Usefulness of a ventilation tube as a partial ossicular replacement prosthesis (PORP) in ossiculoplasty in patients with chronic otitis media

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Background: The principal objective of ossiculoplasty is to reconstruct the sound-conducting system in the ear to the best possible degree after the elimination of pathological lesions from the middle ear. The ossicular chain is reconstructed with the use of the patient’s own properly modelled ossicles and synthetic prostheses. The objective of the study was to assess the degree of hearing improvement after tympanoplasty in patients for whom a ventilation tube was used as a partial ossicular replacement prosthesis (PORP).

Material/Method: Between 2009 and 2012, 387 patients underwent ear surgery at the Otolaryngological Teaching Hospital of the Collegium Medicum at the Jagiellonian University of Cracow. We focussed on the patients in whom a vibrating element in the form of a properly modelled anvil or a ventilation tube was attached to the preserved and normally mobile stapes.

Results: A significant hearing improvement was observed in patients with type 2 tympanoplasty in the course of chronic cholesteatoma otitis media and in patients with simple chronic inflammatory process in whom a ventilation tube was used as a PORP in the reconstruction. Granulation tissue was determined to be an unfavorable factor in the prognosis of hearing improvement following tympanoplasty.

Conclusions: Significant hearing improvement was observed after type 2 tympanoplasty in patients with cholesteatoma whose ossicular chain was not appreciably damaged. A ventilation tube used as a PORP is an effective alternative in the reconstruction of the ossicular chain.

MeSH Keywords: Ossicular Prosthesis • Otitis Media • Tympanoplasty – methods

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Background

The objective of the surgical treatment of patients with chronic otitis media is to eliminate pathological changes, facilitate the drainage and ventilation of the post-operative cavity, and reconstruct the sound-conducting system in the tympanic cavity. Emphasis has recently been focused on the restoration of anatomy (i.e., reconstruction of the posterior-superior wall of the external auditory canal to protect the ear from water) [1–3].

The aim of ossiculoplasty is to reconstruct the sound-conducting system in the ear to the best possible degree after the elimination of pathological lesions from the middle ear. This philosophy of treatment offers a chance to improve hearing without lesions after otosurgery. The ossicular chain is reconstructed with the use of the patient’s own properly modelled ossicles and synthetic prostheses. The patient’s own tissues are an acknowledged material for use in otosurgery [4–6].

The use of artificial prostheses depends on the experience of the medical centre and the accessibility of this material.

It must be borne in mind that the artificial prosthesis cannot come into direct contact with the tympanic membrane graft after the ossicular chain reconstruction, as it may lead to the perforation of the membrane. To prevent this, a strip of cartilage is placed between the prosthesis and the material used to reconstruct the tympanic membrane.

Depending on the degree of damage to the ossicular chain, total ossicular replacement prostheses (TORP) or partial ossicular replacement prostheses (PORP) are used. In the latter case the prosthesis is placed between the head of the stapes and the tympanic membrane, provided that the tympanic membrane is protected with a strip of cartilage [7,8].

For the past decade the Jagiellonian University’s Otolaryngological Teaching Hospital in Cracow has been carrying out international research work as part of “The Otology Audit Group” project. The project has involved research into best practices in tympanoplasty. To achieve the best possible reconstruction of the sound-conducting system in the middle ear, innovative methods and materials have been used in the surgical procedures. One such innovation is the application of the ventilation tube, the use of which is a standard practice in the treatment of secretory otitis media (typically in our department we use a ventilation tube of 0.9 mm in inner diameter, made by Mikolow, Poland) (Figure 1). Typically attached to the tympanic membrane, the tube facilitates proper ventilation and drainage of the middle ear cavity and, in consequence, creates favorable conditions for the auditory tube to resume its normal function.

The material used to produce ventilation tubes has been approved for use in the middle ear surgery and has undergone the standard testing procedures for prostheses made without the use of biomaterials; ventilation tubes have since long been used as typical otosurgical materials worldwide. As a non-standard application, the ventilation tube can be used for the reconstruction of the ossicular chain, especially when the normally mobile stapes has been preserved and the malleus and the incus have not. Many years of experience have shown that the surface of the ventilation tube is highly resistant to the formation of biofilm and the subsequent rejection of the tube by the body. Given its shape and size, the ventilation tube is naturally predisposed to be stably fixed onto the head of the stapes. The above procedure permits the reconstruction of the ossicular chain, consisting of 2 vibrating elements, namely the stapes and the ventilation tube fixed onto it as a PORP (Figure 2). The subsequent procedure – the reconstruction of the tympanic membrane and the securement of the membrane with a strip of cartilage placed between it and the ventilation tube – does not differ from comparable treatments in which a PORP is used. Isolated cases of a similar use of the ventilation tube have been described in the
literature [9]. The adverse effects of using a material of non-biological origin in ossiculoplasty are the same as for other types of PORPs and TORPs.

All the experiments reported in this manuscript were conducted in accordance with the recommendations of IASP and the NIH Guide for the Care and Use of Laboratory Animals and were reviewed and accepted by the local Bioethics Committee.

The objective of the study was to assess the degree of hearing improvement following tympanoplasty, including in patients for whom a ventilation tube was used as a PORP.

Material and Methods

A prospective analysis was carried out that included patients operated on due to middle ear conditions between 2009 and 2012. The patients operated on for the first time due to chronic otitis media were selected for the analysis. The assessment of hearing improvement after the surgery was based on tonal audiometry carried out after 6 and 12 months following tympanoplasty and compared with the results of the test carried out immediately before the surgery. Hearing improvement was assessed on the basis of changes to the average air-bone gap (ABG) as the arithmetic mean for the frequencies of speech: 500 Hz, 1000 Hz, and 2000 Hz. The results were statistically analyzed.

Results

A group of 387 patients underwent otosurgery in the analyzed time span; 134 patients were operated on due to otosclerosis, in 241 cases the surgery was required due to chronic otitis media, and in the remaining cases surgical treatment of the middle ear was necessary because of a tumor, damage, or inborn defect of the ear.

There were 147 patients who underwent otosurgery due to chronic otitis media for the first time. In these patients, the perforation of the tympanic membrane was observed along with the abnormalities of the middle ear mucous (Figure 3).

Damage to the ossicular chain was observed during the course of surgical treatment in 78 patients. In the majority of cases the damage affected the anvil (Figure 4).

Further analysis was concerned with the patients who had a vibrating element in the form of a modelled anvil or a ventilation tube attached to the preserved and normally mobile stapes.

Since the lesions of the middle ear mucous in the patients with reconstruction based on their modelled anvil were diverse, 2 basic groups were defined: patients with cholesteatoma and patients with granulation tissue.

The obtained results were compared with the results observed in the patients who underwent reconstruction with the use of a ventilation tube placed on the stapes in the course of simple chronic otitis media. To prevent perforation of the tympanic membrane, a strip of cartilage was routinely added between the ventilation tube and the tympanic membrane (Table 1).

The effectiveness of treatment was measured in terms of the closure of the air-bone gap (ABG) as referred to the applied method of reconstruction of the ossicular chain.

The analysis of hearing improvement in the designated groups revealed the following interdependencies.
Statistically significant changes pointing to the effectiveness of treatment were observed in group 1. The average value of ABG after 12 months was smaller than the average value of ABG at the beginning of treatment and statistically equal to the average value of ABG after 6 months, while the average value of ABG after 6 months was significantly smaller than the average value of ABG at the beginning of treatment. In accordance with the philosophy behind ossiculoplasty, the elimination of cholesteatoma lesions and the successive type 2 tympanoplasty achieved satisfactory results in the form of hearing improvement.

In group 2 significant changes (the closure of the average value of ABG) were not observed over time. The group consisted of patients with damaged ossicular chain and granulation. Although the performed reconstruction was similar to that in the patients with cholesteatoma (group 1), significant hearing improvement was not observed.

The use of a ventilation tube (group 3) to reconstruct the continuity of the ossicular chain resulted in a statistically significant change of the average value of ABG ($p=0.046$) as early as after 6 months following otosurgery, proving it justifiable to use this material as a PORP in selected cases. The comparison of the results obtained after 6 and 12 months following otosurgery did not reveal significant discrepancies, showing that the improved hearing effect was maintained during the successive checks (Table 2).

Another stage of the analysis consisted in dividing the results of otosurgical procedures into satisfactory and unsatisfactory depending on the average value of ABG (as the average for 500 Hz, 1000 Hz, and 2000 Hz). Table 3 shows the otosurgery evaluation criteria according to which the particular procedures were classified into either of the above categories.

The multi-way contingency tables were analyzed to determine whether the results obtained in the test groups changed with

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Table 1. Analyzed groups of patients with type 2 tympanoplasty.

| Group | N  |
|-------|----|
| 1     | 12 |
| 2     | 22 |
| 3     | 13 |

| Type of reconstruction | Result of otosurgery |
|------------------------|----------------------|
| Ventilation tube/remodeled incus put on intact, mobile stapes | Satisfactory: ≤30 dB, Unsatisfactory: ≥31 dB |

Table 2. Average Air Bone Gap (ABG) in analyzed patients’ groups before surgery and 6 and 12 months after surgical treatment.

| Time (months) | X gr. 1 | SD gr. 1 | X gr. 2 | SD gr. 2 | X gr. 3 | SD gr. 3 |
|---------------|---------|----------|---------|----------|---------|----------|
| 0             | 31.87   | 10.58    | 27.35   | 9.37     | 33.28   | 11.25    |
| 6             | 19.79   | 6.23     | 26.51   | 10.79    | 25.98   | 6.83     |
| 12            | 19.31   | 7.33     | 27.35   | 12.63    | 25.33   | 7.39     |

SD – standard deviation.

Table 3. Effectiveness of otosurgery as average ABG (air bone gap) measured after surgical treatment for speech frequencies (as average for 500 Hz, 1000 Hz and 2000 Hz).

| Type of reconstruction | Result of otosurgery |
|------------------------|----------------------|
| Ventilation tube/remodeled incus put on intact, mobile stapes | Satisfactory: ≤30 dB, Unsatisfactory: ≥31 dB |

Table 4. Average ABG (air bone gap) as a percentage of satisfactory and unsatisfactory results in group 1.

| Time                        | Satisfactory (%) | Unsatisfactory (%) |
|-----------------------------|------------------|--------------------|
| Before surgery              | 58               | 42                 |
| 6 months after surgery      | 100              | 0                  |
| 12 months after surgery     | 92               | 8                  |

Table 5. Average ABG (air bone gap) as a percentage of satisfactory and unsatisfactory results in group 3.

| Time                        | Satisfactory (%) | Unsatisfactory (%) |
|-----------------------------|------------------|--------------------|
| Before surgery              | 38               | 62                 |
| 6 months after surgery      | 85               | 15                 |
| 12 months after surgery     | 77               | 23                 |

Statistically significant changes pointing to the effectiveness of treatment were observed in group 1. The average value of ABG after 12 months was smaller than the average value of ABG at the beginning of treatment and statistically equal to the average value of ABG after 6 months, while the average value of ABG after 6 months was significantly smaller than the average value of ABG at the beginning of treatment. In accordance with the philosophy behind ossiculoplasty, the elimination of cholesteatoma lesions and the successive type 2 tympanoplasty achieved satisfactory results in the form of hearing improvement.

In group 2 significant changes (the closure of the average value of ABG) were not observed over time. The group consisted of patients with damaged ossicular chain and granulation within the middle ear. Although the performed reconstruction was similar to that in the patients with cholesteatoma (group 1), significant hearing improvement was not observed.

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| Time                        | Satisfactory (%) | Unsatisfactory (%) |
|-----------------------------|------------------|--------------------|
| Before surgery              | 58               | 42                 |
| 6 months after surgery      | 100              | 0                  |
| 12 months after surgery     | 92               | 8                  |

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| Before surgery              | 38               | 62                 |
| 6 months after surgery      | 85               | 15                 |
| 12 months after surgery     | 77               | 23                 |
time. When the results changed significantly, the percentage of patients in the satisfactory and unsatisfactory groups was presented after 0, 6, and 12 months from otopsurgery into satisfactory and unsatisfactory groups on the basis of the inclusion criteria (Table 3).

A significant hearing improvement over time after otopsurgery was observed in group 1, where the number of satisfactory results rose from 58% before otopsurgery to 92% at 12 months after surgical treatment. In this group, 42% of the results were unsatisfactory prior to treatment and the percentage decreased to 8% after treatment (Table 4).

In group 2, we found no significant hearing improvement in the closure of cochlear reserve during the 12-month observation following otopsurgery.

The use of a ventilation tube as a PORP (group 3) resulted in a significant hearing improvement. The percentage of patients in the group of satisfactory results defined according to the assumed criteria changed from 38% before treatment to 77% after a year-long observation of these patients (Table 5).

**Discussion**

In the cases of patients with cholesteatoma classified into group 1, their own modelled ossicles were placed on the stapes after eliminating the pathological process. When performed at a relatively early stage, the treatment stopped the pathological process that damaged the ossicular chain and was followed by ossiculoplasty, resulting in significant hearing improvement in the patients with chronic cholesteatoma otitis media.

According to data in the literature, confirmation that the superstructure of the stapes is normal after the cholesteatoma lesions have been eliminated, and the subsequent reconstruction of the ossicular chain by placing the patient’s own modelled ossicle on the head of the stapes, results in hearing improvement in nearly a half of the patients [2–6]. Among the analyzed patients, the improvement was significantly greater in the group with cholesteatoma than in the cases where the ossicular chain was damaged to a comparable degree, but the damage co-occurred with other pathological changes to the middle ear mucous. The same conclusions were reported by other authors, especially in the context of the unfavorable effect of granulomatous lesions in the middle ear on hearing improvement [1,2,7,8,10].

After both 6 and 12 months, significant hearing improvement was also noted in the group of patients where the reconstruction was based on a ventilation tube placed on the head of the stapes. This original method of restoring the continuity of the ossicular chain applied at the Otolaryngological Teaching Hospital of the Collegium Medicum at the Jagiellonian University of Cracow turned out to be a good alternative for the patients whose own modelled ossicles cannot be used due to the scope of damage done to the ossicular chain by the pathological process. The use of this generally available and relatively inexpensive material as a PORP is competitive with other solutions. The ABG closure obtained in this group is comparable to the results obtained by other authors using PORP [11–15]. The use of the ventilation tube as a PORP is an innovative method of reconstructing the ossicular chain.

The significant discrepancies between the average values of ABG for the particular groups are closely linked to the advancement of the pathological process in the middle ear and the possibility of the subsequent reconstruction of the sound-conducting apparatus. In the majority of cases the degree of hearing impairment observed before treatment has a statistically significant link with the condition of the tympanic membrane and the ossicular chain. Judging from the degree of damage to the conductive apparatus in the middle ear, preliminary prognosis is made as to the improvement of hearing after the surgery [16–20].

The differences observed after 6 and 12 months reflect the impact of the reconstruction on the functional improvement of the middle ear. These differences expose the limitations of tympanoplasty in terms of restoring normal functionality of the ossicular chain. The obtained degree of ABG closure verifies the earlier hearing improvement prognoses based on the advancement of the pathological process in the middle ear.

Simple chronic otitis media is characterized by having relatively little damaging effect on the ossicles. Greater damage is observed in the cases of cholesteatoma or granulation tissue in the middle ear. As compared to the group of patients with cholesteatoma, the patients with a predominance of granulomatous lesions did not have their hearing improved to a statistically significant degree after their ossicular chains were reconstructed using the same method. This observation coincides with reports in the literature that hearing improvement in patients with simple chronic otitis media reaches 80%, while in the course of granulomatous lesions it is about 50%. In the cases of cholesteatoma, the hearing level is maintained or improved after the surgery in about 90% of the patients. The above information regarding chronic granulomatous otitis media point to the necessity of non-invasive treatment in the period preceding the surgery, which would be aimed at obtaining “dry ear”. The elimination of otorrhea and an improvement of the condition of the mucous lining the ear have a significant effect on achieving better results of the surgical treatment [21–25].
Conclusions

1. The patient’s own modelled ossicle is a good and acknowledged material in ossiculoplasty.
2. A ventilation tube used as a PORP is an effective alternative in the reconstruction of the ossicular chain.
3. In patients with cholesteatoma and minor damage to the ossicular chain, a significant hearing improvement is observed after ossiculoplasty.
4. The occurrence of granulomatous lesions is an unfavorable factor in the prognosis of patients with chronic otitis media.

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