Retrospective analysis of tympanoplasty in children with cleft palate. A 24-year experience.

Doctoral (Ph.D.) thesis

Gábor Kopcsányi

Department of Pediatrics
University of Pécs Medical School

University of Pécs, Faculty of Health Sciences
Doctoral School of Health Sciences
Head of the Doctoral School of Health Sciences: József Bódis M.D., Ph.D., D.Sc.
Programme leader: Prof. Gábor Kovács L., academician
Tutor: József Pytel M.D., Ph.D.
Co-Tutor: László Lujber M.D., Ph.D.

Pécs, 2015

Introduction

According to our current view, the modern treatment of mesotympanic chronic suppurative otitis media and middle ear cholesteatoma is tympanoplasty. Tympanoplasty allows for the establishment of air-tight middle ear cleft and a novomembrane capable of vibration after healing.

In mesotympanic processes this procedure and the reconstruction of the ossicular chain can be performed either simultaneously or in separate sessions.

We always schedule a two-stage surgery in patients with cholesteatoma after a discussion with the patients and their parents. The first stage is sanation and tympanic membrane reconstruction. Normally the second stage involves revision (residual cholesteatoma removal if necessary) and ossicular chain reconstruction.

In both cases the aim is to achieve a dry, potentially 'swim-proof' ear, to improve or at least preserve hearing, to eliminate chronic purulence or cholesteatoma as well as to protect the neural structures of the inner ear from the further damaging effects of these noxae and potentially prevent recurrence.

There are two common types of surgery of cholesteatomas. The closed technique (canal wall-up tympanomastoidectomy, CWU TM) aims to preserve the posterior bony canal wall thus creating anatomical conditions that are similar to normal („swim-proof" ear). The open technique (canal wall-down tympanomastoidectomy, CWD TM) involves the removal of the posterior bony canal wall, as a result of which the mastoid area remains open towards the external auditory canal. This allows for the easier inspection of the mastoid cavity lined with keratinizing squamous epithelium on ear examination. The author does not use obliteration technics and cartilage tympanoplasty preferred by other authors.

For good postoperative hearing results it is crucial to maintain the air content of the residual or complete middle ear cleft by preserving automatic Eustachian tube function, or if it is not possible, by ventilation tube (grommet) insertion providing adequate middle ear pressure.

In children, maintaining the constant atmospheric pressure of the middle ear is of outstanding importance due to their frequent upper respiratory tract catarrhs. Certain craniofacial anomalies directly affecting the opening mechanism of the Eustachian tube particularly complicate the situation. The most expressed examples of this problem are the different forms of cleft palate and the conditions associated with velopharyngeal insufficiency (VPI).

We should not forget that one of the most significant pathogenetic factors of different chronic otitis processes (mesotympanic and cholesteatomatous) is Eustachian tube dysfunction. It is no wonder that cholesteatoma is much more common in children with cleft palate than in the healthy population (1.8-9.2% vs. 0.003-0.006%).

Contradictory data have been published on the outcomes of ear surgery in cleft patients. Earlier studies mention poor results of tympanoplasty in these patients, while a relatively low number of more recent studies reflect a more optimistic view.

1.1. Objectives

The aim of this work is to investigate whether there are differences in the short and long term outcomes of tympanoplasty performed due to childhood chronic mesotympanic otitis media and cholesteatoma in patients without (NoCleft) and with cleft palate (Cleft). Earlier studies mention poor results of tympanoplasties in these patients, while a relatively low number of more recent studies reflect a more optimistic view.

The outcomes of tympanoplasty of pediatric patients with mesotympanic chronic suppurative otitis media and cholesteatoma are separately discussed because the course of these sicknesses is totally different, however the surgical solution – tympanoplasty – is technically alike.

This study analyses the author's (G.K.) data on pediatric tympanoplasty.

2. Materials and methods

2.1. Mesotympanic processes

Since 1996 the author has performed the surgeries of 'Cleft' patients in the frameworks of the 'Cleft Lip and Palate Team' founded in the same year at the Department of Pediatrics, University of Pécs Medical School. The team is currently responsible for the care of more than 600 cleft patients.

We analysed the surgical data and hearing test results of all the patients ('NoCleft' and 'Cleft') who were operated on due to chronic mesotympanic otitis media between 17th July, 1990 and 30th October, 2012 at the Division of Otorhinolaryngology, Department of Pediatrics, University of Pécs Medical School.

The author performed 190 tympanoplasties on 140 patients' 171 ears with chronic mesotympanic otitis media. He underlines the importance of the potentially preoperative restoration of Eustachian tube function.

He has always applied uniform surgical techniques. He has performed the reconstruction of the tympanic membrane with underlaid fascia grafts in all cases mostly using the aponeurosis of the temporal muscle.

The author does not fear from skin elevation in the region of the pretympanic sinus. Therefore this fascia flap can be pushed forward almost until the border of the anterior quadrants and it can be laid on the neighbouring bony ear canal wall. Normally the surgeon creates one single tunnel in the anterior-superior quadrant which allows for 'pull-back'. Mastoidectomy was performed in nearly all cases. Ossicular chain reconstruction was carried out with autogenous cortical bone columellae in all cases according to the methods described by Bauer.

Ventilation tube (grommet) insertion was always carried out when necessary depending on the results of microscopic and audiological examinations, irrespective of previous operations on the ear and the presence of cleft palate.

2.2. Cholesteatomatous cases

We retrospectively analysed the author's 24-year experience of pediatric tympanoplasty on ears with cholesteatoma (17 July 1990 - 10 March 2014; Division of Otorhinolaryngology, Department of Pediatrics University of Pécs Medical School).

During the period mentioned above, 303 tympanoplasties were performed on 192 ears with cholesteatoma in 170 children. In our present study we analysed the surgical and hearing test data of all 'Cleft' and 'NoCleft' patients with cholesteatoma. No patient selection was applied. The rate of assessable audiological results only depended on whether the patients showed up at an appropriate number of follow-up visits or not.

The surgeon has followed the doctrines of the school of ear surgery marked by the name of Professor Bauer. He aims to apply uniform surgical techniques, which basically means closed techniques. In cholesteatomatous cases he applies combined transcanal-transmastoid approach. The author does not perform reconstruction on the lateral wall of the atticus with bone or cartilage since he does not believe that these could resist the persistent decrease in the pressure of the tympanic cavity. The reconstruction of the tympanic membrane and the removed lateral bony atticus wall is carried out with temporal fascia flap, but always with 'underlay' technique and with the application of 'pull-back' technique, if necessary (Bailey, 1976).

Ossicular chain reconstruction is carried out with autogenous cortical bone columellae (ACBC) according to the methods described by Bauer. The surgeon always schedules a two-stage surgery in patients with cholesteatoma after a discussion with the parents.

2.3. Methods of audiological analysis

József Pytel developed a computer programme for the detailed analysis of tympanoplasty outcomes and statistical data processing (Pytel SoftWare 2003). According to current guidelines, pure-tone averages were calculated by averaging the thresholds for pure tones at 0.5, 1, 2 and 3 kHz.

2.4. Methods of statistical analysis

In most cases, the statistical comparison of the identical data of the two patient groups was performed with Student *t*-test (Microsoft Excel Software). When no sufficient number of data was obtained, Mann-Whitney-Wilcoxon test was used (SPSS Software). Ratio analyses were carried out with large-sample 'z' and small-sample 'chi-square' (χ^2) tests.

3. Results

3.1. Surgical outcomes of mesotympanic processes

During the previously mentioned 22 years, 190 tympanoplasties were performed due to mesotympanic processes (140 patients, 171 ears). Out of this, 159 tympanoplasties were performed in the 'NoCleft' group (119 patients, 144 ears) and 31 tympanoplasties in the 'Cleft' group (21 patients, 27 ears). The average age of the patients was 10.8±3.8 (3.3-21.3) and 10.7±3 (4.7-16) years respectively. Female patients were more represented in both groups, which means 80 female and 64 male ears in the 'NoCleft' and 16 female and 11 male ears in the 'Cleft' group. 25 'NoCleft' and 6 'Cleft' patients required surgeries on both sides.

The graft take rate was 100%. Reperforation occurred in altogether 6 mesotympanic cases (3.5%) with the same distribution in the 'NoCleft' and 'Cleft' groups (5 and 1).

Among all 'NoCleft'mesotympanic cases, intraoperative grommet insertion was considered necessary in only one case. In the 'Cleft' group, intraoperative grommet insertion was necessary in 2 cases and postoperative grommet insertion was required in further 2 ears of all patients.

Short type columella ossiculoplasty was performed in 21 'NoCleft' and 4 'Cleft' patients during their primary surgery.

Due to unsatisfactory hearing improvement, short type columella ossiculoplasty was carried out in 4 'NoCleft' and 1 'Cleft' cases during a second session. A third surgery was required to achieve further hearing improvement in 2-2 cases due to fixation or columella atrophy. Long type columella ossiculoplasty had to be performed on 3 'NoCleft' ears. No long type columella ossiculoplasty was carried out in our 'Cleft' patients with mesotympanic process therefore no comparison can be made in this respect.

3.1.1. Audiological analysis of mesotympanic processes

In regards to hearing gain, the postoperative ABG is considered to be the most important indicator since it reflects the success or failure of our surgical intervention.

3.1.1.1. Total mesotympanic material

The average ABG improvement considering the best postoperative values was 16.54 dB in our mesotympanic material**.** The average preoperative ABG of 28.8 ±10.92 dB improved to 12.26 ±7.66 dB after the surgery. The average postoperative ABG deteriorated by 2.87 dB with time and the last measured average postoperative ABG was 15.13±9.81 dB.

Considering our best postoperative outcomes, ABGs below 20 dB were achieved in 86% of the cases evaluated, with the average follow-up period being 1.6 years. Taking into account the deterioration of average ABGs, this value was 79% at the last measurements. The average follow-up period of these measurements was 3.6 years (best/last percentages of ABGs below 20dB and corresponding average follow-up periods: ABG<20dB=86/79%, average follow- up period: 1.6/3.6 years) **(see Table 1)**.

	Number of operated ears	Number of evaluated ears (%)	Preop.' ABG (dB)	Best 'postop.' AGB (dB)	Maximum improvement (dB)	Last 'postop.' ABG (dB)	Final improvement (dB)	Postop.' best/last deterioration (dB)	ABG<20dB best/last (%)	Average follow-up period best/last (years)
Mesotymp. altogether	171	125 (73)	**28,8** ±10,92	12,26 ±7,66	16,54	**15,13** ±9,81	13,67	**2,87**	86/79	1,6/3,6
NoCleft altogether	144	101 (70)	**28,76** ±10,46	12,78 ±7,47	15,98	**15,59** ±9,5	13,17	**2,81**	86/78	1,5/3,4
Cleft altogether	27	24 (89)	**28,94** ±12,67	10,04 ±8,09	18,9	**13,19** ±10,81	15,75	**3,15**	87/83	1,9/4,4
NoCleft type I	120	83 (69)	**26,21** ±9,21	11,94 ±6,65	14,27	**14,39** ±8,96	11,82	**2,45**	87/80	1,4/3,2
Cleft type I	23	18 (78%)	**24,16** ±10,82	9,76 ±8,29	14,4	**13,14** ±11,6	11,02	**3,38**	88/82	2/4,3
NoCleft type II	21	19 (90%)	**40.37** ±8,32	14,38 ±5,76	25,99	**19,18** ±9,37	21,19	**4,8**	83/67	3/5,2
Cleft type II	4	4 (100)	**36,5** ±11,12	7,25 ±1,47*	29,25	**11,71** ±3,26	24,79	**4,46**	100/100	1,2/8,2

Table 1. (mesotympanic processes). *The horizontal lines indicate the examined groups, the vertical lines denote the examined parameters (NoCleft=without cleft palate; Cleft=with cleft palate; type I=intact ossicular chain, type II=short type stapes head-tympanic membrane columella). In the majority of cases, no significant difference was found between the identical parameters of the two groups except for the cases marked with a star (*) referring to cleft patients with short type columella ossiculoplasty, where their best postoperative ABG was significantly better than that of the 'NoCleft' group.*

3.1.1.2. Comparison ("NoCleft" / "Cleft"

In the following section these parameters are discussed separately in the 'NoCleft' and 'Cleft' groups in this order for better comparison.

Statistically comparing the above-mentioned identical data of the 'NoCleft' and 'Cleft' groups, we came to the following conclusions **(see Table 1)**.

There was no significant difference between the two groups in the preoperative ABG (p=0.468), nor in the best postoperative ABG achieved (p=0.096). Similarly, the statistical analysis did not reveal any significant difference in the last postoperative ABGs measured (p=0.192) or the final improvement (p=0.253). Empirical evidence suggests that hearing results deteriorate by some decibels even after successful tympanoplasty. Theoretically, we would expect more expressed postoperative deterioration in 'Cleft' patients due to their vulnerable Eustachian tube function. However, the statistical analysis of our data mentioned above did not reveal any significant difference in the extent of postoperative deterioration between the two groups (p=0.376).

3.1.1.3. Separate analyses (intact ossicular chain / columella ossiculoplasty)

Our results were also analysed from the aspect of tympanoplasty, whether it was performed with intact ossicular chain or with columella ossiculoplasty.

3.1.1.3.1. Intact ossicular chain

Surgeries with intact ossicular chain (type I) were performed on 120 'NoCleft' and 23 'Cleft' ears **(see Table 1).**

Statistically comparing the identical data of the two groups, no significant difference was revealed in any of the parameters. No significant difference was revealed between the two groups in preoperative ABGs (p=0.187), in the maximum postoperative improvement (p=0.226), in the last measured ABGs (p=0.387), or in the final improvement (p=0.257). Postoperative deterioration did not show any significant difference between the two groups, either (p=0.307).

3.1.1.3.2. Columella ossiculoplasties ("short type")

The following section summarizes the outcomes of columella ossiculoplasties. We have already mentioned that no long type columella ossiculoplasty was performed in 'Cleft' patients with mesotympanic processes therefore we can only compare the outcomes of short type columella ossiculoplasties in the two groups.

Short columella ossiculoplasty was performed on 21 'NoCleft' ears and 4 'Cleft' ears due to mesotympanic processes **(see Table 1)**.

No significant difference was revealed in the preoperative ABGs of the two groups (p=0.766). However, there was a significant difference between the two groups in the best postoperative ABGs (p=0.021) with the better results measured in the 'Cleft' group. This is extremely surprising and it can be attributed to the exceptionally successful tympanoplasties of 'Cleft' patients (altogether 4 short columella ossiculoplasties, out of which 2 were performed in the same patient) and to their strict postoperative follow-up.

No significant difference was revealed in the last postoperative ABGs (p=0.088), in the final improvement (p=0.349) or in the extent of postoperative deterioration (p=0.427) between the two groups.

3.2. Surgical outcomes of middle ear cholesteatomas

During the previously mentioned 24 years 303 tympanoplasties were performed on 192 ears with cholesteatoma in 170 patients. In the 'NoCleft' group, 268 surgeries on 172 ears of 151 patients and in the 'Cleft' group 35 surgeries on 20 ears of 19 patients were performed. The average age of the patients was 10.7 ± 3.6 years (2.4 – 19.5 years) and 9.5 ± 2.7 years (5.5 – 13.7 years) respectively.

Male patients were more represented in both groups: 105 male and 67 female ears and 12 male and 8 female ears, respectively (the sex ratio was the opposite in our mesotympanic material). Bilateral surgery due to cholesteatoma was necessary in 21 and 1 patients, respectively.

The graft take rate of the fascia used for reconstruction was 100%. Small postoperative perforation only developed in 1 'NoCleft' patient.

In patients with cholesteatoma, grommet insertion was necessary in 9 ears in the 'NoCleft' group (3 intra- and 6 postoperative), which means 5% and in 8 ears in the 'Cleft' group (6 intra- and 2 postoperative) accounting for 40%. This means a significant, 8-fold difference in the ratios between the two groups (p=0,00000068; p≈0).

No significant differences were found between the two groups considering the starting point of the cholesteatoma. Apart from 7 congenital cholesteatoma cases in the 'NoCleft' group, in the majority of cases (113 ears) the orifice of the cholesteatoma was found in the posterior-superior quadrant of the pars tensa, while in 52 ears the starting point of the cholesteatoma was epitympanic. In the 'Cleft' group the cholesteatoma developed from the posterior-superior quadrant in 15 ears and from the epitympanum in 5 ears (p=0.230). This corresponds to the previously published data: pars tensa is a more common starting point for cholesteatoma in children, while in adults, epitympanic development from the pars flaccida is more frequent.

As for the extension of the cholesteatoma found during the first surgery, advanced progression with expansion to the atticus and antrum was more common in 'Cleft' patients. In the 'NoCleft' group cholesteatoma was limited to the windows and their surroundings, the retrotympanum and its recesses in 70 ears. Isolated atticus cholesteatoma was found in 9 ears; cholesteatoma compromising the atticus and the tympanic cavity was found in 24 ears; cholesteatoma affecting the antrum, the tympanic cavity and the atticus was revealed in 23 ears and cholesteatoma affecting the mastoid area apart from the areas mentioned above was found in 46 cases. The numbers of cases in the 'Cleft' group were 4; 1; 3; 7 and 5 in the same order of extension.

Although parents gave their approval to the two-stage surgery, only 83 of 172 'NoCleft' ears underwent the second surgery (48%) due to parental indolence. Reoperation was performed in 13 cases, mainly columella ossiculoplasties due to unsatisfactory hearing improvement (displacement or atrophy of the previous columella) or to gain a safety inspection (residual cholesteatoma in stage II).

Residual cholesteatoma was found in 32 cases during the new exploration (stage II, reoperation), small pearl-like lesions were seen in 30 cases and large residual cholesteatoma in 2 cases. This means a residual cholesteatoma ratio of 33% regarding repeated middle ear explorations and 18.6% regarding the total number of ears. Recurrent cholesteatoma was found and treated in 5% of patients undergoing a new exploration (5 cases) and in 3% of all ears.

Stage II surgeries were performed on 12 of 20 ‘Cleft’ ears (60%) and 3 ears underwent reoperation due to unsatisfactory hearing improvement or recurrent cholesteatoma. The rate of residual cholesteatoma was 27% in ‘Cleft’ patients (pearl-like lesions were found in 4 cases during the new exploration). This means a rate of 20% regarding all ‘Cleft’ ears with cholesteatoma. In the ‘Cleft’ group, recurrent cholesteatoma was found in 13% (2 cases), which necessitated the conversion to open technique (recurrent cholesteatoma developed in 10% of all ears).

The results clearly show the explicit difference in the rate of recurrent cholesteatoma between the two groups: the incidence is almost threefold in the ‘Cleft’ group (5% versus 13%); (p=0,219).

As mentioned earlier, we are basically dedicated to closed techniques. However, we had to apply open techniques on 2 ears in the ‘NoCleft’ group due to cholesteatoma affecting the area of the semicircular canals and spreading below the facial canal close to the apex of the mastoid process. There was no hope for the complete removal of the matrix in these areas.

In the ‘Cleft’ group, we had to apply or convert the surgery to open techniques in 3 cases. This was due to extensive cholesteatoma associated with significant sensorineural hearing loss in one case, while in two cases the reason for resorting to open technique was recurrent cholesteatoma developing due to uncontrollable Eustachian tube dysfunction.

The necessity for open technique showed significant differences between the two patient groups (2/172 and 3/20); (chi-square test: p=0.000069; p≈0).

3.2.1. Audiological analysis of cholesteatomas

The most important indicator of hearing outcomes is considered to be the air-bone gap (ABG). ABG reflects the success or failure of our interventions. ‘Pytel Software’ used for data analysis only evaluates ears with the appropriate number of audiograms.

3.2.1.1. Total cholesteatoma material

Maximum postoperative hearing improvement was 14.75 dB in our total cholesteatoma material. The average preoperative ABG of 31.7 ± 12.21 decreased to 16.95 ± 11.73 dB. According to the general experience, the audiological outcomes of tympanoplasty deteriorate by some dBs over the years. In our material the average ABG was 20.07 ± 13.27 on the last measurements. This means an average improvement of 11.63 dB compared to the preoperative values so far. Average ABG deterioration with time was 3.12 dB. Considering the best postoperative results, an air-bone gap of less than 20 dB was achieved in 75% of the cases. The average follow-up time was 2.2 years. On the last measurements, this value was 66% calculating the deterioration of average ABG values below 20 dB. The average follow-up time of the last measurements was 4 years (the rate of best/last ABG values below 20 dB and the respective follow-up times: ABG<20 dB=75/66%; average follow-up time: 2.2/4 years) **(see Table 2)**.

	Number of operated ears	Number of evaluated ears (%)	Preop.' ABG (dB)	Best 'postop.' AGB (dB)	Maximum improvement (dB)	Last 'postop.' ABG (dB)	Final improvement (dB)	Postop.' best/last deterioration (dB)	ABG<20dB best/last (%)	Average follow-up period best/last (years)
Cholest. altogether	192	145 (76)	**31,7 ±12,21**	16,95 ±11,73	14,75	**20,07 ±13,27**	**11,63**	**3,12**	75/66	2,2/4
NoCleft altogether	172	126 (73)	**31,22 ±12,12**	17,04 ±11,91	14,18	**19,93 ±13,27**	**11,29**	**2,89**	74/66	2,4/4
Cleft altogether	20	19 (95)	**34,88 ±12,34**	16,4 ±10,4	18,48	**20,98 ±13,21**	**13,9**	**4,58**	83/67	1,3/4,1
NoCleft type I	61	43 (70)	**23,88 ±10,68**	11,83 ±6,9	12,05	**13,21 ±6,33**	**10,67**	**1,38**	92/90	1,4/2,3
Cleft type I	5	5 (100)	**29,85 ±7,16**	13,62 ±4,92	16,23	**15,97 ±5,47**	**13,88**	**2,35**	100/80	0,6/1,9
NoCleft type II	59	50 (85)	**32,88 ±11,54**	14,69 ±7,97	18,19	**17,98 ±9,8**	**14,9**	**3,29**	80/70	2,6/4,6
Cleft type II	11	11 (100)	**35,57 ±14,34**	12,77 ±5,18	22,8	**17,51 ±11,22**	**18,06**	**4,74**	90/81	1,8/3,8
NoCleft type III	25	22 (88)	**37,56 ±8,57**	23,65 ±14,14	13,91	**30,27 ±15,87**	**7,29**	**6,62**	54/31	2,3/4,2
Cleft type III	2	2 (100)	**36,12 ±4**	27,12 ±8,5	9	**38,75 ±7**	**-2,63**	**11,63**	50/0	0,6/13,3
NoCleft Columell.	84	72 (85)	**34,61 ±11,15**	17,76 ±11,32	16,85	**21,82 ±13,39**	**12,79**	**4,06**	70/57	2,5/4,5
Cleft Columell.	13	13 (100)	**35,66 ±13,28**	14,98 ±7,89	20,68	**20,77 ±13,17**	**14,89**	**5,79**	83/68	1,6/5,2

Table 2 (cholesteatoma). *The horizontal rows refer to the examined groups, the columns contain the examined parameters (‘NoCleft’: without cleft plate; ‘Cleft’: with cleft palate; type I: intact ossicular chain; type II: short-type, stapes head – tympanic membrane columella; type III: long-type, stapes footplate – tympanic membrane columella; Columell.: any columella type). Significant difference cannot be revealed in the identical audiological values of the two groups.*

3.2.1.2. Comparison (“NoCleft” / “Cleft”)

The same parameters are discussed below separately in the same order in the ‘NoCleft’ and ‘Cleft’ groups for better comparison **(see Table 2)**.

The statistical comparison of the data of the two groups revealed the following results. There was no significant difference in preoperative ABGs (p=0.058) or in the best postoperative ABGs (p=0.499). Similarly, no significant difference was revealed between the two groups in the last postoperative ABGs measured (p=0.298) or in the final hearing improvement (p=0.193). As mentioned earlier, hearing outcomes deteriorate by some dBs with time even after successful tympanoplasty. Theoretically, we would assume that this deterioration is more expressed in patients with cleft palate due to their vulnerable Eustachian tube function. However, the statistical analysis of our data did not reveal any significant difference between the two groups in the extent of postoperative ABG deterioration (p=0.117).

3.2.1.3. Separate analyses (intact ossicular chain / columella ossiculoplasty)

We performed separate analyses of tympanoplasties with intact ossicular chain and the surgeries including short- or long-type columella ossiculoplasty.

3.2.1.3.1. Intact ossicular chain

Altogether 61 ‘NoCleft’ ears were operated on with intact ossicular chain, out of which 43 ears had enough follow-up audiograms for software evaluation. Only 5 ‘Cleft’ ears were operated on with intact ossicular chain at the end of the surgery **(see Table 2)**.

The statistical comparison of the identical data did not reveal significant differences in any of the parameters: for preoperative ABG p=0.097, for postoperative ABG p=0.259, for the last ABG measured p=0.176, for postoperative ABG deterioration p=0.311, for the final improvement p=0.247.

3.2.1.3.2. Columella ossiculoplasty

The following section compares the results of surgeries with columella ossiculoplasties regardless of the type of the ossiculoplasty (short- or long-type).

Ossicular chain reconstruction was carried out in 84 ‘NoCleft’ and 13 ‘Cleft’ ears **(see Table 2)**.

The statistical comparison of the identical data of ears with columella ossiculoplasty did not reveal any significant difference in any of the parameters. For preoperative ABG p=0.278, for the best postoperative ABG p=0.271, for the last ABG p=0.458, for postoperative deterioration p=0.231 and for the final hearing improvement p=0.292.

3.2.1.3.2.1. Short type columella ossiculoplasty

We examined the results of ears with short- and long-type ossiculoplasty comparing the outcomes in the ‘NoCleft’ and ‘Cleft’ groups.

In the ‘NoCleft’ group 59, in the ‘Cleft’ group 11 short-type columella ossiculoplasties were performed **(see Table 2)**.

No significant difference was revealed in any of the parameters with statistical methods. For preoperative values p=0.184, for the best postoperative values p=0.396, for the last ABG measured p=0.256, for postoperative deterioration p=0.235 and for the final improvement p=0.376.

3.2.1.3.2.2. Long type columella ossiculoplasty

In general, the outcomes of long-type ossiculoplasty are far below those of short-type ossiculoplasty. The stapes footplate – novomembrane columella cannot physiologically replace the original chain consisting of joints. The chronic suppurative process (with or without cholesteatoma), which destroys the superstructure of the stapes, probably impairs the mobility of the stapes footplate as well. This is supported by the fact that long-type columella ossiculoplasty with stapedectomy leads to better outcomes.

Long-type columella ossiculoplasty was performed in 25 ‘NoCleft’ and only 2 ‘Cleft’ ears **(see Table 2)**.

The statistical comparison of the identical parameters did not reveal and significant difference in this respect, either. For preoperative ABG p=0.463, for the best postoperative ABG p=0.266, for the last postoperative ABG p=0.130, for postoperative deterioration p=0.181 and for the final hearing improvement p=0.419.

4. Discussion

4.1. Discussion (mesotympanic processes)

In our study, the graft take rate was 100% and the rate of reperforation was 3.5% in both groups.

No significant difference was revealed between the two groups in hearing results neither in the preoperative and best postoperative ABGs, nor in the results of the last measurements. Similarly to the data in Gardner and Dornhoffer’s study, the postoperative values of ‘Cleft’ patients were often better (although not significantly) than those of ‘NoCleft’ patients. In our study, we made a separate comparison of the final hearing results and the extent of postoperative deterioration in the two groups and the outcomes of ‘Cleft’ patients did not prove to be significantly worse in these respects, either.

We find it outstanding that after short type columella ossiculoplasties, the best postoperative ABGs of the 4 ‘Cleft’ ears were significantly better than those of the ‘NoCleft’ group. Besides the low number of columella ossiculoplasties in the ‘Cleft’ group, this can probably be attributed to their successful surgeries and strict follow-up.

The average follow-up period of our patients exceeded 3 years. Unfortunately, some of the patients did not show up at control examinations because they no longer had complaints and due to their dry ears achieved by surgery, their parents became less worried about their previously ‘runny ear’ children.

In our study, the ratio of ‘Cleft’ and ‘NoCleft’ patients was 1:5. However, only one intraoperative grommet insertion was necessary in the ‘NoCleft’ group, while in the ‘Cleft’ group, 2 intra- and 2 postoperative ventilation tube insertions were performed. Considering these ratios we can state that the necessity for grommet insertion is more likely to arise in patients with cleft palate, or at least it is in our practice ($p=0,000$; $p\approx 0$).

4.2. Discussion (cholesteatomas)

The incidence of cholesteatoma in children is 3-6/100,000 in the general population, however, in patients with cleft palate the incidence is higher, usually about 1.8-9.2%. In our material this value is 3.2%, which corresponds to the data published by Vincenti et al.

The starting point of the cholesteatoma may also explain the higher incidence of residual cholesteatoma observed in children after the surgery. It is well-known that the epitympanic starting point from Shrapnell’s membrane is more common in adults. In children, the most common starting point is the posterior-superior quadrant of the pars tensa. This creates favourable conditions for the expansion towards the windows, to the neighbouring retrotympanic area and to its recesses, which are difficult to reach surgically. We completely agree with the authors supporting the application of pre-planned two-stage surgery in the case of closed techniques. Stage II or the ‘second look’ allows for the early detection and removal of residual cholesteatoma and creates better conditions for the necessary columella ossiculoplasty.

Adequate Eustachian tube function is one of the key determinants of the success of tympanoplasty. Its absence results in invagination cholesteatoma and it is the most important factor in the development of postoperative recurrent cholesteatoma. Before surgery we must try every possible option for the restoration of Eustachian tube function.

When it cannot be ensured preoperatively, Eustachian tube dysfunction can be prevented by post- or intraoperative ventilation tube insertion.

In children with cleft palate, Eustachian tube dysfunction is considered to be the result of the abnormal insertion of the tensor veli palatine muscle. In infants with cleft palate, the incidence of insufficient Eustachian tube function is nearly 100%.

The different cleft palate repair techniques (tensor veli palatini preservation, transection and transection with tensor tenopexy) do not really influence the necessity for grommet insertion. Nevertheless, in the majority of cases Eustachian tube function recovers some years after the cleft palate surgery. Different studies mention different ages between 5 and 14 years for the completion of this process. Our experience suggests that this age is between 7 and 8 years.

We consider the Valsalva manoeuvre the simplest method for the routine evaluation of Eustachian tube function. Our experience suggests that children are capable of understanding and performing the Valsalva manoeuvre since the age of 5.

Earlier studies report poor outcomes of the tympanoplasties of cleft patients. The low number of more recent studies published on this topic reflects a more optimistic view.

Our audiological results were analysed in detail for comparison. Although the preoperative ABG was slightly worse in the ‘Cleft’ group, the difference was not significant. Considering audiological outcomes, no significant difference was found between the two groups in the other examined parameters including the best postoperative ABG, the last postoperative ABG, postoperative deterioration and final hearing improvement.

The average follow-up time of our last ABG values was 4 and 4.1 years. No significant difference was revealed in the ‘final’ hearing improvement achieved so far, the values were 11.29 dB and 13.9 dB in favour of the ‘Cleft’ group.

We found residual cholesteatoma in 33% of ‘NoCleft’ and in 27% of ‘Cleft’ patients during ‘second look’ surgeries and revisions. For the complete patient material these percentages were 18.6% and 20%.

On the other hand, explicit difference was found in the rates of recurrent cholesteatoma between the two groups. During revision, recurrent processes were found in 5% of ‘NoCleft’ and 13% of ‘Cleft’ patients (p=0,219).

Significant difference was revealed in the necessity for grommet insertion between the two groups. This means an 8-fold difference in the rate of grommet insertions (p=0,00000068).

Similarly, the need for the application of open techniques showed significant differences between the two groups (p=0,000069).

We should consider the fact that after the tympanoplasty of patients with cleft palate Eustachian tube obstruction may develop rapidly even after years of adequate Eustachian tube function and good anatomical and functional results, which immediately destroys the achieved outcomes and we have to resort to revision with open techniques.

The facts that in the majority of patients with cleft palate and cholesteatoma Eustachian tube function can be restored and closed techniques applied in the general population usually lead to definitive recovery with advantageous ‘swim-proof’ ears, give reason for optimism.

5. Conclusion / Summary

Considering the original question of our study, we can conclude that the expectable audiological outcomes of tympanoplasty in children with cleft palate do not significantly differ from those of patients without cleft palate regarding mesotympanic and cholesteatomatous processes.

However, the ‘price’ of these results is the significantly more frequent grommet insertion.

The main advantage of patient management in the frameworks of the ‘Cleft Palate Team’ is that this way cleft patients are ‘more visible’ due to the common supervision of different disciplines than patients without cleft palate. This allows for the earlier and more frequent detection of new Eustachian tube dysfunctions and their adequate prevention as well.

We have to accept that in some cases Eustachian tube dysfunction caused by the underlying disease (cleft palate) ‘takes over’ and we have to resort to open techniques.

We would like to underline that in patients with cleft palate, Eustachian tube obstruction may occur even after long years of normal functioning after tympanoplasty and we have to resort to open techniques.

Summary of novel results

- Surgical and audiological outcomes of cholesteatoma and non-cholesteatoma cases are discussed separately (previously published articles, with a few exceptions, discuss these issues together).
- Not only the audiological results are evaluated and compared, but also some other, associated clinical references: grommet demand, prevalence of residual and recurrent cholesteatomas, need for another surgery type; i.e. a complex approach of evaluation is aimed at.
- Regarding the audiological results, interventions associated with intact ossicular chain and different types of ossicular chain reconstruction are discusses separately.
- Detailed (average, deviation, distribution), well-demonstrated and clear-cut results are shown, due to the Pytel SoftWare, primarily.
- Results of surgeries performed on cleft patients with ear disorders are demonstrated in a significantly higher number than those published in previous articles.
- Advantages of treating cleft patients in a “Cleft Palate Team” are emphasised.
- No significant differences have been detected in the short and long-term audiological outcomes of cleft and non-cleft patients regarding tympanoplastic surgeries performed in children.
- To reach this aim, more frequent grommet insertion is needed in vulnerable cleft patients in mesotympanic cases and cholesteatomas.