Published in final edited form as:

Br J Dermatol. 2016 January ; 174(1): 228–230. doi:10.1111/bjd.14103.

Durometry as an Outcome Measure in Juvenile Localized Scleroderma

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Keywords

Localized scleroderma; morphea; durometer; outcome measure

Localized scleroderma (LS), or morphea, is an autoimmune, inflammatory and fibrotic disease affecting skin and sub-dermal tissues. One of the main cutaneous outcome variables used in LS to monitor the disease is skin thickness (ST), with scoring adapted from systemic sclerosis (SSc), and although validated, the utility of clinician skin thickness scoring is limited by the need for training and ongoing practice^{1, 2}. The durometer, an instrument used to measure material hardness, shows potential as a surrogate, or a tool that can augment the ST score by providing a more objective measure^{3, 4}. This study examines the validity and reliability of the durometer in pediatric LS patients.

For the validity study, patients were recruited from three specialized pediatrics LS clinics with baseline and follow-up visits. One lesion from each patient was chosen as the 'study lesion' and was graded for ST by the physician using the modified Rodnan Skin Score (mRSS) technique¹ and for skin hardness using the durometer³. Study lesions were marked and photographed at the initial visit to improve consistency of measurements at subsequent visits. A Rex durometer was used with a 0 to 100 point scale, with results given in durometer units (DU). The durometer was placed in a vertical position (perpendicular to lesion) and allowed to rest by gravity while the body site being measured was supported so that musculature was relaxed (Figure 1).

Both edges and the center of the study lesion were measured by ST assessment based on mRSS and the durometer. An area of unaffected skin in the same body area, typically contralateral, was measured as a control. By definition, the unaffected skin had a ST score of 0. In addition, the physicians also completed the modified Localized Scleroderma Severity

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The authors do not have any conflicts of interest to disclose.

Disclosures: Part of the data contained in this manuscript was presented in poster format at the 2014 American College of Rheumatology Pediatric Rheumatology Symposium. The abstract for that poster presentation was published in an on-line supplement to *Arthritis & Rheumatism*.

Index (mLoSSI)² and the modified Localized Scleroderma Damage Index (mLoSDI)^{5, 6}, cutaneous measures to capture new or expanding lesions, erythema, and ST of the edge, as well as dermal atrophy, subcutaneous atrophy, dyspigmentation and ST at the center of the lesion (respectively). In order to compare durometer readings of a single study lesion, mLoSSI and mLoSDI scores were calculated for only the body site containing the study lesion. The same lesion was measured in the same manner at a second study visit, which occurred between 25–53 weeks after the initial visit, to determine responsiveness to change.

Data for interrater reliability study was collected from a separate LS sample recruited from one of the pediatric LS clinics (University of Pittsburgh). Two physicians, an experienced (KT) and unexperienced durometer user (SP), evaluated the edges and center of a single study lesion, as well as a contralateral area of unaffected skin, in a single clinic visit using the same durometer. The first observer marked the precise spot for each measure while the second observer was out of the room. Triplicate measures were obtained on edges and center and were averaged to obtain a single value.

All data analysis was performed using SPSS software (SPSS, Version 21, IBM Corp, Armonk, NY). Paired sample t-tests detected any significant differences between durometer measures of the study lesions and unaffected skin. Spearman's correlations examined the relationships between durometer readings and the mLoSSI/mLoSDI. For responsiveness analysis, changes in durometer readings between two visits were calculated and independent samples t-tests were used to determine significant differences in durometer change scores between two defined 'change' groups. The two definitions of 'change' used were as follows: change_A = a difference of at least 2 points in the mLoSSI score of the body area in which the study lesion is located, and change_B = a change in status of the study lesion from 'active' to 'inactive' (per physician judgment). Active lesions were defined as having components of enlargement or erythema, including violaceous color^{2, 6}. For the inter- and intra-rater reliability study, interclass correlation coefficients (ICC) were calculated.

Twenty-three patients were enrolled, with 17 from two academic sites included in the validity analysis^{†1}. Patients with incomplete data or scalp and shin lesions were excluded, as the durometer is known to be unreliable in areas of thin skin directly over a bony surface^{4, 7}. In general, patients were female (76%) and Caucasian (88%). Most study lesions were linear and located on the trunk or limbs, though circumscribed lesions were included (Table 1). On average, patients were 9 years old at the onset of LS symptoms and 13.5 years old during the study. Thirteen of these patients had follow-up information and were used to evaluate responsiveness. Twelve additional patients with similar demographics and clinical features were enrolled at one site (Pittsburgh) for the interrater reliability study.

The **validity study** demonstrated *face validity* of the durometer with the durometer readings discriminating between affected and unaffected skin ($t(16) = 6.334, p < 0.0001$) with a mean durometer reading of 20.7 durometer units for the normal skin and 36.4 for the lesion skin (Table 2). The durometer also showed *convergent construct validity* with the durometer

^{†1}All 3 sites enrolled patients, 9 from the University of Pittsburgh and 8 from Hackensack University were included in the analysis after eliminating those with incomplete data or sites over bony surfaces, such as scalp/shin lesions.

readings of the study lesions moderately correlating with both the ST score ($r = 0.486$) and mLoSSI ($r = 0.538$), and weakly with the mLoSDI ($r = 0.221$). The durometer also demonstrated *responsiveness to change* using the two predetermined change definitions. In general, those subjects with ‘change’ documented utilizing either method were transitioning from active to inactive disease showing lesion and disease improvement. For both change_A, determined by the mLoSSI score, and change_B, determined by lesion activity status, there was a significant difference in durometer change scores between the two groups, $p = 0.05$ and $p = 0.02$ respectively (Table 3). Either method demonstrated a *durometer reading decrease by approximately 8 DU to signify significant improvement in ST* (or increase by 8 DU in those that became active with increased ST).

The **reliability study** demonstrated *high Interrater reliability* with ICC’s of 0.883 – 0.980 for lesion skin and 0.959 – 0.966 for normal skin. Reliability for repeated measurements was also high (ICC range = 0.930 – 0.972).

This is the first study to examine the psychometric properties of the durometer in pediatric LS. The durometer demonstrated reliability appropriately by discriminating between affected and unaffected skin, exhibiting appropriate convergent construct validity with validated LS cutaneous scores, and demonstrating responsiveness to change in a patient’s clinical status. The durometer also showed to be a reliable measurement tool with high reliability between raters with different clinical experience. In the future, larger studies are needed to define durometer ranges for different body areas and examine use in pre-pubertal children. Overall, the durometer holds promise as an outcome measure for skin thickness in pediatric LS patients.

Acknowledgments

Funding: “Research reported in this publication was supported by the National Institute of Arthritis and Musculoskeletal and Skin Diseases of the National Institutes of Health under Award Number AR059722 (Torok PI). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.” Dr. Torok is also supported by the Nancy Taylor Foundation for Chronic Diseases Inc. Dr. Payne-Poff received support from NIAMS T32 AR052282 fellowship training grant.

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Figure 1. The Durometer for assessment of skin hardness

The round durometer reading face attaches to a pencil like support approximately 13mm in diameter, with a flat end containing a 2mm depressible gauge which measures hardness when placed flush on a surface. The user places the durometer support perpendicular to the skin surface being analyzed. This takes seconds to obtain a reading. The Rex durometer, type 00 was used at all centers. It is available in either digital or dial face. The Model DD-3 with a digital face is demonstrated above.

Table 1

Juvenile LS Patient Demographics for Validity Analysis

		n (%)
Gender	Female	13 (76.5)
	Male	4 (23.5)
Ethnicity	Caucasian	15 (88.2)
	Asian	1 (5.9)
	Other	1 (5.9)
BMI Status	Underweight (<5%)	1 (5.9)
	Healthy Weight (5 – 85%)	7 (41.2)
	Overweight (85 – 95%)	3 (17.6)
	Obese (>95%)	6 (35.3)
LS Subtype	Linear – Trunk / Limb	8 (47.1)
	Circumscribed – Superficial	2 (11.8)
	Circumscribed - Deep	1 (5.9)
	Generalized	3 (17.6)
	Mixed	3 (17.6)
Anatomic Location of Study Lesion	Chest and Back	7 (41.2)
	Abdomen	2 (11.8)
	Arms and Legs	8 (47.1)
Study Lesion Status at Initial Visit	Active	10 (58.8)
	Inactive	7 (41.2)

Table 2

Comparison of Durometer Readings between Study Lesion and Normal Skin

Anatomic Group (n)	Normal Skin	Study Lesion	p-value*
Chest and Back (7)			
Mean (SD)	15.14 (4.92)	24.21 (13.69)	0.046
Abdomen (2)			
Mean (SD)	13.50 (N/A)	34.25 (N/A)	N/A
Arms and Legs (8)			
Mean (SD)	27.31 (7.01)	47.56 (6.44)	<0.0001
Overall (17)			
Mean (SD)	20.68 (8.66)	[†] 36.38 (14.93)	<0.0001

* p-values obtained by using paired samples t-tests

[†] Mean (SD) of Study lesion further identified at first visit as Active and Inactive are 41.00 (12.83) and 28.08 (16.94), respectively

Table 3

Difference in Study Lesion Durometer Readings – Visit A to Visit B

	n	Mean Difference	SD	p-value *
Change _A : change in body site mL ₀ SSI	6	1.42	9.36	0.05
	7	-8.64	5.42	
Change _B : change in lesion activity status	2	8.25	3.18	0.02
	3	-8.67	3.51	

* p-values obtained by using independent samples t-tests