



# Hearing and Disease-Specific Health-Related Quality of Life in Patients with Otosclerosis after Stapedotomy – a Trial of the SPOT-25 Questionnaire

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**BACKGROUND:** The study aims to investigate the effect of stapedotomy on audiology measurements and the disease-specific health-related quality of life for patients with otosclerosis using the Danish Stapesplasty Outcome Test-25 as a quality of life measuring tool.

**METHODS:** In this study, 50 patients who had undergone stapedotomy at our department between September 2017 and December 2020 were included. Data collection was performed by audiometric testing (pure tone and speech audiometry) in the pre- and postoperative settings. Health-related quality of life was assessed pre- and postoperatively in 30 patients using the validated Danish Stapesplasty Outcome Test-25.

**RESULTS:** The mean improvement in air conduction thresholds was 27.7 dB and the mean improvement in air-bone gap was 21.8 dB. Health-related quality of life improved significantly after stapes surgery in all subscores of the Stapesplasty Outcome Test-25 (hearing, mental condition, social restriction, and general), except for "tinnitus." The improvement in the audiometric data correlated significantly with the improvement in "total score" and "hearing function" but not with "tinnitus," "social restrictions," and "mental condition."

**CONCLUSION:** Stapedotomy leads to significant improvement in hearing and health-related quality of life. The Stapesplasty Outcome Test-25 can be used as a valuable supplement to the hearing test by assessing health-related quality of life.

KEYWORDS: Otosclerosis, stapesplasty, stapedotomy, health-related quality of life

#### INTRODUCTION

Otosclerosis is defined as a bony transformation, caused by alternating phases of bone resorption and formation leading to a fixation of the stapes footplate<sup>1</sup> and thereby resulting in conductive hearing loss. Approximately 0.3%-0.4% of the Caucasian population is affected by this acquired hearing disability<sup>2,3</sup> with a majority of women (59-69%).<sup>4,5</sup> Affected individuals are facing everyday challenges such as communication deficits, social and psychological impairments, poor physical function and self-sufficiency<sup>6-9</sup> as well as a possible reduction of cognitive functions.<sup>10</sup>

For a series of years, stapes microsurgery has been the primary surgical treatment of conductive hearing loss due to otosclerosis. A stapedotomy involves the removal of the suprastructure of the stapes followed by the opening part of the stapes footplate with a microdrill or laser. A prosthesis is fitted into the opening made in the footplate, connecting the incus to the oval window and restoring ossicular conduction by bypassing the fixed footplate. Traditionally, the success of a performed stapedotomy is measured by the air-bone gap (ABG) closure. In large-scale studies, the postoperative ABGs are reported to be  $\leq$ 20 dB in 98% and  $\leq$ 10 dB in 95% of the patients. However, it has been observed that the results of the audiometric assessment do not always correlate with the patients' own perspective on their handicap. He health-related quality of life (HRQOL) has been an increasingly acknowledged parameter for the evaluation and assurance of high-quality treatment in healthcare provisions in the past decades. Awareness of the importance of hearing disability and handicap led to the development of various self-report instruments, which have been

used extensively in the evaluation of hearing aids and in aural rehabilitation. Still, it is relatively new to apply the patient's perception of their handicap as a measure of surgical outcome. 1,9,17

In a previous study, we validated the translated Danish version of the Stapesplasty Outcome Test-25 (SPOT-25) as a patient-based measuring instrument to assess the disease-specific HRQOL in patients with otosclerosis before and after stapes surgery, respectively. The aim of the present study was to evaluate the results from stapedotomy at our department taking HRQOL into account using the SPOT-25 questionnaire in addition to the traditional audiometric results.

## **MATERIALS AND METHODS**

The study was approved by the Danish Data Protection Agency (J. no: REG-150-2017). Written informed consent was obtained from all participants who participated in this study.

All data management and statistical analyses were performed using Stata version 15 (StataCorp, College Station, Tex, USA).

## The SPOT-25 Questionnaire

The SPOT-25 represents the first-validated, disease-specific instrument to measure HRQOL in patients with otosclerosis. 9,14 It was developed in the German language and has since been translated into Danish. 15 It includes 25 items that constitute 1 total score and 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). The questionnaire refers to a 5-point Likert scale where high scores correlate with a poorer HRQOL. The achievable scores range from 0 (no affection by hearing impairment) to 100 (worst possible impairment of HRQOL). The participants in the present study could either fill out the preoperative SPOT-25 questionnaire on paper or online up to the day before surgery.

# **Audiometric Assessment**

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Standard audiometry with pure-tone air conduction (AC), bone conduction (BC) threshold and speech audiometry was conducted by a certified audiologist using MADSEN Astera (type 1066) from Otometrics©, Taastrup, Denmark.

The pure tone average (PTA4) AC threshold, BC threshold, and airbone gap (ABG) were calculated as averages over the frequencies 0.5, 1, 2, and 3 kHz according to the 1995 guidelines of the Committee

## **MEAN POINTS**

- As living with a hearing disability affects the individuals' healthrelated quality of life (HRQOL), the diagnostic supplement through a HRQOL measuring tool is indicated in the modern clinical assessment of this group of patients.
- The Stapesplasty Outcome Test-25 is the suggested HRQOL measuring tool that has been developed specifically for this purpose in patients with otosclerosis undergoing stapes surgery.
- This study found discrepancies between the patients' perception
  of their postoperative HRQOL and the respective audiometric data
  which underscore the usefulness of integrating HRQOL assessment
  in the evaluation of the effect of stapedotomy on patients with
  otosclerosis.

on Hearing and Equilibrium.<sup>18</sup> The speech recognition threshold was defined as the level where the patient could repeat 50% of 2-digit numbers correctly in a row.

# **Study Population**

The study population consisted of individuals with otosclerosis undergoing stapedotomy from September 2017 to December 2020. All patients were operated on by 1 of 3 experienced otosurgeons.

## **Inclusion Procedure**

A total of 52 patients, with a subsequent surgically confirmed diagnosis of otosclerosis, filled out the SPOT-25 questionnaire preoperatively. Two patients were excluded from the analysis. One was lost to follow-up and the other experienced deafness and vestibulopathy after surgery.

There was no selection of primary surgical treatment with respect to revision surgery, and both patients with unilateral as well as bilateral manifestation were included.

Normal procedure at the department consists of a preoperative assessment including a hearing test, not more than 3 months before surgery and a postoperative assessment including a hearing test approximately 3 months after surgery.

# Surgical Technique

"One-shot" CO₂ laser stapedotomy was performed in all cases.¹9 Smart™ Stapes Piston (Nitinol fluoroplastic, Gyrus ACMI, USA) was inserted in the footplate perforation and attached to the incus neck after heating with 2-3 CO₂ laser shots with a power of 1.0 W set at a pulse duration of 0.10 seconds. In patients with nickel allergy, the Richards Piston (Platinum fluoroplastic, Gyrus ACMI, USA) was inserted instead and manually attached to the incus neck.

At the end of the operation, the oval niche was sealed with Evicel® (Johnson & Johnson, USA).

# **Statistical Analysis**

Continuous data following the normal distribution are generally presented as means and standard deviations (SD), and differences were examined by 2-tailed *t*-tests. These include age at surgery, audiometric thresholds (though with some degree of violation appeared in postoperative measurements and in preoperative BC), and SPOT-25 subgroups (except for "tinnitus" and "general"). Whether a depended or an independent *t*-test was applied appears as a table footnote.

Continuous data not following the normal distribution are generally presented with medians and interquartile ranges (IqR) and differences are examined with non-parametric test of identical medians. These include time from audiometric assessment or SPOT-25 scoring to surgery and from surgery to audiometric assessment or SPOT-25 scoring. Stapesplasty Outcome Test-25 subscores "tinnitus" and "general" also showed some degree of violation of the normality assumption.

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

Categorical data were analyzed by Pearson's chi-square test.

A possible correlation between the SPOT-25 results and the audiometric results was analyzed by Pearson correlation coefficients, *r*, for data following the normal distribution and by Spearman correlation coefficients for data not following the normal distribution.

A P-value less than .05 was considered statistically significant.

#### **RESULTS**

Of the 50 included patients, 30 answered the postoperative SPOT-25 questionnaire. Baseline characteristics of the study population, as well as a comparison of those completing only the preoperative questionnaire to those completing both the pre- and postoperative questionnaires, are presented in Table 1. The patients not

answering the postoperative questionnaire did not differ from those answering it.

The mean age at surgery was 49 years. There was a female predominance with a female: male ratio of 1,3. Median time from preoperative audiometry to surgery was 20 days, while median time from preoperative questionnaire to surgery was 0 days (most preoperative questionnaires were answered a few hours before surgery) (Table 2).

# **Hearing Results**

The mean improvement in AC thresholds was 27.7 dB and the mean improvement in ABG was 21.8 dB (Table 3). A subanalysis showed no significant difference (P = .5674) in AC improvement in 7 cases of

Table 1. Baseline Characteristics and Dropout Analysis

	<b>All</b> 50		<b>+Postop. SPOT-25</b> 30 (60)		- <b>Postop. SPOT-25</b> 20 (40)		Difference
Total number (%)							
	Male	Female	Male	Female	Male	Female	
Sex (%)	18 (36)	32 (64)	13 (43)	17 (57)	5 (25)	15 (75)	0.186¹
	Mean	SD	Mean	SD	Mean	SD	
Age in years at surgery	49	10	47	10	50	11	0.311 <sup>2</sup>
Days to surgery from	Median	ICR	Median	ICR	Median	ICR	
Preop. SPOT25	0	0-0	0	0-1	0	0-0	0.139 <sup>3</sup>
Preop. audiometry	20	13-51	20	11-52	21	13-43	0.966 <sup>3</sup>
Months from surgery to	Median	Range	Median	Range	Median	Range	
Postop. SPOT25	3.1	2.6-3.5	3.1	2.6-3.5	-	-	-
Postop. audiometry	3.4	2.6-3.9	3.1	2.6-3.8	3.5	2.8-4.6	0.684 <sup>3</sup>
	No	Yes	No	Yes	No	Yes	
Revision surgery (%)	43 (86)	7 (14)	28 (93)	2 (7)	15 (75)	5 (25)	0.0671
Year of surgery	n		n		n		
2017	3		3	(100%)	0	(0%)	<0.0014
2018	12		10	(83%)	2	(17%)	
2019	22		5	(23%)	19	(77%)	
2020	13		12	(92%)	1	(8%)	
	Mean	SD	Mean	SD	Mean	SD	
PTA4 improvement	28	12	25	10	32	13	0.060

<sup>+</sup>Postop. SPOT-25, Patients filling out the postoperative questionnaire;

Table 2. Audiometric Results

	Preoperative		Postoperative		Improvement		
	dB	SD	dB	SD	dB	95% CI	Р
Air-conduction threshold	56.6	13.1	28.9	13.7	27.7	24.3-31.0	<.001*
Bone conduction threshold	26.3	10.9	20.3	10.3	5.6	3.9-8.0	<.001*
Air-bone gap	30.9	10.8	9.0	9.5	21.8	12.9	<.001*
Speech-reception threshold	49.3	12.2	21.9	12.4	27.4	23.8-31.0	<.001*

Audiometric measurements in all 50 patients by pure tone average 500, 1000, 2000, and 3000 Hz.

<sup>-</sup>Postop. SPOT-25, patients not filling out the postoperative questionnaire;

 $Difference, statistical\ difference\ between\ +postop.\ SPOT-25\ and\ -postop.\ SPOT-25\ estimated\ by\ the\ given\ analysis.$ 

ICR, interquartile range; SD, standard deviation; PTA4, pure tone average 500, 1000, 2000, and 3000 Hz.

 $<sup>^1</sup>$ Pearson chi  $^2$  test;  $^2$ Independent t-test;  $^3$ Non-parametric test of identical medians;  $^4$ Fishers exact test.

Two patients were missing in bone conduction measurements. Two patients were missing in speech-reception.

<sup>\*</sup>Dependent t-test.

SD, standard deviation.

Table 3. SPOT-25 Scores in the 30 Patients Filling Out Both the Pre- and the Postoperative Questionnaire

	Preoperative		Postoperative		Improvement		
SPOT-25 score	Points	SD	Points	SD	Points	95% CI	Р
Hearing function (items 1-10, max 50)	30.4	8.30	14.6	10.5	15.8	27.3 to 33.5	<.001*
Tinnitus (items 11-13, max 15)	5.0	5.7	3.7	3.8	1.3	-0.1 to 2.7	.0691*
Mental condition (items 14-19, max30)	12.1	5.5	7.4	5.2	4.7	2.7 to 6.7	<.001*
Social restrictions (items 20-24, max 25)	9.3	6.0	5.0	5.0	4.3	2.5 to 6.1	<.001*
General (item 25, max 5)	2.8	1.2	1.4	1.3	1.4	0.8 to 1.9	<.001*
Total (item 1-25, max 125)	60.3	21.6	32.7	23.9	28.6	19.3 to 41.0	<.001*

<sup>\*</sup>Dependent t-test.

revision surgery with a 25.3 dB improvement (95% CI: 5.8-44.8 dB) compared to a 28.0 dB improvement in the 43 cases of primary surgery (95% CI: 25.1-31.0 dB).

#### **HRQOL** Results

The postoperative analysis of the SPOT-25 results showed significant improvement in all subscores but "tinnitus" with an improvement of 1.3 (95% CI: –0.1; 2.7) (Table 3).

An analysis of correlation between the postoperative scores of SPOT-25 and postoperative AC threshold showed a considerable association between the audiometric data and the SPOT-25 subscores "hearing function" and the total score (Figure 1). There was no significant association within the subscores "social restriction," "mental condition," and "tinnitus."

# **Correlation Between Hearing and HRQOL Results**

The Pearson correlation coefficient, *r*, showed a strong correlation between the postoperative PTA4 and the postoperative total SPOT-25 score. The correlation between the postoperative PTA4 and the hearing function was moderate to strong, while the correlation with tinnitus, mental condition, and social restriction was moderate (Figure 1). All correlations were significant.

Looking at improvement in PTA4 compared with improvement in SPOT-25 scores, the Pearson correlation coefficient was moderate and significant for the total score as well as for the hearing function, while no significant correlation was found between improvement in PTA4 compared to the improvement in tinnitus, mental condition, or in social restriction.

## DISCUSSION

Traditionally, the outcome of stapes surgery is measured by the difference in the extent of pre- and postoperative hearing loss and the degree of closure of the ABG which provides reliable objective means of surgical outcomes.8 However, a number of studies from the recent decades are pointing out that the patients' subjective view of their hearing disability is dependent on multiple behavioral and psychosocial aspects and can hence vary significantly from the measured hearing impairment.8.9 Previous studies8.20 describe how patients reacted differently to the impact of even a mild hearing loss. The assumed explanation was that regardless of the substantial improvement after surgery, some patients might still consider even a minimal hearing impairment to be a handicap.

As the use of HRQOL is becoming an increasingly important success parameter in the quality assessment of medical treatments, the SPOT-25 questionnaire aims to measure the subjective view on physical hearing impairment with its psychological and social challenges in everyday life. It uses 4 subscores which helps to create a multifactorial picture of HRQOL.<sup>9,14,17</sup> It was originally designed as a follow-up tool but was recently tentatively used for a retrospective postoperative evaluation inventory.<sup>1</sup> The authors of that study concluded that the SPOT-25 also had proven to be useful in the postoperative setting alone, especially when combined with the Glasgow Benefit Inventory.

The audiometric results of our study met the expectations for improvement after stapes surgery and are in good agreement with previous studies on the topic. We found an average improvement of 27.7 dB in AC thresholds after stapedotomy and a 21.8 dB improvement in ABG, which is in agreement with previous literature. ABG improvement to be 23.9 dB and the AC threshold improvement to be 24.2 dB, respectively. ABG improvement to be 24.2 dB, respectively.

It has been described in the previous literature that the outcome of revision stapes surgery was less successful than primary surgery. We did not find significant difference between the patients who had undergone revision surgery respective to primary surgery, so they were not excluded from the analysis.

The SPOT-25 subscores "Hearing function," "Mental condition," "Social restrictions," "General" (the general perception of HRQOL with a hearing disability) and the total score improved significantly, while the subscore "Tinnitus" improved but not significantly. These findings are in accordance with those of the developers of the SPOT-25 questionnaire.9

Looking at the correlation between the postoperative SPOT-25 scores and the respective audiometric data (Figure 1), we found a moderate to strong correlation between PTA4 results and SPOT-25 subscores on "hearing function" and "general." With regards to improvement in "tinnitus," "mental condition," and "social restrictions," there was no significant correlation to the improvement in PTA4.

The development of tinnitus throughout the progression of otosclerosis is a phenomenon observed in about half of the patients affected<sup>2</sup> which assumably has a major effect on the patients'

SPOT-25, Stapesplasty Outcome Test-25.

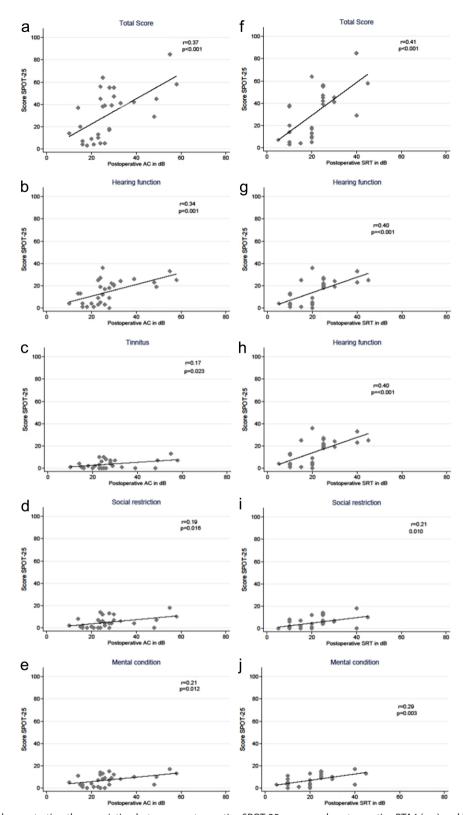


Figure 1. a-j. Scatterplot demonstrating the association between postoperative SPOT-25 scores and postoperative PTA4 (a-e) and in improvement in SPOT-25 scores and improvement in postoperative PTA4 (f-j). The solid line indicates predicted values by linear prediction. The strength of correlation is indicated by "r" with 0 indicating no correlation and -1 and 1 indicating perfect negative and perfect positive correlation, respectively. Evans suggests the following guide for interpretation: 0.00-0.19 "very weak," 0.20-0.39 "weak," 0.40-0.59 "moderate," 0.60-0.79 "strong," 0.80-1.0 "very strong" [Evans JD (1996) Straight forward statistics for the behavioral sciences. Brooks/Cole Pub. Co, Pacific Grove sæt ref ind]. A low P-value indicates strong evidence of the demonstrated correlation. r: Pearson correlation coefficient;  $r_s$ : Spearman correlation coefficient; SPOT-25, Stapesplasty Outcome Test-25.

perceived HRQOL and is not assessed by the audiometric evaluation. Using the SPOT-25 questionnaire as a supplement diagnostic tool can help identify these patients. Similarly, even though the data showed improvement of the subscores "mental condition" and "social restrictions," they did not correlate well with the PTA4 values.

Regarding the differences in surgical technique and piston material, we chose not to discriminate between the participants. This decision was based on previous literature showing neither any significant differences between the usage of nitinol head or titanium band nor between the usage of laser compared to perforator for the surgical outcome assessment of the audiometric results and HRQOL.<sup>1,24,25</sup>

# **Strengths and Limitations**

This was a prospective study to evaluate the results of stapedotomy in our department. After translation of the original SPOT-25 questionnaire<sup>15</sup> into Danish, a re-assessment of the validity and reliability was primarily performed, since there may always be differences in culture and language that need to be considered.

The proportion of patients not answering the postoperative SPOT-25 questionnaire was relatively high. However, the dropout analysis revealed that this was due to a temporary shortfall in the follow-up process in 2018. For the rest of the study period, the response rate was 83%-100% and there was no reason to suspect any other response bias.

As a general aspect for consideration with regards to the SPOT-25 questionnaire, but not as a weakness of our study, it has to be mentioned that the developers of the questionnaire14 excluded 2 items on altered sound perception during the original validation process since these did not reach the defined statistical inclusion criteria preoperatively. It was suggested by Weiss et al<sup>1</sup> to readopt these items for the postoperative evaluation, since altered sound perception is a common phenomenon, which may substantially impact the HROOL, especially in the first months after surgery.<sup>1,26</sup> A good example for this argument was made by Bächinger et al.26 who found that almost half of their patients experienced disturbed sound perception (DSP) about 3 weeks after surgery, which regressed again within a year postoperatively.<sup>26</sup> Since our postoperative questionnaire was collected after approximately 3 months, DSP might have been a phenomenon influencing our SPOT-25 scores at that point. To approach this possibility further, a later follow-up would be interesting to look at.

Similarly to this aspect, it could be assessed, if the phenomenon of loud noise intolerance,<sup>27</sup> vertigo,<sup>28,29</sup> and taste disorder after stapes surgery<sup>26,30</sup> should be added to the postoperative questionnaire, if the aim was to also detect reduced HRQOL due to complications to the surgery. However, these aspects were not the primary focus of our study in which we tried to follow the design of the original SPOT-25 which already had undergone a statistical item reduction.<sup>14</sup>

Finally, both first-time surgery and revision were included in the study. However, when these groups were compared by subanalysis, we found no significant difference in the improvement of hearing levels. The perfect study should also take into consideration the level of possible disease in the contralateral ear as well as the use of hearing aids. Yet, it will require a much larger study population if patients are to be further subdivided.

#### CONCLUSION

The audiometric results in our study were in accordance with previous studies on the topic.

In our analysis of HRQOL, we found a significant improvement in all subscores of the SPOT-25 questionnaire after stapedotomy except for "Tinnitus."

An analysis of correlation between the improvement in SPOT-25 subscores and improvement in AC threshold showed a significant correlation for "hearing function" and total score but not for "tinnitus," "social restrictions," and "mental condition." Therefore, the SPOT-25 can be used as a valuable supplement to the hearing test by assessing HRQOL.

**Ethics Committee Approval:** The study was approved by the Danish Data Protection Agency (J. no: REG-150-2017).

**Informed Consent:** Written informed consent was obtained from all participants who participated in this study.

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