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Validity and internal consistency of the thoracic outlet syndrome index for patients with thoracic outlet syndrome

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Background: No validated scales exist specifically for measuring quality of life (QoL) and functioning level in patients with thoracic outlet syndrome (TOS). This cross-sectional survey examined whether some items adopted from validated QoL scales could be suitable for patients with TOS.
Methods: To find an optimal thoracic outlet syndrome index (TOSI), a panel of 14 specialists experienced in treating TOS independently evaluated the relevance of 19 items adopted from scales used in other upper-extremity syndromes. After undergoing surgery for TOS, 52 patients rated the relevance of those items found by experts to be relevant. Content validity was measured by a content validity index, content validity ratio, and modified κ. The internal consistency of 15 retained items was assessed with the Cronbach α, and its construct validity was assessed by an exploratory factor analysis.
Results: Of the 19 items, 15 were considered relevant for TOS by the panelists, with an overall test content validity index of 0.93. The internal consistency of these 15 items was excellent. The exploratory factor analysis accompanied by a parallel analysis confirmed the uni-dimensionality of the TOSI. All 15 items that the panelists considered relevant were also items that the patients marked with scores over 7 points on an 11-point scale of relevance.
Conclusion: The internally consistent, face- and content-valid TOSI scale is proposed for use in evaluating specifically the QoL in TOS patients, as well as improving future longitudinal studies comparing functioning before and after interventions or spontaneous recovery in TOS patients.
Level of evidence: Level IV; Case Series; Treatment Study

Keywords: Consistency; factor analysis; quality of life; thoracic outlet syndrome; TOS; validity

The ethical committee of the university hospital district approved the study (no. 1755/2017). Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were concluded in conformity with ethical principles of research, and that informed consent for participation in the study came from each participant.

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Thoracic outlet syndrome (TOS) is a rather common condition resulting from various pathologies located around the thoracic outlet.[5,9,12,18,20,21,23,24] Patients with TOS have problems at work, in daily living, and in sports activities, and they often complain of a major negative impact on their quality of life (QoL). Research on QoL provides a framework by which to judge functioning, outcome, and health from the patient's point of view because the patient's observations on alterations in health status are important measures of treatment success.[1] Measuring QoL may be particularly useful in syndromes such as TOS with limited treatment options despite daily limitations.

Even if no specific QoL tools exist for TOS, various instruments allow measurement of QoL via other upper-extremity symptoms, especially in patients with shoulder pain.[4,5] The Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire,[13] Western Ontario Rotator Cuff (WORC) index,[10,16] and Cervical Brachial Symptom Questionnaire (CBSQ)[14] are dimension-specific tools to measure the symptoms and functioning of patients with upper-extremity disorders. What is unknown, however, is whether these more generic or shoulder-specific tools are suitable for TOS, even if some items from these questionnaires would also apply to the symptoms of TOS patients. The aim of our study was to create a valid questionnaire with a minimal number of relevant items when assessing functioning and QoL in TOS patients.

Materials and methods

This was a cross-sectional survey-based study in patients with TOS. We performed item generation in 3 steps according to Kirkley and Griffin[17]: (1) a review of the literature was performed to identify items that may be appropriate from published descriptions of the condition, global health instruments, disease-specific questionnaires in related areas, and existing instruments specific to the condition; (2) "experts," that is, health care providers with expertise in the care of patients with the condition of interest, were interviewed to provide their opinions on important items to be included; and (3) patients with the condition of interest were interviewed. We simplified the last step by giving the patients an appropriate number of questions (19) relevant in other specific conditions concerning the upper extremity and found relevant by our experts.

We explored 3 validated upper-extremity scales—the WORC index (Supplementary Appendix S1), 11-item short version of the DASH questionnaire (QuickDASH) (Supplementary Appendix S2), and CBSQ, without a symptom diagram (Supplementary Appendix S3)—and found a total of 19 items possibly relevant to assess the QoL in TOS patients. We also checked the Upper Extremity Functional Index, Shoulder Disability Questionnaire, and Shoulder Pain and Disability Index, but these provided no more suitable questions for our questionnaire.

The first author (M.V.) suggested 14 items for a new thoracic outlet syndrome index (TOSI) scale, and these were approved by the other authors with the addition of 3 extra items from the 3 aforementioned scales and 2 of our own items from outside these scales. Of the final 19 items, 9 were extracted from the WORC index (items 1, 3, 7, 9-13, and 15), 7 were extracted from the QuickDASH questionnaire (items 1, 2, 7, 8, 11, 14, and 19), and 5 were extracted from the CBSQ (items 6, 9, and 16-18). Some items came from 2 or 3 of these scales (Table I).

Our expert panel of 11 specialists in hand surgery, vascular surgery, and physical and rehabilitation medicine, as well as 3 physiotherapists (Table II), independently evaluated all 19 items in December 2017. The criteria for being an expert were the number of TOS patients treated (median, 115) and length of this activity (median, 30 years). All 14 experts independently evaluated the relevance of all 19 items and indicated their estimations of the validity of each item in TOS patients on a 4-point scale: 1 point, not relevant; 2 points, somewhat relevant; 3 points, quite relevant; and 4 points, highly relevant.

On the basis of the evaluations of our expert panel, the survey of TOS patients occurred in March 2018, with 52 patients providing informed consent for participation in the study. These 52 patients were chosen because we had just performed a thorough follow-up examination on them.

The patients, after adequate conservative treatment, had undergone surgery for disputed neurogenic TOS (ie, not true-neurogenic, arterial, or venous TOS). They evaluated the relevance of the items chosen by the expert panel for evaluating QoL. The patient survey used an 11-point numerical rating scale to assess the perceived relevance of the items, with 0 points denoting not relevant at all and 10 points denoting highly relevant for TOS. These patients, comprising 9 men (17%) and 43 women (83%), had a mean age of 48 years (range, 25-68 years) and had undergone TOS surgery 5 to 36 years earlier. The patient study was performed at the Orton Research Institute, Orton Foundation, Helsinki, Finland.

Statistical analysis

Statistical analysis was carried out in the same way as in our earlier article concerning serratus palsy.[25] The content validity ratio (CVR) for individual scale items was calculated as $CVR = (N_e - N/2)/(N/2)$, in which N_e is the proportion of experts who rated the item as 3 or 4 points on a 4-point scale and N is the total number of experts.[8] For the 14 panelists, the cutoff point for an excellent CVR was set at 0.78 or greater.[19] The content validity index (CVI) for each scale item (I-CVI) was calculated as $I\text{-}CVI = N_e/N$.[8] To compute the modified κ (κ^m), the probability of chance agreement (P_c) was computed first as $P_c = (N/N_e) \times (N - N_e) \times 0.5^N$.[18] Then, κ^m was calculated as $\kappa^m = (I\text{-}CVI - P_c)/(1 - P_c)$. The CVI for the entire scale (S-CVI) was calculated as a proportion of the number of items deemed content valid.[8] Values of I-CVI of 0.78 or greater and S-CVI of 0.90 or greater were considered excellent. A κ^m value of less than 0.40 was considered poor; 0.40 to 0.59, fair; 0.60 to 0.74, good; and greater than 0.74, excellent.

Concerning face validity, the patients expressed their opinions on the relevance of items on the 11-point numerical rating scale described earlier, and their views were presented as means and standard deviations. The internal consistency of the bundle of preserved parts was examined with the Cronbach α. The Cronbach α was accompanied by a 1-sided 95% confidence interval. Exploratory factor analysis was used to estimate the construct structure of the bundle of preserved parts. The purpose was to

Table I Initial 19 questions for expert panel concerning quality of life of TOS patients

Question	Source
1. How much pain do you experience in your shoulder and upper extremity?	QuickDASH questionnaire
2. How much numbness/tingle do you experience in your upper extremity?	CBSQ
3. How much weakness do you experience in your upper extremity?	WORC index
4. How much pain do you experience in your axilla, thorax, neck, or cheek?	Own
5. How much increased vein pattern do you notice on your chest wall or upper extremity?	Own
6. How much swelling do you have in your upper extremity?	CBSQ
7. How much does TOS disturb you in daily activities about the house or yard?	WORC index
8. How much does TOS disturb you in your recreational activities?	QuickDASH questionnaire
9. How much difficulty do you experience in working above your head?	WORC index
10. How much do you use your uninvolved arm to compensate for your injured one?	WORC index
11. How much does TOS disturb your sleep?	WORC index
12. How much frustration do you feel because of TOS?	WORC index
13. How "down in the dumps" or depressed do you feel because of TOS?	WORC index
14. How much does TOS disturb your work in your job?	QuickDASH questionnaire
15. How worried or concerned are you about the effect of TOS on your occupation or work?	WORC index
16. How much does your hand/upper extremity become sore and get tired when using it, especially overhead?	CBSQ
17. How much does your hand/upper extremity get numb or tingle when you are awakening from sleep, or how much do those sensations increase when you wake up?	CBSQ
18. How much is your hand clumsy or weak while trying to hold onto objects or while attempting to open jars, use a key to open a lock, pull a zipper, or button clothing?	CBSQ
19. How much does TOS disturb your heavy household chores (washing windows, spring cleaning)?	QuickDASH questionnaire

QuickDASH, short version of Disabilities of the Arm, Shoulder and Hand questionnaire; *TOS*, thoracic outlet syndrome; *CBSQ*, Cervical Brachial Symptom Questionnaire; *WORC*, Western Ontario Rotator Cuff.

specify whether the scale measures only 1 latent trait, such as QoL, or whether other possible significant latent variables affect the results. Exploratory factor analysis (principal factors) was used with a minimum eigenvalue for retention set at greater than 1.0 (the Kaiser rule).[15] Orthogonal varimax rotation was applied. Retained and excluded factors were also explored visually on a scree plot (visual approximation along with parallel analysis). All the analyses were performed by means of Stata/IC software (version 14; StataCorp, College Station, TX, USA).

Table II Characteristics of expert panel (N = 14)

Characteristic of experts	n
Sex	
Female	5
Male	9
Medical education	
Hand surgeon	6
Vascular surgeon	1
Specialist in physical and rehabilitation medicine	4
Physiotherapist	3
Medical or academic degree	
MD and PhD	7
MD	4
Median clinical experience with treating TOS patients, yr	30
Median no. of TOS patients treated	115

TOS, thoracic outlet syndrome.

Results

Content validity

Analysis of the replies of the 14 expert panelists showed that, of the 19 items, 15 proved relevant (I-CVI $\geq$ 0.78). Of those 15 questions, 6 came from the WORC index: question 3 (question 3 in the WORC index), question 8 (WORC question 11), question 10 (WORC question 12), question 11 (WORC question 13), question 14 (WORC question 15), and question 15 (WORC question 21) (Fig. 1). Five questions came from the QuickDASH questionnaire: question 1 (question 9 in the QuickDASH questionnaire), question 4 (QuickDASH question 10), question 9 (QuickDASH question 6), question 12 (QuickDASH question 8), and question 13 (QuickDASH question 2). Question 14 also exists in the QuickDASH questionnaire. Three questions came from the CBSQ: question 5 (question 3 in the CBSQ), question 6 (CBSQ question 6), and question 7 (CBSQ question 10), and 1 question (question 2) was our own question. In 5 cases, the items were considered relevant because of their excellent κ^m values ($\geq$0.78), even though their CVR values were less than 0.78. The S-CVI for the entire 19-item test was 0.87. The S-CVI was 0.94 when we included only items with an CVR value of 0.78 or greater. After the items with I-CVI values of 0.78 or greater were retained, the S-CVI for the 15-item test was 0.93. Further analysis on internal consistency and construct validity was performed on these 15 retained items (Table III).

The following questions concern the discomfort/limitations you have experienced due to your thoracic outlet syndrome (TOS). In all cases, please enter the degree of severity of the symptoms you have experienced in the last week. (Please mark your answers with an "X")

Pain and physical symptoms

1. How much pain do you experience in your shoulder and upper extremity?

□ 0 □ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7 □ 8 □ 9 □ 10

No pain Extreme pain

2. How much pain do you experience in your axilla, thorax, neck, or cheek?

□ 0 □ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7 □ 8 □ 9 □ 10

No pain Extreme pain

3. How much weakness do you experience in your upper extremity?

□ 0 □ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7 □ 8 □ 9 □ 10

No weakness Extreme weakness

4. How much numbness/tingle do you experience in your upper extremity?

□ 0 □ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7 □ 8 □ 9 □ 10

No numbness/tingle Extreme numbness/tingle

5. How much does your hand/upper extremity become sore and get tired when using it, especially overhead?

□ 0 □ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7 □ 8 □ 9 □ 10

Not at all Extremely sore/tired

6. How much does your hand/upper extremity get numb or tingle when you are awakening from sleep or how much do those sensations increase when you wake up?

□ 0 □ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7 □ 8 □ 9 □ 10

Not at all Extremely numb/tingle

7. How much is your hand clumsy or weak while trying to hold onto objects or while attempting to open jars, use a key to open a lock, pull a zipper, or button clothing?

□ 0 □ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7 □ 8 □ 9 □ 10

Not at all Extremely clumsy/weak

Sports and recreation

8. How much does TOS disturb you in daily activities about the house or yard?

□ 0 □ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7 □ 8 □ 9 □ 10

Not at all Constantly

9. How much does TOS disturb you in your recreational activities?

□ 0 □ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7 □ 8 □ 9 □ 10

Not at all Constantly

Work

10. How much difficulty do you experience in working above your head?

□ 0 □ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7 □ 8 □ 9 □ 10

No difficulty Extreme difficulty

11. How much do you use your uninvolved arm to compensate for your injured one?

□ 0 □ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7 □ 8 □ 9 □ 10

Not at all Constantly

12. How much does TOS disturb your work in your job?

□ 0 □ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7 □ 8 □ 9 □ 10

Not at all Constantly

13. How much does TOS disturb your heavy household chores (washing windows, spring cleaning)?

□ 0 □ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7 □ 8 □ 9 □ 10

Not at all Constantly

Lifestyle

14. How much does TOS disturb your sleep?

□ 0 □ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7 □ 8 □ 9 □ 10

Not at all Extremely much

Emotions

15. How worried or concerned are you about the effect of TOS on your occupation or work?

□ 0 □ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7 □ 8 □ 9 □ 10

Not at all Extremely worried/concerned

Figure 1 Thoracic outlet syndrome index (TOSI).

Face validity

All 15 remaining parts judged essential by the panelists were also marked with relevancy scores over 7 points by the patients (from 0 to 10 points, in which 10 points is highly relevant) (Table IV).

Internal consistency

The Cronbach α was excellent, 0.98, with a 1-sided 95% confidence limit of 0.97 or greater.

Construct validity

On exploratory factor analysis, only 1 factor had an eigenvalue greater than 1.0 (eigenvalue of 12). Parallel analysis confirmed the uni-dimensionality (Fig. 2). After varimax rotation, the items' loadings on the 15 retaining factors ranged widely from 0.36 to 0.85 (Table V).

Discussion

According to our results, we suggest a new 15-item questionnaire, the TOSI, for measuring QoL in TOS patients (Fig. 1). The questionnaire contains those WORC index, QuickDASH questionnaire, and CBSQ items that showed good face, content, and construct validity and internal consistency when evaluated by 14 panelists and by 52 patients with TOS.

Our new tool is evaluative, developed to detect important changes in health status over time and evaluate the effectiveness of treatment.[17] It should be assessed as a preliminary

Table III Content validity of questionnaire

Item no.	No. of experts (out of 14) who rated item as 3 or 4 points*	I-CVR	I-CVI	Modified κ
1	11	0.57	0.79	0.79
2	14	1.00	1.00	1.00
3	13	0.86	0.93	0.93
4	11	0.57	0.79	0.79
5	7	0.00	0.50	0.50
6	10	0.43	0.71	0.71
7	14	1.00	1.00	1.00
8	13	0.86	0.93	0.93
9	14	1.00	1.00	1.00
10	12	0.71	0.86	0.86
11	12	0.71	0.86	0.86
12	10	0.43	0.71	0.71
13	9	0.29	0.64	0.64
14	14	1.00	1.00	1.00
15	13	0.86	0.93	0.93
16	14	1.00	1.00	1.00
17	13	0.86	0.93	0.93
18	12	0.71	0.86	0.86
19	14	1.00	1.00	1.00

I-CVR, content validity ratio for each scale item; *I-CVI*, content validity index for each scale item.

* Four-point scale (1 point, not relevant; 2 points, somewhat relevant; 3 points, quite relevant; and 4 points, highly relevant).

survey toward developing a clinically helpful TOSI scale that would assist both in the evaluation of QoL in TOS patients and in the follow-up of TOS treatment. The TOSI is suitable especially for disputed neurogenic TOS but perhaps not so well for true-neurogenic, arterial, or venous TOS. Our final instrument has domains representing each of those concepts that defines health as a state of complete physical, mental, and social well-being.[27] As Kirkley and Griffin[17] proposed, our patients were not randomly chosen; rather, they represented the full spectrum of patient demographic characteristics, disease categories, and treatment experiences.

The WORC index is a disease-specific QoL measurement tool for patients with rotator cuff disease. Of its 21 questions, 6 appeared to be reliable and disease specific also for TOS, 1 concerning physical symptoms, 1 for sports and recreation, 2 for work, 1 for lifestyle, and 1 for emotions, forming a rather weak complete trait—the level of functioning. The QuickDASH questionnaire is a shortened version of the DASH outcome measure. Instead of 30 items, the QuickDASH questionnaire uses 11 items to measure physical function and symptoms in patients with any or multiple musculoskeletal disorders of the upper limb. Of these 11 items, 6 were suitable also for TOS patients, 2 concerning physical symptoms, 1 for sports and recreation, and 2 for work, strengthening the complete trait. The CBSQ was developed and tested for reliability and validity in a sample of patients presenting with cervical brachial complaints and being evaluated for TOS. Of its 14 questions, 3 were used for our TOSI, all concerning physical symptoms.

There are no data on the new TOSI scale's reliability and sensitivity to capture the dynamics in patients' functioning. The construct validity is not confirmed by confirmatory factor analysis. The shoulder-specific 21-item WORC index includes 5 subareas that form the complete trait—the level of functioning. Reducing the number of items from 21 to 15 may not entirely retain the 5-construct structure. In addition, psychometric properties such as item-test discrimination and difficulty were not investigated in the study. However, this research article reports the first consensus of a self-made expert team on how patients with TOS should be questioned to find out how they assess different subscales of functioning.

The variability of scales in TOS studies before the development of a TOS-specific QoL measurement (TOSI), as in our

Table IV Patients' responses to 15 retained items

Item no.	Item description	Median	Minimum	Maximum	IQR
1	Pain in shoulder and upper extremity	9	0	10	6-10
2	Numbness/tingling in upper extremity	9	0	10	7.5-10
3	Weakness in upper extremity	9	0	10	7.5-10
4	Pain in axilla, thorax, neck, or cheek	8	0	10	5.25-10
5	Difficulties in daily activities about house or yard	9	1	10	8-10
6	Difficulties in recreational activities	9	1	10	7-10
7	Difficulties in working above head	10	1	10	9-10
8	Use of uninvolved arm to compensate for injured one	9	0	10	6-10
9	Difficulties in sleeping	9	0	10	6.5-10
10	Difficulties in work or at job	9	1	10	7-10
11	Concern about effect of TOS on occupation or work	9	0	10	8-10
12	Soreness/fatigue when using upper extremity, especially overhead	10	1	10	8.5-10
13	Numbness/tingling when awakening from sleep	9	0	10	7-10
14	Clumsiness/fatigue while trying to hold onto objects or while attempting to open jars, use key to open lock, pull zipper, or button clothing	9	0	10	8-10
15	Difficulties in heavy household chores (washing windows, spring cleaning)	9	0	10	8-10

IQR, interquartile range; *TOS*, thoracic outlet syndrome.

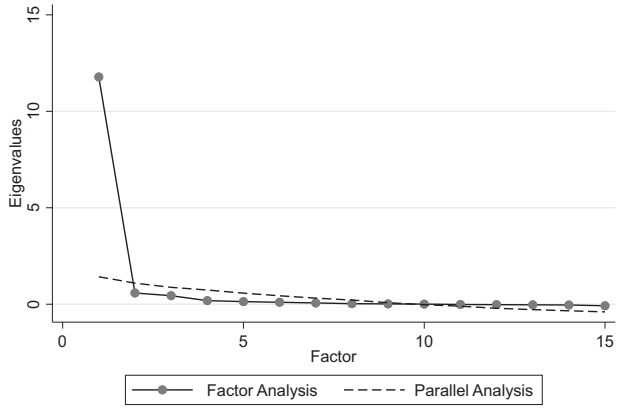

Figure 2 Scree plot of exploratory factor analysis *(solid line)* along with parallel analysis *(dashed line)*.

study, has made comparing and pooling results of different TOS studies difficult. Rochlin et al[22] used 3 surveys to assess QoL in TOS patients: Short Form 12, Brief Pain Inventory, and CBSQ. Chang et al[6] and Weiss and Chang[26] used the Short Form 12 and DASH questionnaire, as did Cordobes-Gual et al[7] and Glynn et al.[11] Bosma et al[3] used the brief 11-item QuickDASH questionnaire and EuroQoL-5D questionnaire. Jordan et al[14] used the CBSQ when determining which factors differentiate patients with a good outcome after treatment of TOS from patients with a poor outcome. Balderman et al,[2] on the other hand, used the QuickDASH questionnaire and CBSQ as patient-reported outcome measures.

Even if earlier, more generic QoL scales are also partly suitable for TOS, to enable the comparability of results, a TOS-specific tool such as the TOSI should be sensitive for all TOS patients, thus also helping in measuring long-term outcomes and comparing different treatment options.[22]

We acknowledge limitations in our study. First, many of our patients had already undergone surgery for TOS decades earlier. Thus, recall bias is possible. We believe, however, that symptoms of TOS requiring surgery would be too severe to forget. Second, it seems that some patients understood our questions incorrectly: When we asked the relevance of items for TOS patients, 4 patients selected only numbers 0 to 4 on the 11-point scale. We assume that they had recovered and that their replies were based on their present symptoms. Third, we performed item reduction before patients were interviewed.[17] We believe, however, that those questions selected from other validated scales for the upper extremity represented a spectrum large enough to evaluate the QoL of TOS patients. Because all our patients had severe treatment-resistant symptoms before their TOS operations, we cannot be sure that our patient assessments would have been exactly the same in TOS patients who had only mild symptoms. All expert panelists, however, also had vast experience in a patient population with mild nonspecific TOS, making us therefore conclude that such validity based on expert panelists could prove valid for other TOS patient populations.

Measuring QoL is important for all health conditions. We suggest further research to confirm the practical value of the now-developed TOSI, the first QoL tool for TOS patients. Future studies should further test psychometric properties of the TOSI. Regenerating self-estimated functioning instruments for specific conditions such as TOS surely can enhance future longitudinal studies comparing functioning before and after interventions or spontaneous recovery.[25] In future studies, among other factors, item response theory or Rasch analysis and the minimal clinically important difference in the TOSI should be calculated.[25]

Table V Factor loadings on retained factors after varimax rotation

Item no.	Item loading	Uniqueness
1	0.57	0.18
2	0.75	0.06
3	0.76	0.09
4	0.44	0.21
5	0.46	0.04
6	0.55	0.10
7	0.83	0.02
8	0.50	0.30
9	0.72	0.07
10	0.62	0.01
11	0.43	0.07
12	0.85	0.01
13	0.85	0.03
14	0.42	0.26
15	0.36	0.19

Conclusion

This research suggests a new validated 15-item self-reported test, the TOSI, to measure the QoL and functional level of patients with TOS. The new TOSI scale is internally consistent as well as face and content valid for TOS patients. It may improve future longitudinal studies comparing functioning before and after interventions or spontaneous recovery in TOS patients.

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Supplementary data

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