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# Functional outcomes of tympanoplasty

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**ABSTRACT:**

**Objective:** We reviewed functional outcomes of tympanoplasty.

**Study design:** The results of tympanoplastic surgery are changing with time. We present late treatment outcomes of different types of tympanoplasty.

**Methods:** Eighty-six patients who underwent tympanoplasty were enrolled in the study. The results of pure tone audiometry performed 7 days before, 3 months, 1 year, and 3 years after the surgery were assessed. Type II tympanoplasty involved implantation of a partial ossicular replacement prosthesis and type III tympanoplasty involved reconstruction with a total ossicular replacement prosthesis and the use of autogenous homogenous material. Statistical analysis was performed.

**Results:** With all four types of tympanoplasty, hearing improvement was achieved 3 months and 1 year after surgery, which was based on the magnitude of the mean ABG reduction ($p<0.001$). In patients who underwent type I, type III and type IV tympanoplasty, the ABG reduction 3 years after surgery was maintained at the level reported 3 months and 1 year after surgery ($p<0.001$). In patients who underwent type II tympanoplasty, however, the mean ABG value was increased within all tested frequencies ($p<0.05$). The mean ABG values reported 3 years after type II and type III tympanoplasty were similar.

**Conclusions:** Based on the long-term results, hearing improvement seems to be less sustainable after reconstruction with the partial ossicular replacement prosthesis compared to the total ossicular replacement prosthesis.

**KEYWORDS:** Chronic otitis media, tympanoplasty surgery, pure tone audiometry

## 1. INTRODUCTION

Chronic middle ear infections (otitis media) damage the middle ear and lead to the development of conductive hearing loss. Surgery is the treatment of choice for chronic otitis media. In general, there are two aims of this approach. The first is to clear the infection by removing abnormal tissue and allowing the postsurgery cavity to heal. The second aim is to improve hearing by reconstructing the sound transmission apparatus, i.e., the eardrum, the ossicular chain and the air-filled cavity within the temporal bone. The original classification of tympanoplastic surgery was described by Wullstein in the 1950s. [1] Here, we use the Tos classification of tympanoplasty , which is a variant of the original Wullstein classification. [2]

A whole range of auto- or allograft materials can be used to reconstruct the sound transmission apparatus [3]. When the body of the second auditory ossicle is intact, interposition of the incus can be performed to make a connection between the malleus or a tympanic membrane graft and the stapes head (minor or short columella). If there is no suitable ossicle or even its fragment, auricular cartilage can be used, which is most frequently harvested from the tragus [3]. Bone cement can also be used to bridge the malleostapedial gap should the incus be completely destroyed [4]. Moreover, a wide range of implants is commercially available [3;5;6;7;8].

The above-described techniques are the essence of the Tos type II tympanoplasty. When the stapes superstructure is missing, a type III tympanoplasty procedure is performed. In this case, bony erosion of the other auricular ossicles usually occurs. Sometimes, the incus body or malleus head remains intact, which may fill the gap between the footplate of the stapes bone and the tympanic membrane graft. Other

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autologous and synthetic graft materials, such as auricular cartilage and implants, can be used for tympanoplasty [3; 9]. The ossicular chain is usually reconstructed using an absorbable gelatin sponge (Gelfoam) or, less frequently, a silastic rubber band (silastic banding technique) to allow for continuity in sound wave transmission. [10]

Pure tone threshold audiometry (PTA) is the most commonly used subjective hearing test. This test allows for separate threshold curves for air and bone conduction (absolute and relative) and air-bone gap (ABG) values for individual frequencies to be determined. PTA is the primary test used for diagnosis, monitoring and evaluation of treatment in patients with hearing impairment, especially those with conductive hearing loss. [11]

In 1995, the Committee on Hearing and Equilibrium at the American Academy of Otorhinolaryngology – Head and Neck Surgery (AAO-HNS) developed guidelines for evaluating the results of surgical treatment of hearing loss based on PTA. The main parameter is the mean ABG, expressed as the arithmetic mean of four frequencies (500, 1 000, 2 000, and 3 000 Hz). The mean air conduction and mean bone conduction response curves are estimated in the same way. [3; 12;13]

An optimal timing of treatment evaluation is crucial as is the method of evaluation. With respect to sustained effects of surgical treatment, a 1-year period is considered as the minimum time interval for evaluating early outcomes and a 3-year period is the minimum time interval for evaluating late outcomes. The aim of this study was to compare functional outcomes following tympanoplasty depending on the type of procedure and time period after surgery.

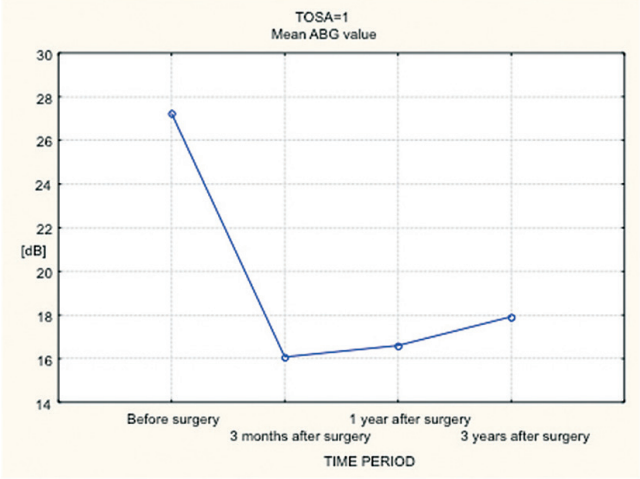


**Fig. 1.** Mean air-bone gap (ABG) for Tos type I tympanoplasty

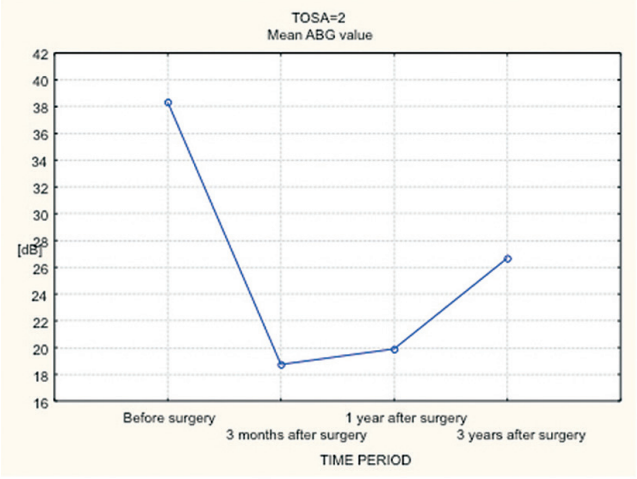


**Fig. 2.** Mean air-bone gap (ABG) for Tos type II tympanoplasty

## 2. MATERIAL AND METHODS

### 2.1 Ethical considerations

This prospective, randomized study (simple random sampling) was approved by the Bioethics Committee of the Nicolaus Copernicus University (KB 588/2011).

### 2.2 Subjects

A representative group of subjects was selected from the patients who were treated for chronic otitis media in the Department of Otolaryngology and Laryngological Oncology, Collegium Medicum, Nicolaus Copernicus University in Bydgoszcz, from 2004 until 2009. The full sample comprised 86 patients. Only adult patients with chronic otitis media were considered eligible, because the course of the disease, treatment approach and treatment outcomes differ remarkably between pediatric and adult patient populations. Of the 86 subjects, 46 (53.5%) were women and 40 (46.5%) were men. The mean age of participants was 40.5 years. For subjects who underwent surgery, the age ranged from 18 to 72 years.

### 2.2 Audiometry

We retrospectively analyzed medical records and results of hearing tests that were performed on an outpatient ba-

sis 3 months and 1 year after surgery. All patients returned for a follow-up examination after a period of at least 3 years after the procedure, according to the study protocol. To standardize test conditions, all audiometric hearing tests were conducted by the same technician within a specified time frame. The measurements were performed at the same time by the same technician in a sound-isolated and sound-proof testing booth, using the Interacoustics AC 40 clinical audiometer. Air conduction and bone conduction threshold curves were plotted during the pure tone audiometry procedure, according to the standardized protocol developed in line with the AAO-HNS guidelines. Each measurement was performed several times (at least 3 times), and the results are provided as the arithmetic mean of all measurements. Testing of bone conduction threshold was performed in the same way, with simultaneous contralateral tone masking by a broadband noise. The ABG value was calculated as the difference between the air and bone conduction thresholds. Pure tone threshold audiometry was performed in all subjects before surgery, and then 3 months, 1 year and at least 3 years later.

For each subgroup, the arithmetic mean of the PTA results was obtained. Moreover, the mean ABG, mean air conduction response and mean bone conduction response were determined for the four tested frequencies. The results were compared for the same time points between different types of tympanoplasty and for specified time points within the same category of procedures.

### 2.3 Statistical analysis

Statistically significant differences between study groups, including longitudinal changes, were assessed using repeated measures analysis of variance (ANOVA). The test was also checked for conformity with assumptions. The data were analyzed for conformity with a normal distribution using the Shapiro–Wilk and Kolmogorov–Smirnov tests with correction for small sample size. The Levene and Forsythe–Brown tests were used to establish within-group homogeneity of variance. The significance of differences between groups was tested using post-hoc tests (Scheffe, Tukey). A detailed analysis of differences between the selected groups was performed using a contrast analysis method.

Due to a small sample size, between-group significant differences were also tested for the same time points (according to the parameter, before surgery, 3 months, 1 year, and 3 years after surgery, or before surgery and 3 years after surgery) using ANOVA or paired t-tests for independent samples. In addition, longitudinal changes were also analyzed for selected subgroups using univariate repeated measures ANOVA and t-tests for dependent samples.

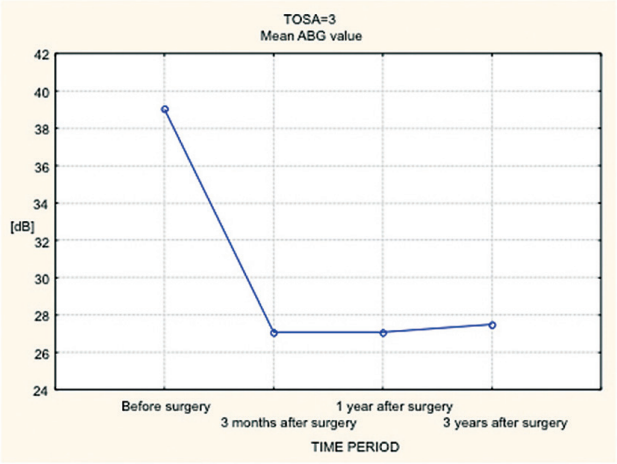


**Fig. 3.** Mean air-bone gap (ABG) for Tos type III tympanoplasty

Because of an insignificant deviation from the assumption that empirical distribution approximates the standard normal distribution, the results were complemented and/or confirmed using nonparametric equivalents of the relevant tests (Kruskal–Wallis ANOVA, Friedman ANOVA, Mann–Whitney U test, Wilcoxon test). Each table has a description that includes information on the relevant test value and the corresponding p value. The results are also presented on graphs for significant between-group differences. The following commonly used levels of significance were selected for statistical inference tests: $p \leq 0.05$; $p \leq 0.01$; and $p \leq 0.001$.

## 3. RESULTS:

Overall, 98 tympanoplasty procedures were performed in 86 study participants. Tos type I tympanoplasty was performed in 51 (52.0%) subjects, of whom 17 underwent only myringoplasty without mastoidectomy. Type II tympanoplasty was performed in 29 (29.6%) patients, type III in 12 (12.2%) and type IV in 6 (6.1%) patients.

Hearing improvement was observed in 62 (63.3%) patients immediately after surgery and was maintained for at least 3 years following surgery in 80.6% (50) of those subjects. During the study, only 15 (15.3%) patients used hearing aids due to a significant hearing impairment.

The results of the analysis of PTA data were classified into several groups according to the type of tympanoplasty . Sta-

tistically significant differences between mean preoperative and postoperative ABG values were observed at each time point in patients who underwent type I tympanoplasty. The mean postoperative ABG values did not differ significantly at any time-point, even 3 years after surgery, suggesting that functional outcomes were maintained over time (Figure 1).

Postoperative ABG values were significantly decreased at each postsurgical time point compared to preoperative values in patients who underwent type II tympanoplasty. Postoperative ABG values were also significantly higher 3 years, compared to 3 months, after type II tympanoplasty, suggesting that the results worsened over time (Figure 2).

Postoperative ABG values were significantly decreased at each postoperative time point in comparison to preoperative values in patients who underwent type III tympanoplasty . The mean post-operative ABG values were not significantly different from each other, even 3 years after surgery, suggesting that functional outcomes were maintained over time (Figure 3).

For type IV tympanoplasty, the mean post-operative ABG values were lower at each time point compared to the preoperative values, but this was not statistically significant. The mean ABG did not change after surgery, and no deterioration of clinical outcomes was observed over time. The lack of a statistical significance was probably due to a small sample size, lack of a normal distribution and high variability of the results (Figure 4).

The analysis of the mean ABG values demonstrated an improvement in hearing after all types of tympanoplasty at each time point. Statistically significant outcomes were observed in Tos type I, II and III. The long-term outcomes (3 years after surgery) significantly deteriorated only in patients who underwent Tos type II tympanoplasty. Some deterioration of clinical outcomes was observed in the remaining study groups over time, but there was no statistically significant difference between groups (Figure 5).

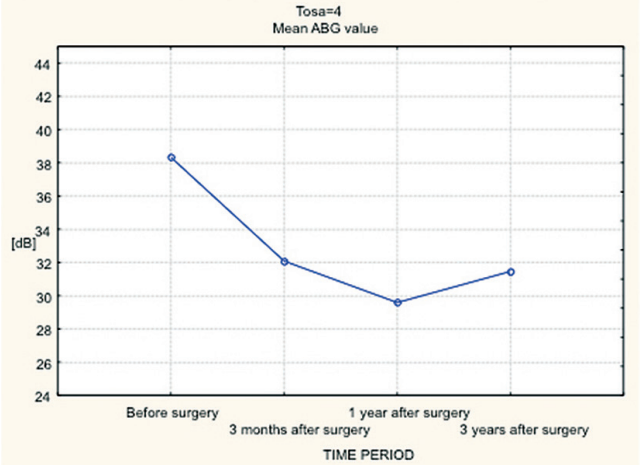


**Fig. 4.** Mean air-bone gap (ABG) for Tos type IV tympanoplasty

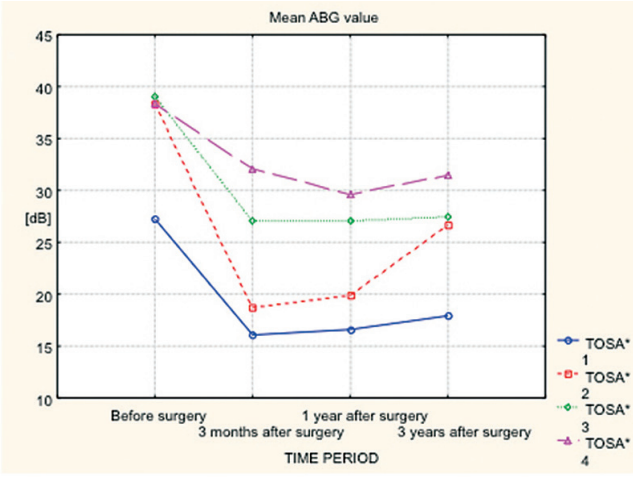


**Fig. 5.** Mean air-bone gap (ABG) for each category of tympanoplasty according to Tos classification

## 4. DISCUSSION:

The mean ABG is the most common outcome measure for tympanoplasty , as a decrease in ABG is considered to be the true measure of surgical success. The mean ABG results were compared at the same time point after surgery between different types of tympanoplasty as classified by Tos. The outcomes were ranked in the following order, from the best to the poorest, according to the category of procedures: type I tympanoplasty (16–18 dB), type II tympanoplasty (early outcomes: 19–20 dB; late outcomes: 27 dB), type III tympanoplasty (27 dB). The poorest outcomes were reported in patients who underwent type IV tympanoplasty (early: 23 dB; late: 27 dB). These findings are supported by previous reports. [14;15]

Somewhat worse results (23–27 dB) were obtained during a pre-defined follow-up period after ossiculoplasty (type II + type III tympanoplasty), similarly to previous reports. [3;16;17;18;19;20] These unsatisfactory outcomes are associated with clinically more advanced otitis media, more serious destruction of the auditory ossicles and the presence of abnormal lesions such as cholesteatoma and granulation

tissue. These findings are supported by reports in the American literature. Exactly the same results were demonstrated by Dornhoffer and Gardner for type II and type III tympanoplasty (type II: 13.5 dB; type III: 14.0 dB). Some authors claim that the presence of an intact malleus is more important for successful surgery than the stapes, and even that an absent stapes superstructure has no effect on post-surgery outcomes. [21] In our study, bony erosion of the malleus was detected in as much as 41.4% of patients who underwent type II tympanoplasty, and this is likely to impact the post-surgical outcome. The mean ABG values ranged from 19 to 20 dB during the short-term follow-up after type II tympanoplasty. These data correspond to those in the literature. [16; 22; 23] The percentage of patients with ABG up to 20 dB was also similar to that reported in the literature. Some authors reported better results (12–14 dB), but their study population was selected from patients with minor abnormalities and less pronounced ossicular damage (Austin–Kartush group A: erosion of the long crus of incus as the only abnormal finding). [24]

The mean ABG value was ~27 dB in the examined time period after type III tympanoplasty. Some authors reported similar treatment outcomes: ABG ≤ 30 dB in 50–65% patients [25;26], and a mean for four frequencies of ~30 dB. [27;28] Others reported somewhat better outcomes (20–23 dB), but these data were from patients who underwent ossicular chain reconstruction with ossicular replacement prostheses. [21; 29]

For the examined time period, the poorest outcomes (29–32 dB) were found in patients who underwent type IV tympanoplasty (i.e., sound isolation of the round window). No statistically significant differences were demonstrated within the examined time intervals. Baseline ABG values after surgery, however, improved by ~6 to 9 dB. ABG values of 20 to 25 dB can be obtained with a properly performed sound isolation procedure. [30]

Many reports suggest that better results can be obtained if there is no middle ear effusion/otorrhea or active inflammation during the perioperative period. [21;31;32;33] Middle ear effusion was present in 88.8% (n=87) of the subjects in the present study just before or during surgery, which probably adversely impacted the results of surgery and graft acceptance rates.

As for the method of reconstruction of the conductive hearing mechanism, the results are considered superior with titanium-based middle ear implants compared to autograft ossiculoplasty. [23; 34] Others, however, report that biomaterials are not superior to autologous ossicles or cartilage grafts. [22; 35; 36; 37] Only autografts were used for ossicular chain reconstruction in our study . The use of these materials made it possible to obtain results similar to those reported by other authors. [16; 19]

Several important factors make it difficult to compare outcomes of surgical treatment between different sites. Investigators use different measures to provide the results. Patient eligibility criteria and sample sizes also vary significantly across studies. Results are usually provided for only one selected category of tympanoplasty and for patients with specific disorders that require, for example, myringoplasty or canal wall-down surgery, as for chronic otitis media with cholesteatoma; or for all categories of ear surgery with the use of specific ossicular replacement prosthesis. [3; 8;17;38] In addition, reports usually cover only a short follow-up period, e.g., several months to just over 1 year. [24; 28;39] Long-term treatment effects, however, are most important to the patients.

Late treatment outcomes were maintained through the follow-up period after type I, type III and type IV tympanoplasty. After type II tympanoplasty, however, these outcomes deteriorated over time. These findings indicate that long-term results of surgery, as measured by the mean ABG value, are maintained after all types of ear surgery, except for type II tympanoplasty. A potential cause of the decreased ABG value is progressive resorption of the cartilage or bone graft (autologous ossicle or cortical bone fragment) attached to the stapes head and loss of stiffness of the ossicular chain. Partially resorbed cartilage or bone grafts can be easily displaced from their original position. [36; 37; 39] A similar instability of the short columella was also observed during revision surgery in patients who had previously undergone type II tympanoplasty with a synthetic prosthesis, while dislocation of a prosthesis in type III of tympanoplasty was hardly ever detected in this group. [40] Dislocation of the prosthesis is particularly common if the malleus handle is absent. [33] Bony erosion of the malleus handle was demonstrated in 28 (28.6%) study participants, which could influence their long-term treatment outcomes.

Robert Vincent uses a silastic rubber band (silastic banding technique) to permanently fix the reconstructed ossicular chain. [40; 41] Although a stapes superstructure is present, ossiculoplasty is performed with a total ossicular replacement prosthesis (TORP). This technique provides a remarkable and sustained improvement, particularly if associated with transposition of the malleus (malleus is relocated towards the stapes head). [40; 41]

Some papers comparing PORP and TORP tympanoplasty demonstrated better results with PORP implants in terms of mean

ABG values. Others have emphasized the advantages of TORP implants, which can be used even if the stapes superstructure is present. [11; 40; 42] A few studies did not demonstrate any difference between middle ear prostheses. Some authors report better results with TORP implants, but only when they are used for open tympanoplasty. [43]

## 5. CONCLUSIONS

We found that the best functional outcomes, based on ABG values, were obtained after type I tympanoplasty and the worst outcomes after type IV tympanoplasty. The mean air-bone gap values 3 years after type II and type III tympanoplasty were similar, but the ABG was lower 3 months and 1 year after type II tympanoplasty. In addition, hearing improvement was maintained longer after type III tympanoplasty than after type II tympanoplasty when autologous material was used.

## CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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