

THE DEVELOPMENT AND INITIAL VALIDATION OF THE SYSTEMIC LUPUS INTERNATIONAL COLLABORATING CLINICS/AMERICAN COLLEGE OF RHEUMATOLOGY DAMAGE INDEX FOR SYSTEMIC LUPUS ERYTHEMATOSUS

DAFNA GLADMAN, ELLEN GINZLER, CHARLES GOLDSMITH, PAUL FORTIN, MATTHEW LIANG, MURRAY UROWITZ, PAUL BACON, STEFANO BOMBARDIERI, JOHN HANLY, ELAINE HAY, DAVID ISENBERG, JOHN JONES, KENNETH KALUNIAN, PETER MADDISON, OLA NIVED, MICHELLE PETRI, MARTIN RICHTER, JORGE SANCHEZ-GUERRERO, MICHAEL SNAITH, GUNNAR STURFELT, DEBORAH SYMMONS, and ASAD ZOMA

Objective. To develop and perform an initial validation of a damage index for systemic lupus erythematosus (SLE).

Methods. A list of items considered to reflect damage in SLE was generated through a nominal group

From the Systemic Lupus International Collaborating Clinics (SLICC) and the American College of Rheumatology Diagnostic and Therapeutic Criteria Committee.

Supported by Syntex Pharmaceutical and the American College of Rheumatology.

Dafna Gladman, MD, FRCPC (ACR Diagnostic and Therapeutic Criteria Committee Liaison to SLICC): The Toronto Hospital, Toronto, Ontario, Canada; Ellen Ginzler, MD, MPH: State University of New York Health Science Center at Brooklyn; Charles Goldsmith, PhD: McMaster University, Hamilton, Ontario, Canada; Paul Fortin, MD, MPH: Montreal General Hospital, Montreal, Quebec, Canada; Matthew Liang, MD, MPH, Jorge Sanchez-Guerrero, MD: Harvard Medical School and Brigham and Women's Hospital, Boston, Massachusetts; Murray Urowitz, MD, FRCPC: The Toronto Hospital, Toronto; Paul Bacon, MD, FRCP: Birmingham University, Birmingham, England; Stefano Bombardieri, MD: University of Pisa, Pisa, Italy; John Hanly, MD, FRCPC, John Jones, MD, FRCPC: Dalhousie University, Halifax, Nova Scotia, Canada; Elaine Hay, MD, Deborah Symmons, MD, MRCP: University of Manchester, Manchester, England; David Isenberg, MD, MRCP: University College and Middlesex Hospital Medical School, London, England; Kenneth Kalunian, MD: University of California, Los Angeles; Peter Maddison, MD: Royal National Hospital for The Rheumatic Diseases, Bath, England; Ola Nived, MD, PhD, Gunnar Sturfelt, MD: University Hospital, Lund, Sweden; Michelle Petri, MD, MPH: Johns Hopkins Medical School, Baltimore, Maryland; Martin Richter, PhD: St. Vincent Hospital, Darlinghurst, Sydney, New South Wales, Australia; Michael Snaith, MD, FRCP: Hallamshire Hospital, Sheffield, England; Asad Zoma, MD: Stonehouse Hospital, Stonehouse, Scotland.

Address reprint requests to American College of Rheumatology, 60 Executive Park South, Suite 150, Atlanta, GA 30329.

Submitted for publication September 6, 1994; accepted in revised form July 21, 1995.

process. A consensus as to which items to be included in an index was reached, together with rules for ascertainment. Each center submitted 2 assessments, 5 years apart, on 2 patients with active and 2 with inactive disease, of whom 1 had increased damage and the other had stable disease. Analysis of variance was used to test the factors physician, time, amount of damage, and activity status.

Results. Nineteen physicians completed the damage index on 42 case scenarios. The analysis revealed that the damage index could identify changes in damage seen in patients with both active and inactive disease. Patients who had active disease at both time points had a higher increase in damage. There was good agreement among the physicians on the assessment of damage in these patients.

Conclusion. This damage index for SLE records damage occurring in patients with SLE regardless of its cause. The index was demonstrated to have content, face, criterion, and discriminant validity.

Over the last 4 decades there has been an important reduction in mortality among patients with systemic lupus erythematosus SLE (1). However, it has been noted that disease activity, particularly when individual organs are considered, may result in specific organ damage, resulting in organ dysfunction (i.e., kidney failure) and increased morbidity. In patients who survive longer than 10 years, the cause of death is unlikely to be simply active SLE (1). Thus, the management of patients with SLE is directed not only at preventing death, but also at reducing the morbidity

resulting from the disease or its therapy. It has become clear that a method to estimate this morbidity in these patients is necessary.

The Conference on Prognosis Studies in SLE was convened in Toronto in 1985. The participants, a group of clinicians and methodologists who have been investigating disease activity in SLE, concluded that, in order to describe prognosis in SLE, the disease activity, accumulated damage, and health status of the patient need to be evaluated (2).

The NATO group, comprising investigators from centers in Canada, Great Britain, Sweden, and the United States, has validated 3 disease activity indices for SLE (3-5). Having confirmed that the 3 indices used by members of the NATO group (the SLE Disease Activity Index, the Systemic Lupus Activity Measure, and the British Isles Lupus Assessment group index) were comparable, members of the group decided that further efforts should be directed at developing a damage index for SLE.

A conference was then held in November 1991 in Boston. The participants included rheumatologists who have previously worked on the assessment of damage in SLE, in addition to the members of the NATO group. The aim of the conference was to review previous work on the damage index, to assess whether the suggested items for the index were variables which could be detected in patient profiles, and to develop an index which could be tested for validity, reproducibility, and sensitivity to change (6). This report describes the development and initial validation of the instrument, the Systemic Lupus International Collaborating Clinics/American College of Rheumatology (SLICC/ACR) Damage Index for SLE.

METHODS

Generation of the index: nominal group process. Prior to the 1985 Conference on Prognosis Studies, the participants were asked to assess the importance of individual items that might be included in a damage index (7). A list of items that should be included in a damage index, with definitions for ascertainment, was generated. The participants in the Boston conference reviewed these documents and submitted their comments and suggestions for inclusion or exclusion of certain items.

To familiarize the participants of the Boston conference with the concepts included in the damage list, as well as to test whether these variables were easily detectable, 20 patient profiles which reflected accumulated damage were prepared, and each conference participant completed a damage index for each of these patients, prior to the conference. The reports were entered into a computer and ana-

lyzed. Analysis of variance for the overall score of the damage index revealed patient variability, suggesting that the patient profiles chosen reflected variability of damage. There was, however, a significant variation among the raters. During the Boston conference, the participants reviewed these results and discussed the items which caused most disagreement. The interrater variation was attributed to the absence of agreed-upon definitions prior to application of the index.

The participants further agreed that the aim was to count items of damage in individual systems. The generated score would not reflect the quantity of pathologically abnormal tissue, or the impact of the damage on the patient's life or function. Each of the proposed items was then reviewed. Rules for inclusion of an item in the damage index were established. It was agreed that in order for a feature to represent damage, it had to be present for at least 6 months. The importance of the item, with definition and ascertainment criteria, were considered in detail. An item was retained only when there was agreement among the participants that it should be kept in the index. Thus, content validity was obtained from the members of the group.

Testing of the index. To assure content and face validity, participants from each center were asked to show the instrument to physicians in their center who were not SLICC participants, and to have them complete a questionnaire relating to the suitability of the instrument. For criterion and discriminant validity, each SLICC member was asked to select 4 patients with a disease history of at least 5 years. The 4 patients' cases were to cover the spectrum of disease duration at the center. These patients were selected such that 2 assessments, 5 years apart, reflected active disease and increased damage in 1 patient, active disease and stable damage in 1, inactive disease and increased damage in 1, and inactive disease and stable damage in 1. The disease activity assessment of the patients included in the case scenarios was based on the usual assessment by the physician submitting the case. It had previously been demonstrated that the physicians participating in this group assess patients the same way regardless of the instrument used to assess disease activity (4). The times at which damage was assessed were clearly marked on each case history, as time 1 and time 2.

These case scenarios were submitted to one center, where they were rewritten in a uniform format. These reformatted case scenarios were then sent to all participants in 3 separate packages, each containing 14 cases. In each package, cases from different centers, as well as cases of patients with active and inactive disease, were mixed. Each participant was asked to complete 2 SLICC index forms for each patient, representing time 1 and time 2. The forms were returned to one center, where all information was entered on computer for analysis.

Analysis. Descriptive statistics included mean scores and standard deviation by the factors studied, which included physician, time (first or second assessment), amount of damage, and activity status. Analysis of variance (ANOVA) was used to test the effects of the factors and estimate the variance components for the factors. These estimates permitted the construction of ANOVA estimators for the proportions of variance due to each factor. The SAS

Table 1. Systemic Lupus International Collaborating Clinics/American College of Rheumatology Damage Index for Systemic Lupus Erythematosus*

Item	Score
Ocular (either eye, by clinical assessment)	
Any cataract ever	1
Retinal change <i>or</i> optic atrophy	1
Neuropsychiatric	
Cognitive impairment (e.g., memory deficit, difficulty with calculation, poor concentration, difficulty in spoken or written language, impaired performance level) <i>or</i> major psychosis	1
Seizures requiring therapy for 6 months	1
Cerebrovascular accident ever (score 2 if >1)	1 (2)
Cranial or peripheral neuropathy (excluding optic)	1
Transverse myelitis	1
Renal	
Estimated or measured glomerular filtration rate <50%	1
Proteinuria ≥ 3.5 gm/24 hours	1
<i>or</i>	
End-stage renal disease (regardless of dialysis or transplantation)	3
Pulmonary	
Pulmonary hypertension (right ventricular prominence, or loud P2)	1
Pulmonary fibrosis (physical and radiograph)	1
Shrinking lung (radiograph)	1
Pleural fibrosis (radiograph)	1
Pulmonary infarction (radiograph)	1
Cardiovascular	
Angina <i>or</i> coronary artery bypass	1
Myocardial infarction ever (score 2 if >1)	1 (2)
Cardiomyopathy (ventricular dysfunction)	1
Valvular disease (diastolic, murmur, or systolic murmur >3/6)	1
Pericarditis for 6 months, <i>or</i> pericardiectomy	1
Peripheral vascular	
Claudication for 6 months	1
Minor tissue loss (pulp space)	1
Significant tissue loss ever (e.g., loss of digit or limb) (score 2 if >1 site)	1 (2)
Venous thrombosis with swelling, ulceration, <i>or</i> venous stasis	1
Gastrointestinal	
Infarction or resection of bowel below duodenum, spleen, liver, or gall bladder ever, for cause any (score 2 if >1 site)	1 (2)
Mesenteric insufficiency	1
Chronic peritonitis	1
Stricture <i>or</i> upper gastrointestinal tract surgery ever	1
Musculoskeletal	
Muscle atrophy or weakness	1
Deforming or erosive arthritis (including reducible deformities, excluding avascular necrosis)	1
Osteoporosis with fracture or vertebral collapse (excluding avascular necrosis)	1
Avascular necrosis (score 2 if >1)	1 (2)
Osteomyelitis	1
Skin	
Scarring chronic alopecia	1
Extensive scarring or panniculum other than scalp and pulp space	1
Skin ulceration (excluding thrombosis) for >6 months	1
Premature gonadal failure	1
Diabetes (regardless of treatment)	1
Malignancy (exclude dysplasia) (score 2 if >1 site)	1 (2)

* Damage (nonreversible change, not related to active inflammation) occurring since onset of lupus, ascertained by clinical assessment and present for at least 6 months unless otherwise stated. Repeat episodes must occur at least 6 months apart to score 2. The same lesion cannot be scored twice.

statistical package using the General Linear Model, running on a SUN Sparc 2+ workstation, was used to perform these analyses. The model was an additive linear model that

included 19 physicians, 2 time points, 2 activity levels (active or inactive), 2 damage levels (increased or stable), and 2 interactions (time by activity and time by damage). All

Table 2. Percentage of variation explained by factors in the model

Error	75
Physician	1.5
Time	0.00
Damage	0.00
Activity	0.00
Time × activity	2.5
Time × damage	21.0

analyses were also conducted on the 4 subgroups of patients: active disease and increased damage, active disease and stable damage, inactive disease and increased damage, and inactive disease and stable damage. *P* values less than 0.05 were considered significant, and no correction was made for multiple testing.

RESULTS

The SLICC/ACR Damage Index. As a result of discussion at the conference, an index consisting of 12 different organ systems, the SLICC/ACR Damage Index for SLE, was developed (Table 1). Definitions were included in the body of the document where possible, but a glossary, based primarily on the ACR glossary (8), was also established (Appendix 1).

Content and face validity. The instrument was given to 18 individuals who were not members of the SLICC group, with instructions to review and assess it (Appendix 2). Seventeen of the 18 individuals responded. The majority (16 of 17) agreed with the index. Several points were raised regarding the definitions of the items considered in the damage index. These were discussed at a second session, during the

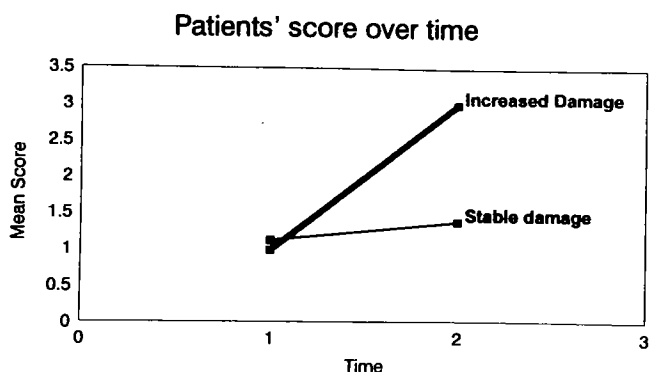


Figure 1. Mean Systemic Lupus International Collaborating Clinics/American College of Rheumatology (SLICC/ACR) Damage Index scores in patients considered to have increased damage over the 5-year period and those considered to have stable damage during the same period of time. In patients considered to have increased damage, the SLICC/ACR Damage Index score was increased by 2.08 points, whereas in patients whose damage was stable, the score was increased by 0.24 points.

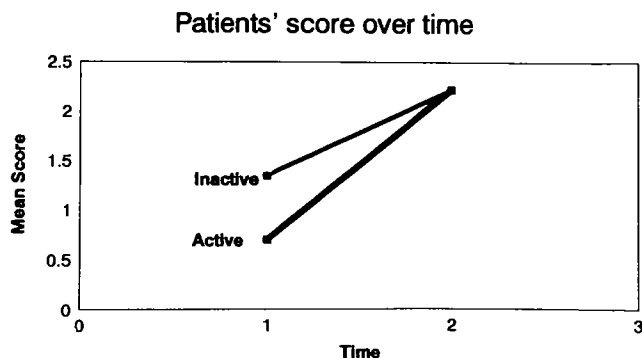


Figure 2. Mean Systemic Lupus International Collaborating Clinics/American College of Rheumatology (SLICC/ACR) Damage Index scores in patients considered to have active disease at 2 time points 5 years apart and those considered to have inactive disease at the same 2 time points. In patients with active disease at both time points, the SLICC/ACR Damage Index score was increased by 1.48 points, whereas in those with inactive disease at both time points, the score was increased by 0.83 points.

International Lupus Conference, in London in April 1992, and were incorporated into the SLICC Damage Index.

Criterion and discriminant validity. Twenty physicians, members of the SLICC, completed the damage index on 42 case scenarios. One physician did not complete the second assessment; therefore, all analyses were completed with and without that physician's scores.

As expected, the factors time, damage, and disease activity were statistically significant, as were the interactions of time with activity and time with damage. Although the differences due to physicians were statistically significant, the effects due to physicians were small relative to the main disease responses, which were clearly due to the combinations

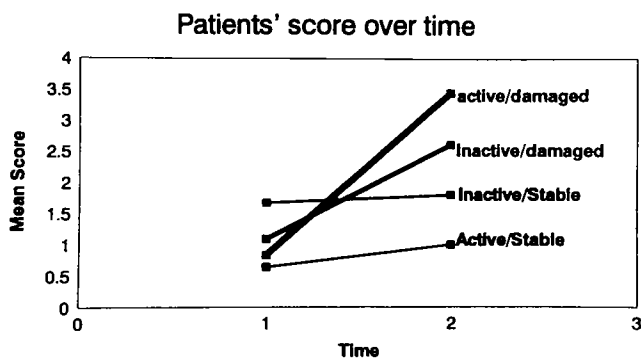


Figure 3. The effect of disease activity and damage at 2 time points 5 years apart on the Systemic Lupus International Collaborating Clinics/American College of Rheumatology Damage Index score.

of time, activity, and damage (1.5%; Table 2). The intraclass correlation coefficient was 0.553.

In the subanalyses, physicians, cases, and time were all statistically significant (2-tailed $P = 0.0286$). In the cases of inactive disease and stable damage, the time effect was not statistically significant. Except for this last set of cases, the smallest source of variation in these analyses was the physician source (Table 2). Thus, the damage index could identify changes in damage seen in patients with both active and inactive disease. In patients whose disease was identified as stable, the damage index score did not change significantly (Figure 1). The analysis further showed that there was a slightly larger change in patients whose disease was active at both time points, compared with patients whose disease was thought to be inactive at both time points (Figure 2). Figure 3 summarizes the effects of disease activity and damage on the damage index score at 2 time points.

DISCUSSION

In the assessment of prognosis in patients with SLE, it is clear that both clinical disease activity and accumulated damage are important factors. Even for the assessment of therapies, it is important to be able to evaluate the effect of the treatment not only in terms of reducing disease activity, but also in terms of reducing the chance of accumulated damage over time. Therefore, the development of an instrument that would allow the evaluation of accumulated damage over time is both necessary and useful for the overall assessment of patients with lupus.

The instrument developed by the SLICC/ACR group provides an opportunity for clinicians and researchers to assess the accumulated damage in patients with SLE. This instrument includes assessment of 12 organ systems. It records damage occurring in patients with lupus, regardless of its cause. Damage may result from previous disease activity leading to organ failure (e.g., renal failure or neurocognitive abnormality), or from medications (e.g., avascular necrosis or diabetes). It may also result from intercurrent illness, such as surgery or cancer. To avoid confusion between active inflammation and damage, an item has to be present for at least 6 months to be included in the damage index. It is assumed that persistent inflammation for at least 6 months would cause some tissue injury, resulting in damage. The damage index does not include hematologic items, such as cytopenias, since the group believed it would be impossible to differentiate transient effects of drugs which might recur at intervals. Although one would

prefer to have precise definitions for each item, such that they could be confirmed by specific techniques (e.g., magnetic resonance imaging or computed tomography), it was believed that it would be more appropriate to base the definitions on clinical judgment so as to allow easy use (Table 1), since not all technological instruments are readily available to everyone.

This SLICC/ACR Damage Index for SLE has been evaluated by 17 additional individuals who are not members of the SLICC group. By and large, these individuals agreed that the instrument was appropriate. Moreover, this instrument has now been tested in the present study, and demonstrates clear criterion validity. It has been shown to be able to discriminate changes in disease damage in patients with both active and inactive disease. These results demonstrate that the damage index is performing as it was intended. Indeed, the SLICC/ACR Damage Index has been evaluated in a large group of patients with SLE, and its ability to record damage was demonstrated (9).

The SLICC Damage Index for SLE is now ready for use by both clinicians and researchers. Questions remain to be answered regarding its intraobserver and interobserver variability, the usefulness of the weighting of each system, and its sensitivity to change over time in clinic patient populations. Several of these issues are currently being addressed. Nonetheless, it is anticipated that the SLICC/ACR Damage Index will be useful both as a descriptor for patient populations included in studies, and as an outcome measure for therapeutic trials and studies of prognosis.

REFERENCES

1. Gladman DD: Prognosis of SLE and factors that affect it. *Curr Opin Rheumatol* 3:789-796, 1992
2. Bombardier C, Gladman DD, Urowitz MB, Caron D, Chang CH, and the Committee on Prognosis Studies in SLE: Derivation of the SLEDAI: a disease activity index (SLEDAI) for lupus patients. *Arthritis Rheum* 35:630-640, 1992
3. Isenberg D, Bacon P, Bombardier C, Gladman DD, Goldsmith CH, Kalunian K, Liang M, Maddison P, Nived O, Richter M, Snaith M, Symmons D, Urowitz MB, Zoma A: Criteria for assessing disease activity in systemic lupus erythematosus. *J Rheumatol* 16:1395-1396, 1989
4. Gladman DD, Goldsmith CH, Urowitz MB, Bacon P, Bombardier C, Chang CH, Isenberg D, Kalunian K, Liang M, Maddison P, Nived O, Richter M, Snaith M, Symmons D, Zoma A: Cross-cultural validation and reliability of three disease activity indices in SLE. *J Rheumatol* 19:608-611, 1992
5. Gladman D, Goldsmith C, Urowitz M, Bacon P, Bombardier C, Isenberg D, Kalunian K, Liang M, Maddison P, Nived O, Richter M, Snaith M, Symmons D, Zoma A: Sensitivity to change of 3 SLE disease activity indices: international validation (abstract). *Arthritis Rheum* 33(suppl 9):S82, 1990
6. Gladman DD, Ginzler E, Goldsmith C, Fortin P, Liang M, Urowitz M, Bacon P, Bombardier S, Hanly J, Hay E, Isenberg D, Jones J, Nived O, Petri M, Richter M, Sanchez-Guerrero J,

- Snaith M, Sturfelt G, Symmons D: Workshop report: Systemic Lupus International Collaborative Clinics (SLICC): development of a damage index in SLE. *J Rheumatol* 19:1820-1821, 1992
7. Urowitz MB: Late mortality and morbidity. In: Proceedings of the Second International Conference on Systemic Lupus Erythematosus. Singapore, Professional Services International, 1989
8. ARA Glossary Committee: Dictionary of The Rheumatic Diseases. Volume I: Signs and Symptoms. New York, Contact Associates International, 1982
9. Gorgos L, Goldman D, Petri M: The ACR/SLICC Damage Index in systemic lupus erythematosus (abstract). *Arthritis Rheum* 36 (suppl 9):S68, 1993

APPENDIX 1: SYSTEMIC LUPUS INTERNATIONAL COLLABORATING CLINICS/AMERICAN COLLEGE OF RHEUMATOLOGY DAMAGE INDEX FOR SYSTEMIC LUPUS ERYTHEMATOSUS: GLOSSARY OF TERMS

Damage:	Nonreversible change, not related to active inflammation, occurring since <i>diagnosis</i> of lupus, ascertained by clinical assessment and present for at least 6 months unless otherwise stated. Repeat episodes must occur at least 6 months apart to score 2. The same lesion cannot be scored twice.	
Cataract:	A lens opacity (cataract) in either eye, ever, whether primary or secondary to steroid therapy, documented by ophthalmoscopy.	
Retinal change:	Documented by ophthalmoscopic examination, may result in field defect, legal blindness.	
Optic atrophy:	Documented by ophthalmoscopic examination.	
Cognitive impairment:	Memory deficit, difficulty with calculation, poor concentration, difficulty in spoken or written language, impaired performance level, documented on clinical examination or by formal neurocognitive testing.	
Major psychosis:	Altered ability to function in normal activity due to psychiatric reasons. Severe disturbance in the perception of reality characterized by the following features: delusions, hallucinations (auditory, visual), incoherence, marked loose associations, impoverished thought content, marked illogical thinking, bizarre, disorganized or catatonic behavior.	
Seizures:	Paroxysmal electrical discharge occurring in the brain and producing characteristic physical changes including tonic and clonic movements and certain behavioral disorders. Only seizures requiring therapy for 6 months are counted as damage.	
CVA:	Cerebrovascular accident resulting in focal findings such as paresis, weakness, etc., or surgical resection for causes other than malignancy.	
Neuropathy:	Damage to either a cranial or peripheral nerve, excluding optic nerve, resulting in either motor or sensory dysfunction.	
Transverse myelitis:	Lower-extremity weakness or sensory loss with loss of rectal and urinary bladder sphincter control.	
Renal:	Estimated or measured glomerular filtration rate <50%, proteinuria ≥ 3.5 gm/24 hours, or end-stage renal disease (regardless of dialysis or transplantation).	
Pulmonary:	Pulmonary hypertension (right ventricular prominence, or loud P2), pulmonary fibrosis (physical and radiograph), shrinking lung (ra-	diograph), pleural fibrosis (radiograph), pulmonary infarction (radiograph), resection for cause other than malignancy.
		Cardiovascular:
		Angina or coronary artery bypass, myocardial infarction (documented by electrocardiograph and enzyme studies) ever, cardiomyopathy (ventricular dysfunction documented clinically), valvular disease (diastolic murmur, or systolic murmur >3/6), pericarditis for 6 months, or pericardiectomy.
		Peripheral vascular:
		Claudication, persistent for 6 months, by history, minor tissue loss, such as pulp space, ever, significant tissue loss, such as loss of digit or limb, or resection, ever, venous thrombosis with swelling, ulceration, or clinical evidence of venous stasis.
		Gastrointestinal:
		Infarction or resection of bowel below duodenum, by history, resection of spleen, liver, or gall bladder ever, for whatever cause, mesenteric insufficiency, with diffuse abdominal pain on clinical examination, chronic peritonitis, with persistent abdominal pain and peritoneal irritations, on clinical examination, oesophageal stricture, shown on endoscopy, upper gastrointestinal tract surgery, such as correction of stricture, ulcer surgery, etc., ever, by history, pancreatic insufficiency requiring enzyme replacement or with a pseudocyst.
		Musculoskeletal:
		Muscle atrophy or weakness, demonstrated on clinical examination, deforming or erosive arthritis, including reducible deformities, (excluding avascular necrosis) on clinical examination, osteoporosis with fracture or vertebral collapse (excluding avascular necrosis) demonstrated radiographically, avascular necrosis, demonstrated by any imaging technique, osteomyelitis, documented clinically, and supported by culture evidence, tendon ruptures.
		Skin:
		Scarring, chronic alopecia, documented clinically, extensive scarring or panniculum other than scalp and pulp space, documented clinically, skin ulceration (excluding thrombosis) for more than 6 months.
		Premature gonadal failure:
		Secondary amenorrhea, prior to age 40.
		Diabetes:
		Diabetes requiring therapy, but regardless of treatment.
		Malignancy:
		Documented by pathologic examination, excluding dysplasias.

APPENDIX 2: INSTRUCTIONS TO INDIVIDUALS TESTING THE SYSTEMIC LUPUS INTERNATIONAL COLLABORATING CLINICS/AMERICAN COLLEGE OF RHEUMATOLOGY DAMAGE INDEX FOR SYSTEMIC LUPUS ERYTHEMATOSUS

SLICC/ACR content validity assessment
SLICC/ACR Damage Index

Introduction

The total damage in a patient with SLE may result from:

1. SLE itself
2. Any other pathologic process such as:
 - Atherosclerosis
 - Hypercoagulability
 - Hypertension
 - Therapy for SLE
 - Other comorbid conditions

A global damage index would describe the total of all the damage that has occurred from any mechanism in any one patient. For the purpose of this assessment the damage is considered only if present for at least 6 months.

This index is assessed irrespective of:

- Current SLE disease activity
- The amount or duration of any therapy
- The disability of the patient

Please answer the following questions by circling the appropriate response.

1. I have read and understood the SLICC/ACR Damage Index introduction. Y N
2. I have reviewed the attached SLICC/ACR SLE Damage Index. I agree this index is a suitable damage index. Y N

If *no*, please note in writing on the attached index form any suggestions for improvement.

3. Any other suggestions? Please note at the end of this page.