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The Final thesis

**Long-term health-related Quality of Life after Stapedotomy in Otosclerosis Patients**

(title)

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## Summary

### Background and objective

Otosclerosis, or otospongiosis, is a condition of stapes fixation due to irregular spongy bone formation. The condition has an association with hearing disability which may lead to deficits in communication as well as social and psychological limitations. Preferred treatment choices are stapedotomy or stapedectomy together with prosthesis placement. Patient's subjective evaluation of the treatment outcome, health-related quality of life (HRQoL), has recently been receiving more attention. In the field of otorhinolaryngology, otology specific survey, EOS-16, has been recently developed and a positive correlation has been observed between EOS-16 and a generic HRQoL survey, 15D. The objective of this thesis is to investigate if the health-related quality of life persists one, five and ten years after otosclerosis surgery. The objectives are evaluated by comparing otology specific and generic HRQoL surveys (EOS-16 and 15D) together with objective audiograms.

### Methods

Data collection was based on the patient records at the Department of Otorhinolaryngology in Helsinki University Hospital. The data collection provided 339 patients in total from which 293 patients fulfilled the inclusion criteria. The surveys were sent in two cycles to ensure the maximum number of participants. During the first survey period from all 293 included patients 143 (48,8 %) replied. 150 patients received a second cycle of surveys and from those 36 patients (12,3 %) replied, meaning that total response rate was 179 (61,1 %). From all patients included into the research, 114 patients (38,9 %) did not reply before the deadline.

Audiograms of all 179 patients were searched automatically from the hospitals data base. 161 patients (89,9 %) had their audiograms present in the systems and files and from those 123 (76,4 %) had both pre- and postoperative audiograms, 33 (20,5 %) had only postoperative and 5 (3,1 %) had only preoperative audiogram available. The Pre- and postoperative audiograms were most prevalent among one-year postoperative patients, 55 audiograms (44,7 %), second most among 5 years postoperative patients, 49 audiograms (39,9 %), and the least among 10 years postoperative patients, 19 audiograms (15,4 %).

## Results

The analysis included evaluation of EOS-16 and 15D scores, pre- and postoperative pure-tone averages (PTA) as well as change in pure-tone average. When comparing aforementioned parameters together with one-, five- and ten-year follow-up groups, no statistically significant differences were observed. EOS-16 scores did correlate well with the audiometric outcomes, while from all parameters pure-tone average after surgery was the single best predictor of good health related quality of life. Burden caused by tinnitus had no correlation with audiometric results.

## Conclusions

Otosclerosis can present in relatively young age and cause significant burden for the patient suffering from it. The individuals living with the disease and its consequences for many years, may experience not only hearing impairment and tinnitus but also deficits in communication as well as social and psychological limitations. The result of persisting quality of life ten years after otosclerosis surgery, evaluated by both otology specific and generic health-related quality of life surveys and audiometric parameters, is clinically significant. EOS-16 is a useful instrument in determining the impact of interventions in otologic patients.

## Keywords

Otosclerosis; Stapedotomy; Stapedectomy; Health-related quality of life; HRQoL; Otology.

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## 1. Introduction

Otosclerosis, or otospongiosis, is a condition of stapes fixation due to irregular spongy bone formation. Bony overgrowth involves footplate of the stapes and prevents its natural movement and function. (1) The location and extent of the lesion vary as well as the severity and clinical manifestation of otosclerosis (2). The leading symptom of the condition is progressive conductive hearing loss with normal otoscopic findings of tympanic membrane (1). Due to occasional involvement of cochlea, otosclerosis may manifest as isolated sensorineural hearing loss or in severe cases as total deafness. Otosclerosis is an autosomal dominant hereditary disease and from those with clinical otosclerosis approximately 60 % have positive family history of the condition. The etiology is thought to be multifactorial combining complex genetic and environmental factors. (2) Since otosclerosis has an association with hearing disability it also has a potential to lead deficits in communication as well as social and psychological limitations (3).

Among hearing loss, subjective tinnitus is one of the most prevalent symptoms of otosclerosis development (4). The etiology of tinnitus is still not fully discovered. One of the hypothesis is that rich vascularization of newly formed bone could cause pulsatile waves, sensed as tinnitus. (5) However, one study suggests that tinnitus could occur due to changes in reduction of the inner ear fluid vibration or production of toxic metabolites existing due to otosclerosis (6). All in all, subjective tinnitus is a symptom that causes significant problem for the patient experiencing it and thus it should be taken into a consideration when evaluating treatment options (7)(5).

Partial (stapedotomy) or complete (stapedectomy) removal of fixed stapes from the footplate together with prosthesis placement is the preferred treatment choice of otosclerosis (1). The goal is to restore the fluid vibration within cochlea, increase sound amplification and further on bring hearing thresholds to acceptable levels. (8) The surgery is usually performed as an outpatient procedure under local anesthesia. Nowadays, majority of surgeons favor stapedotomy over stapedectomy as studies indicate that short- and long-term results in stapedotomy are slightly better in early and late postoperative air conduction thresholds at 4 kHz, than in patients undergoing stapedectomy. However, in bigger picture the outcomes of both patient groups seem to remain stable over long-term follow up and no significant difference in early or late pure tone average (PTA), air-bone gap (ABG) or speech discrimination score has been detected. Possible postoperative complications include infection, vertigo, facial paralysis, tinnitus, taste disturbance, hyperacusis and tympanic membrane perforation. (2) Although the postoperative complications

may cause significant burden, otosclerosis surgery is currently the best treatment options for better bone conduction and closure of air-bone gap (8). Treatment results are generally good and disease-specific surveys show that otosclerosis surgery improves both hearing and patient's health-related quality of life (HRQoL) (3). Also, the surgery seems to be cost-effective procedure with a little cost and maximum benefit for the patient (9). In most cases the hearing improvement achieved after surgery is known to lasts for many years (10).

The evaluation of treatment results has primarily been based on functional parameters, although patient's subjective evaluation of the outcome, health-related quality of life, has recently been receiving more attention (11). Commonly the evaluated parameters have been the degree of closure of patients air-bone gap and pure-tone average (8). In 2021 J. Laakso et al published EOS-16, a health-related quality of life (HRQoL) survey, to provide an otology specific instrument for evaluation of patients' health-related quality of life in everyday otologic practice. The EOS-16 is designed for evaluation of health-related quality of life in wide range of chronic ear conditions and it is applicable for evaluation of effectiveness and cost-effectiveness of treatment as well. (12) This particular HRQoL survey, the EOS-16, is a core element of this Long-term health-related quality of life after stapedotomy in otosclerosis patients -thesis. The other survey used in this study is a generic HRQoL, 15D, survey. It is a 15-dimensional and standardized instrument that has been widely used to measure health-related quality of life, either as a profile or as single index score (13). In previous studies, a positive correlation has been observed between EOS-16 and 15D values (12).

The objective of this thesis is to evaluate if the health-related quality of life persists one, five and ten years after otosclerosis surgery. The evaluation is done by comparing both otology specific and generic HRQoL surveys (EOS-16 and 15D) and objective audiograms. Additionally, other patient specific characteristics were evaluated including age at the time of surgery and at the time of response to the inquiry, sex, BMI, operated ear, type of surgery and postoperative complications.

## 2. Materials and methods

### 2.1 Research design and ethics

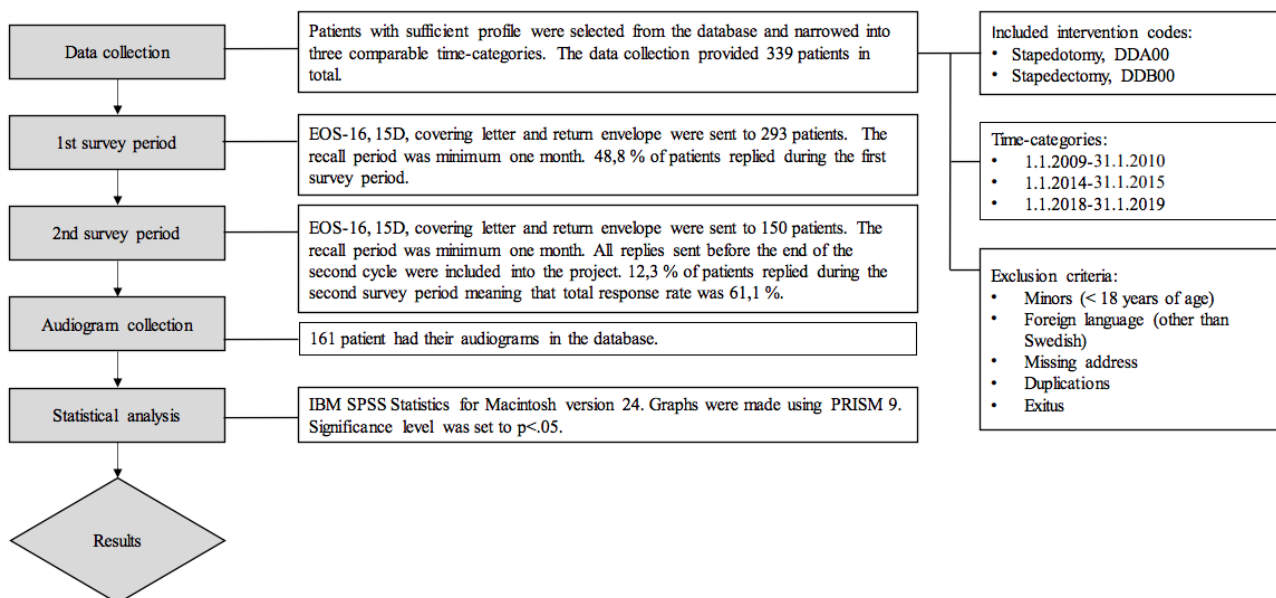
Prior to commence, ethical committee was approached regarding ethical approval for the research project. The research was based on retrospective analysis of patient records together with a HRQoL survey. The aim of the study was to ascertain if the health-related quality of life persists one, five

and ten years after otosclerosis surgery. The study protocol was approved by Helsinki University Hospital Ethics committee and a research permit was obtained for research center. Informed consent was gathered with the inquiry from all participated patients.

## 2.2 Data collection

Data collection was based on the patient records at the Department of Otorhinolaryngology in Helsinki University Hospital. The collection was started by choosing appropriate intervention codes from standard intervention coding system. Chosen codes were Stapedotomy, DDA00, and Stapedectomy, DDB00. Patients who were operated due to otosclerosis under aforementioned intervention codes and had the diagnosis of otosclerosis unchanged after the operation, were included into the project. Timeframe was narrowed into three comparable categories; one, five and ten years after the operation.

The data collection provided 339 patients in total. Defined exclusion criteria included minors (< 18 years of age), foreign language (other than Swedish), exitus, duplications and missing address, meaning that in total 46 patients were excluded from the research.



**Figure 1. Study design.** Flow chart of study protocol and data collection. Listed intervention codes, comparable time-categories and defined exclusion criteria.

### 2.3 Health related quality of life (HRQoL) surveys

The health-related quality of life was examined by using EOS-16 survey as well as generic HRQoL survey, 15D. The EOS-16 survey included sixteen questions, covering pain or other discomforts of affected ear, hearing impairment, symptoms of balance, limitations and needed measures or treatment. Each question from 1-14 were numerated from 0 (no problem) to 4 (very severe problem) and 15-16 regarding the actions or treatment needed, from 0 (I haven't) to 4 (over 4 times). The best overall score was 0, reflecting good status and no complaints regarding the ear. The worst score overall score was 64, reflecting very severe problems with the operated ear.

Generic HRQoL survey, 15D, covered more general health-related questions and evaluated mobility, vision, hearing, breathing, sleeping, eating, speech, excretion, general activities, mental functions, discomforts and symptoms, depression, distress, vitality, and sexual activity. These fifteen dimensions all had five levels which were used to reflect the patient's health status. Among the five dimensions, number 1 reflected normal health status with no complaints, while number 5 reflected severe health problems with disabling features. The best score was 15 and the worst score was 75.

### 2.4 First survey period

Thus, 293 patients who fulfilled the criteria were included into the project and received an inquiry containing EOS-16, 15D, covering letter and return envelope. The inquiry was performed in two cycles to ensure maximum number of participants. During the first survey period, all 293 patients received the inquiry and were expected to return their answers within minimum of one month. 143 patients (48,8 %) replied during the first survey period.

### 2.5 Second survey period

The second cycle was performed with same protocol as the first cycle except that the inquiry was sent only for those who did not reply during the first survey period. With the second cycle we were able to maximize the number of participants and give a gently remind for the patients to participate, if they wanted to. In total 150 patients received the second cycle of inquiry with minimum one-month deadline to reply. Late replies from the first cycle were still included into the project and the latest deadline for all returns was set into the end of second survey period. During the second cycle,



36 patients (12,3 %) replied meaning that total response rate was 179 (61,1 %). From all patients included into the research, 114 patients (38,9 %) did not reply before the deadline.

## 2.6 Audiograms

Objective measurements of pre- and postoperative hearing were performed via audiograms. The audiograms of all 179 patients were searched automatically from the hospitals data base and no control audiograms from the present moment was included. From the preoperative audiograms only one which was the closest to the operation was included, while from postoperative audiograms the one which was measured one year after the operation, or the first measurement after that, was included. However, all patients did not have their audiograms present in the database and thus those audiograms were searched manually from the patient files.

From the 179 patients who answered the inquiry, only 161 patients (89,9 %) had their audiograms present in the systems and files. From those 161 patients, 123 (76,4 %) had both pre- and postoperative audiograms, 33 (20,5 %) had only postoperative and 5 (3,1 %) had only preoperative audiogram available. Both pre- and postoperative audiograms were most prevalent among one-year postoperative patients, 55 audiograms (44,7 %), second most among 5 years postoperative patients, 49 audiograms (39,9 %), and the least among 10 years postoperative patients, 19 audiograms (15,4 %).

## 2.7 Patient characteristics

Additional to the main parameters (EOS-16, 15D and audiograms), characteristics of the participated patients were evaluated, including age at the time of surgery and at the time of response, sex, BMI, surgical type and method, operated ear and possible complications.

## 2.8 Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics for Macintosh version 24. Graphs were made using PRISM 9. Significance level was set to  $p < 0.05$ . Descriptive statistical analysis was selected to show central tendencies, dispersion and/or variation. Analysis of statistically significant difference between groups was performed by t-test. Continuous variables were analyzed

by simple linear regression model, as appropriate. Pearson correlation coefficient was used to measure correlation.

### 3. Results

The total response rate of the study was 61,1 % (Table 1.). The lowest response rate was among the patients who were operated 10 years ago (52,4 %), while the highest among those who were operated the most recently (72 %). This may be due to missing address, which has not been updated into the hospital data bases.

This study included 179 participants among whom the mean age at the time of surgery was 48,7 years with standard error of 12,2, while the total range was 18-75 years. At the time of response, the mean age was 54,3 years with standard error of 12,7. The mean body mass index (BMI) among all 179 patients was 25,34 with standard error of 5,15. When comparing the age at the time of surgery and BMI between one, five and ten-year postoperative follow up groups, no statistical differences were observed within the groups by t-test. (Table 1.)

	All participated (n = 179)	1 year Postoperative (n = 58)	5 years Postoperative (n = 68)	10 years Postoperative (n = 53)
Age at surgery, y	48.7 (12.2)	49.3 (12.3)	47.6 (12.5)	49.5 (11.9)
Age at response, y	54.3 (12.7)	59.9 (12.1)	53.0 (12.4)	50.8 (12.2)
Sex (male), n (%)	66 (37)	18 (31)	27 (40)	21 (40)
Body Mass Index	25.34 (5.15)	25.73 (4.62)	25.41 (4.45)	24.77 (2.89)
Intervention code, n (%)				
1. Stapedotomy, DDA00	172 (96)	57 (98)	63 (93)	52 (98)
2. Stapedectomy, DDB00	7 (4)	1 (2)	5 (7)	1 (2)
Operated ear, n (%)				
1. Right	87 (48)	33 (57)	33 (49)	21 (40)
2. Left	91 (51)	25 (43)	34 (50)	32 (60)
3. Both	1 (1)	0	1 (1)	0
Method of operation, n (%)				
1. Endaural	134 (75)	37 (64)	56 (82)	41 (77)
2. Transcanal	45 (25)	21 (36)	12 (18)	12 (23)

**Table 1. Patient characteristics.** Follow up groups of one, five and ten years after otosclerosis surgery.

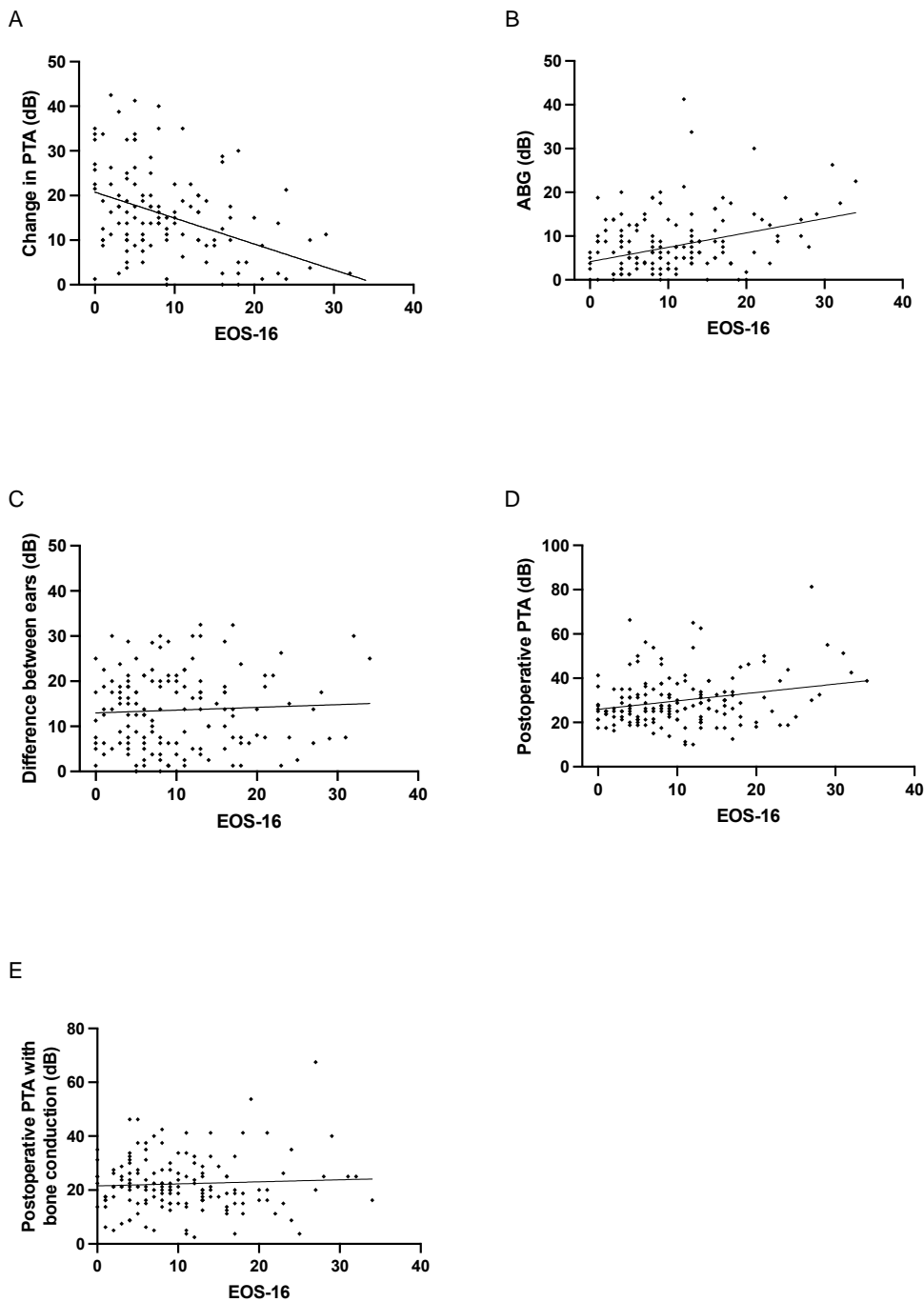
Otosclerosis is known to be female predominant disease and in this study as well two thirds of the participants were female in all follow up groups. As mentioned before, surgeons nowadays prefer stapedotomy over stapedectomy and this can be seen in our data as well. Only 7 (4%) surgeries were stapedectomies and vast majority stapedotomies (96 %). Operated side of the ear remained equal (48 % and 51 %) and had very little difference between follow up groups.

The analysis included evaluation of EOS-16 and 15D scores, pre- and postoperative pure-tone averages as well as change in pure-tone average. When comparing aforementioned parameters together with one-, five- and then-year follow up groups, no statistically significant differences were observed within the groups by t-test (Table 2.). This indicates that the quality of life and the audiometric results do persist in all follow up groups. Simple linear regression was used to test if audiological parameters significantly predicted EOS-16 score and thus the quality of life of the patients. Statistically significant correlation was observed with change in pure-tone average ( $\beta = -0.581$ ,  $R^2 = 0.171$ ,  $p < 0.001$ ) (Fig. 2A), postoperative air-bone gap ( $\beta = 0.329$ ,  $R^2 = 0.106$ ,  $p < 0.001$ ) (Fig. 2B), postoperative pure-tone average ( $\beta = 0.380$ ,  $R^2 = 0.061$ ,  $p = 0.002$ ) (Fig. 2D) and EOS-16 scores. EOS-16 scores did correlate well with the audiometric outcomes, while from all parameters postoperative pure-tone average was the single best predictor of good health related quality of life (Fig. 2).

When observing the results of EOS-16 questionnaire alone, the major problems affecting to the health-related quality of life reported to be distress caused by tinnitus, hearing related issues and the fear that the symptoms of the ear will get worse in the future (Fig. 3).

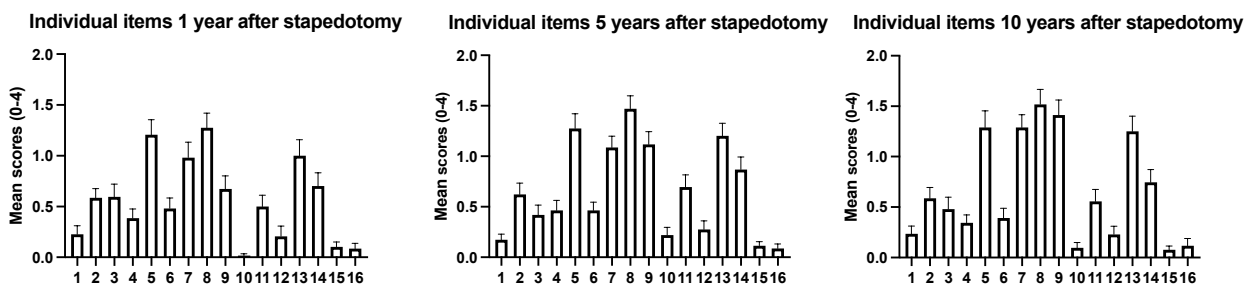
	All participated (n = 179)	1 year Postoperative (n = 58)	5 years Postoperative (n = 68)	10 years Postoperative (n = 53)
EOS-16, mean (SD)	10.03 (7.49)	8.98 (7.76)	10.52 (7.50)	10.56 (7.20)
15D, mean (SD)	0.93 (0.07)	0.93 (0.06)	0.93 (0.09)	0.92 (0.07)
Preoperative PTA, dB mean (SD)	45.46 (13.60)	45.29 (13.97)	44.73 (12.26)	48.18 (15.82)
Postoperative PTA, dB mean (SD)	29.79 (11.38)	29.38 (10.33)	30.29 (11.38)	29.54 (13.21)
Change in PTA, dB mean (SD)	15.51 (12.60)	15.58 (11.29)	13.79 (11.65)	19.52 (17.10)
Postoperative ABG, dB mean (SD)	7.88 (7.05)	7.63 (7.73)	8.17 (8.14)	6.38 (14.48)

**Table 2. Results.** Follow-up groups of one, five and ten years after otosclerosis surgery. There were no significant differences between groups.



**Figure 2.** Simple linear regressions were performed on the audiological parameters and EOS-16 total scores and thus their relationship to quality of life. (A) Change in pure-tone averages (PTA) due to stapedotomy was statistically significant,  $\beta = -0.581$ ,  $R^2 = 0.171$ ,  $p < 0.001$ . (B) Postoperative (after one year from stapedotomy) air-bone gap (ABG) was statistically significant,  $\beta = 0.329$ ,  $R^2 = 0.106$ ,  $p < 0.001$ . (C) Difference in pure-tone average between ears one year after

stapedotomy was not significant,  $\beta = 0.061$ ,  $R^2 = 0.003$ ,  $p = 0.544$ . (D) Postoperative pure-tone average was statistically significant,  $\beta = 0.380$ ,  $R^2 = 0.061$ ,  $p < 0.01$ , and thus the single best predictor of good health related quality of life. (E) Postoperative pure-tone average using bone conduction thresholds was not significant,  $\beta = 0.076$ ,  $R^2 = 0.003$ ,  $p = 0.50$ .



**Figure 3.** Individual EOS-16 scores (mean, SEM), comparison between groups 10, 5 and 1 year after stapedotomy. Item 5 is related to tinnitus, items 7-9 to hearing, 13 to fear that ear symptoms will become more difficult in the future, item 14 to quality of life.

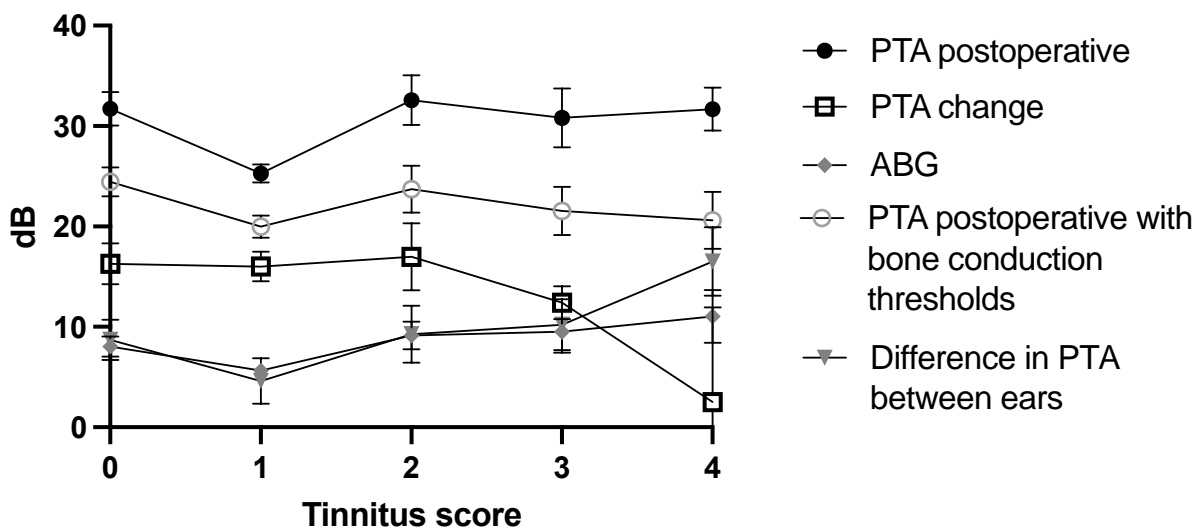
From all 179 patients, 20 (11 %) had some level of complications according to the patient files (Table 3.). The most prevalent postoperative issue was tinnitus and from all patients 9 (5 %) were reported to suffer from it. Majority of them (55 %) were operated five years ago. The second most reported complication was taste disturbance in total of 5 (3 %) patients from all participants and from them vast majority (80 %) were operated 10 years ago.

In this study group, 3 (2 %) patients from all who participated got a postoperative infection. The rate of infection between follow up groups remained stable and each group had one patient who experienced either bacterial or viral infection of the operated ear. Approximately 1 % experienced either vertigo, prosthesis dislocation or allergy as a complication of the surgery. From those who experienced complications, 6 (30 %) patients ended up with a revision surgery. Half of them were re-operated due to tinnitus.

The burden caused by tinnitus seemed significant when comparing to the rate of other reported issues, but it had no correlation with audiometric results. When comparing the audiological parameters and EOS-16 scores with the symptom of tinnitus, there were no predictive values (Fig. 4). The audiometric data including change in pure-tone average, post-operative pure-tone average or air-bone gap had no correlation with tinnitus item of EOS-16 (item 5) alone.

	All participated (n = 179)	1 year Postoperative (n = 58)	5 years Postoperative (n = 68)	10 years Postoperative (n = 53)
Complications, n (%)				
1. Infection	3 (2)	1 (2)	1 (1)	1 (2)
2. Taste disturbance	5 (3)	0	1 (1)	4 (8)
3. Vertigo	1 (1)	0	1 (1)	0
4. Tinnitus	9 (5)	2 (3)	5 (7)	2 (4)
5. Prosthesis dislocation	1 (1)	0	0	1 (2)
6. Allergy	1 (1)	0	0	1 (2)

**Table 3.** Complications recorded from patient files during the last postoperative visit one year after the surgery.



**Figure 4.** Comparison of audiological parameters with the EOS-16 survey regarding the problem of tinnitus (Item 5). EOS-16 score for tinnitus ranged between 0-4 points. From audiological parameters postoperative pure-tone averages (PTA), change in pure-tone averages, air-bone gap (ABG), bone conduction threshold with postoperative pure-tone average and difference in pure-tone average between ears were observed. Postoperative outcomes were measured one year after stapedotomy. No predictive values were observed. Whether the surgery was successful or unsuccessful, the effect towards the burden caused by tinnitus was statistically insignificant.

#### 4. Discussion

Otosclerosis is a disease with burden associated with hearing disability, possible deficits in communication as well as social and psychological limitations. While the surgery is known to be an effective treatment, and the disease-specific surveys show that stapes surgery improves both hearing

and patient's health-related quality of life, no otology specific HRQoL (EOS-16) survey based research was done before. (3) In previous studies, positive correlation between posturographic scores and self-reported quality-of-life questionnaires after stapedotomy was observed, as well as significant improvements in air conduction hearing thresholds and decrease reliance on hearing aids (14)(15).

In this study, we wanted to investigate the health-related quality of life after otosclerosis surgery and see if it persists one, five and ten years after the operation. The results indicated that both, the health-related quality of life and audiologic outcomes, does persist 10 years after the surgery. Since otosclerosis can present in relatively young age and thus the individual would live with the disease and its consequences for many years, the results of persisting good outcomes are clinically significant.

Binaural hearing has thought the improve speech perception, quality of life, tinnitus and psychological comorbidities (16). In this study, no correlation was observed in PTA and EOS-16 scores between the ears, indicating that the quality of life of participants did not decrease due to uneven perception of sound.

While complications are relatively uncommon, some qualities repeatedly decreased the health-related quality of life in the current study. Tinnitus was the most frequently reported as an issue during postoperative visit, but it did not always result to revision surgeries nor correlate with audiometric results. With patients experiencing tinnitus, usually conservative treatment options can first be tried to relieve the symptom and improve the quality of life before invasive measures (17). Additionally, tinnitus is a frequent symptom of otosclerosis and a high pitch tinnitus present preoperatively is not always resolved even though the surgery and hearing improvement were successful (6). In this study group, time, conservative approach and adaptation may have decreased the burden of the symptom and thus not affecting to the audiometric results nor leading to invasive measures in majority of the patients. However, no statistics were gathered about preoperative symptoms nor disability caused by tinnitus, and when comparing to the rate of other reported issues tinnitus seemed to cause burden. Since the prevalence of tinnitus during otosclerosis is suggested to be 60-90 %, might be that the patients in this study were experiencing tinnitus during both pre- and postoperative period and thus were more resilient for postoperative tinnitus (5). Also, the otosclerosis surgery is known to alleviate tinnitus among most patients and thus lead to more preferable outcome despite the persistent symptom (18). However, whether the surgery was

successful or unsuccessful, in our postoperative data the effect towards the burden caused by tinnitus was statistically insignificant (Fig. 4).

## 5. Conclusion

Otosclerosis can present in relatively young age and cause significant burden for the patient suffering from it. The individuals living with the disease and its consequences for many years, may experience not only hearing impairment and tinnitus but also deficits in communication as well as social and psychological limitations. The result of persisting quality of life 10 years after otosclerosis surgery, evaluated by both otology specific and generic HRQoL surveys and objective audiograms, is clinically significant. Stapedotomy or stapedectomy seems to be a cost-effective surgery that improves both the health-related quality of life and hearing in patients suffering from otosclerosis. The positive correlation between better postoperative pure-tone average and good EOS-16 scores provide a useful tool for clinician to evaluate the success of the performed surgery. When achieved pure-tone average is good we can assume that it has positive impact on patient's health-related quality of life.

## 6. Limitations

The study was a retrospective analysis with no real-time follow ups. The limitations of survey study focus on validated questionnaire, which aims to measure subjective experience as objectively as possible. Although the surveys were studied and validated, there may have been room for individual interpretation. When comparing follow up groups and the amount of both audiograms present, only 15,4 % of participants were from 10 year follow up group, which might be so due to changes in medical record system approximately ten years ago.

## 7. Recommendations

Application of EOS-16 and 15D for further prospective research among patients with otosclerosis. Also, paying attention to pre- and postoperative tinnitus among patients with otosclerosis and undergoing operation.



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Ear Outcome Survey-16 (EOS-16©) <span style="float: right;">v1.1</span>					
Name:		Date:			
Personal ID:					
<b>Below is a list of the symptoms and problems associated with ear disorders. With the help of the survey, we will find their occurrence and impact on your Quality of Life.</b>					
Select the level of difficulty that best describes your problems over <b>THE LAST THREE MONTHS</b> . If you have symptoms in both ears, answer the questions about the ear with more severe symptoms. If you answer the survey for a post-treatment control visit, please answer for the treated ear.	No problem	Mild problem	Moderate problem	Severe problem	Very severe problem
1. I have had pain in my ear.	0	1	2	3	4
2. I have had an itch in my ear.	0	1	2	3	4
3. I have felt pressure in my ear.	0	1	2	3	4
4. I have felt moisture in my ear.	0	1	2	3	4
5. I have heard a buzzing or ringing sound in my ear (tinnitus).	0	1	2	3	4
6. I have experienced dizziness or disequilibrium.	0	1	2	3	4
7. My hearing has worsened.	0	1	2	3	4
8. I have had problems hearing because of background noise.	0	1	2	3	4
9. I have had difficulty locating the direction of a sound.	0	1	2	3	4
10. Protecting my ear from water has restricted my life.	0	1	2	3	4
11. Because of ear problems, I face challenges in my daily activities / at school / at work.	0	1	2	3	4
12. Symptoms related to my ears limit my hobbies.	0	1	2	3	4
13. I fear that the symptoms related to my ears will worsen in the future.	0	1	2	3	4
14. I feel like my ear problems have negatively affected my quality of life.	0	1	2	3	4
Select the option that best describes your situation. Answer the questions for the <b>PREVIOUS THREE MONTHS</b> .	I haven't	Once	Twice	3-4 times	Over 4 times
15. I have consulted a doctor because of my ear problems.	0	1	2	3	4
16. I have used antibiotic ear drops (as prescribed).	0	1	2	3	4
<b>Overall score:</b> _____					

## QUALITY OF LIFE QUESTIONNAIRE (15D©)

Please read through all the alternative responses to each question before placing a cross (x) against the alternative which best describes **your present health status**. Continue through all 15 questions in this manner, giving only **one** answer to each.

### QUESTION 1. MOBILITY

- 1 ( ) I am able to walk normally (without difficulty) indoors, outdoors and on stairs.
- 2 ( ) I am able to walk without difficulty indoors, but outdoors and/or on stairs I have slight difficulties.
- 3 ( ) I am able to walk without help indoors (with or without an appliance), but outdoors and/or on stairs only with considerable difficulty or with help from others.
- 4 ( ) I am able to walk indoors only with help from others.
- 5 ( ) I am completely bed-ridden and unable to move about.

### QUESTION 2. VISION

- 1 ( ) I see normally, i.e. I can read newspapers and TV text without difficulty (with or without glasses).
- 2 ( ) I can read papers and/or TV text with slight difficulty (with or without glasses).
- 3 ( ) I can read papers and/or TV text with considerable difficulty (with or without glasses).
- 4 ( ) I cannot read papers or TV text either with glasses or without, but I can see enough to walk about without guidance.
- 5 ( ) I cannot see enough to walk about without a guide, i.e. I am almost or completely blind.

### QUESTION 3. HEARING

- 1 ( ) I can hear normally, i.e. normal speech (with or without a hearing aid).
- 2 ( ) I hear normal speech with a little difficulty.
- 3 ( ) I hear normal speech with considerable difficulty; in conversation I need voices to be louder than normal.
- 4 ( ) I hear even loud voices poorly; I am almost deaf.
- 5 ( ) I am completely deaf.

### QUESTION 4. BREATHING

- 1 ( ) I am able to breathe normally, i.e. with no shortness of breath or other breathing difficulty.
- 2 ( ) I have shortness of breath during heavy work or sports, or when walking briskly on flat ground or slightly uphill.
- 3 ( ) I have shortness of breath when walking on flat ground at the same speed as others my age.
- 4 ( ) I get shortness of breath even after light activity, e.g. washing or dressing myself.
- 5 ( ) I have breathing difficulties almost all the time, even when resting.

**QUESTION 5. SLEEPING**

- 1 ( ) I am able to sleep normally, i.e. I have no problems with sleeping.
- 2 ( ) I have slight problems with sleeping, e.g. difficulty in falling asleep, or sometimes waking at night.
- 3 ( ) I have moderate problems with sleeping, e.g. disturbed sleep, or feeling I have not slept enough.
- 4 ( ) I have great problems with sleeping, e.g. having to use sleeping pills often or routinely, or usually waking at night and/or too early in the morning.
- 5 ( ) I suffer severe sleeplessness, e.g. sleep is almost impossible even with full use of sleeping pills, or staying awake most of the night.

**QUESTION 6. EATING**

- 1 ( ) I am able to eat normally, i.e. with no help from others.
- 2 ( ) I am able to eat by myself with minor difficulty (e.g. slowly, clumsily, shakily, or with special appliances).
- 3 ( ) I need some help from another person in eating.
- 4 ( ) I am unable to eat by myself at all, so I must be fed by another person.
- 5 ( ) I am unable to eat at all, so I am fed either by tube or intravenously.

**QUESTION 7. SPEECH**

- 1 ( ) I am able to speak normally, i.e. clearly, audibly and fluently.
- 2 ( ) I have slight speech difficulties, e.g. occasional fumbling for words, mumbling, or changes of pitch.
- 3 ( ) I can make myself understood, but my speech is e.g. disjointed, faltering, stuttering or stammering.
- 4 ( ) Most people have great difficulty understanding my speech.
- 5 ( ) I can only make myself understood by gestures.

**QUESTION 8. EXCRETION**

- 1 ( ) My bladder and bowel work normally and without problems.
- 2 ( ) I have slight problems with my bladder and/or bowel function, e.g. difficulties with urination, or loose or hard bowels.
- 3 ( ) I have marked problems with my bladder and/or bowel function, e.g. occasional 'accidents', or severe constipation or diarrhea.
- 4 ( ) I have serious problems with my bladder and/or bowel function, e.g. routine 'accidents', or need of catheterization or enemas.
- 5 ( ) I have no control over my bladder and/or bowel function.

**QUESTION 9. USUAL ACTIVITIES**

- 1 ( ) I am able to perform my usual activities (e.g. employment, studying, housework, free-time activities) without difficulty.
- 2 ( ) I am able to perform my usual activities slightly less effectively or with minor difficulty.
- 3 ( ) I am able to perform my usual activities much less effectively, with considerable difficulty, or not completely.
- 4 ( ) I can only manage a small proportion of my previously usual activities.
- 5 ( ) I am unable to manage any of my previously usual activities.

**QUESTION 10. MENTAL FUNCTION**

- 1 ( ) I am able to think clearly and logically, and my memory functions well
- 2 ( ) I have slight difficulties in thinking clearly and logically, or my memory sometimes fails me.
- 3 ( ) I have marked difficulties in thinking clearly and logically, or my memory is somewhat impaired.
- 4 ( ) I have great difficulties in thinking clearly and logically, or my memory is seriously impaired.
- 5 ( ) I am permanently confused and disoriented in place and time.

**QUESTION 11. DISCOMFORT AND SYMPTOMS**

- 1 ( ) I have no physical discomfort or symptoms, e.g. pain, ache, nausea, itching etc.
- 2 ( ) I have mild physical discomfort or symptoms, e.g. pain, ache, nausea, itching etc.
- 3 ( ) I have marked physical discomfort or symptoms, e.g. pain, ache, nausea, itching etc.
- 4 ( ) I have severe physical discomfort or symptoms, e.g. pain, ache, nausea, itching etc.
- 5 ( ) I have unbearable physical discomfort or symptoms, e.g. pain, ache, nausea, itching etc.

**QUESTION 12. DEPRESSION**

- 1 ( ) I do not feel at all sad, melancholic or depressed.
- 2 ( ) I feel slightly sad, melancholic or depressed.
- 3 ( ) I feel moderately sad, melancholic or depressed.
- 4 ( ) I feel very sad, melancholic or depressed.
- 5 ( ) I feel extremely sad, melancholic or depressed.

**QUESTION 13. DISTRESS**

- 1 ( ) I do not feel at all anxious, stressed or nervous.
- 2 ( ) I feel slightly anxious, stressed or nervous.
- 3 ( ) I feel moderately anxious, stressed or nervous.
- 4 ( ) I feel very anxious, stressed or nervous.
- 5 ( ) I feel extremely anxious, stressed or nervous.

**QUESTION 14. VITALITY**

- 1 ( ) I feel healthy and energetic.
- 2 ( ) I feel slightly weary, tired or feeble.
- 3 ( ) I feel moderately weary, tired or feeble.
- 4 ( ) I feel very weary, tired or feeble, almost exhausted.
- 5 ( ) I feel extremely weary, tired or feeble, totally exhausted.

**QUESTION 15. SEXUAL ACTIVITY**

- 1 ( ) My state of health has no adverse effect on my sexual activity.
- 2 ( ) My state of health has a slight effect on my sexual activity.
- 3 ( ) My state of health has a considerable effect on my sexual activity.
- 4 ( ) My state of health makes sexual activity almost impossible.
- 5 ( ) My state of health makes sexual activity impossible.