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ORIGINAL PAPER

The utility of PROMIS domain measures in dermatologic care

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Abstract
Patient-reported outcome (PRO) measures play an important role in clinical care. Currently, a broad-spectrum, validated PRO measure suitable for all dermatology patients, as part of clinical care, does not exist. Patient-reported Outcome Measures Information System (PROMIS) measures track specific domain outcomes across all diseases. To assess the relevance and utility of a computer-adaptive health assessment consisting of three PROMIS domains in routine dermatologic care. This retrospective study evaluated a PROMIS health assessment, consisting of three computer-adaptive test domains (pain interference, anxiety, and depression), administered as part of routine clinical care in three dermatology clinics at an academic medical center. The primary objective was to identify clinically significant associations between high PROMIS domain scores (i.e., *t* score > 55) and dermatologic disease, as well as change in PROMIS domain scores in response to treatment. The majority of patients who initiated the assessment completed all domains (88.7%). In patients with atopic dermatitis, acne, hidradenitis suppurativa, and psoriasis, high PROMIS scores correlated with clinically relevant outcomes, such as severe disease, unsuccessful treatment, uncontrolled disease, and the presence of a mental health condition. PROMIS Pain Interference, anxiety and depression identified patients with severe disease, unsuccessful treatment regimens, poorly-controlled disease, and/or mental health comorbidities for multiple skin conditions. Further utilization of PROMIS domains in routine clinical care will promote patient-centered care and improve quality of care.

Keywords PROMIS · Dermatology · Atopic dermatitis · Acne · Pain · Anxiety

Introduction

Patient-reported outcome (PRO) measures play an important role in monitoring response to treatment and overall health. PROs are not commonly used as part of routine clinical care, except in psychiatry and primary care [13, 14, 19]. PRO measures are common in dermatology clinical trials to capture the impact of skin disease and itch on quality of life (e.g. Skindex or ItchyQoL) [5, 7, 24, 25]. We proposed initiating a validated, trackable PRO measure to assess patients' current skin condition and overall health in an academic dermatology outpatient setting. Patient-reported Outcome Measures Information System (PROMIS), developed and validated by the National Institutes of Health (NIH), employs domain-specific measures to assess a patient's physical, mental, and social health (i.e., well-being) [1, 9, 27]. The advantage of domain-specific measures over disease-specific measures is the ability to monitor a patient's well-being throughout the healthcare system. Post-hoc analyses of six longitudinal studies demonstrated the beneficial potential of PROMIS measures in a variety of clinical settings including congestive heart failure, chronic obstructive pulmonary disease, chronic back pain, rheumatoid arthritis, cancer, and major depression [6]. Our goal was to identify the most meaningful PROMIS domains for general dermatologic care.

At each clinic visit to the academic outpatient dermatology department, patients completed computer-adaptive tests (CATs) for three PROMIS domains (Anxiety, Pain Interference, and Depression) on a tablet upon arrival. The provider could view the domain scores immediately in the patient's electronic medical record for utilization during the clinic visit. We hypothesized that PROMIS domain scores would provide insight into the effects of the skin condition on a patient's overall biopsychosocial health and help monitor

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clinical outcomes (i.e., severity of disease and treatment response).

Methods

Study design

This was a retrospective cohort study examining the relevance and utility of PROMIS measures in clinical care at an academic dermatology department. This study was conducted under institutional review board approval. The PROMIS health assessment generated up to three different domain scores (anxiety, pain interference, and depression) for each patient. PROMIS health assessment data included t-scores, administration rate, decline rate, quit rate, ineligibility, completion time, duration time, test type (adult or pediatric), clinic site, date of visit, subject code (a unique four-digit number for each patient), age, gender, race, ethnicity, visit type (new (NPV) or follow-up (FUV), and visit diagnoses.

A unique numeric subject identity and visit identity was recorded for de-identification prior to analyses. Each visit had a PROMIS status of: "not administered" (patient not offered the tablet); "declined" (patient pressed "decline" button); "ineligible" (patients not meeting prementioned eligibility criteria); "quit" (assessment stopped before completing all domains); or "completed" (completed all three PROMIS domains). Study results reported herein utilized all available PROMIS domain scores. Due to the ability of patients to quit during the health assessment, the number of visits analyzed within each domain differed. Diagnosis groups were created using primary and secondary visit diagnoses (ICD10 codes) which enabled comparison of PROMIS scores within specific diagnoses.

PROMIS health assessment

The PROMIS health assessment consisted of CATs for three domains (Anxiety, Pain Interference, and Depression) administered on an iPad during check-in for a clinic appointment. The number of questions each patient received within each domain was dependent on his or her answers. The number of questions ranged from 4 to 12 per domain or 12–36 questions total for the entire health assessment. Ineligibility criteria included: patients under five years of age, patients unable to use the tablet, patients unable to answer the questions due to physical or intellectual disability, and deficient English language skills. Participation in the PROMIS health assessment was voluntary and patients could quit the assessment at any point. Completion of at least four question within a domain generated a domain score. All PROMIS domains were measured using a *t* score metric ranging from 0 to 100, with a mean of 50 and standard deviation (SD) of 10 [9]. The mean *t* score of 50 represented the average health of the general population within that domain. High *t* scores represented worse outcomes for the domains tested (i.e., high Anxiety, high Pain Interference, or more severe Depression). To determine clinical relevance of the PROMIS domain scores, we categorized domain scores as "normal range" (i.e. ≤ 55) or "clinically significant" (i.e. > 55). A change of four points or more was classified as a clinically minimally important difference (MID), based on previous published analysis [3, 30].

Data handling and groupings

A unique numeric subject identity and visit identity was recorded for de-identification prior to analyses. Each visit had a PROMIS status of: "not administered" (patient not offered the tablet); "declined" (patient pressed "decline" button); "ineligible" (patients not meeting prementioned eligibility criteria); "quit" (assessment stopped before completing all domains); or "completed" (completed all three PROMIS domains). Study results reported herein utilized all available PROMIS domain scores. Due to the ability of patients to quit during the health assessment, the number of visits analyzed within each domain differed. Diagnosis groups were created using primary and secondary visit diagnoses (ICD10 codes) which enabled comparison of PROMIS scores within specific diagnoses.

Systematic chart reviews

To gain insight into the clinical relevance of high PROMIS scores in dermatologic disease, a systematic chart review was performed of age-matched and gender-matched patients with "clinically significant" scores ($N = 20$) and "normal range" scores ($N = 20$) in four diagnosis groups of chronic skin diseases (i.e., atopic dermatitis (AD), acne, hidradenitis suppurativa (HS), and psoriasis). Chart review was performed to assess the severity of disease (mild or severe); improvement with treatment (yes or no); control of disease (yes or no); treatment type (systemic, topical, both); and presence of mental health comorbidity (yes or no). Additional clinical characteristics of disease included: percent body surface area (%BSA) of disease for AD patients and scarring for acne patients.

Statistical analyses

All statistical analyses were performed at a 5% level of significance using JMP14 Pro or Microsoft Excel. All collected domain *t* scores were included in these analyses. Descriptive statistics characterized our dermatology population. Two-tailed analysis of variance (ANOVA) and Tukey's

test analyzed differences in mean PROMIS domain scores, diagnosis subsets, demographic groups, and treatment response. Two-tailed Fisher Exact tests examined relationships between "clinically significant" PROMIS domain scores and demographic factors. For the systematic chart review, two-tailed Fisher Exact tests identified relationships between "clinically significant" PROMIS domain scores and clinical characteristics of disease. For treatment responses, paired *t* test compared PROMIS scores between baseline and follow-up visits.

Results

Patient characteristics

Out of 41,540 clinic visits, patients initiated the PROMIS health assessment in 7,213 visits. Of initiated visits, patients quit the assessment at 236 visits resulting in no PROMIS scores (Fig. 1). The results reported herein includes analyzable PROMIS data from 6,977 clinic visits. All three domains were completed in 91% of visits in an average time of 3.80 ± 0.08 min (Fig. 1). The majority of patients who completed the PROMIS health assessment were Caucasian (80%) females (62%) with mean age of 47 years (age range: 8–92 years) (Table 1). Most dermatology visits had patients with normal range PROMIS domain scores (pain interference = 68.70%; depression = 81.71%; anxiety = 71.16%). The proportion of visits with "clinically significant" scores (i.e., > 55) varied by PROMIS domain, ranging from 18 to 31% (Table 2). This study focused on the "clinically significant" scores (high domain scores) to better understand the relationship between dermatologic disease and biopsychosocial health. We evaluated the association of "clinically significant" scores with clinically relevant outcomes determined by chart review and overall assessment for four chronic skin conditions commonly seen in our clinics (AD, acne, HS, and psoriasis; Tables 1, 2). In these four skin conditions, the proportion of visits with PROMIS scores above 55 varied by PROMIS domain and ranged between 14 and 66% (Table 2).

Skin conditions influence physical and mental health

Systematic chart review of age-matched and gender-matched patients with "clinically significant" scores revealed associations between PROMIS domains and disease-specific clinically relevant outcomes (Table 3). In the four chronic skin disease subsets, more severe disease was associated with "clinically significant" PROMIS domain scores. In patients with AD or HS, higher disease severity was associated with high Pain Interference scores (Table 3). Additionally, high Anxiety scores associated with uncontrolled AD (15/20 (75%) vs. 8/20 (40%), $p = 0.027$), and high Depression scores associated with severe AD (11/20 (55%) vs. 4/20 (20%), $p = 0.048$). In patients with acne, high Anxiety scores were associated with clinical severity, acne scarring, and the presence of a mental health comorbidity (Table 3). In patients with psoriasis, high depression scores were associated with

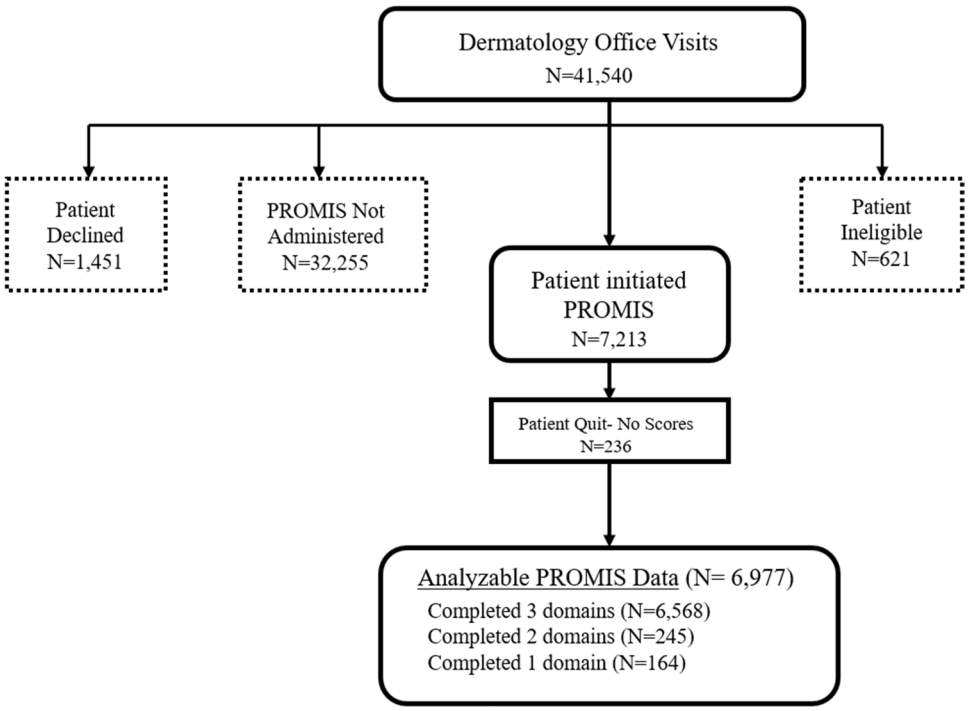

Fig. 1 This diagram shows the flow of the PROMIS health assessment in clinical care at University of Rochester Dermatology. Data analyzed in this study included 4,633 clinic visits from 4069 patients

Table 1 Patient Demographics

	All patients ($n=6021$)	Atopic dermatitis ($n=130$)	Acne ($n=527$)	Hidradenitis suppurativa ($n=118$)	Psoriasis ($n=258$)
Age (years)					
Mean	47.42	34.85	27.02	34.54	44.83
(Range)	(6–94)	(8–79)	(10–72)	(12–69)	(11–79)
Gender					
Male	2286 (37.96%)	51 (39.23%)	158 (29.98%)	20 (16.95)	112 (43.24%)
Female	3735 (62.03%)	79 (60.77%)	369 (70.02%)	98 (83.05%)	146 (56.56%)
Race					
African American/Black	821 (13.63%)	34 (26.15%)	118 (22.39%)	63 (53.39%)	20 (7.75%)
Asian	101 (1.68%)	9 (6.92%)	21 (3.99%)	0 (0.00%)	5 (1.94%)
Other	212 (3.52%)	9 (6.92%)	35 (6.64%)	2 (1.70%)	8 (3.10%)
Unknown	63 (1.05%)	2 (1.54%)	10 (1.90%)	1 (0.85%)	0 (0.00%)
Caucasian/White	4824 (80.12%)	76 (58.46%)	343 (65.09%)	52 (44.07%)	225 (87.21%)
Ethnicity					
Hispanic	242 (4.02%)	8 (6.15%)	35 (6.64%)	2 (1.70%)	13 (5.04%)
Non-Hispanic	5717 (94.95%)	121 (93.08%)	483 (91.65%)	114 (96.61%)	245 (94.96%)
Unknown	62 (1.03%)	1 (0.77%)	9 (1.71%)	2 (1.70%)	0 (0.00%)

Table 2 Distribution of PROMIS Scores across visits

	All analyzable visits ($n=6977$)[a]	Atopic dermatitis ($n=184$) [a]	Acne ($n=639$) [a]	Hidradenitis suppurativa ($n=171$) [a]	Psoriasis ($n=318$) [a]
Overall Mean PROMIS Scores [95% CI]					
Pain interference	50.15 [49.91.50.39]	49.86 [48.24,51.48]	45.17 [44.50, 45.84]	58.36 [56.80,59.92]	51.11 [49.96, 52.27]
Depression	47.46 [47.23, 47.69]	48.76 [47.33, 50.19]	45.93 [45.19, 46.69]	53.84 [52.00,55.67]	47.93 [46.91, 48.96]
Anxiety	50.12 [49.87, 50.36	51.28 [49.83,51.28]	48.04 [47.21, 48.87]	55.12 [53.37,56.87]	51.08 [49.92, 52.24]
N (%) Visits—Clinically Significant Scores[b]					
Pain interference	2184 (31.30%)	66 (35.87%)	87 (13.60%)	113 (66.08%)	110 (34.59%)
Depression	1276 (18.29%)	50 (27.17%)	107 (16.74%)	67 (39.18%)	66 (20.76%)
Anxiety	2012 (28.84%)	66 (35.87%)	166 (25.98%)	89 (52.05%)	107 (33.65%)
Mean Clinically Significant PROMIS Scores [95% CI][c]					
Pain interference	62.39 [62.14, 62.64]	62.07 [60.59, 63.56]	59.80 [58.46,61.15]	64.31 [63.21, 65.41]	62.64 [61.51,63.77]
Depression	61.61 [61.25, 61.98]	61.04 [59.30, 62.78]	61.25 [59.96,62.54]	64.34 [62.63, 66.06]	61.24 [59.70, 62.77]
Anxiety	61.86 [61.57, 62.15]	61.53 [60.00,63.07]	61.35 [60.28, 62.42]	64.18 [62.78, 65.58]	62.30 [61.03, 63.58]

disease severity, uncontrolled disease, and unsuccessful treatment (Table 3).

Pain interference and anxiety scores reflect treatment response

PROMIS domains were evaluated on their predictability to detect treatment response in small patient cohorts (Fig. 2). Based on the systematic chart review, Pain Interference was expected to be responsive to improvements in AD or HS, anxiety to be responsive to improvements in acne, and depression to be responsive to improvements in psoriasis. In AD patients who initiated systemic therapy, Pain Interference scores significantly decreased between baseline and follow-up visits with documented disease improvement between visits (Fig. 2a). In acne patients on isotretinoin, anxiety scores significantly decreased between baseline and follow-up visits (Fig. 2b). In HS patients who had documented improvement on treatment between visits, Pain Interference scores significantly decreased between baseline and follow-up visits (Fig. 2c). Due to the many treatment approaches for psoriasis, we evaluated changes in domain scores between patients who were well-controlled ($N=17$) and poorly controlled ($N=13$) on biologics. Despite the associations between high depression scores and psoriasis in the systematic chart review, there were no significant

Table 3 Systematic chart review for associations with PROMIS domain scores

	Clinically significant ($N=20$)	Normal range ($N=20$)	2-tailed Fisher's Exact
Atopic dermatitis (AD) and pain interference			
% Body surface area (BSA)	29.0% (20.5, 37.4)	9.3% (0.9,17.7)	$p<0.0019$*
Severity			
Severe	17 (85%)	9 (45%)	$p=0.0187$*
Mild	3 (15%)	11(55%)	
Improved with treatment			
Yes	11 (55%)	20 (100%)	$p=0.0012$*
No	9 (45%)	0 (0%)	
Controlled disease			
Yes	4 (20%)	14 (70%)	$p=0.0036$*
No	16 (80%)	6 (30%)	
Hidradenitis suppurativa (HS) and pain interference			
Severity			
Severe	14 (70%)	3 (15%)	$p=0.0011$*
Mild	6 (30%)	17 (85%)	
Mental health comorbidity			
Yes	18 (90%)	12 (60%)	$p=0.0324$[a]
No	2 (10%)	8 (40%)	
Acne and anxiety			
Severity			
Severe	10 (50%)	4 (20%)	$p=0.048$*
Mild	10 (50%)	16 (80%)	
Scarring			
Yes	11 (55%)	2 (10%)	$p=0.005$*
No	9 (45%)	18 (90%)	
Mental health comorbidity			
Yes	12 (60%)	3 (15%)	$p=0.008$*
No	8 (40%)	17 (85%)	
Psoriasis and depression			
Severity			
Severe	11 (55%)	4 (20%)	$p=0.048$*
Mild	9 (45%)	16 (85%)	
Controlled disease			
Yes	10 (50%)	3 (15%)	$p=0.041$*
No	10 (50%)	17 (85%)	
Improved with treatment			
Yes	4 (20%)	14 (70%)	$p=0.004$*
No	16 (85%)	6 (30%)	
Mental health comorbidity			
Yes	17 (85%)	7 (35%)	$p=0.003$*
No	3 (15%)	13 (65%)	

changes in Depression scores between visits for well-controlled or poorly-controlled psoriasis. However, Pain Interference scores significantly decreased between visits for psoriasis patients who were well-controlled on biologics (Fig. 2d). Conversely, patient with poorly-controlled psoriasis on biologics had unchanged or increased mean scores for Pain Interference.

Discussion

Utilization of PRO measures in routine clinic care enhances healthcare analysis and can contribute to a future of person-centered medicine. Our study demonstrated that certain PROMIS domain scores broaden the clinical impression of dermatologic disease by incorporating the effect of

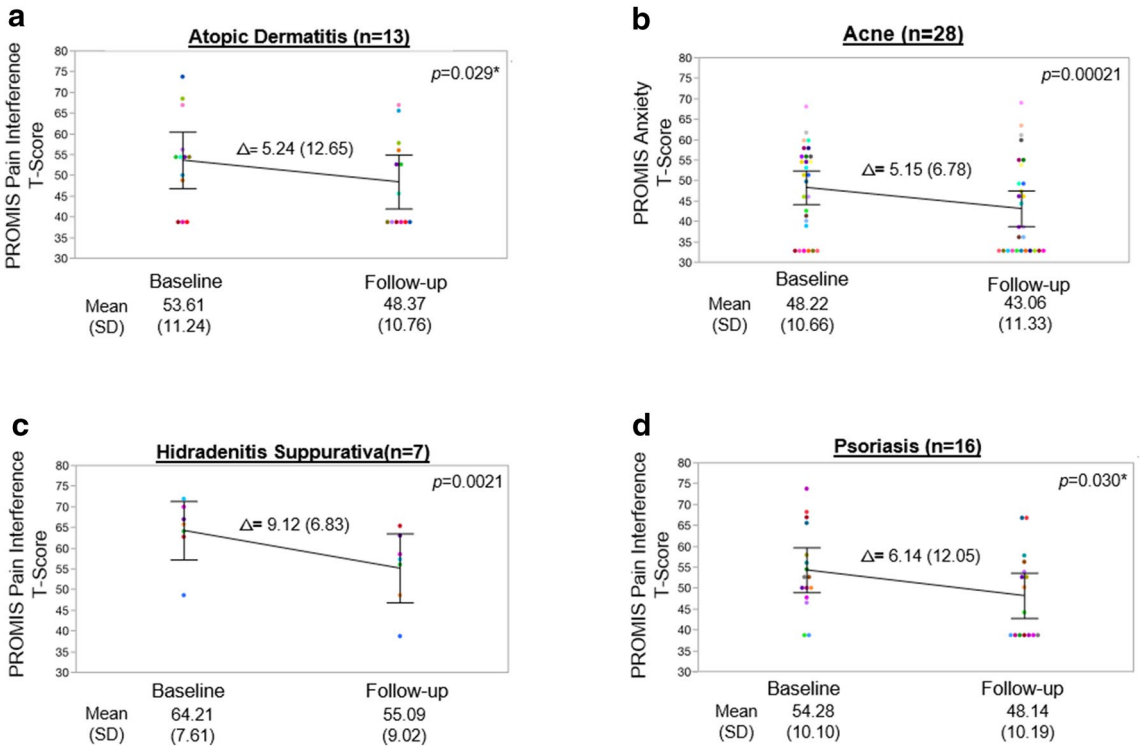

Fig. 2 PROMIS pain interference and anxiety can detect treatment response. Baseline and follow-up visit scores were compared for four patient cohorts. Each colored point in the graphs represents a patient **a** Pain interference scores significantly decreased in patients with atopic dermatitis (AD) who initiated systemic therapy between visits. **b** Anxiety scores significantly decreased in patients with acne between visits who were on isotrentinoin. **c** Pain interference scores significantly decreased in patients with hidradenitis suppurativa (HS) who had improvement of disease with treatment **d** Pain Interference scores significantly decreased in psoriasis patients who were well-controlled on a biologic therapy. Δ = mean change in PROMIS score; *p value for one-tailed t-test

skin disease and treatment on overall well-being from the patient's perspective. The ability to track treatment response with PRO measures provides a more patient-centered approach to care. Until recently, reliable PROs for clinical dermatology have been limited [12]. However, the importance of PRO incorporation into clinical care is now being recognized in dermatology [23–25]. A benefit of PROMIS measures over disease-specific measures is their utility and reliability across medical diagnoses and specialties [4, 6, 11]. With such a large array of uncommon diagnoses in dermatology, having a patient-centered method of following patient progress could be especially useful.

Although our study demonstrated the relevance of PROs in routine clinical dermatologic care, we were unable to perform extended longitudinal analyses on the current patient cohort. Longitudinal analyses would have allowed us assess how PROs change with disease over time. However, we showed that the PROs were responsive to improvements in disease between two visits, which suggests that PROs are reliable measures over time for impact of disease on patient's well-being. Future studies could provide valuable insight into chronic skin diseases by evaluating how various treatment regimens alter PROs over time. Furthermore, tracking provider PRO utilization and patient satisfaction during clinic visits could facilitate evaluation of the influence of PROMIS measures on patient-provider communication and quality of care.

Our study further supports the bidirectional relationship with psychological well-being and chronic skin conditions [15, 17, 20–22, 26, 28, 29, 31]. We have shown chronic skin disease directly influences a patient's physical health, as well as mental health. Although, PROMIS Pain Interference was the best surrogate for AD severity and treatment response, severe disease also associated with higher Anxiety and Depression scores similar to acne and psoriasis. Patients with AD are more likely to have depression, as well as flares in disease severity with increased stress [15, 22, 29, 31]. HS and psoriasis are both associated with anxiety, depression and impaired quality of life, and disease perception has been shown to trend with these measures [17, 20, 21, 26, 28]. We found an association between uncontrolled psoriasis and high PROMIS Depression scores, but were unable to detect a treatment response using the Depression domain. It is possible that a larger longitudinal sampling of psoriasis patients over time may reveal changes in both Pain Interference and

Depression domains. Furthermore, a social health domain would deepen our understanding of the psychosocial burden of disease. Recent studies have confirmed the role of internalized stigma and stigma-stress in the psychosocial burden of psoriasis [2, 16]. PROs assessing stigma would be useful in monitoring of chronic skin conditions, such as psoriasis and acne. Similar to other medical conditions, such as neurological disorders, it is important to understand the effects of disease on mental and social health to ensure the best overall treatment for the patient [8, 10, 18].

Utilization of PRO measures in clinical care will facilitate the assessment of patients' biopsychosocial health and the burden of their skin condition on their overall well-being, as well as elucidate patients' perceptions of their skin condition. Overall, we demonstrated how PROMIS pain interference, anxiety, and depression domains provided insight into disease severity and treatment response in multiple skin conditions. Patient-centered care requires an understanding the impact of skin conditions, as well as other diseases, on physical, mental, and social health. Future studies will evaluate the use of an Itch domain and social health domain in routine dermatologic care as part of the PROMIS health assessment. Continued use of PROs in routine clinical care will improve patient-provider communication and advance healthcare.

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Data availability Dr. Ryan Wolf has full control of the primary data and agrees to allow the journal to review these data if requested.

Compliance with ethical standards

Conflict of interest All authors have no conflicts of interest to disclose.

Ethics approval This study was approved by the University of Rochester Research Subject Review Board (RSRB#: 00062591 and 00069111).

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