anti-DNase I concentrations were evaluated by conventional ELISA, as described elsewhere [1]. The beads were synthesized using original technique [2], modified ELISA and recovery of the beads for repeating use was performed according to the previously published protocols [2]. Antibody concentrations were expressed as relative optical density units (ODU). The cutoff values for conventional and modified ELISA were 0.061 and 0.057 ODU, respectively. All the means and operation characteristics were expressed as values (95% confidence intervals). Differences were considered significant when $p<0.05$.

Results: Mean anti-DNase I concentrations in SLE patients (negative and positive together) were 0.088 (0.031–0.145) and 0.079 (0.033–0.125) ODU for conventional and modified ELISA, respectively; in the control group they were 0.068 (0.020–0.116) and 0.063 (0.019–0.107) ODU, respectively. Differences within these couples were not significant. Diagnostic sensivity and specificity of modified ELISA were 64.74 (53.09–76.39) and 85.01 (72.95–97.07)%, coinciding with those for conventional ELISA. LOQ for the modified ELISA was slightly lower than for the conventional one. Accuracy and repeatability of modified ELISA were also insignificantly higher than those for conventional approach. There was no substantial change in all the parameters of modified ELISA after single recovery of beads.

Conclusions: The newly developed ELISA for anti-DNase I antibodies was demonstrated to have equivalence or advantage in some analytical parameters over conventional ELISA. Considering some economic and maintenance benefits, our innovation can be an alternative tool to improve SLE diagnostics.

References:

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THU0671 CAN AN INNER DISPOSABLE GLOVE BE USED UNDER AN ELECTROGONIOMETRIC GLOVE FOR MEASURING FINGER MOVEMENT WITHOUT LOSS OF ACCURACY?

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Background: Improving joint mobility is an important outcome for patients with arthritis, but finger joint range of motion is rarely measured in clinic. Electronic gloves with movement sensors have been developed to measure joint movement accurately and it is now possible to assess dynamic mobility of the finger joints. However these gloves are expensive and it is likely that when carrying out measurements in the patient population they would be used with inner disposable gloves to avoid nonsocomical infection. Establishing accuracy and usability of electronic gloves whilst wearing disposable inner gloves is therefore an important pre-requisite for studies in patients with arthritis.

Objectives: To establish the accuracy and repeatability of measurements of finger movement obtained using two different electrogoniometric gloves worn with and without an inner disposable glove.

Methods: We used two different types of electrogoniometric glove for the purpose of this study. One is the commercially available 5DT dataglove 14 Ultra (5DT, 2011) and the other was produced to our specifications by Tyndall National Institute, University College Cork. We called this the “IMU glove”. We developed a graphical interface for both devices to facilitate detailed evaluation of joint movement in each finger. Both gloves were tested using a protocol adapted from Dipietro, Sabatini, & Dario, (2003).

Results: Table 1 displays comparison of Coefficient of Variation (CV) readings for both data gloves. Figure shows this information graphically.

Sensor	No surgical glove		Surgical glove underneath	
	5DT	IMU	5DT	IMU
Index MCP	2.97	2.86	3.22	3.88
Middle MCP	7.01	6.77	9.02	6.39
Ring MCP	6.10	4.37	6.28	4.32
Little MCP	24.17	6.07	9.55	8.25
Index PIP	1.96	9.72	2.92	14.69
Middle PIP	4.40	10.29	2.98	12.53
Ring PIP	5.38	9.95	5.00	11.03
Little PIP	9.11	3.71	10.07	5.46

Results show no significant change for 5DT angular readings with and without a surgical glove worn underneath the data glove. Results for PIP sensors show an improvement in repeatability with a surgical glove. CV variance was smaller for MCP sensors with a surgical glove worn underneath the data glove compared with no surgical glove.

CV for the IMU data glove show negligible changes in MCP readings when a surgical glove is worn underneath. PIP readings show small changes when using a surgical glove.

Conclusions: Inner disposable gloves can be worn when using electrogoniometric gloves for testing finger movement without loss of accuracy or any significant discomfort in patients with arthritis.

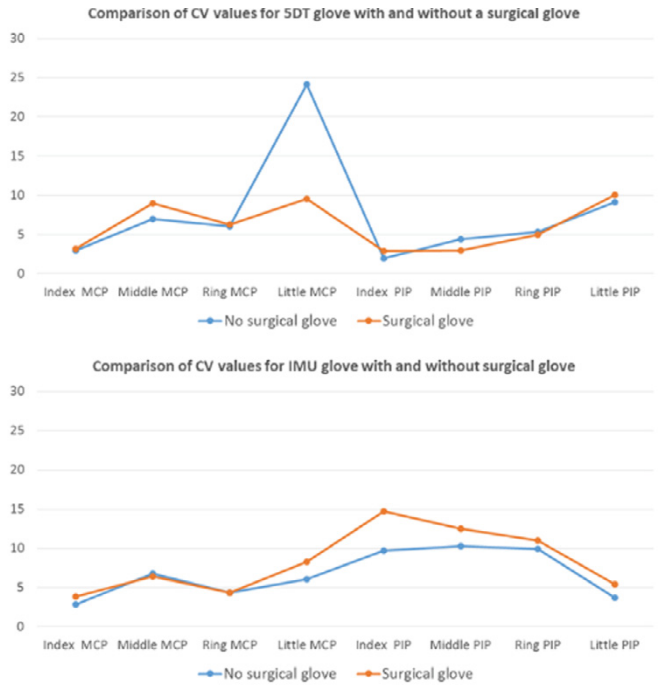

Figure 1: Comparison of Coefficient of Variation (CV) values for mean angular readings for both data gloves, with and without a surgical glove worn underneath.

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THU0672 REAL WORLD EVIDENCE COMPARING THE PATIENT REPORTED OUTCOMES MEASUREMENT INFORMATION SYSTEM TO THE CDAI IN RHEUMATOID ARTHRITIS PATIENTS

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Background: Patient (Pt) reported outcomes (PROs) play a role in overall disease evaluation, therapeutic response assessment and care of rheumatoid arthritis (RA) patients (Pts). The Pt Reported Outcomes Measurement Information System (PROMIS [P]) questionnaires developed by the NIH have been validated and are a feasible assessment tool in RA (Bartlett 2015).

Objectives: AWARE (Comparative and Pragmatic Study of Golimumab Intravenous (IV) Versus Infliximab in RA) is a real-world study of golimumab IV (G-IV) vs. infliximab (IFX) in RA and will assess infusion reactions, disease activity and multiple PROs as outcomes measures.

Methods: AWARE is a prospective, noninterventional, ongoing US-based study in which 1,200 adult Pts will be enrolled on initiation of treatment with G-IV or IFX. Objectives include PRO assessments of Pt response to treatment using the PROMIS-29 Profile v2.0 (P29v2), P Pain Interference Short Form-6b (PISF) and P Fatigue Short Form-7a (FSF), 36-Item Short Form Health Survey (SF-36v2) and the Clinical Disease Activity Index (CDAI). We report an interim analysis from the first 353 Pts of baseline PROMIS questionnaire and CDAI scores, and their inter-relationships. PROMIS questionnaire results are scored on a 0 to 100 scale, normed to the US population and reported as a “T-score” (mean of 50 and standard deviation (SD) of 10). PROMIS T scores were compared across CDAI disease activity (DA) categories.

Results: Baseline mean (SD) CDAI score was 33.46 (±15.79), with 73.4% of pts with high DA (HDA), 22.1% with moderate disease activity (MDA), 3.7% with low disease activity (LDA) and 0.8% pts in remission. PROMIS scores are shown below. All P29v2 domains, PISF and FSF scores were significantly worse in pts with CDAI>22 vs. CDAI≤22 ($p<0.05$). The same was true for SF-36 domains (data not shown). PROMIS scores are shown below for all pts, and also based on CDAI DA category. PROMIS T scores across all domains (P29v2 domains, PISF and FSF) were compared to CDAI disease activity category (below). As shown, PROMIS T scores correlated with CDAI disease category, with HDA Pt T scores significantly (*, $p<0.05$) greater than those of MDA, LDA and Remission pts (excepting the Sleep Disturbance domain).