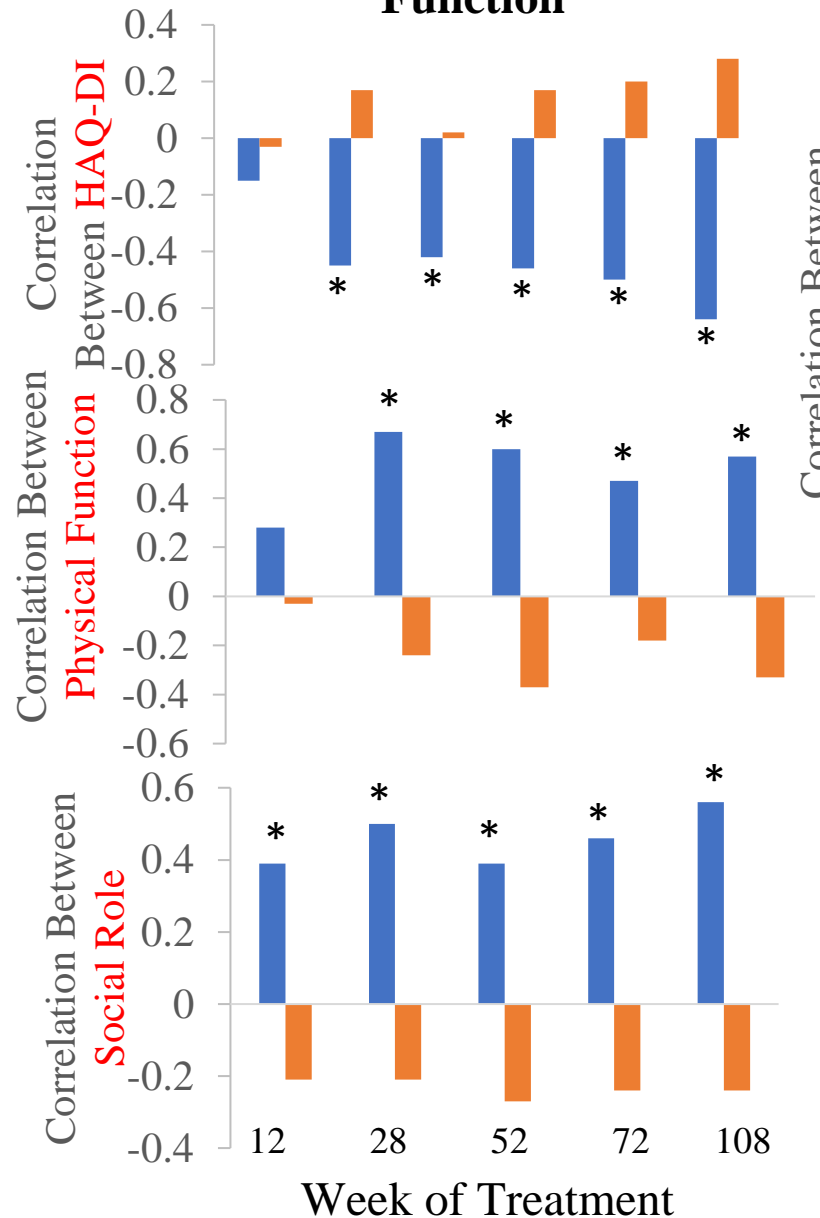


Blue – ACR CRISS

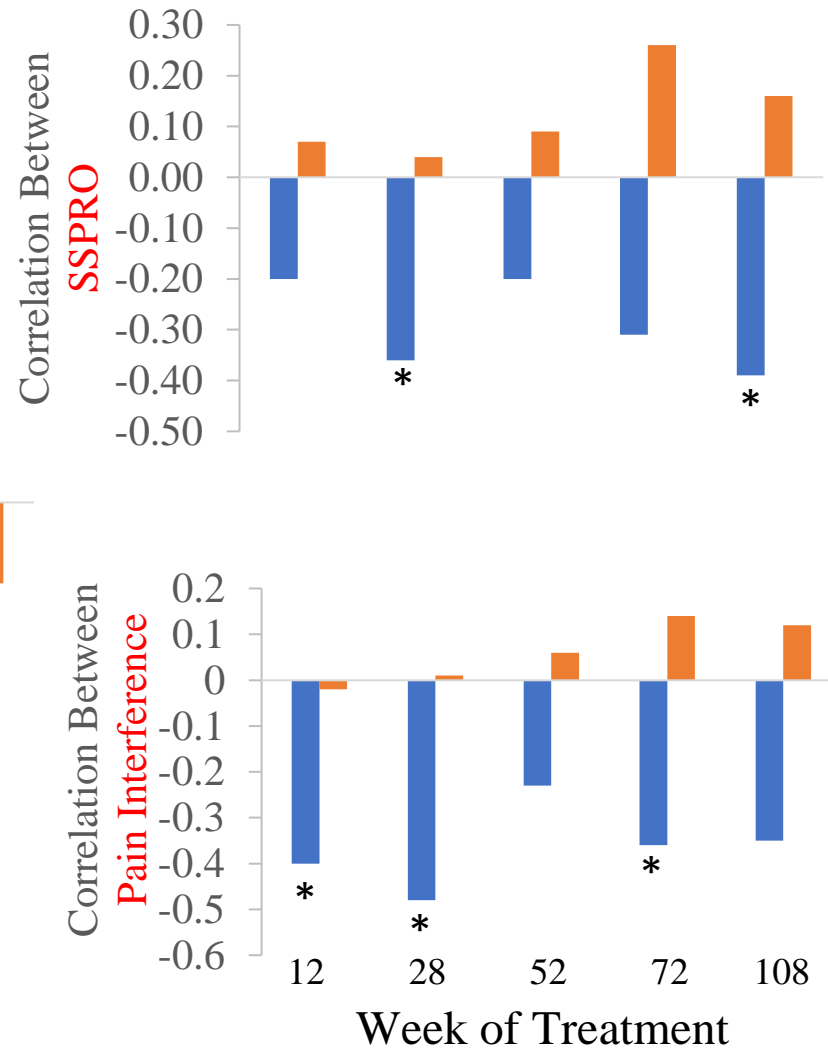
Orange - mRSS

ACR CRISS score has stronger correlations with PROs than change in mRSS

Function



Symptoms



Summary and Conclusions

- The composite ACR CRISS score consistently correlated with patient-reported function and symptoms outcomes, including patient-reported outcomes not captured in the ACR CRISS score calculation
- ACR CRISS score correlated with these PRO more strongly than change in mRSS, a physician measurement of skin thickness
- ACR CRISS score may serve as an efficacy outcome that broadly reflects how the patient feels and functions

Investigators and study coordinators

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