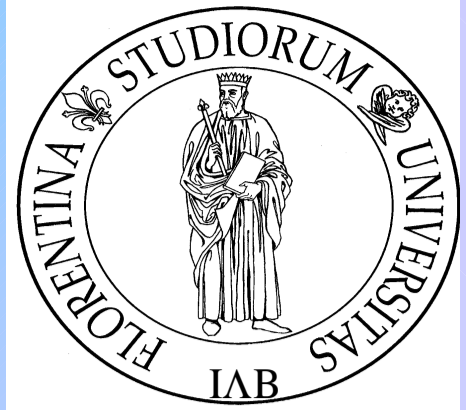


# VALIDITY AND RELIABILITY OF THE ITALIAN VERSION OF THE MOUTH HANDICAP IN SYSTEMIC SCLEROSIS SCALE (MHISS)

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**TABLE 2: Mouth Handicap in Systemic Sclerosis (MHISS) scale English**

	Never	rarely	occasionally	often	always
1. I have difficulties opening my mouth	0	1	2	3	4
2. I have to avoid certain drinks (sparkling, alcohol, acidic)	0	1	2	3	4
3. I have difficulties chewing	0	1	2	3	4
4. My dentist has difficulties taking care of my teeth	0	1	2	3	4
5. My dentition has become altered	0	1	2	3	4
6. My lips are retracted and/or my cheeks are sunken	0	1	2	3	4
7. My mouth is dry	0	1	2	3	4
8. I must drink often	0	1	2	3	4
9. My meals consist of what I can eat and not what I would like to eat	0	1	2	3	4
10. I have difficulties speaking clearly	0	1	2	3	4
11. The appearance of my face is modified	0	1	2	3	4
12. I have trouble with the way my face looks	0	1	2	3	4

**TABLE 2: Mouth Handicap in Systemic Sclerosis (MHISS) scale Italian**

	Mai	raramente	occasionalmente	spesso	sempre
1. Ho difficoltà ad aprire la bocca	0	1	2	3	4
2. Devo evitare alcuni tipi di bevande (frizzanti, alcoliche, acide)	0	1	2	3	4
3. Ho difficoltà a masticare	0	1	2	3	4
4. Il mio dentista ha difficoltà a prendersi cura dei miei denti	0	1	2	3	4
5. La mia dentatura si è alterata	0	1	2	3	4
6. Le mie labbra sono retratte e/o le mie guance sono infossate	0	1	2	3	4
7. La mia bocca è secca	0	1	2	3	4
8. Devo bere spesso	0	1	2	3	4
9. Devo mangiare le cose che posso e non le cose che vorrei	0	1	2	3	4
10. Ho difficoltà a parlare con chiarezza	0	1	2	3	4
11. L'aspetto della mia faccia si è modificato	0	1	2	3	4
12. L'aspetto della mia faccia mi crea problemi	0	1	2	3	4

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## BACKGROUND

- In Systemic Sclerosis (SSc), the involvement of skin, tendon, joint, vessels and internal organs leads to handicap and disability. Thus, outcome measures reliably assessing handicap are mandatory to follow-up disease evolution and treatment efficacy.
- In SSc, global disability is assessed by Health Assessment Questionnaire (HAQ) (1), and scleroderma HAQ (sHAQ), more specific for SSc, as it adds to HAQ 5 visual analogue scales, evaluating Raynaud's phenomenon, digital ulcers, gastro-intestinal and lung symptoms and overall disease severity (2).
- More recently, hand disability was studied by specific instruments, such as Durouoz index (3) and Hand Mobility in Scleroderma (HAMIS) scale (4), able in assessing district-specific handicap and in following-up treatment (5).
- In SSc, the frequent mouth and face involvement leads to problems in mouth function and hygiene, such as reduced mouth opening, altered dentition, difficulties in dental care, sicca syndrome, and aesthetic modifications, due to skin sclerosis and telangiectasias.
- Mouth Handicap in Systemic Sclerosis scale (MHISS) is a specific tool quantifying the handicap associated with mouth disability in SSc patients, exploring problems not assessed by HAQ and Short Form 36 (SF 36) (6).
- MHISS scale has not been translated and validated in Italian Language

## AIM

To validate the Italian version of MHISS, by assessing its test-retest reliability, internal and external consistency, in Italian SSc patients.

## METHODS

- 40 SSc patients (7 dSSc, 33 lSSc; 6 men, 34 women; mean age and disease duration: 57.27±11.41 and 9.4± 4.4, respectively; 22 affected with sicca syndrome) were evaluated by MHISS scale, mouth opening (cm), SF-36 summary physical (SPI) and mental index (SMI), HAQ.
- MHISS, assessing the handicap associated with mouth disability in SSc (6), is organized in 12 items (each scored 0-4, with a total score ranging from 0 to 48) and divided in 3 subscales:
  - Subscale 1 (range 0-20) examines handicap related to reduced mouth opening (5 items: 1, 3, 4, 5 and 6);
  - Subscale 2 (range 0-20) assesses handicap related to sicca syndrome (5 items: 2, 7, 8, 9 and 10);
  - Subscale 3 (range 0-8) examines aesthetic concerns (2 items: 11 and 12).
- MHISS was translated following a forward-backward translation procedure, with independent translations to Italian and counter-translation to English, according to international methodology (7). Test-retest reliability was evaluated, comparing the results of the first and second administration, by intra-class correlation coefficient (ICC), internal consistency by Cronbach's  $\alpha$  and external consistency was assessed by comparison with mouth opening.

	SSc	lSSc	dSSc	P (dSSc vs lSSc)
MHISS subscale 1	6.60 ± 2.85	6.45 ± 2.98	7.28 ± 2.21	NS
MHISS subscale 2	7.82 ± 2.59	7.45 ± 2.65	9.57 ± 1.27	0.0187
MHISS subscale 3	3.22 ± 1.14	3.15 ± 1.17	3.57 ± 0.97	NS
total MHISS	17.65±5.20	17.06 ±5.42	20.43±2.88	0.0224

## CONCLUSIONS

MHISS specifically measures mouth handicap in SSc patients and evaluates aspects not assessed by HAQ and SF 36. Our results support its validity and reliability in Italian SSc patients. The lower values of MHISS total score and subscales in our group in respect to the original one (6) may be explained by the high presence of lSSc patients in our series.

## RESULTS

- Total MHISS score in our patients was 17.65 ± 5.20, with scores of subscale 1 (handicap related to reduced mouth opening) of 6.60 ± 2.85 and scores of subscale 2 (handicap related to sicca syndrome) and 3 (aesthetic concerns) of 7.82 ± 2.59 and 3.22± 1.14, respectively.
- Total score and score of subscale 2 were higher in dSSc than in lSSc patients (table I).
- The latter result may be explained by the higher prevalence of sicca syndrome in dSSc in respect to lSSc (7/7-100% versus 15/33 -45.5%); 0.0109 by Fisher exact test) (table 1).

MHISS has good test-retest reliability (ICC: 0.91) and internal consistency (Cronbach's  $\alpha$ : 0.99).

A good external consistency is confirmed by the significant correlation of MHISS with mouth opening ( $\rho$ : -0,3869, p: 0.0137). MHISS is not significantly related with HAQ, SF-36 SMI and SPI and skin score.

• Tables 2 and 3 show English and Italian MHISS version validated by us.

**TABLE 1: Mouth Handicap in Systemic Sclerosis (MHISS) scores in SSc Italian patients**