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Using the Localized Scleroderma Cutaneous Assessment Tool (LoSCAT) to classify morphoea by severity and identify clinically significant change

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Summary

Background Validated scoring measures in morphoea can facilitate clinical trials.
Objectives To ascertain the clinical significance of scores on the Localized Scleroderma Cutaneous Assessment Tool (LoSCAT) and identify the change in scores correlated with clinically meaningful change.
Methods A prospective study of 120 participants from the Morphea in Adults and Children (MAC) cohort was undertaken. Physician's subjective assessments of severity and of improvement were completed at each visit. Receiver operating characteristic analysis determined LoSCAT scores corresponding with mild, moderate and severe disease, and absolute and percentage changes in scores corresponding with improved or worsened disease activity or damage.
Results Mild, moderate and severe activity corresponded with LoSCAT activity index (LoSAI) scores of 0–4, 5–12 and 13 and over, and with Physician's Global Assessment of activity (PGA-A) scores of 0–10, 11–30 and 31 and over. Mild, moderate and severe damage corresponded with LoSCAT damage index (LoSDI) scores of 0–10, 11–15 and 16 and over, and with PGA of damage (PGA-D) scores of 0–18, 19–30 and 31 and over. Improved activity was best indicated by LoSAI decrease of at least 2 points or 27·5%, or PGA-A decrease of at least 6 points. Improved damage was best indicated by LoSDI score decrease of at least 2 points. Worsening activity was best indicated by LoSAI increase of at least 2 points or 19·5%, or PGA-A increase of at least 4 points. Worsening damage was best indicated by LoSDI increase of at least 25·5%.
Conclusions The LoSCAT can be used to classify patients with morphoea by disease severity, and identify clinically significant improvement in activity.

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Conflicts of interest
None to declare.

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What's already known about this topic?

- The Localized Scleroderma Cutaneous Assessment Tool (LoSCAT) is a clinical tool that separately quantifies disease activity and damage in morphoea, and prior studies have demonstrated validity and reliability.

What does this study add?

- The LoSCAT can be used to classify patients with morphoea by disease severity into mild, moderate and severe groups, and to identify clinically significant improvement in disease activity in patients with morphoea.
- The LoSCAT may be limited in its ability to detect clinically significant changes in disease damage.

Morphoea (localized scleroderma) is a sclerosing skin condition that can result in significant cosmetic and functional impairment. Morphoea has a heterogeneous clinical presentation reflected in previously described subtypes, and may involve relatively little body surface area (circumscribed), or large parts of the cutaneous surface (generalized). Morphoea also has two distinct phases of evolution that include an active, inflammatory stage and an inactive, sclerotic, atrophic phase. Active disease may be characterized by erythema and enlarging, indurated lesions, while damage reflects the lasting sequelae after activity subsides and may include atrophy, thickened skin, or dyspigmentation.

To date, the only validated clinical measure that accounts for the evolution of morphoea lesions over time is the Localized Scleroderma Cutaneous Assessment Tool (LoSCAT), a clinical tool that separately quantifies disease activity and damage (Fig. 1). The LoSCAT is composed of an activity index (LoSAI) and a damage index (LoSDI), along with Physician's Global Assessment both of disease activity (PGA-A) and of damage (PGA-D).[1] Since its validation, the LoSCAT has been employed in therapeutic and quality-of-life studies in morphoea.[2–4] However, no studies have determined the score distributions for the LoSAI or LoSDI that correspond with mild, moderate and severe disease, necessary to put an individual score into clinical context. And while prior studies have suggested that the LoSCAT is responsive to change,[5] none have precisely quantified the change in LoSCAT component scores that correspond with clinically significant change. In order to use this measure to demonstrate efficacy in clinical trials, and to characterize the patient population for whom various therapies are appropriate, it is important to know how to use the LoSCAT to characterize disease severity and define improvement.

Therefore, in the current study, we determined how the LoSAI and LoSDI, as well as the PGA-A and PGA-D, could be used to classify patients as having mild, moderate and severe disease, and to determine change in score of the LoSCAT components that corresponds with clinically significant change in activity and damage.

Patients and methods

Patients were selected from the Morphea in Adults and Children (MAC) cohort at the University of Texas at Southwestern Medical Center (UTSWMC). The MAC cohort includes prospective data on clinical and demographic features, and LoSCAT scores of participants (cohort characteristics previously described).[6,7] Patients enrolled between August 2008 and June 2015, with a diagnosis of morphoea based on clinicopathological criteria, and who completed at least one study visit between July 2014 and June 2015, were included. The study was approved by the UTSWMC Institutional Review Board (IRB), and patients were enrolled with IRB-approved informed consent and Health Insurance Portability and Accountability Act forms.

At each visit, predefined case report forms were completed and the principal investigator completed all LoSCAT components. For the LoSAI, morphoea lesions are scored for activity based on degree of erythema (0–3), induration in lesions (0–3) and presence of new/enlarged lesions within the last month (0 or 3). [The LoSAI is modified from the prior activity index, the modified Localized Scleroderma Skin Severity Index (mLoSSI), used in earlier versions of the LoSCAT, which included skin thickness, rather than induration, as the third criterion for disease activity.[5]] Lesions are scored in 18 body sites, and LoSAI score is calculated by adding the scores for lesions in each area. Scores range from 0 to 162, with higher scores indicating more severe activity. For the LoSDI, morphoea lesions are scored for damage based on degree of dyspigmentation (0–3), dermal atrophy (0–3), subcutaneous atrophy (0–3) and central sclerosis or thickness (0–3), and LoSDI is calculated by adding the scores for lesions in each body site. Scores range from 0 to 216, with higher scores indicating more severe damage. PGA-A and PGA-D scores range from 0 to 100, with freedom to select any value along this range, and higher scores indicate more severe disease (Fig. 1).

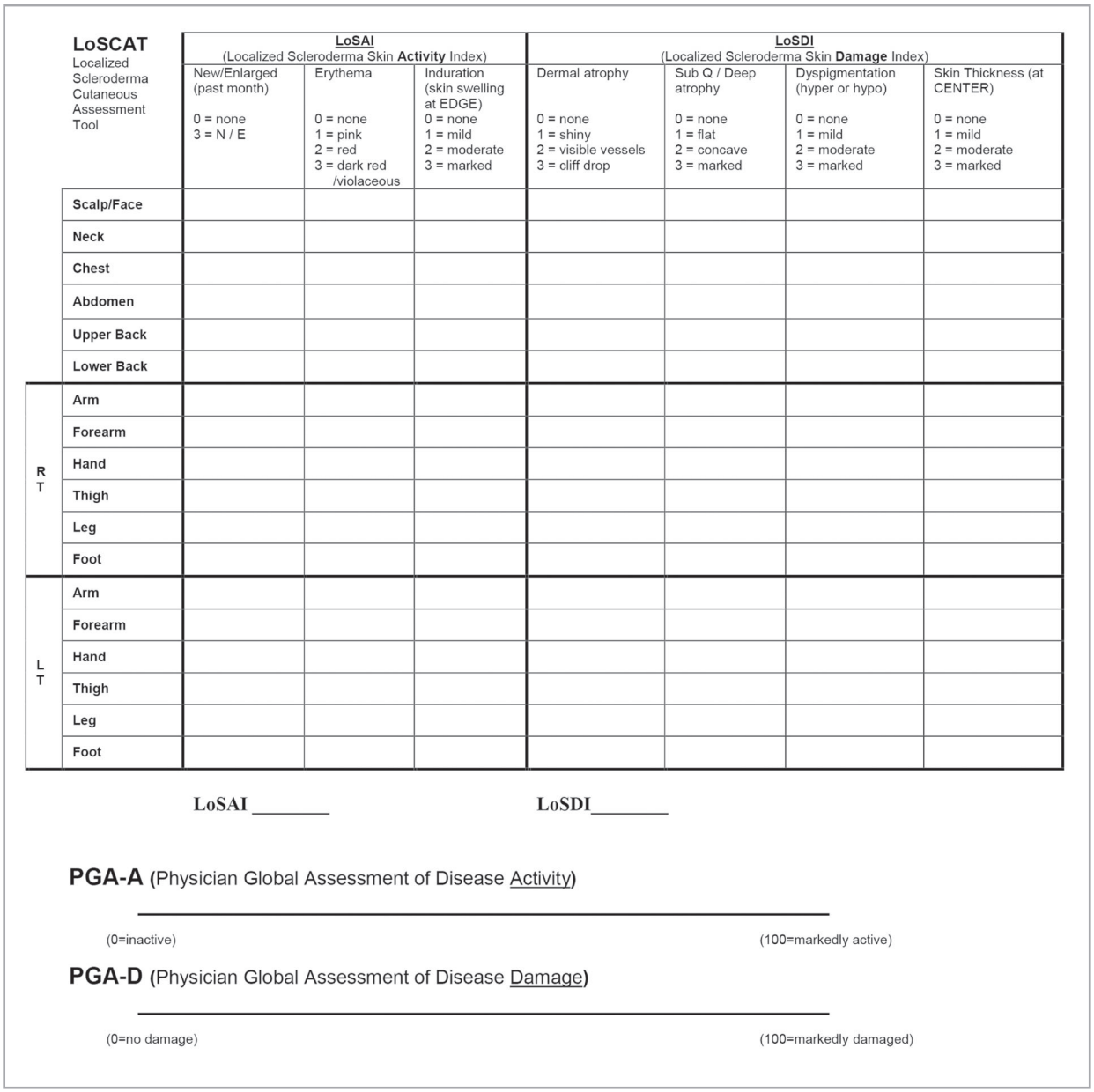
At each visit, patients were assigned a physician's subjective assessment of disease severity (PSAS) for both activity and damage separately by one rater (H.T.J.), based on a global assessment in which the rater classifies a patient as having mild, moderate or severe disease activity, and mild, moderate or severe damage. At follow-up visits, the rater similarly assigned a physician's subjective assessment of improvement (PSAI) in morphoea, based on a global assessment of disease activity as improved, unchanged, or worse since the last visit. Similar PSAI was assigned for change in damage severity.

Severity analysis

The optimal LoSAI, LoSDI, PGA-A and PGA-D score ranges corresponding with each severity group based on PSAS assignments were determined by receiver operating characteristic (ROC) analyses. Two analyses were used for each measure, one for mild vs. moderate and severe disease, and one for severe vs. moderate and mild disease. Cut-off scores corresponding with severity groups were chosen based on assessing the ROC analysis with a predetermined cut-off for sensitivity of 90% and specificity of 80% whenever possible. Sensitivity was prioritized for clinical reasons, given the harm of missing and failing to treat active disease. When the point of optimization for sensitivity and specificity fell between two points on the ROC curve, scores were selected within this range based on clinical practicality (integers) and attempt to optimize the percentage of patients correctly classified by that cut-off score. Scores that fell between the upper limit of mild and lower limit of severe were designated as indicating moderate disease.

Clinically significant change analysis

LoSAI, LoSDI, PGA-A and PGA-D scores associated with clinical improvement and worsening were estimated by calculating the mean absolute change and percentage change in scores for



LoSCAT
Localized Scleroderma Cutaneous Assessment Tool

		LoSAI (Localized Scleroderma Skin **Activity** Index)			LoSDI (Localized Scleroderma Skin **Damage** Index)			
		New/Enlarged (past month) 0 = none 3 = N / E	Erythema 0 = none 1 = pink 2 = red 3 = dark red /violaceous	Induration (skin swelling at EDGE) 0 = none 1 = mild 2 = moderate 3 = marked	Dermal atrophy 0 = none 1 = shiny 2 = visible vessels 3 = cliff drop	Sub Q / Deep atrophy 0 = none 1 = flat 2 = concave 3 = marked	Dyspigmentation (hyper or hypo) 0 = none 1 = mild 2 = moderate 3 = marked	Skin Thickness (at CENTER) 0 = none 1 = mild 2 = moderate 3 = marked
	Scalp/Face							
	Neck							
	Chest							
	Abdomen							
	Upper Back							
	Lower Back							
RT	Arm							
RT	Forearm							
RT	Hand							
RT	Thigh							
RT	Leg							
RT	Foot							
LT	Arm							
LT	Forearm							
LT	Hand							
LT	Thigh							
LT	Leg							
LT	Foot							

LoSAI _____ LoSDI_____

PGA-A (Physician Global Assessment of Disease Activity)

(0=inactive) (100=markedly active)

PGA-D (Physician Global Assessment of Disease Damage)

(0=no damage) (100=markedly damaged)

Fig 1. The Localized Scleroderma Cutaneous Assessment Tool (LoSCAT).

each group based on PSAI assignments. When the baseline score for a given measure was zero, 0·5 points were added to the zero score to allow the percentage change to be calculated. The optimal LoSAI, LoSDI, PGA-A, and PGA-D change scores corresponding with clinically significant change were determined by two ROC analyses for each measure, one for improvement (improved vs. unchanged) and one for worsening (worsened vs. unchanged). Change scores that fell between the negative score change indicative of improvement and the positive score change indicative of worsening were designated as indicating stable disease. The final absolute and percentage change scores for each measure associated with clinical improvement and worsening were chosen based on similar ROC analysis as described above for severity scores. Analyses were conducted using GraphPad Prism v. 6·0 statistical software (GraphPad Software, La Jolla, CA, U.S.A.).

Results

A total of 120 patients met inclusion criteria with initial visits assessed by the PSAS, with median disease duration of 48 months (range 1–732) at time of initial visit. A total of 54 patients had at least two study visits and were included in the clinically significant change analysis for a total of 203 (83 follow-up) visits. Follow-up visits occurred at a range of 2–60 months (median 10), with a range of 1–6 (median 1) follow-up visits per patient. The study population mirrored prior reports for demographic features of morphoea, and included

94 adults and 26 children. All major morphoea subtypes were represented, with generalized (46 of 120, 38·3%) and linear (54 of 120, 45·0%) the most frequent (Table 1).

Severity analysis

At initial visits, LoSAI scores ranged from 0 to 132 (maximum 162, median 0) and LoSDI scores ranged from 0 to 68 (maximum 216, median 0), while PGA-A and PGA-D scores ranged from 0 to 100 (median 0) and 0 to 90 (median 20), respectively. Eighty-one initial visits (67·5%) represented mild activity, 17 represented moderate activity, and 22 represented severe activity based on PSAS assignments (Table 1).

Based on ROC analyses, LoSAI scores of 0–4 indicated mild activity, 5–12 moderate activity, and 13 and up severe activity. These cut-offs satisfied preset sensitivity and specificity criteria, and 88% of patients (106 of 120) were correctly classified into severity groups by these cut-offs (Fig. 2a).

ROC analysis of the LoSDI was not as straightforward. Analysis of mild vs. moderate/severe damage revealed that a cut-off of LoSDI scores < 5·5 had 89·7% sensitivity and 34·6% specificity for classifying mild damage, while including scores < 11·5 resulted in sensitivity of 67·6% and specificity of 82·7% for classifying mild damage. In ROC analysis of mild/moderate vs. severe damage, including scores > 8·5 had 90·9% sensitivity but only 47·1% specificity for classifying severe disease, while including scores > 15·5 had 72·7% sensitivity and 82·7% specificity for classifying severe disease. Thus, based on predetermined parameters, cut-off scores could not be reliably identified for damage severity based on LoSDI scores. By classifying LoSDI scores of 0–10 as indicating mild damage, scores of 11–15 as indicating moderate damage, and 16 and over as indicating severe disease, 55·8% of patients (67 of 120) were correctly classified (Fig. 2b).

Based on ROC analysis, PGA-A scores of 0–10 indicated mild activity, 11–30 moderate activity, and 31 and up severe activity. These cut-offs satisfied preset sensitivity and specificity criteria, and 91·7% of patients (110 of 120) were correctly classified into severity groups (Fig. 2c).

Based on ROC analysis, PGA-D scores of 0–18 indicated mild damage, 19–30 moderate damage, and 31 and up severe damage. Based on these cut-off scores, 84·2% of patients (101 of 120) were correctly classified into severity groups (Fig. 2d).

Table 1 Characteristics of the 120 patients included in the analysis[a]

Sex	
Male	28 (23·3)
Female	92 (76·7)
Morphoea subtype	
Linear	54 (45·0)
Plaque	15 (12·5)
Generalized	46 (38·3)
Indeterminate	5 (4·2)
Age (years), median (range)	46·5 (5–90)
Paediatric patients	26 (21·7)
Adult patients	94 (78·3)
Race/ethnicity	
White	100 (83·3)
African-American	6 (5·0)
Hispanic	12 (10·0)
Other	2 (1·7)
Initial LoSAI, median (range)	0 (0–132)
Initial LoSDI, median (range)	0 (0–68)
Initial PGA-A, median (range)	0 (0–100)
Initial PGA-D, median (range)	20 (0–90)
PSAS: activity	
Mild	81 (67·5)
Moderate	17 (14·2)
Severe	22 (18·3)
PSAS: damage	
Mild	52 (43·3)
Moderate	45 (37·5)
Severe	23 (19·2)
PSAI: activity	
Improved	35 (42·2)
Unchanged	40 (48·2)
Worsened	8 (9·6)
PSAI: damage	
Improved	21 (25·3)
Unchanged	53 (63·8)
Worsened	9 (10·8)

Data are presented as n (%) unless stated otherwise. LoSAI, Localized Scleroderma Cutaneous Assessment Tool (LoSCAT) activity index; LoSDI, LoSCAT damage index; PGA-A, Physician's Global Assessment of disease activity; PGA-D, PGA of damage; PSAS, physician's subjective assessment of severity; PSAI, PSA of improvement. [a]A total of 120 patients with 203 total visits were included in the analysis; 120 initial visits were analysed to determine cut-off scores (PSAS), and 83 visits were analysed for clinical change (PSAI), representing 54 patients who had at least two study visits included.

Clinically significant change analysis

Of 83 follow-up visits (54 patients), there were 35 instances of improved activity, 21 instances of improved damage, eight instances of worsening activity, and nine instances of worsening damage. The majority of follow-ups represented unchanged disease activity (48·2%) and damage (63·8%) (Table 1).

Based on ROC analysis of absolute change scores on the LoSAI, a reduction in score of 2 points or more indicated improved activity, while an increase in score of 2 points or more indicated worsening activity. These cut-off scores correctly classified 88% of patients (78 of 83). ROC analysis of percentage change scores on the LoSAI suggested that reduction in scores of 27·5% or more indicated improved activity, while an increase in scores of 19·5% or more indicated worsening activity (Table S1; see Supporting Information). These cut-off scores correctly classified 96% of patients (80 of 83). No cases of improved or worsened activity were misclassified as unchanged activity.

ROC analysis of absolute change scores on the LoSDI suggested that a reduction in scores of 2 points or more indicated improvement in damage, while an increase in scores of 3 points or more indicated worsened damage. These cut-off

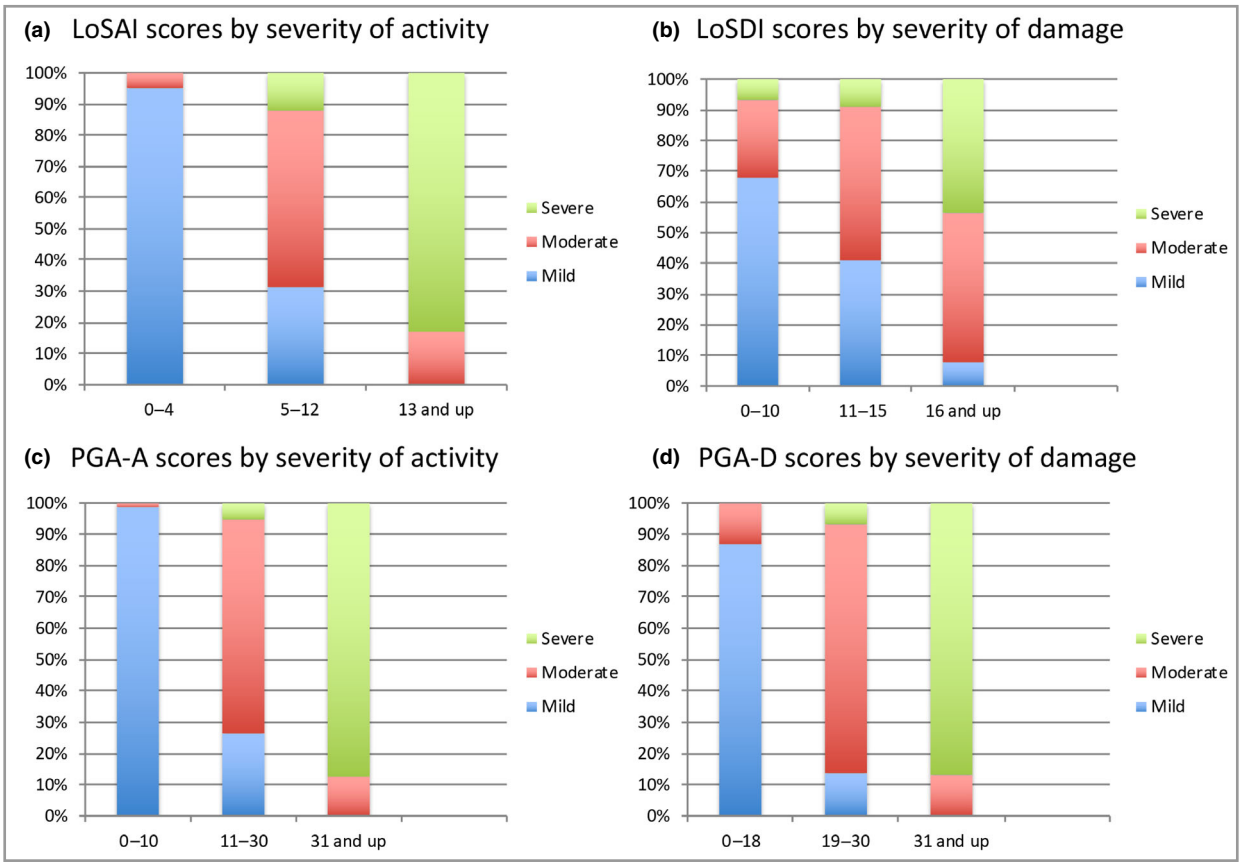


Fig 2. Distribution of physician's subjective assessment of disease severity (PSAS) by Localized Scleroderma Cutaneous Assessment Tool (LoSCAT) component cut-off scores. For the range of scores on each LoSCAT component as suggested by receiver operating characteristic analysis, the percentage of patients within each category of disease severity according to PSAS is shown. LoSAI, LoSCAT activity index; LoSDI, LoSCAT damage index; PGA-A, Physician's Global Assessment of activity; PGA-D, PGA of damage.

scores correctly classified 64% of patients (53 of 83). The majority of misclassified cases involved cases of stability that were misclassified as worsening (16 of 30) or cases of stability misclassified as improved (12 of 30). ROC analysis of percentage change scores on the LoSDI suggested that an increase in score of 25·5% or more indicated clinical worsening. While sensitivity and specificity could not be optimized based on predetermined parameters, ROC analysis suggested that a decrease in scores of greater than 7·5% was indicative of improved damage (Table S1; see Supporting Information). These cut-off scores correctly classified 64% of patients (53 of 83). The majority of misclassified patients (17 of 30) involved cases of stability misclassified as improved.

Based on ROC analysis of absolute change scores on the PGA-A, a reduction in a score of 6 points or more indicated improved activity, while an increase in a score of 4 points or more indicated worsened activity. These cut-off scores correctly classified 94% of patients (78 of 83). The majority of misclassified cases involved cases of improvement that were misclassified as unchanged (3 of 5). Though sensitivity and specificity could not both be optimized for ROC analysis of percentage change scores on the PGA-A, results suggested that a reduction in scores of 8·5% or more indicated improved activity, while an increase in scores of 10% or more indicated worsening damage (Table S1). These cut-off scores correctly classified 93% of patients (77 of 83). The majority of misclassified cases involved cases of stability misclassified as improvement (3 of 6).

Though sensitivity and specificity could not both be optimized, ROC analysis of absolute change scores on the PGA-D suggested that a reduction in scores of 3 points or more indicated improved damage, while an increase in scores of 4 points or more indicated worsening damage. These cut-off scores correctly classified 68·7% of patients (57 of 83). The majority of misclassified cases involved cases of stability that were misclassified as worsening (17 of 26). Though sensitivity and specificity could not both be optimized, ROC analysis of percentage change scores on the PGA-D suggested that a reduction in scores of 16% or more indicated improvement in damage, while an increase in scores of 21% or more indicated worsening in damage (Table S1). These cut-off scores correctly classified 72·3% of patients (60 of 83). The majority of misclassified cases involved cases of stability that were misclassified as worsening (15 of 23).

Discussion

We conducted a prospective cohort study to ascertain the clinical significance of individual LoSCAT component scores and values that correspond to clinically meaningful change. In this study, ROC analysis successfully determined change in scores on the LoSAI and PGA-A that indicate clinically meaningful change in morphoea activity, and these scores accurately classified a majority of patients. In the case of the PGA-A, increasing cut-off scores would have optimized specificity, but this would have resulted in misattributing improvement to some cases that were not classified as clinically improved by the PSAI. For the purposes of clinical trials, the risk of missing activity based on an insensitive measure cut-off and thus mistakenly attributing therapeutic benefit to a treatment was thought to be greater than the harm of overcalling activity.

The current results on the responsiveness of the LoSCAT to change are consistent with studies of early versions of the LoSCAT, which demonstrated sensitivity to change for both the original LoSCAT activity index and the mLoSSI (now the LoSAI), and the PGA-A in patients who improved after therapy.[1,5,8] Specifically, in a study of 29 paediatric patients using distribution-based methods, researchers found that a change of approximately 6 points on the LoSAI (interquartile range 4–8) reflected minimal clinically important difference (MCID) in disease, while changes in the LoSDI were not significant.[5] These prior studies were limited by small sample sizes, shorter follow-up durations (< 1 year), and an exclusively paediatric population, which reflects predominantly the linear subtype.[5] The difference in calculated MCID between the prior and the present study may be due to different methodologies, but may also suggest that different morphoea subtypes might require different cut-off scores to determine MCID and disease severity because of their unique clinical features.

In the current study, based on ROC analyses, change scores on damage components of the LoSCAT that corresponded with clinically significant change could not be determined. This is likely due to the stable nature of morphoea-associated damage, resulting in a smaller range of scores and limiting ROC analysis. By optimizing the percentage of patients correctly classified for clinical utility, percentage change scores corresponding to improved and worsening damage could be approximated as 10% decrease on the LoSDI or 15% decrease on the PGA-D, or a 25% increase on the LoSDI or 20% increase in PGA-D, respectively. While clinical trials in morphoea are largely aimed at treating disease activity, successful treatment of activity should stabilize damage, making these cut-off values useful for investigating this hypothesis.

In the current study, analysis for the severity of damage as measured by the LoSDI failed to determine clear cut-off values; however, the PGA-D accurately classified damage severity. These results point out potential shortcomings of the LoSDI, which is computed by the addition of cutaneous features (e.g. dyspigmentation, atrophy) present by body site, making the number of body sites affected a major driver of scoring. On the other hand, the PGA-D is a global assessment that includes extracutaneous features as well as psychosocial impact.[9] Thus, a patient with hemifacial atrophy might have a low LoSDI score, given limited body site involvement, though s/he experienced substantial damage in terms of facial atrophy, asymmetry and psychological distress. In this scenario, the corresponding higher PGA-D better captures overall severity. This discrepancy contributed to our inability to determine cut-off scores for severity groups for the LoSDI with the current methodology, as the PSAS also includes extracutaneous disease features not incorporated in the LoSDI, and attempts to improve specificity of cut-off scores would have misclassified cases of severe damage such as the one described.

Taken together, these results suggest that the LoSDI may not be an adequate measure of overall damage in morphoea, but rather reflect the severity of cutaneous changes only. One possible solution to make the LoSDI a more effective index would be to add binary boxes to check for the presence of additional extracutaneous features (contractures, limb length discrepancy, etc.) that would upgrade severity, even when numerical LoSDI score would not meet the cut-off for severe damage. The Cutaneous Lupus Erythematous Disease Area Severity Index, a validated measure in cutaneous lupus, makes use of similar methodology.[10] Alternatively, practitioners may wish to rely on the PGA-D as a measure of severity when considering cases that involve cosmetic or functional impairment as a result of morphoea damage. Further studies are needed to determine whether such modifications facilitate more sensitive measurement of damage from morphoea.

These results reflect the experience of one centre with one experienced rater determining disease severity, which limits reliability of the methodology. While this study did include patients with varying degrees of disease severity, it included a limited number of patients with worsening disease. The LoSCAT is also susceptible to floor effects, as the range of scores in the present study (and in many prior) do not encompass the whole range of possible scores, and even fewer fall in the top 25% of possible scores. Thus, the calculated cut-off scores are not in the tertiles of the hypothetical ranges of the LoSCAT components, and may be limited in their ability to detect clinically significant differences between patients at the low end of the score ranges.[11]

Future studies are planned to attempt to validate suggested cut-off scores and MCID in a larger, more diverse validation cohort, with consideration of changes to minimize floor effects. Such studies could assess the performance of cut-off measures in patients with mild or moderate vs. severe disease at baseline, or validate cut-off scores across morphoea subtypes to determine whether MCID can be more reliably calculated for specific morphoea populations. By defining more precise score changes associated with meaningful clinical improvement, the LoSCAT can be more effectively used in clinical trials to demonstrate therapeutic benefit of interventions in morphoea.

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Supporting Information

Additional Supporting Information may be found in the online version of this article at the publisher's website:

Table S1 Responsiveness of Localized Scleroderma Cutaneous Assessment Tool (LoSCAT) components for detecting clinically significant change (improvement or worsening) based on receiver operating characteristic analyses.