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STAPEDOPLASTY – SURGICAL TREATMENT OF HEARING LOSS CAUSED BY OTOSCLEROSIS

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Abstract

Otosclerosis is a condition of abnormal bone growth around the stapes bone, one of the tiny bones of the middle ear. This leads to a fixation of the stapes. The stapes bone must move freely for the ear to work properly and hear well. Hearing loss is the most functional deficit caused by otosclerosis. However, tinnitus (noise or ringing in the ears) is frequently reported by otosclerotic patients, especially in those patients with inner ear involvement. The best therapy in achieving a significant improvement is surgical repair of the stapes – stapedoplasty. Analysis of early hearing results (1 month after surgery) shows efficiency of surgical treatment and improvement in hearing.

Keywords*: audiogram, hearing loss, otosclerosis surgery, stapes akylosis, stapedoplasty.*

Introduction

Otosclerosis is a metabolic bone disease (disease caused by some defect in the chemical reactions of the cells of the body) with background of genetic predisposition. Otosclerosis affects the auditory ossicles in the middle ear (auditory ossicles of the middle ear transmit acoustic vibrations from the eardrum to the inner ear) and bony labyrinth – anatomical structure of the inner ear. Disease causes fixation of the stapes and manifests as conductive or mixed hearing loss (Flint, Haughey, Lund, Niparko, & Richardson, 2010). There are three main types of hearing loss described in literature: conductive hearing loss (where the problem lies in the middle ear – ear drum or ossicles), sensorineural hearing loss (where there is damage in the inner ear – cochlea or hearing nerve) and mixed hearing loss (where there is a combination of conductive and sensorineural hearing loss). Prevalence of histologic otosclerosis (otosclerosis seen under the microscope) in Caucasians is estimated as 2.5% (Declau, Spaendonck, Timmermans, Michaels, Liang, Qiu, & Heyning, 2007). The female to male ratio of histologic otosclerosis is 1:1, but clinical form, with symptoms of hearing loss, occurs twice as often in females than males (Niedermeyer, Häusler, Schwub, Neuner, Busch, & Arnold, 2007). The mean prevalence of clinical otosclerosis in Caucasians is 3 patients per 1000 inhabitants (0.3%) (Declau et al., 2007). Otosclerosis is a cause of all forms of hearing loss in 5-9% and cause of a conductive hearing loss (where the problem lies in the middle ear – ear drum or ossicles) in 18-22% of cases (Markou & Goudakos, 2009). The time of manifestation of

the disease is a period from 20 till 45 years (Gleeson, Browning, Burton, Clarke, Hibbert, Jones, Lund, Luxon, & Watkinson, 2008). The patient's age at the time of the surgery has an upward trend, so in 1979 the mean age was 39.60 ± 10.83 years, but in 1990 – 40.74 ± 10.78 years (Niedermeyer et al., 2007). The increase of patient's age when otosclerosis manifests probably is related to water fluorination, vaccination against measles, use of lower doses of hormone contraception, increase of mean age of population and growth of socio-economic level (Niedermeyer et al., 2007).

In 1704 Valsalva for the first time described stapes akylosis (stiffness of a joint due to abnormal fixation of the bones) as hearing loss (Häusler, 2007). But only in 1956 first removal of stapes with implantation of teflon prosthesis and vein graft was carried out to a woman with otosclerosis, achieving improvements in hearing (Shea, 1998). At this point era of modern stapedial surgery began, when different modifications of stapedoplasty became the "gold standart" of treatment for clinical forms of otosclerosis, because effective treatment with drugs was not found till nowadays.

In the worldwide such topics as epidemiology, aetiology, genetic inheritance, histological findings, diagnostic options of otosclerosis and results of medicamental treatment are widely studied. But most publications are about options of surgical treatments of otosclerosis and efficiency of them. Otosclerosis is widespread cause of conductive or mixed hearing loss among middle-aged patients in Latvia, but there is no precise statistical data about the prevalence of the disesase among Latvian population. In the ENT clinic of Pauls Stradiņš Clinical University Hospital in Rīga, Latvia stapedoplasty with metal-fluoroplast prosthesis of Schuctnecht type is used in surgical treatment of otoclerosis. Since the results of the operation are not studied yet, this reaserch work is devoted to the exploration of the efficiency of stapedoplasty and its influencing factors.

Aim of the study: To assess the outcomes of stapedoplasty for otosclerosis and to investigate the impact of different factors on the efficiency of the operation.

Research objectives:

1. To assess hearing acuity with pure-tone audiometry (PTA) before and after stapedoplasty.
   PTA is a hearing test which relies on patient response to pure tone stimuli. It is used to identify hearing threshold levels of an individual, enabling determination of the degree, type and configuration of a hearing loss.
2. To evaluate the efficiency of stapedoplasty by measuring air-bone gap (ABG).
   ABG is the difference between the thresholds for hearing when the stimuli are delivered by air conduction and by bone conduction during PTA. Air conduction testing is performed by presenting a pure tone to the ear through an earphone and measuring the lowest intensity in decibels (dB) at which this tone is perceived 50% of the time. This measurement is called threshold. The testing procedure is repeated at specific frequencies from 250 to 8000 hertz (Hz, or cycles per second) for each ear, and the thresholds are recorded on a graph called an audiogram. Bone conduction testing is done by placing an oscillator on the mastoid process (a large, bony prominence on the base of the skull behind the ear, containing air spaces that connect with the middle ear cavity) and measuring threshold at the same frequencies.
3. To analyze and compare the preoperative factors that potentially influence the outcome of stapedoplasty.

Materials and methods of study

The retrospective study was made in the ENT clinic of Pauls Stradiņš Clinical University Hospital in Rīga, Latvia. During this study medical histories of The Center of Ambulatory Services were used. The study contains data about 42 patients with otosclerosis who underwent surgical treatment in the period from January 2009 to June 2012. 8 patients underwent bilateral stapedoplasties. Selection of the patients was made according to the following criteria: primary stapedoplasty with Schuctnecht piston (revision excluded), PTA threshold obtained 1 month after surgery. 50 stapedoplasties conform to selection criteria. All stapedoplasties were operated on by one experienced otologist. In telephone survey the data from 30 patients about 32 cases were obtained. Results of the study were recorded in MS Excel tables. All results were analysed with the software package SPSS Statistics, version 21.0. Statistical analysis was performed and the significance was set at $p<0.05$.

Main results of the research

Audiological evaluation was carried out using pure-tone audiometry before and 1 month after surgery. Air-bone gaps were calculated from air conduction and bone conduction thresholds. Changes of the mean air-bone gap (mean interval between air and bone conduction) depending on the frequency were analysed. The lower the frequency, the greater ABG in the range from 0.25 to 2 kHz. There is statistically significant correlation (t-test, $p<0.001$) between ABG before and after stapedoplasty (see Figure 1).

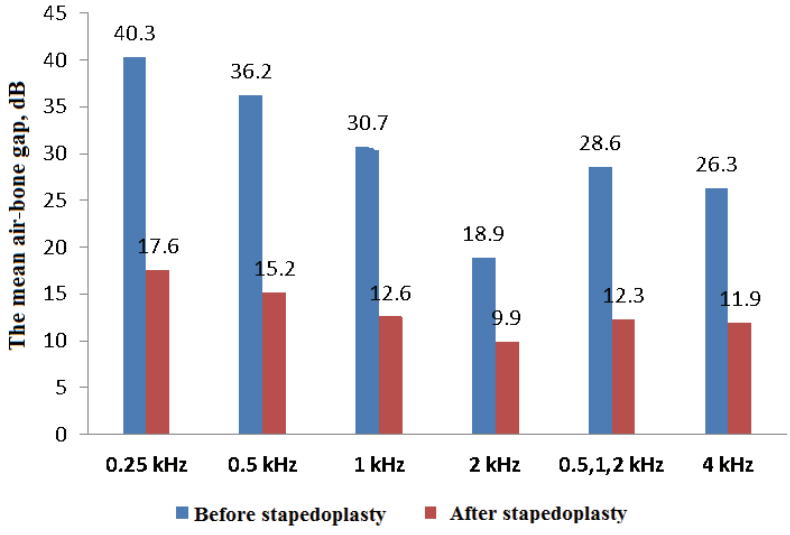

Figure 1. Changes of the mean ABG depending on the frequency

The results of stapedoplasty were considered as excellent if the mean postoperative ABG in the range from 0.5 to 2 kHz was < 10 dB; as good if the mean postoperative ABG in the range from 0.5 to 2 kHz was in the interval from 11 to 20 dB; as satisfactory if the mean postoperative ABG in the range from 0.5 to 2 kHz was > 20 dB (see Figure 2).

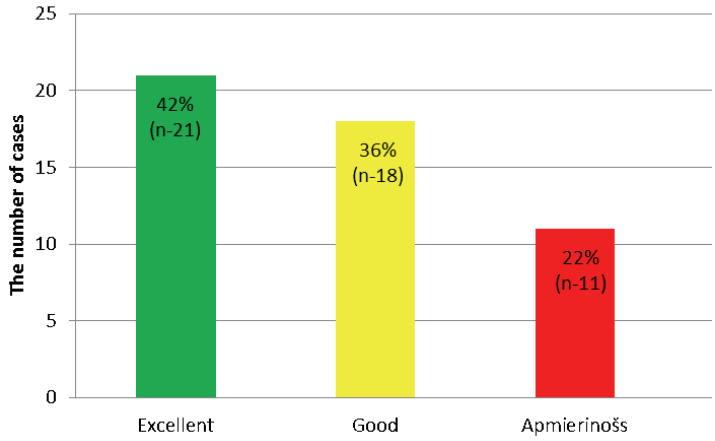

Figure 2. The results of stapedoplasty in the range of 500-1000-2000 Hz.
X^2 test, $p<0.05$

The mean air conduction before and after stapedoplasty was measured in the range from 0.25 to 4 kHz. Also the difference of them was calculated, i.e., the improvement of the mean air conduction in decibels in each of the frequencies and in the range from 0.5 to 2 kHz (see Figure 3).

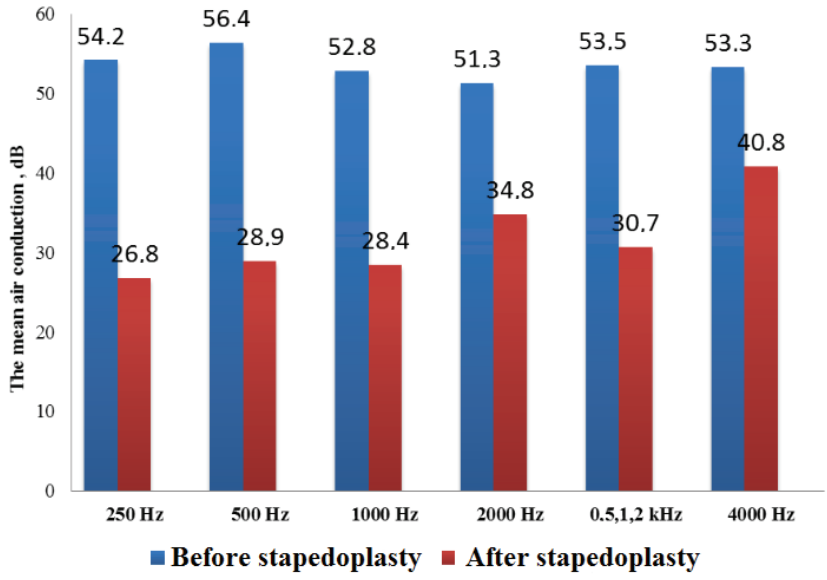

Figure 3. Changes of the mean air conduction depending on the frequency.
χ^2 test, $p<0.001$

The mean bone conduction before and after stapedoplasty was measured in the range from 0.25 to 4kHz. Also the difference of them was calculated, i.e., the improvement of the mean bone conduction in decibels in each of the frequencies and in the range from 0.5 to 2 kHz (see Figure 4).

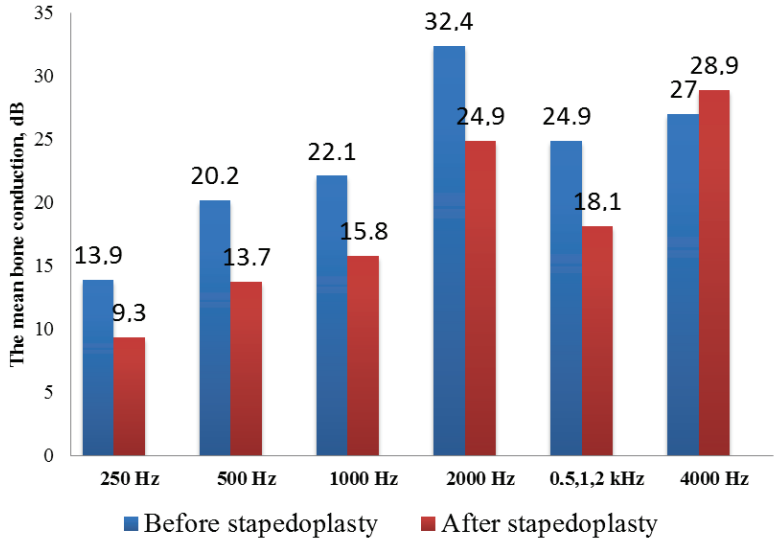

Figure 4. Changes of the mean bone conduction depending on the freguency. χ^2 test, $p<0.001$

The degree of hearing loss was measured before and after stapedoplasty. Hearing was considered as normal when the mean air conduction threshold in the range from 0.5 to 2kHz was 15dB or less; mild hearing loss – 16-25dB; moderate hearing loss – 26-40dB; moderately severe hearing loss – 41-55dB; severe hearing loss – 56-70dB; profound hearing loss – 71-90dB (see Figure 5).

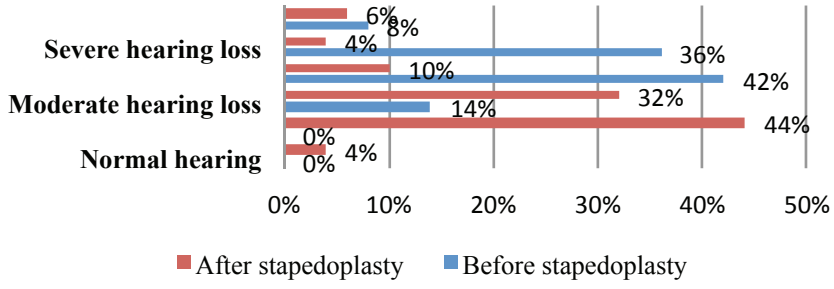

Figure 5. The changes of the degree of hearing loss 1 month after stapedoplasty. χ^2 test, $p=0.028$

The distribution of patients by gender was as follows: 29 (69.05%) females and 13 (30.95%) males (χ^2 test, $p<0.05$). After the independent sample t-test there was no statistically significant difference between females and males and the postoperative result of the mean ABG ($t=0.847$, $p=0.497$). There was no statistically significant difference between the gender and the result of stapedoplasty (χ^2 test, $p=0.922$).

The age of 42 patients included in the study group at the time of surgery ranged from 16 to 71 years. The mean age (±SD) of patient was 41.80±11.93 years. There was no correlation between patient's age and the postoperative result of the mean ABG (Pearson test, $r=0.186$, $p=0.196$).

6 (18.8%) respondents found positive family history of hearing loss, and 26 (81.2%) –

did not. From those who had a positive family history: 3 (50.0%) had a sick mother, 1 (16.7%) – a father and 2 (33.3%) – a brother or sister.

8 (16.0%) patients had damage in one ear (monaural), 42 (84.0%) patients had damage of both ears (binaural).

The duration of the medical history varied from 1 to 15 years. The mean length (±SD) of history was 4.91 ± 3.62 years.

7 (28%) women noted the first symptoms of otosclerosis (hearing impairment, noise) during pregnancy or during breast-feeding, and 9 (36%) – worsening of symptoms.

The prevalence of tinnitus before stapedoplasty was 46.9% (n=15), but after stapedoplasty 31.1% (n=10). There is a statistically significant difference between the mean ABG postoperatively and patients with resistant tinnitus and patients whose tinnitus disappeared (t= .789, p=0.001) (see Figure 6).

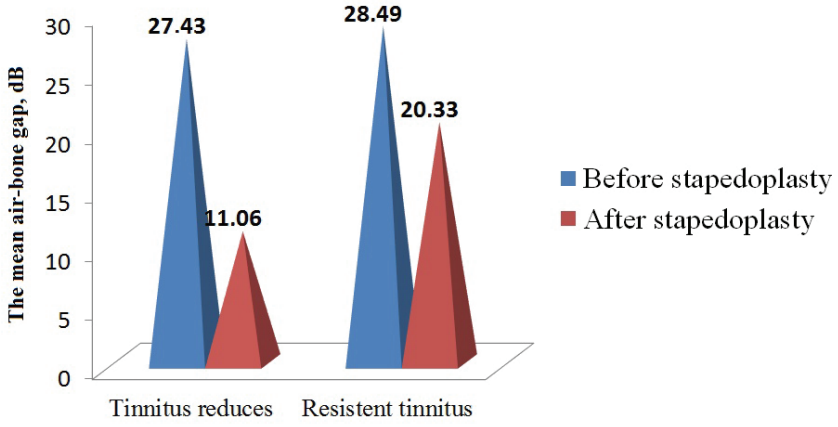

Figure 6. The mean air-bone gap before and after stapedoplasty depending on tinnitus. T=3,789, P=0,001

Discussion

From this data we can clearly see that female-to-male ratio is 7:3, which is similar to the results of the other studies (Mahafza, Al-Layla, Tawalbeh, Abu-Yagoub, & Atwan, 2013). Patient gender does not affect the results of stapedoplasty (Marchese, Conti, Cianfrone, Scorpecci, Fetoni, & Paludetti, 2009). The mean age (±SD) of the patients is 41.80±11.93 years. Kolo & Ramalingam (2013) reported mean age of 43 years with the trend to grow. In this study, age does not affect postoperative result. These data is in contrast to those reported by Marchese et al. (2009), who found out that the age of more than 50 years is a risk factor for unsuccessful result of stapedoplasty. Binaural damage is observed in 84% of patients, which is similar to the results reported by Mahafza et al. (2013) (about in 82% of clinical otosclerosis) and by Lee, Aviv, Chen, Nedzelski, Fox, & Symons (2016) (about in 84% of radiological otosclerosis). In this study, patients with binaural damage show significantly worse results of hearing, but Marchese et al. (2009) reported data that binaural otosclerosis has no effect on postoperative ABG. The researchers found a positive correlation between cochlear reserve and postoperative ABG, especially cochlear reserve >40 dB worsens the prognosis of stapedoplasty. Similar results were also shown by Marchese et al. (2009), who believed that cochlear reeve more than 30 dB increases the risk of unsuccessful stapedoplasty, i.e. ABG > 10 dB. The mean duration of illness before stapedoplasty is 4.91 ± 3.62 years, but

by *Kolo* & Ramalingam (2013) 5.96 ± 6.18 years. In this study, patients with the duration of the disease more than 5 years have significantly worse hearing results, but Marchese et al. (2009) did not find a correlation between the duration of the disease and postoperative hearing results. The goal of the stapedoplasty is to achieve the reduction in cochlear reserve, i.e. to achieve the mean postoperative ABG from 0 to 10 dB in the frequency ranged 0.5-1-2 kHz. Such result is evaluated as excellent. In this study, excellent postoperative result is achieved in 42% of cases. The outcome is lower in comparison with the results of the other publications. Reduction of ABG till 20 dB is reached in 78% of cases, but ABG over 20 dB remains in 22%. Dancuc, Pejakovic, Komazec, & Vlaški (2012) reported that ABG reduces till 10 dB in 70% and till 20 dB in 97% of cases. Ataide, Bichinho, & Patruni (2013) showed similar results. Sargent (2016) found out that excellent results of stapedoplasty were achieved in 90% of cases. Saki, Nikakhlagh, Hekmatshoar, & Mofrad (2011) reported that excellent results are achieved in 64% of cases, good results (ABG is 11-20 dB) in 30%, and satisfactory results in (ABG> 20 dB) 6%. Gierek & Klimczak-Gołab (2006) published data about 1716 stapedoplasties where ABG reduced till 10 dB only in 28.9%, while the ABG in interval of 11-20 dB was in 64.8% of all operations. Maurizio et al. [2005] reported that in the early period (7 days) after stapedoplasty reduction of ABG to 20 dB was achieved in 71% of cases, but later (3 months) – in 96% of cases.

A smaller amount of excellent results can be explained, firstly, by the fact that not all patients who underwent stapedoplasty, were included in the study, but only those who carried out the audiogram at Pauls Stradiņš Clinical University Hospital in Rīga outpatient center 1 month after surgery. This means that the cohort was compiled of patients who lived in Rīga or nearest district, and it can be assumed that those who have traveled to control audiometry from distant Latvian regions, were more likely to have a complaint or was not satisfied with postoperative result. Secondly, control audiometry was performed 1 month after stapedoplasty, which is a very early time to evaluate definitive postoperative result. Most studies suggest that early results of the stapedoplasty should be evaluated 6 months after the surgery. It can be assumed that patients will have a better hearing improvement after six months. Thirdly, in the study group, 82% of patients had mixed hearing loss and only 16% had conductive hearing loss, which is also indicative of the fact that otosclerotic process has spread to the inner ear and cannot expect as good results as when only isolated stapes ankylosis with conductive hearing loss is seen.

The largest improvement in air conduction is observed in frequency of 500 Hz, which coincides with the data obtained in the study of Dancuc et al. (2012). The best bone conduction improvement is observed in frequency 2 kHz, which is explained by the 52% of Carhart notch existence in preoperative audiogram, but after Kashio et al. (2011) data only in 32%. Little deterioration can be observed of bone conduction in frequency of 4 kHz 1 month after surgery, which coincides with Maurizio et al. (2005) report. It can be assumed that this is due to the inner ear operational trauma and believed that it will reduce later. The lower the frequency, the greater is postoperative ABG, which means in sequence from 250 Hz till 2 kHz ABG gradually decreases. Such relationships are also reported by Ueda Miyazawa, Asahi, & Yanagita (1999).

The prevalence of tinnitus 1 month after stapedoplasty decreased from 47% to 31%. Baradaranfar & Dabirmoghaddam (2004) reported reduction of tinnitus from 68% to 19%. Positive family history is found in 18.8%, but Mahafza et al. (2013) reported 35.6%. It has no effect on postoperative results (Marchese et al., 2009). Pregnancy, lactation and the number of children has no effect on postoperative ABG, like also in reports of Lippy, Berenholz, Schuring and Burkey (2005) and Marchese et al. (2009).

Conclusions

1. The largest improvement in air conduction (i.e., 27.5 dB) is at 500 Hz, while the smallest (i.e., 12.5 dB) is at 4 kHz. The greatest improvement in bone conduction (i.e., 7.5 dB) is at 2 kHz, but at frequency of 4 kHz was observed increase in bone conduction of 1.9 dB.
2. Excellent results of stapedoplasty, i.e., postoperative ABG<10 dB, was achieved in 42% (n=21) of patients. Postoperative ABG<20 dB was observed in 78% of patients. Satisfactory result stapedoplasty, i.e., postoperative ABB>20 dB was achieved in 22% (n=11) of patients. The best reduction of ABG observed in frequency of 2 kH (i.e. ABG<10 dB) in 80% of the patients, but the worst at 250 Hz – only in 32% of patients. The prevalence of tinnitus 1 month after stapedoplasty decreased from 47% to 31%.
3. Patients' sex, age, positive family history of hearing loss, otosclerosis form, pregnancy, lactation and children does not affect the result of surgery. Worse results of stapedoplasty are experienced by patients with cochlear reserve >40 dB, binaural damage, resistant tinnitus and with clinical otosclerosis >5 years.

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STAPEDOPLASTY – SURGICAL TREATMENT OF HEARING LOSS CAUSED BY OTOSCLEROSIS

Summary

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Otosclerosis is the abnormal formation of new bone in the middle ear that gradually immobilizes the stapes (stirrup bone) and prevents it from vibrating in response to sound, causing a progressive conductive and/or sensorineural hearing loss. The prevalence of clinical otosclerosis is 0.3–0.4% in the general population and 18–22% in those with conductive hearing loss.

Aim of the study: To assess the outcomes of stapedoplasty for otosclerosis and to investigate the impact of different factors on the efficacy of the operation. **Materials and methods of study:** Retrospective study. During this study Ambulatory Services Center medical histories of patients with otosclerosis, who had been treated surgically in the period from January 2009 to June 2012, were used. Selection of the patients was made according to the following criteria: primary stapedoplasty with Schuctnecht piston (revision excluded), pure tone mean (PTA) threshold obtained 1 month after surgery. 50 stapedoplasty causes conform to selection criteria. In telephone survey the data on 32 cases were obtained. Results of the studies were recorded in MS Excel tables. All results were converted to SPSS Statistics 21.0 program for further processing.

Results: From the study population 69.05% (n=29) were female and 30.95% (n=13) male. The mean age of female patients was 41.78±10.98 years, of the male patients 38.00±14.42. Monaural damage was in 16.0% (n=8), but binaural damage in 84.0% (n=24) patients. Mean duration of symptoms was

4.91±3.62 years. Mean air-bone gap (ABG) before surgery up 30 dB was in 24% (n=12) patients, from 31 to 40 dB – 52% (n=26), but more about 40 dB – 24% (n=12).

Pure tone mean of air conduction, bone conduction and pure tone mean of ABG showed statistically significant improvement in all frequencies (Student t-test $p<0.001$). ABG mean at 0.5, 1, and 2 kHz after surgery was reported as less than 10 dB in 42% (n=21) of patients, between 11 to 20 dB in 36% (n=18) and more than 20 dB in 22% (n=11) (χ^2 test $p<0.05$). The best mean air conduction before/after surgery difference was 27.5 dB at 500 Hz. The best mean bone conduction before/after surgery difference was 7.5 dB at 2 kHz, but at 4 kHz bone conduction was increased to 1,9 dB. The best mean ABG before/after surgery difference was 22.7 dB at 250 Hz.

Conductive hearing loss was detected in 16% (n=8) causes, mixed hearing loss in 82% (n=41), but sensorineural hearing loss in 2% (n=1). 18.8% (n=6) of respondents had a positive family history of hearing loss and 81.2% (n=26) – negative. 28.8% (n=7) women showed manifestations of otosclerosis during pregnancy or lactation, but a worsening of symptoms – 36% (n=9). Tinnitus prevalence in operated ear before stapedoplasty was 46.9% (n=15), but after stapedoplasty decresed to 31.1% (n=9). 9.4% (n=3) patients observed events in the disease, which is characterized by paroxismal tinnitus, dizziness, nausea.

Conclusions: In this study stapedoplasty resulted in a complete or <20 dB of ABG closure in a great majority of the patients (78%). Patients' sex, age, positive family history of hearing loss, hearing loss type, pregnancy, lactation and children number do not affect the result of stapedoplasty (ANOVA or Student's t-test $p>0.05$). Worse results of stapedoplasty are in patients with ABG before surgery more than 40 dB (ANOVA test $p=0.01$), with a binaural damage (Student's t-test $p=0.026$), resistant tinnitus (Student's t-test $p=0.01$) and with clinical otosclerosis over the last 5 years (ANOVA test, $p=0.008$).