Full-length manuscript

Title: Measuring the impact of systemic sclerosis on oral health-related quality of life in a UK population

Running title: Oral health-related quality of life

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Structured Abstract:

Background: The objective of the present study was to identify the impact of systemic sclerosis (SSc) upon oral health-related quality of life (OHRQoL) of affected individuals resident in the UK.

Methods: A total of 100 patients and their partners or carers were invited to complete questionnaires regarding the impact of SSc on quality of life and psychological wellbeing using valid and reliable patient-reported outcome measures (OHIP-14, MHISS, OIDP, MDAS and HADS. A total of 50 patients with SSc and 18 partners or carers who acted as controls returned the completed questionnaires. Statistical analyses were performed for comparisons of different variables.

Results: All the mean scores of OHIP-14 [SSc (16.5±12.4) Vs controls (6.06±7.6, *P* .001)], MHISS components were significantly higher in patients than those of control group [SSc (21.26±12) Vs controls (4.8±7.3, *P*<.0001)]. Majority of OIDP mean scores were significantly worse in patients compared with controls [SSc (10±8.7) Vs controls (1.72±3.4, *P*<.0001)]. The mean of total MDAS [SSc (11.7±5.3) Vs controls (9.5±4.4)] and HADS scores were higher in patients compared to controls [SSc depression (4.8±3.3) and anxiety (6±4.6) Vs controls (3.7±3.1) (4.7±3.9)].

Conclusions: Although the present study are limited by the low response rate and its cross-sectional design, present results highlighted that systemic sclerosis has a negative impact on OHRQoL of the affected individuals hence the evaluation of associated psychological impact including anxiety and depression symptoms is needed to better understand, monitor and evaluate the disease comorbidity in patients with SSc.

Keywords: Systemic sclerosis, Oral health, Quality of life.

Introduction:

Systemic sclerosis (SSc) is a rare chronic autoimmune connective tissue disorder that has the propensity to affect multiple organ systems due to the associated pathological microvascular impairment, fibrosis of internal organs and impaired physical functioning [1]. Affected individuals can have a high level of physical and psychological symptoms (e.g. pain, fatigue, depression, anxiety and fear) [2]. Patients with SSc have a standardised mortality ratio of 3.5 and higher rates of psychological morbidity compared to the general population [3-5]. As a consequence with the aforementioned adverse side effects of the disease, its chronicity and the lack of a definitive cure, patients with SSc frequently have a reduced health-related quality of life (HRQoL) in comparison to general population controls [6].

Approximately 90% of individuals with SSc have orofacial features such as fibrosis of the facial skin, microstomia, salivary gland dysfunction, dysphagia as well as a potential risk of caries, periodontal disease and perhaps head and neck malignancy [6-8]. Hence patients with SSc can have a spectrum of oral and maxillofacial features that may interfere with both function and aesthetic appearance and can lessen their oral health-related quality of life (OHRQoL) [7,9]. Despite its numerous and significant oral and peri-oral manifestations, there are however little data regarding the adverse oral health impact on the daily lives of large group of patients with SSc.

According to the World Health Organisation, quality of life (QoL) is defined as “the absence of disease or physical or mental weakness as well as person’s ability to lead a productive and enjoyable life” (WHO). The Canadian Dental Association defines the oral health-related quality of life (OHRQoL) as “a state of the oral and related tissues and structures that contribute to the physical, mental and social well-being and enjoyment of life’s possibilities, by allowing the individual to speak, eat and socialise without feeling pain, discomfort or embarrassment”[10]. A number of studies have explored the impact of SSc upon both HRQoL and OHRQoL using a different patient-reported outcome measures (PROMs) such as the Oral Health Impact Profile (OHIP), Hospital Anxiety and Depression Scale (HADS) and Oral Impact on Daily Performance (OIDP) and have demonstrated that SSc can have, perhaps predictably, significant level of negative impact upon a patient’s general and oral health-related quality of life [6,11-14]. No disease-specific tool exploring the oral impact of SSc has been used to date in a UK population to explore the aforementioned impacts on aesthetics and function.

The Mouth Handicap in Systemic Sclerosis (MHISS) was developed to evaluate the limitations of the oral condition in SSc individuals by measuring the degree of restriction of mouth opening, dryness of the mouth and aesthetic orofacial appearance. It is the only disease-specific PROMS focussing on OHRQoL in SSc [15] and has been employed in several studies and validated in different populations in France, Italy and Netherlands with excellent test-retest reliability and good construct and divergent validity [12,16,17]. The impact of the oral manifestations of SSc in a UK population using MHISS has not been reported in the literature, thus the aim of this study was to assess the impact of SSc upon OHRQoL and general well-being using a number of specific and non-specific employed quality of life instruments such as the SSc oral health-specific questionnaire (MHISS), oral health-related questionnaires (OHIP-14, OIDP) and the general psychological health-related questionnaires (HADS, MDAS).

Material and Methods:

Study design and participants:

This was an observational cross-sectional study to evaluate the self-perceived general and OHRQoL in patients with SSc in the UK. A total of 100 invitations were distributed during Outpatient Rheumatology Clinic of the Royal Free Hospital – London and Scleroderma family day – UK in May 2017, as this event was mainly for SSc registered patients. All patients had a diagnosis of SSc confirmed by a Rheumatology team and each patient was confirmed if s/he is a SSc patient verbally before participated in the study. Each invitation included two questionnaires; one for the patient to answer, and another one to be answered by partner or carer. The questionnaires aimed to assess the impact of SSc on quality of life and psychological wellbeing using valid and reliable patient-reported outcome measures. In each questionnaire there is a written self-reported confirmation for the patient to be included in the study as SSc patient. Controls were recruited as a partners or carer of patients with SSc with similar age as the spectrum of SSc patients. Also, all participants include patient and partner or carer, were over 18 years of age and had adequate command of the spoken and written English language to comprehend the study questionnaires. Participants were asked to return the completed questionnaires on-site or by post in a stamped addressed envelope to one of the authors (SRP). A total of 50 patients returned the questionnaire (50% response rate), but only 18 of them were able to send the answers of their partners or carers (18% response rate). All data were completed, so no exclusion was conducted to patients or control participants.

Disease duration was measured as the time between the diagnosis and the time of recruitment to the study. The disease categorisation divided into three groups: diffuse cutaneous SSc (dcSSc), limited cutaneous SSc (lcSSc) and mixed/overlap SSc. lcSSc was defined as skin involvement distal to the elbows and knees, with or without face involvement. dcSSc was defined as skin involvement proximal to the elbows and knees, with or without truncal involvement. Mixed and/or overlap SSc was proposed to describe existing SSc and other autoimmune connective tissue diseases with the presence of related clinical features and/or serological autoantibodies [18,19]. Orofacial features related to SSc were reported in relation to patients' perceptions and not as a consequence of any formal clinical examination.

Outcome measures:

All participants were given detailed written information concerning the study and requested to answer all the included questionnaires. Information collected included sociodemographic data including age, sex, ethnicity, marital status and clinical diagnosis. Participants were given OHRQoL and psychological self-administered questionnaires including (OHIP-14, MHISS, HADS, MDAS and OIDP).

OHIP-14 is a modified short version instrument to measure OHRQoL in adults with oral diseases. OHIP was originally developed as a 49-item tool representing seven domains including functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap. This was subsequently refined to the 14 item OHIP-14 by including two questions in each of the seven OHIP aspects [20]. Each question is rated on a 5-point Likert scale to record the frequency of the oral problems. Patients are invited to answer questions by choosing from 0-4 scale while 0=never and 4=very often. The total score ranges from 0 to 56 by summing the score for all items.

MHISS was developed by Mouthon et al. in 2007 to identify and evaluate the limitations of the oral manifestations of SSc on affected individuals. It consists of 12 items (with five levels of answers), divided into three subscales as subscale one examines impact related to reduced mouth opening, subscale 2 examines impact related to dryness of the mouth and subscale 3 examines aesthetic concerns [15]. The total score ranges from 0 to 48 by summing the score for all items.

HADS is a psychological assessment tool used to identify and evaluate psychological distress. It consists of 2 main domains concerning anxiety and depression respectively. The HADS includes seven questions for each domain with a score range from 0 to 21 with 0 implying no depression, or anxiety while 21 reflects the highest level of depression or anxiety. Scores ranging between 0 – 7 are considered as normal, 8 – 10 as borderline based on a cut-off point more or equal to 8 and sores more than 10 represent abnormal values [21].

The Modified Dental Anxiety Scale (MDAS) is an assessment tool regarding anxiety related to receiving dental care. It includes questions assessing fears associated with visiting dentists as well as four other scenarios comprising anticipated anxiety in relation to sitting in a dentist’s waiting room, having a scale and polish dental procedure, having a tooth drilled or having a local anaesthetic injection. A five-point response format is employed ranging from 1 (not anxious) to 5 (extremely anxious) with the lowest possible score being five and the maximum possible score of 25. Scores of 19 and above are considered to reflect extreme dental anxiety [22].

OIDP is an assessment tool of oral quality of life that attempts to determine oral impacts that can significantly affect a person’s daily life. The OIDP is based on

Locker's adaptation of the World Health Organisation's (WHO) classification of impairments, disability and handicap concepts model and tends to measure the most significant oral impacts [23]. The OIDP scale assesses the frequency and severity of oral impacts among nine daily performances in the past 12 months using a scale from 0 – 5, where 0 is no effect and 5 is a very severe effect. The total score is calculated by adding all subscores, then divided by the maximum score (45) and multiplied by 100; the range of values is therefore from 0 – 100. Higher total OIDP scores indicate the more severe effect of oral impacts on daily life and represent the poorer quality of life.

Data collection and statistical analysis:

After completion of the data collection, all data were transferred to Excel spreadsheets, tabulated and adjusted for later interpretation where appropriate. Descriptive statistical analysis was calculated for demographics and disease features. Mean, median, standard deviation and interquartile range were calculated for continuous variables and frequency counts (number and percentage) were calculated for ordinal and nominal variables. In patients and controls, further statistical analysis was performed for comparisons of different variables. Shapiro-Wilks tests were used to test normality, so parametric test including Chi-squared tests and independent t-tests, in addition to non-parametric tests including Fisher's exact test and Mann-Whitney U tests were used as appropriate. For all statistical tests, the threshold of significance was set at a *P*-value < 0.05. All statistical analysis was performed using the SPSS statistical software package (version 25).

Ethical approval was sought for this study; however, as this was considered to be an evaluation of service, ethical approval was not deemed necessary.

Results:

Baseline characteristics of patients with SSc and controls:

The SSc group comprised 48 females (96%) with a group mean age of 62.5 years (SD = 10.8). The control group comprised only 4 females (22.2%) with a group mean age of (67 ±8.8) years. Participants with SSc had disease duration (13.2 ±10.9) years. The majority of participants in both groups were married. More than two-thirds (70%) of the SSc patients and (94.4%) of the control group were British white. Almost 88% of participants had an education level at degree level or above. Twenty-four patients had diffuse cutaneous SSc (dcSSc), 13 patients had limited cutaneous SSc (lcSSc) and six patients had mixed/overlap SSc while 7 patients did not report their disease type. When asked about their oral disease in the acquiring questionnaire, 48% (*P* = .001) of the participants reported the experience of facial skin tightness and telangiectasia, 44% (*P* = .003) reported having dysphagia and 42% (*P* = .005) reported having microstomia. Patient demographics, disease characteristics and self-reported orofacial features are summarised in Tables 1 and 2.

Oral health-related quality of life measures:

In all OHRQoL measures (OHIP-14, MHISS and OIDP), strong statistically significant trends in impairment were observed between patients and controls except for the OIDP component related to problems enjoying contact with others. The total mean OHIP-14 score was significantly lower in the patients with SSc (16.5 ±12.4) compared with controls (6.06 ±7.6, *P* .001). Indeed all the mean scores of OHIP-14 components were significantly lower in patients with SSc than the control subjects (Table 3).

The MHISS scores highlighted similar results. The total mean MHISS score was significantly higher in patients (21.26 ±12) compared with controls (4.8 ±7.3, *P* <.0001).

Also, and perhaps unsurprisingly, patients reported significantly higher scores in all MHISS components (mouth opening restriction, mouth dryness, aesthetic concerns) than controls, *P* <.0001 (Table 3).

With regard to the oral impact of SSc upon daily performances, the total mean score for patients was (10 ±8.7) compared with controls (1.72 ±3.4, *P* <.0001). The mean scores of nine components of the OIDP reflecting the presence of the last 12 months were significantly poorer in the patients compared with controls. The only exception was that enjoyment of contact with others was not reduced. However, oral impacts were very frequent for most patients than controls as 88% of SSc patients reported had difficulty performing at least one element of the OIDP compared to 44.4% in controls. Overall, the more prevalent oral impacts among SSc patients were difficulty eating (76%), difficulty relaxing and sleeping (52%), problems smiling without embarrassment and difficulty cleaning teeth (50%). Among controls, although the prevalence was very low compared to patients, the most prevalent oral impacts referred to finding problems smiling without embarrassment (6%), difficulty relaxing and sleeping (4%) and difficulty eating (3%) (Table 3).

Anxiety and depression measures:

There were no significant differences between patients and controls for both HADS and MDAS scales. However, there was a trend for patients with SSc to have higher scores for both depression and anxiety of HADS and MDAS total score. Patients with SSc had a higher mean score for HADS depression (4.8 ±3.3) and anxiety (6 ±4.6) compared to their partners or carers (3.7 ±3.1) (4.7 ±3.9) respectively. In patients with SSc, the rates of abnormal depression and anxiety were (6% and 18%) respectively, higher than in controls compared to (5.5%) for both depression and anxiety in controls. 16% of patients had borderline rates of both depression and anxiety compared to controls (5.5% and 16.6%) respectively. Similarly, the mean of total MDAS score was higher among patients compared to controls (11.7 ±5.3), (9.5 ±4.4) respectively which indicates a moderate trend of dental anxiety level. Overall, twelve per cent of patients had an MDAS score of 19 or more which suggests extreme dental anxiety and phobia compared with no extreme level of dental anxiety among the control group. Almost half of the patients with SSc (46%) reported a moderate level of dental anxiety compared to 38.9% in controls. However, 38% of patients had an MDAS score of between 5 and 9, indicating low/no dental anxiety compared with 61.1% of the control group (Table 4).

Discussion:

Systemic sclerosis is a complex autoimmune disorder that gives rise to small vessel disease and fibrosis of the mucocutaneous surfaces and viscera, particularly the lungs and gastrointestinal tract. Co-morbidity of the disease is considered high among affected individuals due to the multisystem involvement, the unpredictability of disease and variable response to therapy [1,5]. The clinical consequences of SSc can lessen the quality of life of patients through activity limitations, impairments and/or disability, thus understanding the impact of systemic sclerosis upon HRQoL may help to address the healthcare needs and aid healthcare providers to better-overcome any unmet patients needs for this rare condition. In the present study a variety of PROMs were used to explore generic and specific HRQoL, along with general and dental-specific anxiety in patients with SSc and non-affected controls (OHIP-14, MHISS, HADS, MDAS and OIDP). The results indicate that SSc radically lessen the HRQoL and that psychological problems, including depression and anxiety, may arise in patients with SSc.

When considering the oral cavity specifically, patients with SSc are commonly affected by a variety of orofacial features that can impact upon OHRQoL. These features include increased susceptibility to dental decayed and increased risk of periodontal disease, reduction in saliva production, limited mouth opening and tightening of the perioral tissues [6,8]. Thus patients with SSc can have significant mouth disability quite unique to this condition, hence the need to use a SSc specific tool to capture the impact of these oral and perioral features [24,25]. The present results demonstrated that patients with SSc report significantly higher scores in all MHISS components (mouth opening restriction, mouth dryness, aesthetic concerns) when compared with controls. Facial disability and reduced mouth opening were common amoungst our cohort in contrast to other studies where dry mouth is more prominent. [6,12,16]. The impact of reduced mouth opening or trismus on oral function of patients cannot be underestimated. Research regarding trismus has focussed on patients developing this as a consequence of cancer therapy. In a study by Johnson et al. the authors report that trismus has a significant impact on health-related QoL and on the mental health of the patients [26]. According to the present findings anxiety and depression, as measured by HADS, are higher in individuals with SSc than in control subjects. Specific questions regarding trismus are not commonly included in OHRQoL instruments therefore the use of MHISS in this patient population is critical.

All subscales and total scores in both OHIP and OIDP were higher in the SSc group when compared with the control group. This is similar to findings in other studies reported the significant impact of OHRQoL in patients with SSc [6,13,14]. Unique to the present study is that using OIDP has allowed us to compare OHQoL in paients with

SSc with the findings of the UK Adult Dental Health Survey (ADHS). According to the most recent ADHS in the UK, one-third of participants report having difficulty with at least one item in the OIDP, in contrast to the present patient population who report significantly higher results (88% in patients with SSc). The most prevalent oral impacts among SSc patients were difficulty in eating (76%), relaxing and sleeping (52%), problems smiling without embarrassment and difficulty cleaning teeth (50%). Patients with SSc scored a significant level of impact in all scores except problems enjoying contact with others. This perhaps may be related to the benefits of perceived help and support from either relatives and friends and/or support groups [27].

With the confirmation of the high impact of SSc on OHRQoL and the worsening of dental diseases such as caries and periodontal disease in this patient group the need for dental treatment is undoubtedly greater than in the average population. Dental anxiety is considered to be one of the most important psychological barriers to patients accessing dental care [28]. The present results highlight that up to 12% of SSc patients have extreme dental anxiety while 46% reported a moderate level of dental anxiety. Results from the latest dental health survey [29] indicated a relationship between dental anxiety and dental attendance. Participants with extreme dental anxiety have been found to be less likely to attend unless having problems with their teeth 22% than attending for a routine dental check-up 8%. Therefore dental anxiety may act as a psychological barrier to seeking dental care and might lead to negatively impact on OHRQoL.

Limitations of the current study include that no sample size calculation was carried out, the use of a convenience sample of healthy controls (partners or carer of patients with SSc) rather than age and sex matched controls and the self-reported of oral manifestations of SSc for example patients reported hyposalivation without clinical confirmation of reduced salivary flow. Also, one of the main limitations of the study is between patients and controls in term of the demographic variables, especially in term of gender. As we tried to pair the patients with controls from the same environment as partners or carers, we could not keep the balance to have matched controls in the study especially age-matched participants. Using multivariate analysis was more appropriate to adjust the covariate than using bivariate analysis. However, this was hampered by the small sample size, especially of the control group (18% response rate) and 50% response rate was recorded for patients, which reflect a relatively high attrition in both groups. The low response rate in health care surveys has been reported in the literature and different explored methods have been employed to improve such obstacles including reminders and using online surveys rather than paper or postal surveys. However, similar findings have been previously reported in other cohort of patients with SSc that giving a response rate of 45.3% [30]. Such low response rate might be related to the lengthy and complexity of the survey provided that can result in responded fatigue hence providing more convenience and flexibility by using digital surveys may result eliminating barriers that prevent respondents from accessing the surveys and help increasing the response rate.

Also, having a great variability between patients and controls in term of gender was a major reason not to use multivariate regression analysis. It is crucial in future studies to have matched controls for the more appropriate outcome.

However, the strengths of this study are the assessment of oral health-related quality of life along with the evaluation of associated psychological impact including anxiety and depression symptoms and dental anxiery in a cohort of patients who may develop significant disease-specific orofacial manifestations.

Conclusion:

Systemic sclerosis has a negative impact on both general and OHRQoL of the affected individuals that might be not routinely captured by healthcare assessment of disease severity. Although, not all used HRQoL measures have been validated specifically in SSc, the present data suggest that patients with SSc have significantly impaired global and oral health-related quality of life. Indeed, there is a high level of anxiety and depression compared to controls. This study is not without limitations as it has a cross-sectional design associated with low response rate and without detailed clinical evaluation. However, the strengths of this study include the assessment of oral health-related quality of life at the same time along with the evaluation of associated psychological impact including anxiety and depression symptoms. Given the impact of poor OHRQoL and psychological distress on the lives of patients, health care providers should make efforts to collaborate and develop early multidisciplinary targeted interventions to improve the disease comorbidity in patients with SSc. Research is required to better understand, monitor and evaluate patients with SSc in any health care setting and clinical trials.

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No conflict of interest was reported by the authors.

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Table 1. Baseline characteristics of patients with SSc (n = 50) and controls (n = 18)

Variables		Patients with SSc	Control subjects	*P*-value
Age (year), mean (SD)		62.5 (10.8)	67 (8.8)	.093
Disease duration (years), mean (SD)		13.2 (10.9)	-	-
Female, n		48 (96%)	4 (22.2%)	<0.0001
Marital status	Single, n	10 (20%)	2 (11.1%)	.265
	Married, n	27 (54%)	15 (83.3%)	
	Divorced, n	10 (20%)	1 (5.6%)	
	Widowed, n	2 (4%)	0 (0%)	
	Unknown, n	1 (2%)	0 (0%)	
Education level	No degree-level	6 (12%)	2 (11%)	.756
	At degree-level or above	44 (88%)	16 (89%)	
Work status	Working/Not working,	42%/58%	50%/50%	.558
Work time (Full/Part-time)		28%/72%	78%/22%	.708
Smoking, n		0 (0%)	2 (11%)	.017
Alcohol, n		23 (46%)	14 (78%)	.020
Ethnicity	British White, n	35 (70%)	17 (94.4%)	.404
	Other White, n	5 (10%)	0 (0%)	
	Indian, n	4 (8%)	1 (5.6%)	
	Black Caribbean, n	2 (4%)	0 (0%)	
	Pakistani, n	1 (2%)	0 (0%)	
	Other ethnicity, n	3 (6%)	0 (0%)	
Disease subtype	Diffuse cutaneous SSc, n	24 (48%)	-	-
	Limited cutaneous SSc, n	13 (26%)	-	-
	Mixed/Overlap SSc, n	6 (12%)	-	-
	Unknown, n	7 (14%)	-	-

Table 2. Orofacial symptoms reported related to SSc reported by patients with SSc (n = 50) and control subjects (n = 18)

Orofacial features	Patients with SSc %	Control subjects %	*P*-value
Microstomia	42	5.6	.005
Bleeding / recession gums	32	50	.174
Loose / mobile teeth	30	22.2	.528
Loose / mobile denture	12	11.1	.920
Bruising / ulceration of the lining of the mouth (oral mucosa)	30	11.1	.113
Tightness of facial skin / oral mucosa	48	5.6	.001
Altered breath smell (halitosis)	12	0	.124
Difficult root canal treatment (endodontics)	16	0	.071
Difficulties with dental extractions	22	0	.030
Oral infection	18	16.7	.899
Speech impairment (dysarthria)	10	0	.163
Swallowing difficulty (dysphagia)	44	5.6	.003
Altered taste sensation (dysgeusia)	12	0	.124
Tongue atrophy / ankylosis / rigidity	16	0	.071
Salivary gland swelling / hypofunction	20	5.6	.154
Facial / oral telangiectasia (pigmentation)	48	5.6	.001
Fissured / cracked lips	28	0	.012

Table 3. Comparison of OHRQoL between patients with SSc (n = 50) and control subjects (n = 18)

Instrument	Scale	Patients with SSc subjects		Control subjects		*P*-value
		Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	
OHIP-14	Functional limitations	2.48 (1.8)	2 (1-4)	0.89 (1.5)	0 (0-2)	.001
	Physical pain	3.44 (2.3)	3 (2-5)	1.89 (1.9)	1.5 (0-3)	.015
	Psychological discomfort	3..18 (2.8)	2 (0-6)	1.56 (1.9)	1 (0-3)	.044
	Physical disability	2.32 (2.5)	2 (0-4)	0.5 (1.33)	0 (0)	.002
	Psychological disability	2.18 (2.2)	1 (0-4)	0.72 (1.2)	0 (0)	.010
	Social disability	1.34 (1.6)	1 (0-2)	0.33 (0.68)	0 (0)	.015
	Handicap	1.52 (1.8)	0.5 (0-3)	0.17 (0.38)	0 (0)	.004
	OHIP total	16.5 (12.4)	13 (6-28)	6.06 (7.6)	2.5 (0-9)	.001
MHISS	Mouth opening restriction	9.38 (7.1)	9.5 (2-16)	1.72 (3.1)	0 (0-3)	<.0001
	Mouth dryness	8.44 (4.1)	10 (7-11)	2.5 (3.8)	0.5 (0-4)	<.0001
	Aesthetic concerns	3.52 (2.9)	4 (0-6)	0.61 (1.33)	0 (0)	<.0001
	MHISS total	21.26 (12)	22.5 (11-30)	4.8 (7.3)	3 (0-7)	<.0001
OIDP	Difficulty eating	2.08 (1.5)	2 (1-3)	0.33 (0.84)	0 (0)	<.0001
	Difficulty speaking	0.29 (1.1)	0 (0-2)	0.22 (0.94)	0 (0)	.004
	Difficulty cleaning teeth or dentures	1.42 (1.6)	0.5 (0-3)	0.17 (0.5)	0 (0)	.002
	Difficulty going out	0.46 (0.9)	0 (0)	0 (0)	0 (0)	.024
	Difficulty relaxing and sleeping	1.46 (1.7)	1 (0-3)	0.28 (0.5)	0 (0)	.009
	Problems smiling without embarrassment	1.6 (1.8)	0.5 (0-3)	0.5 (0.85)	0 (0)	.054
	Difficulty carrying out major role or work	0.74 (1.1)	0 (0)	0 (0)	0 (0)	.005
	Problems with emotional instability	0.76 (1.08)	0 (0)	0.11 (0.32)	0 (0)	.013
	Problems enjoying contact with others	0.52 (0.9)	0 (0)	0.11 (0.32)	0 (0)	.088
	Total score	10 (8.7)	8 (2-16)	1.72 (3.4)	0 (0)	<.0001

Table 4. Comparison of anxiety and depression measures between patients with SSc (n = 50) and control subjects (n = 18)

Tools	Variables	Patients with SSc		Control subjects		*P*-value
		Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	
HADS	Depression	4.8 (3.3)	5 (2-7)	3.7 (3.1)	4 (0-6)	.213
	Anxiety	6 (4.6)	5 (2-8)	4.7 (3.9)	5 (0-7)	.364
MDAS	Total	11.7 (5.3)	10.5 (7-15)	9.5 (4.4)	8 (5-13)	.110

Table legends:

Table 1. Baseline characteristics of patients with SSc (n = 50) and controls (n = 18)

Table 2. Orofacial symptoms reported related to SSc reported by patients with SSc (n = 50) and control subjects (n = 18)

Table 3. Comparison of OHRQoL between patients with SSc (n = 50) and control subjects (n = 18)

Table 4. Comparison of anxiety and depression measures between patients with SSc (n = 50) and control subjects (n = 18)