OUTCOME MEASURES FOR SPONDYLOARTHRITIS AND FOOT DISORDERS

The following instrument has been developed to measure the impact of foot/ankle involvement in rheumatoid arthritis. Click on the link below to gain access to these measures.

Measuring foot health quality of life.

The Leeds Foot Impact Scale

The Leeds Foot Impact Scale (LFIS) is a quantitative measure of foot impacts associated with Rheumatoid Arthritis. It was developed using the needs-based approach and subjected to a rigorous validation process. The LFIS is composed of 2 domains: Impairment & Footwear (IF) on page 1 and Activities & Participation (AP) on page 2. Each positive response is scored as 1, and total responses are summed. The LFIS is freely available for use for clinical research purposes. To obtain a copy please click on the link below. There may be a charge for commercial use.

[link to LFIS]

Ref. Helliwell PS, Reay N, Gilworth G, Redmond AC, Slade A, Tennant A, Woodburn J, Development of a foot impact scale for rheumatoid arthritis. Arthritis & Rheumatism (Arthritis Care & Research) 2005: 53;3. 418-422

Measuring disease activity in Psoriatic Arthritis (PsA).

The following instruments have been developed to measure disease activity in PsA. Click on the links below to gain access to these measures.

Leeds Dactylitis Index

The Leeds Dactylitis Index (LDI) is the only validated tool for assessing dactylitis. The LDI employs the Leeds Dactylometer to measure digit circumference. The validity of this instrument has been assessed using the OMERACT filter. The instrument and tool have

demonstrated good evidence of responsiveness in clinical trials. In addition, the instrument incorporates a definition of dactylitis (a 10% difference in the ratio of circumference of the affected digit to the contralateral digit). Using the contralateral digit as a normator enables any inter-individual variation in measurement technique to be minimised. The instrument comes with an assessment sheet which provides automatic computation of the Leeds Dactylitis Index.

If you would like to purchase a dactylometer, please visit https://www.mie-uk.com/dactylometer/index.html.

[link to LDI]

Ref. Helliwell PS, Firth J, Ibrahim GH, Melsom RD, Shah I, Turner DE. Development of an assessment tool for dactylitis in patients with psoriatic arthritis. The Journal of Rheumatology 2005;32(9):1745–1750.

Leeds Enthesitis Index

Entheseal inflammation and dactylitis are common in patients with PsA. Entheseal inflammation is a typical feature of PsA and is one of the features which distinguishes it from RA. The Leeds Enthesitis Index (LEI) examines tenderness at six sites: 2 sites at each of the lateral epicondyles of the humerus, medial condyles of the femur and the insertion of the Achilles tendon. The LEI was developed specifically for PsA.

[link to LEI]

Ref. Healy PJ, Helliwell PS. Measuring clinical enthesitis in psoriatic arthritis: assessment of existing measures and development of an instrument specific to psoriatic arthritis. Arthritis Rheum 2008;59:686–91.

Composite measures for assessing disease activity in psoriatic arthritis

The GRACE score

The GRACE score was developed within the GRAPPA collaboration composite disease index endeavour (1). The approach was suggested by Fransen et al. (2), where desirability functions are developed for variables deemed important in assessing disease activity, based

on the original core domains selected for PsA RCTs at OMERACT 8 (3). Desirability functions for tender and swollen joint counts, health assessment questionnaire (HAQ) and patient global assessment of disease activity by visual analog scale (VAS) were derived using data gathered by an internet based survey of GRAPPA members. Remaining functions (patient VAS for skin, patient VAS for joints, psoriasis area and severity index (PASI), and psoriatic arthritis quality of life index (PsAQoL) were developed with data obtained from 109 responses in a subsequent internet survey (85 rheumatologists and 24 dermatologists). Cutoffs were determined according to the median of responses and used to transform each variable into linear functions ranging from 0 (totally unacceptable state) to 1 (normal). The 8 transformed variables were then combined using the arithmetic mean (AMDF: arithmetic mean of desirability functions).

The variables assessed are as follows:

Patient global, measured in mm, 0 - 100 scale

Patient arthritis, measured in mm, 0 – 100 scale

Patient skin, measured in mm, 0 – 100 scale

Swollen joint count: full 66 swollen joint count

Tender joint count: full 68 tender joint count

Psoriasis Area and Severity Index (PASI), range 0 – 72

Health Assessment Questionnaire (HAQ), range 0 – 3

Psoriatic arthritis Quality of Health questionnaire (PsAQoL), range 0 - 20

Cut-offs used in AMDF

Measure	Cut point 1	Cut point 2	Cut point 3
Swollen joint count*	1	3	5
Tender joint count*	2	5	8
VAS patient global (0 – 100)*	15	30	50
VAS patient skin (0 – 100)#	10	30	50
VAS patient joints (0 – 100)#	10	30	50
HAQ (0 – 3) #	0.5	1.0	2.0
PASI (0 – 72) #	3.5	9.5	15.0
PsAQoL (0-20)#	3	7	11

^{*}indicates cut-offs obtained in development of MDA criteria

indicates cut-offs obtained with GRAPPA

Cut point 1 between remission and low disease activity

Cut point 2 between low disease activity and moderate disease activity

Cut point 3 between moderate disease activity and high disease activity

The GRACE index is obtained by the following equation from the AMDF (this was done to make the 'direction' of the score consistent with the other measures):

$$GRACE = (1 - DF) * 10.$$

A link to an SPSS syntax file, and an Excel file for calculating the GRACE is given below.

Following a data driven GRAPPA exercise, and a face to face meeting, cut-offs for response and disease activity have been developed (4, 5).

High disease cut-off = 4.7

Low disease cut-off = 2.3

GRACE

Improvement			
Final GRACE score	>2.0	<2.0 but >1.0	<1.0
≤2.3	1	2	3
>2.3 but <4.7	2	2	3
≥4.7	2	3	3

^{1 =} good response; 2 = moderate response; 3 = poor response

[link to GRACE.SPS] [link to GRACE.XLS]

Refs.

- 1. Helliwell PS, FitzGerald O, Fransen J, Gladman DD, Kreuger GG, Callis-Duffin K, et al. The development of candidate composite disease activity and responder indices for psoriatic arthritis (GRACE project). Ann Rheum Dis. 2013;72(6):986-91.
- 2. Fransen J, Kavanaugh A, Borm GF. Desirability scores for assessing multiple outcomes in systemic rheumatic diseases. Communications in Statistics Theory and Methods. 2009;38:3461-71.
- 3. Gladman DD, Mease PJ, Strand V, Healy P, Helliwell PS, Fitzgerald O, et al. Consensus on a core set of domains for psoriatic arthritis. [6 refs]. Journal of Rheumatology34(5):1167-70. 2007.
- 4. Helliwell PS, FitzGerald O, Fransen J. Composite Disease Activity and Responder Indices for Psoriatic Arthritis: A Report from the GRAPPA 2013 Meeting on Development of Cutoffs for Both Disease Activity States and Response. The Journal of Rheumatology. 2014;41(6):1212-7.
- 5. Coates L, Helliwell PS. Defining low disease activity states in psoriatic arthritis using novel composite disease instruments. J Rheumatol. 2016;43:371-5.

The Psoriatic arthritis disease activity score (PASDAS)

The PASDAS is a data derived composite disease activity measure developed by GRAPPA in a multinational effort (1). The index is calculated using the following formula:

PASDAS = $((0.18 \times VPhysician global VAS) + (0.159 \times VPatient global VAS) - (0.253 \times VSF36 - PCS) + (0.101 \times LN (Swollen joint count + 1)) + (0.048 \times LN (Tender joint count + 1)) + (0.23 \times LN (Leeds Enthesitis Count + 1)) + (0.377 LN (Dactylitis count + 1)) + (0.102 \times LN (CRP + 1)) + (2)*1.5.$

The variables assessed are as follows:

Physician global, measured in mm, 0 - 100 scale

Patient global, measured in mm, 0 - 100 scale

SF36 physical function sub-scale (can be derived from full SF36 or SF12)

Swollen joint count: full 66 swollen joint count

Tender joint count: full 68 tender joint count

Leeds Enthesitis index (LEI) score range 0 - 6

Dactylitis count range from 0 - 20 and is a simple count of digits thought to be affected by dactylitis

C reactive protein (CRP), measured in mg/L

Links to an SPSS syntax file and an Excel file for calculating the PASDAS are below.

Cut-offs for disease activity and response.

Following a data driven GRAPPA exercise, and a face to face meeting, cut-offs for response and disease activity have been developed (2, 3).

High disease cut-off = 5.4

Low disease cut-off = 3.2

Very low disease cut-off = 1.9

Psoriatic Arthritis Disease Activity Score (PASDAS)

	Improvement		
Final PASDAS score	>1.6	<1.6 but >0.8	<0.8
≤3.2	1	2	3
>3.2 but <5.4	2	2	3
≥5.4	2	3	3

^{1 =} good response; 2 = moderate response; 3 = poor response

[link to PASDAS.SPS] [link to PASDAS.XLS]

Refs.

- 1. Helliwell PS, FitzGerald O, Fransen J, Gladman DD, Kreuger GG, Callis-Duffin K, et al. The development of candidate composite disease activity and responder indices for psoriatic arthritis (GRACE project). Ann Rheum Dis. 2013;72(6):986-91.
- 2. Helliwell PS, FitzGerald O, Fransen J. Composite Disease Activity and Responder Indices for Psoriatic Arthritis: A Report from the GRAPPA 2013 Meeting on Development of Cutoffs for Both Disease Activity States and Response. The Journal of Rheumatology. 2014;41(6):1212-7.
- 3. Coates L, Helliwell PS. Defining low disease activity states in psoriatic arthritis using novel composite disease instruments. J Rheumatol. 2016;43:371-5.

<u>Instrument for screening for psoriatic arthritis in patients with psoriasis</u>

Psoriasis Epidemiology Screening Tool (PEST)

The Psoriasis Epidemiology Screening Tool, or PEST, is a screening tool that can help recognize the signs of psoriatic arthritis in psoriasis patients. The PEST tool is free to use and there are no copyright issues. Several translations are available (see below). These translations will soon be available on the GRAPPA App. Please feel free to translate and validate the PEST, but please do write to us and send us a copy of your translated version. We also ask that you send us copies of any papers that result from studies using the tool.

Ref. Ibrahim GH, Buch MH, Lawson C, Waxman R, Helliwell PS. Evaluation of an existing screening tool for psoriatic arthritis in people with psoriasis and the development of a new instrument: the Psoriasis Epidemiology Screening Tool (PEST) questionnaire. Clin Exp Rheumatol 2009;27:469–74.

Available translations:

Arabic [LINK]	French [LINK]	Korean [LINK]
Austrian German [LINK]	German [LINK]	Norwegian [LINK]
Cantonese [LINK]	Hebrew [LINK]	Russian [LINK]
Mandarin [LINK]	Italian [LINK]	Swedish [LINK]
Dutch [LINK]	Japanese [LINK]	UK English [LINK]

Instrument for assessing functional capacity in ankylosing spondylitis

The Revised Leeds Disability Questionnaire (RLDQ)

The Revised Leeds Disability Questionnaire (RLDQ) was developed to measure functional loss in ankylosing spondylitis. It was developed with a technique known as Guttman scaling, a predecessor to Rasch analysis. Essentially all the questions within a domain are scaled in terms of difficulty.

[LINK TO RLDQ]

Ref. Abbott CA, Helliwell PS, Chamberlain MA. Functional assessment in ankylosing spondylitis: evaluation of a new self-administered questionnaire and correlation with anthropometric variables. Brit J Rheum 1994;33:1060-66.