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Original Article

# Validity and Test–Retest Reliability of the translated Stapesplasty Outcome Test 25 for Measurement of Disease-Specific Quality of Life in Patients with Otosclerosis

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**OBJECTIVES:** To assess the validity and test–retest reliability of the Danish Stapesplasty Outcome Test 25 (SPOT-25) version.

**MATERIALS and METHODS:** The German SPOT-25 questionnaire—consisting of 25 questions within the subscores "hearing function," "tinnitus," "mental condition," "social restrictions," and "general quality of life," found to be significant in terms of health-related quality of life in patients with otosclerosis—was translated into Danish in a three-step process according to the guidelines provided by the International Collegium of Rehabilitative Audiology. In total, 35 patients with otosclerosis were included as cases and 35 individuals without ear-problems as controls. The SPOT-25 questionnaire was filled out once by the patients and twice by the controls. Pure tone average (0.5, 1, 2, and 3 kHz) (PTA4) was obtained for cases.

**RESULTS:** The SPOT-25 clearly discriminated the individuals with otosclerosis from con-trols within all subscores ($p<0.001$). The internal consistency within the subscores was good to excellent with Cronbach alpha values of 0.85–0.95. The reproducibility (estimated by the control group) was moderate to high, with an intraclass correlation of 0.58-0.94 within the subscores. Although the SPOT-25 subscores within "hearing" and "social restrictions" showed a moderate correlation with PTA4 (Pearson correlation coefficient 0.51 and 0.42, respectively), this was not the case for the subscores regarding "tinnitus," "mental condition," and the "general."

**CONCLUSION:** The SPOT-25 questionnaire can be used as a valuable complement to audiometric data in patients with otosclerosis, especially for estimating factors such as tinnitus and "mental condition," which do not correlate with the audiometric data.

**KEYWORDS:** Otosclerosis, stapes surgery, health-related quality of life

## INTRODUCTION

Otosclerosis is a common cause of acquired hearing disability, leading to communication deficits and social and psychological restrictions [1].

In the assessment of healthcare, patient-based measuring instruments regarding the quality of life (QOL) and perceived handicap have become increasingly important for securing a high quality of treatment [2]. Hearing impairment has been associated with adverse psychosocial effects, including decreased QOL and well-being, poorer mood, depression, social isolation, poorer physical functioning, and self-sufficiency [3]. Health-related Quality Of Life (HRQOL) has become an important quality criterion over the past decades [3]. Stapes surgery is a well-established treatment method for conductive hearing loss caused by otosclerosis. Within the field of otology, surgical results are normally achieved by the improvement in air-bone-gap. These numbers do not always correlate well with the patient-reported QOL before and after the stapes surgery [4]. The questionnaire Stapesplasty Outcome Test 25 (SPOT-25) was recently developed by Lailach et al. [4,5] in German, consisting of 25 questions regarding disease-specific HRQOL. This study aimed at obtaining measures of the validity and test–retest reliability of this Danish translation of the original SPOT-25.

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## MATERIALS AND METHODS

The study was approved by the Danish Data Protection Agency Region Zealand (J.no REG-150-2017).

### SPOT-25 Questionnaire

The SPOT-25 represents the first validated disease-specific instrument to measure HRQOL in patients with otosclerosis.[5] It was developed in the German language and includes 25 items. The questionnaire can be divided into 4 subscores: hearing function (items 1–10), tinnitus (items 11–13), mental condition (items 14–19), and social restrictions (items 20–24). In addition, 1 item focuses on the general evaluation of the impact of otosclerosis on HRQOL (item 25). Each question needs to be rated on a six-point ordinal scale from 0 (i.e., no impact) to 5 (i.e., most severe impact), depending on the level of inconvenience or frequency of symptoms.

### Translation

The questionnaire was translated in a three-step process according to the guidelines provided by the International Collegium of Rehabilitative Audiology (3). First, the original SPOT-25, developed by Lailach et al.[4,5], was translated into Danish by 3 native German speakers (1 ear-nose-throat [ENT] specialist, 1 ENT nurse, and 1 secondary school German teacher) independently, who had lived in Denmark for more than 20 years and were fluent in Danish. There was no significant difference between the 3 translated versions. The 3 questionnaires were combined into 1 final Danish SPOT-25 questionnaire by the last author.

Second, the Danish version was translated back to German by the first author, who is a native German speaker, has lived in Denmark for more than 10 years, and is fluent in Danish. Translation was performed without the knowledge of the original German questionnaire. Both the original and retranslated German versions of the SPOT-25 were then compared by the same author. There were no substantial differences between these 2 German versions; therefore, it was decided to adopt the final Danish version for further scientific and clinical use (Appendix 1).

### Audiometric Assessment

The air-conduction thresholds were calculated as average over the frequencies 0.5, 1, 2, and 3 kHz according to the 1995 guidelines of the Committee on Hearing and Equilibrium [6].

### Study Population

The cases consisted of 35 patients who completed the questionnaire before stapedotomy from September 2017 to November 2019. The patients were operated by 3 experienced ear surgeons.

Otosclerosis was suspected in patients with a bone conduction hearing loss combined with missing stapes reflexes; an intact, non-irritated eardrum; and no history of ear chronic ear disease. Only the patients with intraoperative findings of fixation of the stapes footplate were included. Before participating, all the patients were informed about the means and perspectives of the study and had to give their written consent.

The control group consisted of 35 individuals with no history of hearing problems or prior ear surgery and who had no history of working within ENT. All the participants in the control group were informed about the means and perspectives of the study and had to give their written consent.

### Statistical Analysis

The normal distribution of summarized data was investigated with quantile-quantile plots.

A nonparametric Mann–Whitney U test was chosen for comparing the results of the patients and the controls because the summarized data from the questionnaires did not follow normal distribution.

The consistency within the subscores as well as within the total score was examined by Cronbach's alpha statistics.

The correlation between SPOT-25 subscores and the measured pure tone average (0.5, 1, 2, and 3 kHz) (PTA4) levels were examined by Pearson correlation analysis.

Test–retest reliability was estimated by intraclass correlation. All data management and statistical analyses were performed using Stata version 15 (StataCorp, College Station, TX, USA).

## MAIN POINTS

- The German SPOT-25 has been translated int Danish and validated.
- The SPOT-25 represents an important supplement to audiometric data as it ac-counts for the disease specific health related quality of life (HRQOL) in patients with otosclerosis.
- Using the SPOT-25 to compare pre- and postoperative data on HRQOL will bring another dimension to the evaluation of stapes surgery.

## RESULTS

The mean age at the surgery of the 35 patients was 49 years (standard deviation [SD], 8.9), ranging from 31 to 72 years. Of these, 11 (31%) were male and 24 (69%) were female. The mean time from answering the first questionnaire to surgery was 2.7 days (SD, 10.3), ranging from 0 to 55 days. All the 35 patients underwent HRQOL measurement using the Danish SPOT-25 and pure tone audiometry.

For the controls, the mean age at answering the first questionnaire was 27 years (SD, 6.3), ranging from 23 to 56 years. Of these 16 (46%) were males and 19 (54%) were females. The mean time from answering the first to answering the second questionnaire was 11.5 days (SD, 11.1), ranging from 4 to 51 days.

### Validity

### Mann–Whitney U Test

A comparison of the subscores of the control group with those of the patient group using the Mann–Whitney U test showed a clear discrimination with significantly higher scores in individuals with otosclerosis than in controls (Table 1).

**Table 1.** Mann-Whitney U-test showing highly significant values in cases compared with controls

| | Case preoperative | | | Control 1 | | | Mann-Whitney U-test* |
|---|---|---|---|---|---|---|---|
| **SPOT-25 subscores** | **Q1** | **Median** | **Q3** | **Q1** | **Median** | **Q3** | **p-value** |
| Hearing function (Items 1–10, max 50) | 27 | 32 | 40 | 2 | 2 | 4 | <0.001 |
| Tinnitus (Items 11–13, max 15) | 1 | 6 | 2 | 0 | 0 | 2 | <0.001 |
| Mental condition (Items 14–19, max 30) | 10 | 13 | 17 | 0 | 0 | 1 | <0.001 |
| Social restrictions (Items 20–24, max 25) | 4 | 8 | 13 | 0 | 0 | 0 | <0.001 |
| General (Item 25, max 5) | 2 | 3 | 4 | 0 | 0 | 0 | <0.001 |
| Total (Item 1-25, max 125) | 48 | 62 | 78 | 2 | 4 | 7 | <0.001 |

* Results from Mann-Whitney U-test showing highly significant values in cases com-pared with controls.

**Table 2.** Surgically confirmed otosclerosis

| | Preoperative SPOT-25 | | Pearson correlation with PTA | |
|---|---|---|---|---|
| **SPOT-25 sub-scores** | **Median** | **Cronbach α*** | **Coefficient**** | **p** |
| Hearing function (Items 1–10) | 32 | 0.87 | 0.42 | 0.011 |
| Tinnitus (Items 11–13) | 6 | 0.95 | 0.01 | 0.946 |
| Mental condition (Items 14–19) | 13 | 0.86 | 0.25 | 0.148 |
| Social re-strictions (Items 20–24) | 8 | 0.85 | 0.37 | 0.027 |
| General (Item 25) | 3 | - | 0.04 | 0.800 |
| Total (Item 1-25) | 62 | 0.88 | 0.37 | 0.032 |

* Cronbach alpha statistics showing good to excellent internal consistency (>0.85) within subscores.
** The Pearson correlation coefficients showing a moderate correlation (>0.35) be-tween SPOT-25 scores in hearing, social restrictions and in total and the measured preoperative PTA4 levels.
PTA: Preoperative Pure Tone Average (Air conduction 0.5, 1, 2, and 3 kHz)

**Table 3.** The degree of correlation was high in hearing function, tinnitus, and total scores

| | Control 1 | Control 2 | | | Test-retest reliability* | | | |
|---|---|---|---|---|---|---|---|---|
| **SPOT-25 subscores** | **Median*** | **Q1** | **Median** | **Q3** | **Intraclass correlation** | **95% CI** | | p |
| Hearing function (Items 1–10, max 50 ) | 2 | 2 | 2 | 4 | 0.94 | 0.89 | 0.97 | <0.001 |
| Tinnitus (Items 11–13, max 15) | 0 | 0 | 0 | 0 | 0.90 | 0.80 | 0.95 | <0.001 |
| Mental condition (Items 14–19, max 30) | 0 | 0 | 0 | 1 | 0.65 | 0.30 | 0.82 | 0.001 |
| Social restrictions (Items 20–24, max 25) | 0 | 0 | 0 | 0 | 0.59 | 0.19 | 0.79 | 0.005 |
| General (Item 25, max 5) | 0 | 0 | 0 | 0 | 0.58 | 0.18 | 0.79 | 0.006 |
| Total (Item 1-25, max 125) | 4 | 2 | 4 | 6 | 0.91 | 0.83 | 0.96 | <0.001 |

* Qurtiles are presented in table I
** A high degree of intraclass correlation between first and second answers by subgroup was found in hearing, tinnitus and in total, while a moderate degree of correlation was found in mental condition, social restrictions and in general quality of life.

### Cronbach's Alpha

The Cronbach's alpha test revealed a good to excellent internal consistency within subscores of the questionnaire, i.e., "hearing function," "tinnitus," "mental condition," and "social restrictions" in individuals with surgically confirmed otosclerosis (Table 2).

### Pearson Correlation

The estimated Pearson correlation coefficients comparing the subscores with measured PTA4 showed a moderate correlation between PTA4 and scores in hearing, social restrictions, and the total score, whereas the PTA4 did not correlate with the scores in tinnitus, mental restriction, and the general QOL (Table 2).

### Test–Retest Reliability

The degree of correlation was high in hearing function, tinnitus, and total scores (Table 3), whereas the degree of correlation was moderate in mental condition, social restrictions, and general QOL.

## DISCUSSION

The original SPOT-25 questionnaire [4,5] was translated from German into Danish in a three-step-process according to the guidelines provided by the International Collegium of Rehabilitative Audiology.

We found that the SPOT-25 questionnaire effectively distinguished individuals with otosclerosis from healthy individuals with higher

scores in all the subscores and highly significant values estimated by the Mann–Whitney U test. The highest subscores within the case group were observed for the items of "hearing function" (64% of max) and "general" (60% of max), followed by "mental condition," "tinnitus" and "social restriction," whereas the controls scored highest within the items of "hearing function" followed by "tinnitus" and "mental condition." None of the scores of the control group were above 4% of max. These findings correlate well with the assumption that healthy individuals reach lower subscores within the questionnaire than the individuals with a hearing impairment.

The internal consistency within the subscores was good to excellent with Cronbach's alpha values >0.85. Comparing the SPOT-25 subscores in individuals with otosclerosis with the only objective values available, the hearing tests, resulted in Pearson correlation coefficients showing a moderate correlation between the SPOT-25 subscores in "hearing," "social restrictions," and the total score. The fact that no correlation was demonstrated between subscores in "tinnitus," "mental condition," and "general" and the PTA4 values underscores the importance of taking these HRQOL measurements into consideration in patients with otosclerosis because they are not taken into account only by looking at PTA4.

The test–retest revealed a high degree of correlation in "hearing function," "tinnitus," and total scores, whereas the degree of correlation was moderate in "mental condition," "social restrictions," and "general QOL." Looking at the test–retest results for each specific question in Appendix 2, it becomes apparent that the intraclass correlation coefficient is low for questions irrelevant to a normal hearing person. For example, do q14–q17 (mental condition), q20 (social restrictions), and q25 (general) all presuppose that the responder had a hearing loss. As the controls had normal hearing, the questions were irrelevant and probably difficult to answer, which most likely resulted in the low correlation coefficient.

Considering the increasing importance of integrating the disease-specific QOL as a success parameter within the field of medicine, the SPOT-25 aims at giving a measurement of the subjective view on physical hearing impairment with its psychological challenges, restrictions of social interaction in everyday life, and interpersonal relationships. Using 4 subscores helps to achieve a multifactorial picture of QOL [4,5,7]. The test has already been successfully used in Germany to assess HRQOL in patients with otosclerosis and is currently furthermore translated to Dutch with a similar objective [7].

## CONCLUSION

The SPOT-25 showed a good to excellent internal consistency within the subscores. It clearly discriminated individuals with otosclerosis from normal hearing people. The reproducibility was estimated to be good. Although the SPOT-25 subscores within "hearing" and "social restrictions" showed a moderate correlation with the audiometric data, this was not the case for the subscores regarding "tinnitus," "mental condition," and the general impact of otosclerosis on HRQOL. Therefore, data on HRQOL from the SPOT-25 questionnaire are a valuable complement to the audiometric data.

We are currently working on a follow-up study using the SPOT-25 questionnaire to evaluate the effect of stapes surgery on HRQOL in addition to the standard hearing assessment.

**Ethics Committee Approval:** Ethics committee approval was received for this study from Danish Data Protection Agency Region Zealand (REG-150-2017).

**Informed Consent:** Written and oral consent war obtained by all participants of the study prior to participation.

**Peer-review:** Externally peer-reviewed.

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**Conflict of Interest:** The authors have no conflict of interest to declare.

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Appendix 1

**Stapesplasty Outcome Test 25 (SPOT-25)**

| For at kunne vurdere sværhedsgraden af hvert symptom, bedes du markere det passende tal for hvert af de nedenstående spørgsmål. | Intet problem | Meget lille problem | Lille problem | Middelstort problem | Stort problem | Værre kan det ikke blive |
|---|---|---|---|---|---|---|
| 1. Høretab | 0 | 1 | 2 | 3 | 4 | 5 |
| 2. Tale lyder afdæmpet og utydeligt | 0 | 1 | 2 | 3 | 4 | 5 |
| 3. Jeg har svært ved at afgøre, hvilken retning lyden kommer fra | 0 | 1 | 2 | 3 | 4 | 5 |
| 4. Jeg har svært ved at forstå en person fra lang afstand. | 0 | 1 | 2 | 3 | 4 | 5 |
| 5. Jeg overhører telefonen eller vækkeuret | 0 | 1 | 2 | 3 | 4 | 5 |
| 6. Jeg har svært ved at forstå noget i højlydte omgivelser | 0 | 1 | 2 | 3 | 4 | 5 |
| 7. Jeg har svært ved at forstå, når flere mennesker taler samtidigt | 0 | 1 | 2 | 3 | 4 | 5 |
| 8. Jeg har svært ved at forstå, hvad der bliver sagt i telefonen | 0 | 1 | 2 | 3 | 4 | 5 |
| 9. Jeg har svært ved at lytte til musik og fjernsyn | 0 | 1 | 2 | 3 | 4 | 5 |
| 10. Jeg har svært ved at kommunikere med folk, der ikke kender mit høreproblem | 0 | 1 | 2 | 3 | 4 | 5 |
| 11.Øresusen (tinnitus - pivelyde, susen) | 0 | 1 | 2 | 3 | 4 | 5 |
| 12.På grund af min øresusen (tinnitus) har jeg problemer med at forstå andre | 0 | 1 | 2 | 3 | 4 | 5 |
| 13. Min øresusen (tinnitus) påvirker mig i hverdagen når der også er baggrundsstøj | 0 | 1 | 2 | 3 | 4 | 5 |
| 14. Mine øreproblemer gør mig umotiveret eller giver mig mindre lyst til at foretage mig noget | 0 | 1 | 2 | 3 | 4 | 5 |
| 15. Pga. høretabet er jeg bange for at misforstå andre | 0 | 1 | 2 | 3 | 4 | 5 |
| 16. Høretabet fører til situationer, der er pinlige for mig | 0 | 1 | 2 | 3 | 4 | 5 |
| 17. Jeg er bekymret for, at mine høreproblemer vil blive værre i fremtiden | 0 | 1 | 2 | 3 | 4 | 5 |
| 18. At bære høreapparater fører til, at mit høreproblem bliver synligt for andre | 0 | 1 | 2 | 3 | 4 | 5 |
| 19. Jeg frygter en operation eller re-operation | 0 | 1 | 2 | 3 | 4 | 5 |
| 20. På grund af mit høreproblem, er jeg tilbageholdende med at opsøge nye bekendtskaber/ venner. | 0 | 1 | 2 | 3 | 4 | 5 |
| 21. På grund af mit høreproblemer har jeg udfordringer i jobbet eller ved ærinder i det offentlige (kommune, indkøb e.l.) | 0 | 1 | 2 | 3 | 4 | 5 |
| 22. På grund af min dårlige hørelse føler jeg mig meget anstrengt (træt) | 0 | 1 | 2 | 3 | 4 | 5 |
| 23. Indskrænkning af min arbejdsevne | 0 | 1 | 2 | 3 | 4 | 5 |
| 24. At bruge høreapparater ville indskrænke mig (på arbejde, privat, i fritiden) | 0 | 1 | 2 | 3 | 4 | 5 |
| 25. Den samlede nedsættelse af min livskvalitet på grund af mit høreproblem. | 0 | 1 | 2 | 3 | 4 | 5 |

ID:_____ Dato:_____

**Appendix 2**

| | Case | | | Control 1 | | | Control 2 | | | Test-retest reliability* | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **SPOT-25** | **Q1** | **Med** | **Q3** | **Q1** | **Med** | **Q3** | **Q1** | **Med** | **Q3** | **Intraclass correlation** | | **95% CI** | p |
| Q1* | 3 | 4 | 4 | 1 | 2 | 2 | 1 | 2 | 2 | - | - | - | - |
| Q2 | 3 | 4 | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0.90 | 0.81 | 0.95 | <0.001 |
| Q3 | 3 | 4 | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0.88 | 0.77 | 0.94 | <0.001 |
| Q4 | 3 | 4 | 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0.78 | 0.57 | 0.89 | <0.001 |
| Q5 | 1 | 3 | 4 | 0 | 0 | 1 | 0 | 0 | 0 | 0.87 | 0.74 | 0.93 | <0.001 |
| Q6** | 3 | 4 | 4 | 0 | 0 | 0 | 0 | 0 | 0 | -0.03 | -1.03 | 0.49 | 0.534 |
| Q7 | 3 | 4 | 4 | 0 | 0 | 1 | 0 | 0 | 1 | 0.95 | 0.95 | 0.98 | <0.001 |
| Q8 | 1 | 3 | 4 | 0 | 0 | 1 | 0 | 0 | 1 | 0.82 | 0.66 | 0.91 | <0.001 |
| Q9 | 1 | 3 | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0.58 | 0.17 | 0.79 | 0.006 |
| Q10 | 1 | 2 | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0.80 | 0.60 | 0.90 | <0.001 |
| Q11 | 1 | 3 | 4 | 0 | 0 | 0 | 0 | 0 | 0 | - | - | - | - |
| Q12 | 0 | 1 | 4 | 0 | 0 | 1 | 0 | 0 | 1 | 0.90 | 0.80 | 0.95 | <0.001 |
| Q13 | 0 | 1 | 4 | 0 | 0 | 0 | 0 | 0 | 0 | - | - | - | - |
| Q14 | 0 | 1 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0.03 | -1.03 | 0.49 | 0.534 |
| Q15*** | 2 | 3 | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0,00 | -0,97 | 0,49 | 0,499 |
| Q16 | 1 | 2 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | -0.03 | 1.03 | -0.49 | 0.534 |
| Q17 | 3 | 4 | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0.00 | -0.97 | 0.49 | 0.499 |
| Q18 | 0 | 2 | 4 | 0 | 0 | 1 | 0 | 0 | 1 | 0.78 | 0.57 | 0.89 | <0.001 |
| Q19 | 0 | 1 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0.54 | 0.09 | 0.77 | 0.013 |
| Q20 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | -0.02 | -1.01 | 0.48 | 0.527 |
| Q21 | 1 | 3 | 4 | 0 | 0 | 0 | 0 | 0 | 0 | - | - | - | - |
| Q22 | 1 | 2 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | - | - | - | - |
| Q23 | 0 | 2 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | - | - | - | - |
| Q24 | 1 | 2 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0.89 | 0.78 | 0.94 | <0.001 |
| Q25 | 2 | 3 | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0.58 | 0.18 | 0.79 | 0.006 |

* When all controls answered "0" on both occasions the Intraclass correlation could not be calculate. This is indicated with a "-". However, it indicates a full correlation, i.e. =1.

** When 2 controls on the second occasion answered 1 point different compared with the first answer the correlation coefficient was (+/-) 0.03 (Q6, Q14, Q16)

*** When 1 control on the second occasion answered 1 point different compared with the first answer the correlation coefficient was 1.21e-16 (Q15, Q17)