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) vist/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 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 is 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.

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

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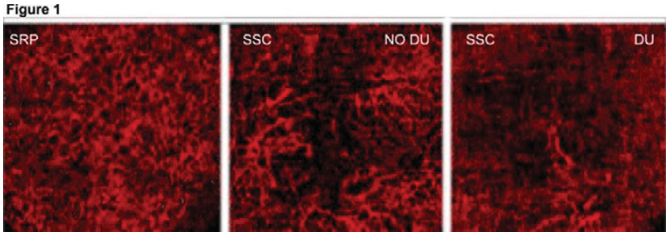
Background: Reduction in capillaries number is the defining feature of microvascular disease in Systemic Sclerosis (SSc) and it concurs to the ischemic manifestations of the disease. Digital Ulcers (DUs) are the major complication of ischemic peripheral vasculopathy.
Dynamic optical coherence tomography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