Methods: A total of 294 patients were randomized (1:1:1) to either PRO-based tele-health follow-up carried out by a nurse (PRO-TN) or a rheumatologist (PRO-TR), or conventional out-patient follow-up by physicians. The Flare-RA (2) was used as decision aid for assessing disease activity.

The primary outcome was change in DAS28 after week 52. Secondary outcomes were: physical function, quality of life and self-efficacy. The non-inferiority margin was a DAS28 change of 0.6. Mean differences were estimated following per-protocol, intention to treat (ITT) and imputation (IMP).

Results: Overall patients had low disease activity at baseline and end follow-up. Demographics and baseline characteristics were similar between groups. Non-inferiority was established for DAS28. In the ITT analysis mean difference in DAS28 between PRO-TR vs. control were -0.10 (90% CI -0.30; 0.13) and -0.19 (-0.41; 0.02) between PRO-TN vs. control. When including one yearly visit to the outpatient clinic, patients in PRO-TN had a total of 1.72 (SD 1.03) visit/year, PRO-TR 1.75 (SD 1.03) visit/year and control 4.15 (SD 1.0) visits/year. This included extra visits due to inflammatory flare.

Overall more than 80% of the patients in all three groups answered that they were "very satisfied" with the consultation form they received and no differences were found between the three groups.

Conclusions: Among RA patients with low disease activity or remission a PRO-based tele-health follow-up for tight control of disease activity in RA can achieve similar disease control as conventional outpatient follow-up. The degree of disease control did not differ between patients seen by rheumatologists or rheumatology nurses.

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Validation of outcome measures and biomarkers

THU0658 WNT/ β -CATENIN PATHWAY IS AFFECTED IN PRIMARY SJÖGREN'S SYNDROME

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Background: Sjögren's syndrome (SS) is a chronic autoimmune disease that causes salivary and lacrimal gland dysfunction, resulting in oral and ocular dryness. The pathogenesis of SS is still unknown. The Wingless (Wnt)/ β -catenin pathway has been recently shown to play an important role in inflammation.

Objectives: The aim of the present study was to determine serum and salivary levels of *Dickkopf-related protein 1* (DKK1) and sclerostin those are inhibitor of Wnt/ β -catenin signaling pathway and to evaluate the expression of Wnt-1 and Wnt-3a in the salivary gland, in patients with primary SS.

Methods: 30 patients with primary SS, 30 patients with systemic lupus erythematosus (SLE) and 29 healthy controls were enrolled in the study. Fasting blood and saliva samples were obtained from the participants. Serum and salivary levels of DKK1 and sclerostin were measured by enzyme-linked immunosorbent assay. Wnt-1 and Wnt-3a expression were also immunohistochemically assessed in salivary gland. EULAR SS Disease Activity Index (ESSDAI), and EULAR SS Patient Reported Index (ESSPRI) in the SS group and Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) in the SLE group were recorded.

Results: Serum DKK1 and sclerostin levels were decreased in the SS and SLE groups compared to the controls (Table 1) ($p < 0.001$ for both). Salivary sclerostin levels were similar among the study groups ($p > 0.05$ for all). Salivary DKK1 levels were higher in the SS group compared to the control and SLE group ($p = 0.004$ and $p = 0.009$, respectively). Moreover, serum DKK1 level was higher in the SS group than in the SLE group ($p = 0.046$). Serum DKK1 level was positively correlated with serum sclerostin level in the SS, SLE and control groups ($r = 0.677$; $p < 0.001$, $r = 0.783$; $p < 0.001$, and $r = 0.829$; $p < 0.001$, respectively). ESSPRI was

Table 1. Demographics and clinical variables in the study groups

	HC	SLE	SS	P ₁ (SLE vs. HC)	P ₂ (SS vs. HC)	P ₃ (SS vs. SLE)
Serum DKK1, ng/ml	49.8±14.9	27.8±11.8	35.2±8.8	<0.001	<0.001	0.046
Salivary DKK1, ng/ml	30.6±5.9	31.1±6.9	36.3±6.9	0.944	0.004	0.009
Serum Sclerostin, ng/ml	12.9±5.1	5.7±4.1	5.5±3.8	<0.001	<0.001	0.984
Salivary Sclerostin, ng/ml	16.1±3.4	15.7±2.5	15.6±3.7	0.877	0.838	0.996

negatively correlated with serum DKK1 and sclerostin levels ($r = -0.363$; $p = 0.049$ and $r = -0.416$; $p = 0.022$, respectively) in the SS group.

Moreover, in the salivary gland tissues, the positivities of Wnt-1 (71.4% vs. 46.2%, $p = 0.182$) and Wnt-3a (71.4% vs. 53.8%, $p = 0.345$) were relatively higher in the SS group compared to the control group, respectively.

Conclusions: According to the best of our knowledge, this study is the first study evaluating the activity of Wnt/ β -catenin pathway in the primary SS. The altered serum levels of DKK1 and sclerostin in primary SS and SLE suggest that Wnt/ β -catenin pathway is affected in these inflammatory diseases. Salivary DKK1 level is increased in primary SS in contrast to SLE. On the other hand, Wnt-1 and Wnt-3a expressions on the salivary gland are increased in primary SS. Therefore, it may be concluded that Wnt/ β -catenin pathway acts pathogenic roles on the glandular inflammation.

Disclosure of Interest: None declared

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THU0659 SKIN MICROVASCULAR FLOW ASSESSED BY DYNAMIC OPTICAL COHERENCE TOMOGRAPHY: FIRST NON-INVASIVE QUANTITATIVE OUTCOME MEASURE OF MICROVASCULAR DAMAGE IN SYSTEMIC SCLEROSIS

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Background: Reduction in capillaries number is the defining feature of microvascular disease in Systemic Sclerosis (SSc) and it concurs to the ischemic manifestations of the disease. Digital Ulcers (DUs) are the major complication of ischemic peripheral vasculopathy.

Dynamic optical coherence tomography (D-OCT) is a recently developed imaging technique that allows non-invasive in vivo study of the microvasculature of the skin. In addition to the skin architecture and vessels morphology, it offers information about flow status, allowing the functional and quantitative evaluation of the microcirculation.¹

Objectives: To determine the face and content validity of D-OCT as outcome measure of the skin microvascular disease, assuming the presence of current DUs, distal to the DIP joints, as gold standard for ischemic peripheral vasculopathy in SSc.

Methods: A total of 54 patients were enrolled in this cross-sectional study, including 18 SSc patients with current DUs (DU group); 18 SSc patients without current DUs (no DU group) and 18 patients with Raynaud's phenomenon and SSc specific ANA, who did not fulfilled ACR/EULAR 2013 classification criteria (SRP group).

For each patient, we performed a D-OCT scan on both index and middle fingers, on the dorsal aspect of the second phalanx, employing *Vivosight Scanner* (Michelson Diagnostics). The speckle variance signal of D-OCT images within the first mm of skin depth was extracted, quantified as area under the curve (AUC) and defined as Micro Vascular Flow (MVf).

MVf comparison between the groups was done using parametric or non-parametric tests as appropriate. Statistical Analysis was performed with SPSS V.22.

Results: All three groups were comparable in terms of age and gender distribution ($p > 0.80$ for both) as well as disease duration and clinical subset between the two SSc groups ($p = 0.839$ and $p = 0.646$, resp.). With a scan time <1 minute, D-OCT allowed the visualization and quantification of capillaries within the first millimeter of skin depth (Figure 1).

The distribution of MVf was not significantly different among the four fingers within each group (DU group: $p = 0.459$, no DU group: $p = 0.953$ and SRP group: $p = 0.616$). On the contrary, the distribution and median MVf for all fingers was significantly different among the 3 groups: DU group = 0.134 (IQR 0.121–0.134), no DU group = 0.153 (IQR 0.132–0.153) and SRP group = 0.167 (IQR 0.148–0.167) ($p < 0.0001$), as well as in the DU group vs. no DU group ($p < 0.001$) or DU vs SRP group ($p < 0.001$).

Further, sub analysis of the DU group showed that 10 of the total 20 DUs were on the left index finger. Within this subgroup the MVf of patients on Sildenafil ($n = 6$) was significantly higher than the rest of the group (0.148 ± 0.021 vs. 0.113 ± 0.019 , $p = 0.03$).

Figure 1

Conclusions: MVf assessed by D-OCT is a quantitative, non-invasive surrogate outcome measure of severe peripheral ischemic vasculopathy in SSc. Longitudinal

studies assessing its sensitivity to change will inform whether MVF can be used as end point of skin microvascular involvement in SSC.

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Disclosure of Interest: None declared

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THU0660 POLYMYALGIA RHEUMATICA TREATMENT SERUM BIOMARKERS VERSUS RHEUMATOID ARTHRITIS

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Background: Polymyalgia rheumatica (PMR) is a systemic inflammatory disorder with unknown etiology and overlapping symptoms with giant cell arthritis and late-onset rheumatoid arthritis (RA). To date, no proteomics studies have been performed on PMR patients, and the number of biomarker studies remain limited. **Objectives:** The primary aim of this study was to thoroughly investigate the corticosteroid treatment serum proteome of PMR with a focus on acute-phase reactions, complement system, and cytokines.

Methods: Filter-aided sample preparation for mass spectrometry, cell free DNA (cfDNA) assay, and 10plex cytokine assay were applied to PMR serum samples from the same patients before and after treatment, DMARD-naïve RA patients, and healthy controls.

Results: The core serum proteomes of the four groups were remarkably similar, and consisted of >200 proteins, which included acute-phase reactants, coagulation and complement proteins (figure), immunoglobulins, and apolipoproteins, and several more. Acute Phase Serum Amyloid A (SAA1) was differentially less abundant after PMR treatment, and CRP (after adjusting for two patients with low baseline CRP). cfDNA were more abundant in both groups of PMR compared to healthy controls. Complement factors were narrowly distributed and not affected by PMR treatment. The individual serum proteome of each PMR patient provided more than 100 differentially abundant proteins, and highlights the heterogeneity of patients.

Conclusions: We have established the core serum proteome of PMR in response to treatment, and compared it with RA and healthy controls. The results suggest a functional role of SAA1, and increased cfDNA in the pathogenesis of PMR indicates the activation of NETs.

Disclosure of Interest: None declared

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THU0661 CLINICAL RELEVANCE OF DETECTING ANTI-ADALIMUMAB ANTIBODIES WITH A DRUG-TOLERANT ASSAY

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Background: Adalimumab (Ada) has proven effective in treating rheumatoid arthritis (RA) and spondyloarthropathies (SpA), although approximately 30% of responders will present secondary clinical failure. Immunocomplex formation between antibodies to Ada (ATA) and Ada can increase drug clearance. Most of the assays to measure ATA present drug interference. Currently, different assays are available to measure total ATA (free and complexed).

Objectives: To compare the detection of ATA along Ada treatment between two

assays: one drug-sensitive and another drug-tolerant assay. Study the association of ATA with the clinical status.

Methods: This is a prospective observational study with 63 patients with rheumatic diseases under Ada treatment enrolled at Biological Therapy Unit of Hospital La Paz. Serum Ada levels were measured by ELISA and serum ATA levels by two assays: an in-house two-site (bridging) ELISA (bELISA) to detect uncomplexed ATA (free ATA) and a drug-tolerant assay developed by Immundiagnostik (Bensheim, Germany) (IDK) to measure simultaneously free and complexed ATA (total ATA). Samples were evaluated at 0, 0.2, 0.5, 1, 1.5 and 2 years after Ada initiation.

Results: Out of the 63 studied patients, 12 (19%) had RA and the rest (51, 81%) had different spondyloarthropathies (24, 38%) ankylosing spondylitis, 9 (14%) psoriatic arthritis, 14 (22%) undifferentiated spondyloarthritis and 4 (6%) spondyloarthritis associated with inflammatory bowel disease). Thirty-one patients (49%) received concomitant methotrexate (26% RA patients and 74% SpA patients), 13 (21%) received another DMARDs associated to Ada and 19 (30%) were on monotherapy. Out of the 63 patients, in 27 (43%) no ATA were detected. Thirty-six patients (57%), were IDK+ and 12 patients (19%) were bELISA+ (all of them IDK+). The presence of ATA by bELISA was associated with absence of serum Ada levels. However, most (78%) samples with complexed ATA had low circulating Ada levels (1.65 mg/ml in ATA+ vs 6.25 mg/ml in ATA-, $p < 0.0001$). ATA appeared by IDK at earlier treatment stages than by bELISA, statistically different at all studied time points. In patients who dropped-out (30 patients, 48%) ATA detection was frequent and significant by both methods. Ten patients (33%) bELISA ATA+ dropped-out vs 2 patients bELISA ATA+ in those who continued treatment ($p < 0.0001$). Twenty-four patients (80%) IDK ATA+ dropped-out vs 12 patients (36%) who continued treatment ($p < 0.0001$). The percentage of ATA detected by IDK was higher than by bELISA, with a tendency of more IDK ATA+ among patients with less survival (24,80% IDK positive vs 10,33% bELISA +; $p = 0.06$).

Conclusions: ATA are detected by a drug-tolerant assay at earlier stages of treatment than by bELISA. The antibodies formed early are associated with lower levels of circulating Ada, indicating higher drug clearance. This information might be useful to implement the Therapeutic Drug Monitoring. However, the detection of early complexed ATA has not demonstrated a significant advantage over the bELISA to predict treatment survival.

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THU0662 COMPARING ELECTRONIC COLLECTION OF PATIENT REPORTED OUTCOMES AT HOME VERSUS TOUCH-SCREENS IN THE WAITING AREA AMONG PATIENTS WITH ARTHRITIS IN CLINICAL PRACTICE: A RANDOMISED AGREEMENT STUDY WITH ONLINE RECRUITMENT USING DANBIO

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Background: Collection of patient-reported outcomes (PROs) is an important aspect of modern treatment strategies. Electronic capture in waiting areas by touch screens is part of routine care in the Danish DANBIO registry¹. It is not known whether this data collection can be replaced with electronic data entry from home.

Objectives: To test the feasibility of online patient recruitment via touch screens and to investigate if electronic reporting of PROs from home (ELECTOR IT-platform) is comparable to reporting completed at the hospital among patients with rheumatoid arthritis (RA) or axial spondyloarthritis (AS).

Methods: Patients with RA or AS were recruited via touch screens and randomized to one of two groups by a pre-computed list generated through DANBIO; the first group completing the PROs at home and then at the hospital-site, and vice versa for the second group. All patients completed the Health Assessment Questionnaires (HAQ), the Visual Analogue Scales (VAS) for fatigue, pain and global health and the annual visit questions. Furthermore, AS patients completed the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) and the BAS Function Index (BASFI). Pearson's Chi-square test, independent samples t-test and Mann-Whitney U test were calculated. Smallest detectable differences (SDDs), 95% confidence intervals (CIs) and intra-class correlation coefficients (ICCs) were calculated. Clinicaltrials.gov identifier: NCT02818478.

Results: A total of 952 patients received invitation, 45% accepted, 127 patients were contacted by phone, and 56 (44%) gave consent to participate. 22 patients with RA and 20 patients with AS completed the trial.

All differences between scores from home vs hospital were smaller than SDD, and all were non-significant ($p < 0.05$), except for BASFI and BASDAI item 5. ICC ranged from 0.947–0.990 ($p < 0.00001$). Annual visit questions showed 96% concordance between the two methods. 50% of the patients preferred from home data entry over hospital and 10% vice versa.

Conclusions: Recruitment of patients for a randomized trial via touch screens was feasible. PROs collected from patients' own devices at home generated