Abstract 616 Table 3 Comparing measures of Type 1 and Type 2 SLE activity among patients with different HCQ levels.

	Under-exposed HCQ (n=30)	Subtherapeutic HCQ (n=55)	Therapeutic HCQ (n=71)	p-value
Type 1 SLE Activity:				
Type 1 PGA	0.8 (0.6)	0.6 (0.6)	0.6 (0.6)	0.08
Type 1 PGA ≥1	**18 (60%)**	**15 (27%)**	**19 (27%)**	**0.004**
Active LN	5 (18%)	4 (7%)	9 (13%)	0.3
SLEDAI	**4.4 (4.3)**	**2.7 (3.6)**	**2.7 (2.8)**	**0.05**
Clinical SLEDAI	**2.5 (2.8)**	**0.9 (1.9)**	**1.2 (2.2)**	**0.006**
Type 2 SLE Activity:				
Type 2 PGA	**1.0 (0.7)**	**0.6 (0.6)**	**0.7 (0.6)**	**0.03**
Type 2 PGA ≥1	**18 (60%)**	**17 (31%)**	**28 (39%)**	**0.03**
Polysymptomatic Distress Score[1]	**13.0 (8.0)**	**8.2 (6.7)**	**7.8 (6.1)**	**0.003**
Widespread Pain Index	**5.6 (5.2)**	**3.7 (4.2)**	**3.1 (3.5)**	**0.03**
Symptom Severity Score	**6.6 (4.2)**	**4.5 (3.2)**	**4.6 (3.2)**	**0.02**
Fatigue[2]	14 (58%)	26 (54%)	24 (44%)	0.5
Cognitive dysfunction[2]	9 (41%)	11 (24%)	9 (17%)	0.08
Unrefreshed sleep[2]	13 (54%)	19 (40%)	18 (33%)	0.2
Depression[2]	15 (65%)	22 (46%)	19 (37%)	0.09

Footnotes: continuous variables are summarized by mean (standard deviation); [1]Polysymptomatic distress score is the sum of widespread pain index and symptom severity score; [2]Fatigue, cognitive dysfunction, unrefreshing sleep, and depression are components of the symptom severity score; the percentage of patients reporting moderate-severe levels of these symptoms.

Abstract 616 Table 4 Comparing HCQ levels across SLE groups.

	Minimal (n=51)	Mixed (n=50)	Type 1 (n=18)	Type 2 (n=37)	p-value
HCQ level, ng/ml, median (IQR)	922 (486-1247)	664 (60-1322)	1080 (660-1160)	1033 (429-1416)	0.2
Under-exposed HCQ (n=39)	5 (10%)	17 (34%)	2 (11%)	6 (16%)	0.06
Subtherapeutic HCQ (n=55)	23 (45%)	15 (30%)	5 (28%)	12 (32%)	
Therapeutic HCQ (n=71)	23 (45%)	18 (36%)	11 (61%)	19 (51%)	

Footnotes: continuous variables are summarized by median (interquartile range); Minimal = low type 1 & 2 SLE activity; mixed = high type 1 & 2 SLE activity; type 1=high type 1 but low type 2 SLE activity; Type 2 = high type 2 but low type 1 SLE activity.

but we have limited information on how HCQ may help with type 2 lupus activity.

In this study, we tested HCQ blood levels in patients with lupus taking this medication and found that levels were low in more than half of the patients, suggesting that these patients were not taking the medication consistently. Patients with low HCQ levels had higher Type 1 and Type 2 lupus activities compared to patients with higher HCQ levels. Our findings suggest that in some patients, Type 2 lupus activity is related to inflammation, and having low HCQ levels is allowing the inflammatory Type 2 lupus symptoms to be active.

617 EVALUATION OF SLE OUTCOME MEASURES IN TELEMEDICINE: INTERIM ANALYSIS RESULTS

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Background Telemedicine (TM) became central to rheumatology care during the COVID-19 pandemic. Accumulating evidence suggests high acceptance, satisfaction, and feasibility of TM. There is a paucity of data on the use of TM in systemic lupus erythematosus (SLE). Due to the complexity of SLE outcome measures, clinicians and clinical trialists have raised concerns about the accuracy of TM-derived disease activity measures. This study aims to evaluate the level of agreement between physician-assessed virtual and face-to-face SLE outcome measures. Here we describe the study design and data on the first 50 participants evaluated.

Purpose To investigate whether physician assessments of SLE disease activity obtained during TM visits are comparable with those obtained during face-to-face (F2F) visits.

Methods This is an observational, longitudinal study of 200 SLE participants with varying levels of disease activity from 4 academic lupus centers serving diverse populations. The study is supported by the US Department of Defense. Each study participant is evaluated at 2 visits (baseline and a follow-up visit) as dictated by usual care. Virtual physical exam guidelines were established, and rely on physician-directed patient self-examination of major organ systems. At each visit, participants are evaluated by the same physician first via videoconference-based TM immediately followed by a F2F encounter. SLE disease activity measures (BILAG, hybrid SLEDAI, PGA, LFA-REAL™, CLASI, Swollen and Tender Joint Count [TSJC] and CGIC) are completed after the TM encounter and repeated after the F2F encounter. Tandem physician and participant feedback tools for TM and F2F encounters assess satisfaction, comfort, and which portion of the physical exam was difficult to evaluate virtually. In a pre-planned interim analysis of data from the first 50 participants, the degree of agreement between TM and F2F disease activity measures was analyzed using the paired-T-test and intra-class correlations (ICC). Bland-Altman plots of the differences between TM and F2F and scatter plots were also generated.

Results 50 participants were enrolled, 25 completed the follow-up visit. The baseline characteristics are summarized in table 1, 82% women, mean age 38.9 ± 13. The current enrollment spans a wide range of physician determined categories of disease activity (25% inactive, 56% mild/moderate, 18% severe). The study population is racially and ethnically diverse. The mean differences between TM and F2F in various disease activity measures showed that TM tended to slightly underestimate disease activity, but the differences were not statistically significant (table 2).

Estimated ICC were between 0.87 and 0.99, showing a high level of correlation between TM and F2F measures. There were 10 SLEDAI item discrepancies (5 arthritis; 3 rash; 1 alopecia; 1 pleurisy) and 11 BILAG domain discrepancies (3 constitutional; 1 mucocutaneous; 6 musculoskeletal; 1 cardio). The Bland Altman plots of TM-F2F differences and scatter plots also indicate substantial agreement, although a few outliers were observed (figure 1). Differences were largest for swollen joint counts. Physicians reported high levels of satisfaction (highly satisfied or satisfied) for 42 (84%) of the telemedicine visits. In 44 (88%) of the TM visits, physicians felt they were able to satisfactorily address the issues and concerns that prompted the visit. The physicians were unambiguous that they could adequately assess the participant's disease activity in 30 (60%) of the TM visits, were unsure for 17 (34%), and reported not being able to assess the participant's disease activity in 3(6%) of visits. Following the F2F encounter, the physicians confirmed that their virtual encounter assessments were accurate for 47 (94%) of visits.

Conclusion These interim data show a high level of agreement between the virtual and F2F disease activity measures. Discrepancies will be further probed to better understand potential areas for improvement. An additional 150 participants will be enrolled in this study to provide the rigorous quantitative and qualitative data on the comparability between virtual and F2F disease activity measures needed to promote confidence in and acceptance of TM in lupus clinical care and research.

Abstract 617 Table 1 Demographic and clinical characteristics (N=50):

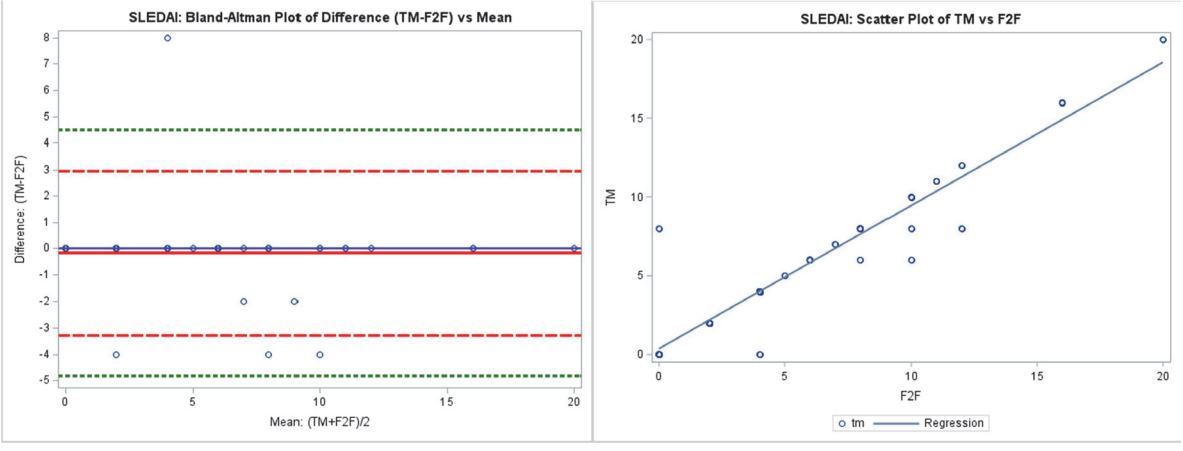
Variable	
Age (Years), Mean (SD)	38.9 (13.0)
Gender, N(%)	
Female	41 (82%)
Male	9 (18%)
Race, N (%)*	
Black or African American	21 (42%)
White	17 (34%)
Asian	9 (18%)
Other	3 (6%)
Ethnicity, N (%)*	
Hispanic/Latino	16 (32%)
Non-Hispanic/Latino	34 (68%)
Education (Years), Mean (SD)*	14.5 (2.2)
Disease Activity, N (%)†	
Asymptomatic	13 (25%)
Mild/Moderate	28 (56%)
Severe	9 (18%)
Number of ACR criteria, Mean (SD)‡	6.9 (1.8)
Fibromyalgia Symptom Scale Total Score, Mean (SD)	9.2 (6.4)
PHQ9 Total Score, Mean (SD)§	6.9 (5.8)
Length of Virtual Visit (Minutes), Mean (SD)	14.4 (7.1)
Length of F2F Visit (Minutes), Mean (SD)	15.3 (7.1)
Plan changed after F2F Visit, Mean (SD)	6 (12%)

* Race, Ethnicity, and Years of Education reported by patients† Physician determined category of disease activity‡ Based off the 1997 Revised American College of Rheumatology (ACR) criteria for Classification of SLE
§ Patient Health Questionnaire-9

Abstract 617 Table 2 Analysis of (TM-F2F) differences for overall study population:

Variable	Range	Mean (SD)	Paired T-Test P-value	ICC
Hybrid SLEDAI (N=50)*	(-4, 8)	-0.16 (1.56)	0.47	0.94
BILAG (N=50)†	(-8, 10)	-0.14 (2.64)	0.71	0.95
LFA-REAL™ (N=50)‡	(-78, 34)	-2.1 (19.5)	0.46	0.94
PGA (N=49)§	(-36, 25)	-1.14 (7.47)	0.29	0.94
CLASI (N=50)¶				
Activity	(-4, 3)	-0.08 (0.83)	0.50	0.92
Damage	(-6, 1)	-0.18 (1.12)	0.26	0.87
Total Joint (N=50)				
Tender	(-6, 5)	-0.18 (1.37)	0.36	0.99
Swollen	(-11, 8)	-0.68 (2.67)	0.08	0.96
CGIC (N=50)#	(-1, 1)	0 (0.20)	1.0	0.94

*Systemic Lupus Erythematosus Disease Activity Index
† British Isles Lupus Assessment Group 2004 Index
‡ Lupus Foundation of American Rapid Evaluation of Activity in Lupus
§ Physician Global Assessment
¶Cutaneous Lupus Erythematosus Disease Area and Severity Index #Clinicians Global Impression of Change



Abstract 617 Figure 1 Bland-Altman plots of (TM-F2F) differences and scatter plots