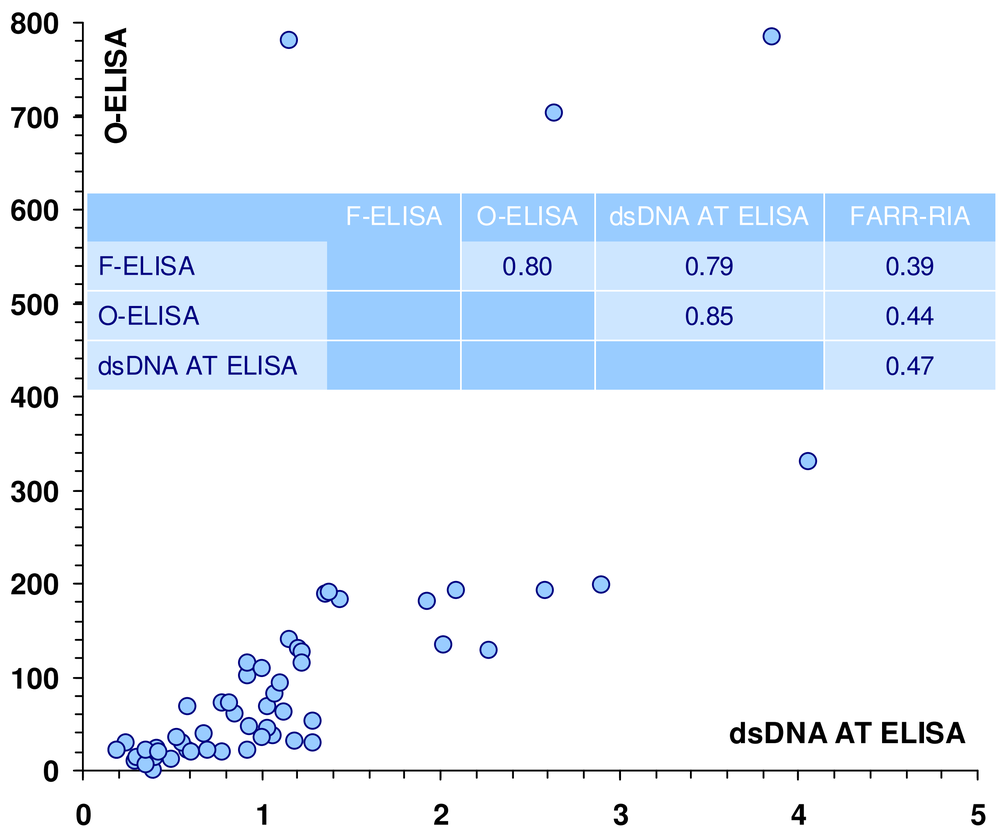
Evaluation of a novel dsDNA ELISA for SLE disease activity measurement

M. Mahler[1], M. van Liempt[1], J. Schulte-Pelkum[1], S. Schneider[2], T. Alexander[2], A. Kromminga[3], M. Fooke[1], F. Hiepe[2]
[1]Dr. Fooke Laboratorien GmbH, Neuss, Germany; [2]Charité University Medicine, Berlin, Germany, Department of Rheumatology and Clinical Immunology; [3]Labor Lademannbogen, Hamburg, Germany

Background: Anti-dsDNA antibodies in serum are known to correlate with disease activity in systemic lupus erythematosus (SLE). However, most studies revealed that the standardization of anti-dsDNA assays is rather poor. The aim of this study was to technically compare the novel dsDNA AT (activity test) ELISA to various anti-dsDNA assays in correlation to the disease activity as measured by the SLE activity index (SLEDAI).

Methods: Sera from SLE patients diagnosed according to the 1997 revised ACR criteria (n=55) were tested for anti-dsDNA antibodies by two separate ELISA test systems (Dr. Fooke, F-ELISA and Orgentec, O-ELISA), FARR-RIA (DPC), *Crithidia luciliae* immunofluorescence test (CLIFT; Werfen Group) and by a novel dsDNA activity test ELISA (dsDNA AT ELISA, Dr. Fooke). SLEDAI 2k score was available for 54 patients. Anti-dsDNA antibodies were regarded positive for this score if the ELISA value (Orgentec) was ≥ 50 IU/ml and/or the CLIFT was positive.

Results: Moderate to good correlations between assays were found (Figure 1). Anti-dsDNA antibody titres were significantly higher in active SLE patients (n=33; SLEDAI>6) compared to the inactive group (n=21; SLEDAI≤6) using dsDNA AT ELISA, the FARR-RIA, the F-ELISA, but not using the CLIFT according to Mann-Whitney test (Figure 2).



	F-ELISA	O-ELISA	dsDNA AT ELISA	FARR-RIA
F-ELISA		0.80	0.79	0.39
O-ELISA			0.85	0.44
dsDNA AT ELISA				0.47

Figure 1 Correlation between different dsDNA assays. The diagram shows the correlation between the O-ELISA (Orgentec) and the novel dsDNA AT ELISA (Dr. Fooke). The table summarizes the correlation values for all comparisons according to Spearman.

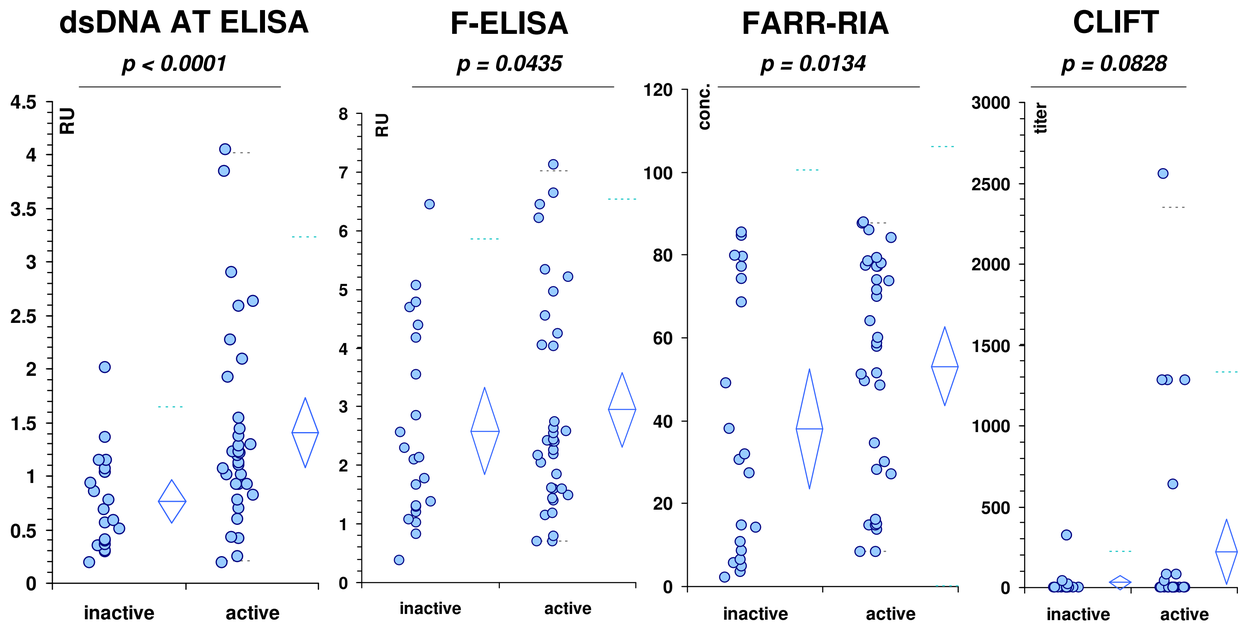


Figure 2 Comparative descriptive analysis. Anti-dsDNA reactivity in active and inactive SLE patients measured by different methods. Differences were calculated according to the Mann-Whitney test.

When anti-dsDNA titres were compared to SLEDAI scores by Spearman, correlations were: r=0.09, *p*=0.5332 (F-ELISA), r=0.34, *p*=0.0124 (FARR-RIA) and r=0.40, *p*=0.0025 (dsDNA AT ELISA) (Figure 3).

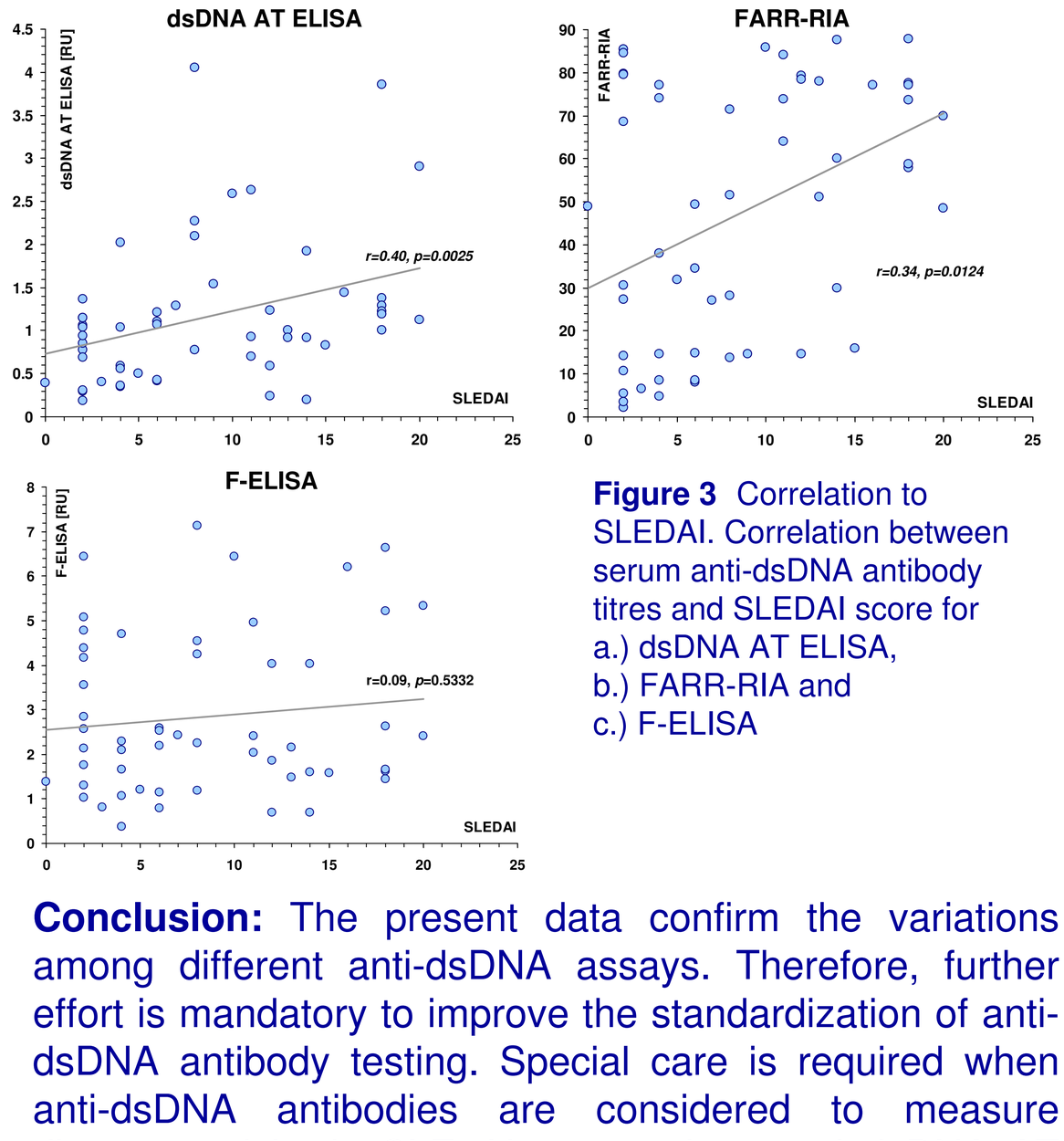


Figure 3 Correlation to SLEDAI. Correlation between serum anti-dsDNA antibody titres and SLEDAI score for
a.) dsDNA AT ELISA,
b.) FARR-RIA and
c.) F-ELISA

Conclusion: The present data confirm the variations among different anti-dsDNA assays. Therefore, further effort is mandatory to improve the standardization of anti-dsDNA antibody testing. Special care is required when anti-dsDNA antibodies are considered to measure disease activity in SLE. However, the novel dsDNA AT ELISA showed higher association with SLEDAI score compared to all other methods used in this study.

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