

MODERN TECHNIQUES IN RECONSTRUCTIVE MIDDLE EAR SURGERY

Summary of Ph.D. thesis

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Pécs

2011

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ABBREVIATIONS

ABG	–	air-bone gap
ACBC	–	autogenous cortical bone columella
COM	–	chronic otitis media
dB	–	decibel
GIC	–	glass ionomer cement
IM	–	incudo-malleolar
im	–	intramuscular
IS	–	incudo-stapedial
EAC	–	external auditory canal
HL	–	hearing loss
KTP	–	potassium-titanil-phosphate
ME	–	middle ear
LPI	–	long process of the incus
OC	–	ossicular chain
PORP	–	partial ossicular replacement prosthesis
PTA	–	pure tone average
RP	–	retraction pocket
TC	–	TC
TM	–	tympanic membrane
TORP	–	total ossicular replacement prosthesis
TTM	–	tendon of the tensor tympani muscle
VT	–	ventilation tube

I. Introduction

Congenital malformation, trauma, acute or chronic otitis media (COM), otosclerosis, benign or malignant tumors can give rise to damage the middle ear (ME) elements requiring surgical reconstruction. COM outrages the other causes both in importance and occurrence; this condition can be found in the background of most of the reconstructive ME surgeries. Tympanoplasty is the modern surgical solution of COM and its residua. The surgery itself results in a closed, air-filled tympanic cavity (TC) and attempts to decrease the conductive component of the existing hearing loss (HL) or to preserve good hearing. Traditionally, tympanoplasty can be divided into sanation and reconstruction. Sanation means the removal of a certain ME pathology (e.g. cholesteatoma) and reconstruction covers the creation of a continuous, vibrating tympanic membrane (TM) and/or a mobile, continuous ossicular chain (OC) in place of the impaired eardrum and/or ossicles. In the mesotympanal type of COM, sanation is achieved by means of closing of TC by reconstructing the TM. In this case, the creation of a new TM serves both sanation and reconstruction. During the past half century, otosurgeons used autografts, homografts, heterografts and allografts to reconstruct the TM and the OC.

II. Aims

1. We investigated the anatomical and functional efficacy of OC reconstruction with glass ionomer cement (GIC), in the lack of the long process of the incus (LPI), which is the most common type of OC defects.
2. Cutting the tendon of the musculus tensor tympani (TMT) makes the anterior quadrants of the TM mobile and alleviates the inspection of the anterior part of the TC therefore it is often carried out even if it was not absolutely necessary. The function of the tendon i.e. to maintain the proper position of the handle of the malleus and control the excessive lateral movement of the attached TM, may be inevitable for a successful restoration of the sound conduction in special cases. The aim of this paper was to describe such a case, the method of the reconstruction of the tendon with GIC was reported for the first time.
3. We elaborated an experimental animal model suitable to investigate different ME surgery methods, assign their efficacy, observe the possible complications and to gain specimens for histological examination.
4. Numerous authors, who have described the surgical steps in their GIC ossiculoplasty procedures in detail, did not mention whether the mucosa had been removed from the recipient auditory ossicle or not. The question arises of whether GIC adheres more strongly and more lastingly to a bare bone surface or to bone covered with mucosa. Any significant difference in this respect might furnish an explanation for certain unsuccessful functional results. The aim of the present study was an anatomic and histologic assessment of the durability of the bonding between GIC and the intact or denuded auditory ossicle in an experimental animal model.
5. The first domestic observations on the potassium-titanyl-phosphate (KTP) laser assisted stapledotomy with a self-crimping, thermal shape memory Nitinol piston are reported.

6. The anterior and subtotal tympanic membrane perforation continues to be one of the greatest problems in middle ear surgery. It is generally accepted that the method used for the repair of posterior perforations may not be appropriate for either anterior or subtotal perforations. The anatomic and functional efficacy of the KTP laser assisted myringoplasty used for the repair of anterior and subtotal TM perforations was evaluated. Taking rate, re-perforation rate, postoperative air-bone gap (ABG) and bone conduction level were determined.
7. A wide variety of management options for childhood retraction pocket (RP) exists. The excision of the RP with simultaneous VT insertion is one of these. The efficacy of this method was evaluated. The influence of age, bilaterality, stage and extent of the RPs on the results was determined. A new staging system was introduced to ease the selection of candidates with good prognosis for this procedure.
8. The anatomic and functional results of childhood tympanoplasties performed by one surgeon using the same OC reconstruction technique for nearly three decades were evaluated. Taking rate, re-perforation rate, change in air conduction, bone-conduction and ABG, edifying curves of individual follow up, follow up reliability and studying were demonstrated.

III. The usage of glass ionomer cement in the middle ear surgery

The GIC was invented by Wilson and Kent. The mixture of a calcium-aluminum-fluorosilicate powder base and a liquid acid sets by chemical gelation through a mildly exothermic reaction. The produced thermal energy is not high enough to cause damage to the neighbouring tissues. The anorganic fluorosilicate glass particules immerse into a hydrogel matrix held together by ionic cross links and hydrogen bridges. The mixture of the powder and the liquid results in a whitish, paste-like material with porcelainlike translucency that adheres well to bone and metal, then hardens within a few minutes. In the state of this paste-like consistency the material is suitable for the application within the ME. Bridging over larger OC defects would require more time. Fortunately, another dose of GIC paste can be put onto the free surface of the already hardened cement. Step by step, even extensive OC lesions can be repaired by repeating the procedure. Should unintendedly contaminate the chorda tympani, the uncovered facial nerve, the tympanic nerve, the round window or the stapedial footplate the GIC can be eliminated by suction immediately. The cement is to be applied onto bare dry bony surface. Before hardening any moisture including blood should be avoided in the field of luting to prevent ions required for the strong bonding from being washed out from the GIC. Once hardened, humidity carries no danger anymore. The GIC is biocompatible and biostable.

As a luting agent, the GIC was first used in dentistry, then was introduced to orthopaedics and ME surgery in 1989. *Hehl et al.* bridged over disrupted incudo-stapedial (IS) joint, fixed columellas to the head of stapes and fixed pistons to the LPI during stapedotomy. *Geyer and Helms* obliterated mastoid cavity and reconstructed the posterior wall of the external auditory canal (EAC) with GIC. *Kupperman and Tange* reported the extrusion of the material after skull base repairs and mastoid obliteration with GIC. GIC can be used for OC repair, in case of partial or total defect of the LPI, lack of the incus, lack of the head of the malleus and the

body of the incus, and lack of the malleus handle. Luxation developed in either of the IS or IM joints can be fixed with it. Others reported successful reconstruction with GIC in LPI defects developed after stapedotomy. The replacement of EAC with GIC proved unsuccessful due to the extremely prolonged or lack of epithelialization of the large GIC surface. After closure of large skull base defects with GIC the cement had a contact with the liquor, that solved toxic amount of aluminum out of the material resulting in encephalopathy. The application of GIC was prohibited in some countries. Contrarily, during GIC ossiculoplasty only a tiny amount of cement is used, that does not come into permanent contact with body fluids.

IV.1. Reconstruction of the long process of the incus with glass ionomer cement

Introduction

The most frequent lesion of the OC involves the LPI. In the majority of cases the TM is also impaired, therefore reconstruction of both the TM and the OC is necessary in order to re-establish normal sound conduction. The isolated, relatively small defect of the LPI can be reconstructed by incus transposition or insertion of a partial ossicular replacement prosthesis (PORP). Nevertheless, one may consider these methods of reconstruction disproportionate. This situation has stimulated several authors not to sacrifice a functioning incudo-malleolar (IM) joint and not to create an acoustic short circuit by using a PORP, but to apply various techniques in order to bridge over the defect of the long process and to restore the physiologic state of the OC.

Material and methods

All patients underwent tympanoplasty, including GIC repair of an impaired LPI and IS joint between November 1994 and November 2006 in the Department of Otorhinolaryngology & Head and Neck Surgery, Pécs University. Reconstructions extending to a larger part of the OC were excluded. Thirty-five patients (16 males and 19 females, 8-69 years, average 33.4 years, 19 right and 16 left ears) met these criteria. Three products were applied with equal contentment: Glass Ionomer Liner No 74013L DPD/3M, St. Paul, USA; G.C. Fuji IX G.P. G.C.C., Tokyo, Japan and Ketac Cem Glasionomerzement, ESPE, Seefeld, Germany. Although in one revision surgery we found the previously inserted ionomer cement (Ketac Cem) fragmented in the middle ear, we kept on using this material during the following cases with our entire satisfaction.

The components were mixed by hand during the operation. The mucous membrane was removed from the lateral surface of the remnant of the process with a preparation needle, a fine diamond burr, or a KTP laser. When a diamond burr was used, we found advisable to fix the remnant of the LPI with a fine hook so as to avoid disruption of the IM joint. The mucous membrane was not removed either from the remainder of the lenticular process if it was preserved in contact with the head of the stapes, or from the superstructure of the stapes. This way, a firm contact between the GIC and the stapes superstructure was avoided, and an artificial joint was created. A small amount of the GIC was placed on the remnant of the incus with a preparation needle and this action was repeated several times, if necessary, until

the prolonged process reached the head of the stapes and the last dose of cement surrounded the head of the stapes. After setting, fine palpation of the neck of the malleus confirmed the transference of the movements to the stapes.

In the majority of the ears, both ossicular and TM reconstruction were necessary because of the presence of central perforations of different extents (10 ears), marginal perforations resulting from the excision of RPs (17 ears) or small cholesteatomas of retraction type (3 ears). In 3 ears, the TMs had been reconstructed in a previous operation. It was possible to elevate the partially adherent TM without injury in one ear. Finally, in another ear, the anterior quadrants of the TM affected by myringitis granulosa were covered with split thickness retroauricular skin grafts. The perforations were closed with temporal fascia. When the perforation was confined to the posterior quadrants, a simple underlaid technique was used. Perforations extending to the anterior quadrants were closed by using Bailey's technique.

The pure tone average (PTA) was calculated at 500, 1000, 2000 and 3000 Hz. The postoperative ABG PTA was chosen as a measure of the audiological efficiency of the reconstructive technique. Paired samples test was used to determine significance and standard deviation was calculated.

Results

Reconstruction of the TM was necessary in 31 cases: all of the operations were surgically successful. Failures in the ossicular reconstruction likely resulted in an impaired postoperative sound transmission. Nevertheless, the follow ups revealed retraction in 4 cases. This condition, indicating a tubal malfunction, might have influenced the audiological results. It appeared useful to indicate the best ABG results during the observation period, the ABG results at around one year (6th–18th months) and at the most recent follow-up (Table 1).

The obtained follow up results were divided into 3 groups for practical reasons: "good", i.e. $ABG \leq 10$ dB, "acceptable", i.e. $10 \text{ dB} < ABG \leq 20$ dB, and "failure", i.e. $ABG > 20$ dB. At around 1 year postoperatively 52% and 27% of the patients belonged to the "good" and the "acceptable" group, whereas, 40% and 34% did according to the most recent audiograms. The physiological reconstruction of the ossicular chain apparently proceeded in accordance with our expectations in 14 of the 35 patients. Six other ears were classified as "good" during the initial observation period, but after 3-5 years the gap had widened; 4 of them shifted into the "acceptable" and 2 into the "failure" group. In 15 ears, a postoperative ABG PTA < 10 dB was never observed; 13 of the 15 belonged to the "acceptable" group, 8 of them remained in this group, while 5 ears shifted into the "failure" group. Two ears were considered to be "failures" immediately after the operation; in the other 7 ears, the ABGs widened during the observation period. In the three cases of preoperative $ABG \leq 10$ dB (9%) the safe removal of the retraction pocket involved the removal of the atrophied, though still sound transmitting part of the long process. Unfortunately, their previous low ABG (< 10 dB) became worse (20-30 dB) after the reconstruction. The procedures did not have detrimental effect on the bone conduction of the non-operated ears. The follow-up times varied between 0.5 and 12 years (2.49 years in average). Fourteen patients were followed up for less than 1 year, 10 of them were operated on within a year. The averages of the ABG PTAs, their standard deviations and the percentage distribution of patients with different ABG PTA ranges are shown in Table 1. The average of the postoperative ABG PTAs decreased significantly compared to the average of the preoperative ABG PTAs ($df=34$, $p<0.001$).

Table I. The hearing results. Averaged at 4 frequencies (0,5-1-2-3 kHz).

		<i>The percentage distribution of air-bone gap averages</i>							
<i>Air-bone gap</i>	<i>Average (dB)</i>	<i>Standard deviation n</i>	<i>0 – 10 dB</i>	<i>11 – 20 dB</i>	<i>21 – 30 dB</i>	<i>31 – 40 dB</i>	<i>41 – 50 dB</i>	<i>50 –</i>	
Preoperative	27.5	12.164	9%	20%	34%	26%	11%	-	
Postoperative (best)	11.4	10.328	54%	34%	6%	6%	-	-	
Postoperative (~1 year)	12.2	10.238	52%	27%	18%	3%	-	-	
Postoperative (last)	14.7	9.789	40%	34%	20%	6%	-	-	

		<i>The percentage distribution of the change in bone and air conduction averages</i>							
<i>Change (negative values indicate better hearing)</i>	<i>Átlag (dB)</i>	<i>SD</i>	<i><-30 dB</i>	<i><-20 – -29 dB</i>	<i>-19 – -10 dB</i>	<i>-9 – 0 dB</i>	<i>1 – 10 dB</i>	<i>11 – 20 dB</i>	<i>21 – 30 dB</i>
Bone conduction	0.2	5.114	-	-	3%	43%	48%	6%	-
Air conduction	-14.6	12.862	14%	23%	31%	14%	12%	6%	-

Discussion

Determining the causes of the failures and their prevention is of particular interest from a surgical aspect. The “failure” group included 4 ears, which clearly demonstrated the clinical signs of a tubal malfunction. A revision operation was performed in one of these ears. The ionomer cement was found fragmented and an autogenous bone columella was inserted. It was noted in the surgery report on the previous operation of this patient that the setting time of the cement was unusually long. A prolonged duration of setting is an indication of the deteriorated condition of the ionomer cement. It is recommended to store a spare pack of GIC in the operating theatre.

In 2 of the 4 ears showing tubal malfunction, a Shah ventilation tube was repeatedly inserted, which temporarily shifted one of these ears into the “good” group. In 2 other cases, the state of the stapes superstructure was not explored during the operation because of the inflammatory condition in the oval window niche. The connection between the head of the stapes and the remainder of the long process was re-established in order to give the patients a chance to avoid a second-look operation, but without success. Revision surgery is required with the suspicion of a lesion of the stapes superstructure. In the remaining 3 unsuccessful cases, a revision operation would also reveal the cause of the failure. The offered revisions were rejected by the patients. The TMs are normal and the tympanic cavities are well aerated, but the ABG PTAs are 21-24 dB.

Theoretically, after a successful TM reconstruction and in the presence of a well-aerated TC, it might be expected that the reconstruction of the long process would result in normal sound conduction, indicated by a minimal ABG. In practice, this is not the case in every patient. If the aeration of the TC after tympanic reconstruction is normal, the TM makes an appropriate mechanical contact with the malleus handle, and the ABG is narrower than indicative of an ossicular discontinuity, it is difficult to explain the existence of an ABG in the interval 10-20 dB. Although other possibilities must be considered as well, the cause may be a subtle fixation of the other parts of the ossicular chain (mainly the annular ligament), which cannot be detected by palpation during the operation. This incomplete fixation may be

present at the time of the operation or may develop later. Of course, this explanation is only speculative in the absence of a sensitive instrument for intraoperative measurement of the motility of the ossicular chain. We consider that the presented results reflect the good efficiency of this method of reconstruction; nevertheless the long-term duration of the achieved good results has been proved by only a small number of ears to date. After we had experienced the reported good functional results we chose this technique more frequently. The longest follow-up period for an ear with an “acceptable” result is 12 years, and that for a “good” result is 10 years. This situation is encouraging and indicates that more trials are worthwhile with this method.

IV.2. Reconstruction of the tendon of the tensor tympani muscle with glass ionomer cement

Introduction

Cutting the tendon of the musculus tensor tympani makes the anterior quadrants mobile and alleviates the inspection of the anterior part of the TC therefore it is often carried out even if it were not absolutely necessary. Usually the ear surgeon has a concern in the reconstruction of the tympanic membrane and/or the ossicular chain and not too much attention is paid to the tendon.

Case report

The first stage of a planned two stage tympanoplasty was performed on the right ear of a 9-year-old male patient for cholesteatoma in 1989 (operated on by Prof. Miklós Bauer). The cholesteatoma, the head of the malleus and the body of the incus were removed, the TTM cut. The handle of the malleus was preserved in connection with the remnant of the tympanic membrane. The stapes was intact but between it and the promontory the matrix was left intentionally because its removal seemed to jeopardize the inner ear function in the infected environment. The TM was reconstructed with an underlaid fascia graft.

After the operation, signs of the tubal malfunction appeared: the reconstructed tympanic membrane was retracted but adhesions to the medial wall were prevented by the silastic sheeting. The ventilation of the ME was maintained using Shah’s VT. One year later the planned second stage was performed. A small residual cholesteatoma was found between the superstructure of the stapes and the promontory. Its reliable removal was possible only after the removal of the superstructure of the stapes. An unplanned third stage was decided for the sake of safety. The third operation was performed in 1992. No residual cholesteatoma was found in the ME. Through an opening of the silastic sheeting the TM and the mobile footplate were connected with an ACBC. Because of the permanent tubal malfunction a Shah’s VT was inserted in the antero-superior quadrant simultaneously. This operation resulted in a considerable improvement in hearing, which lasted for four months. Then the

patient appeared with a retracted VT and a retracted TM. The TM was relaxed and it touched the medial wall of the TC. After the reinsertion of a Shah's VT the TM became tens, regained its normal position and the conductive component almost disappeared (air-bone gap 10 dB). This series of events repeated itself monotonously 3-4 times/year but after 3 years the restoration of the air content of the TC did not result in the good hearing mentioned above. Since 1998 a wide ABG characteristic of a disrupted OC appeared. It was suspected that the long lasting pressure of the retracted TM on the ABC had caused its atrophy. The regular reinsertion of the VT was continued till 2000, when the already 20-year-old patient became able to perform Valsalva manoeuvre by which he maintained the air content of his TC. In this new period the position of the TM changed dramatically. Once it touched the medial wall, after Valsalva it was extremely bulging. The patient was willing to undertake a revision operation for an improvement in his hearing. A new drum to footplate columella was necessary but it was evident that no columella can be measured exactly if the TM can make the observed extreme excursions. The reconstruction of the TTTM was decided.

In 2001 the right TC was reopened. A bare bone surface was prepared both on the upper end of the malleus handle and on the cochleariform process with diamond burr. The bare surfaces were covered with a small amount of GIC. After setting, both ends of a piece of about 2 mm. length of a surgical suture material (Dagrofil 4.0) were immersed in fluid GIC and placed between the prepared surface of the malleus handle and that of the cochleariform process. After setting the malleus handle became firmly bound to the medial wall but maintained its motility. The handle of the malleus determined the exact position of the TM. An ACBC was placed between the mobile footplate and the TM. On the lateral end of the columella an incision was made for the handle of the malleus. One side of the columella was covered with GIC to prevent atrophy. This operation resulted in a considerable improvement in hearing, the preoperative 55.0 dB. air-bone gap has been reduced to 3.3 dB. Seven years after the ME was found aerated and an ABG of 15.0 dB was measured.

Discussion

To eliminate or significantly reduce the conductive HL on the long run is a challenging mission for an otosurgeon. Permanent tubal dysfunction and technical nuances may influence and deteriorate the sound conduction even if it was restored successfully for a relatively long postoperative period of time. It seems to be probable that the more parts of the original sound conducting structures can be preserved the more probable it is to achieve a long term improvement in hearing, therefore maximal possible conservation of the original structures of the sound conductive system can be recommended during the curative phase of tympanoplasties. The described case illustrates the fact that even the neglected function of the TTTM can be necessary to the success in special cases. In this special case, however, the silastic sheeting prevented the adhesions not only between the medial wall of the TC and the graft but between the upper end of the malleus handle as well. It seems to be advisable to keep in mind this possibility during tailoring the silastic sheeting after cutting the tendon.

IV.3. Middle ear surgery experimental animal model

The functional result of the reconstruction of the OC with GIC can be adequately measured by means of intermittent audiological tests. Evaluation of biocompatibility, the bonding strength to the ossicle, the presence of inflammatory or foreign body reaction in the neighbouring tissues or structural reorganization of the bone tissue can be carried out by histological examination. This would require the removal of the ossicle-GIC complex from the host ME. As specimens from humans can not be gained for experimental purpose, an animal model was worked out aiming at carrying on a follow up on the implanted GIC into the ME. The applicability of GIC in the ME surgery, its biocompatibility, the linkage between the ossicle and the GIC was planned to be evaluated by means of histological examination. The chosen species should be: 1) filogenetically close to homo sapiens, so as to the macroscopic and microscopic anatomy and the immune processes in the ME of the animal resembles to those in humans; 2) not too small, as it would make the manipulation in the ME very difficult and the ossicles vulnerable at removal; 3) unaggressive; 4) kept and fed easily; 5) resistant to diseases; 6) available unexpensively. A rodent, the pannon white rabbit (*Oryctolagus cuniculus domesticus*) from the Leporidae family met these criteria.

The animals were sedated with an intramuscular (im) injection of 20 mg xylazine (Sedaxylan, Eurovet Animal Health BV, Bladel, The Netherlands), and were anesthetized with an im injection of a mixture of ketamine (Calypsol, Richter Gedeon Rt., Budapest, Hungary) at a dose of 35 g per 1000 g body weight and 20 mg xylazine. The animals were stabilized on a surgical table. The preauricular skin was shaved and disinfected with 5% iodine in 95% alcohol. Under aseptic conditions, a small horizontal 3 cm long skin incision was made over the EAC under an operating microscope, and the canal was entered at the junction of the bony and the cartilagenous parts. The lateral wall of the bony EAC was partially removed with a strong pair of pliers to afford a better view of the TM. A tympanomeatal flap was raised. The tympanic bulla was opened through the pars flaccida, the lateral attic wall was partially removed and the OC was identified.

IV.4. The effect of denudation on the durability of linkage between the auditory ossicle and glass ionomer cement

Introduction

Numerous authors who have described the surgical steps in their GIC ossiculoplasty procedures in detail, did not mention whether the mucosa had been removed from the recipient auditory ossicle or not. The question arises of whether GIC adheres more strongly and more lastingly to a bare bone surface or to bone covered with mucosa. Any significant difference in this respect might furnish an explanation for certain unsuccessful functional results. As far as we are aware, no other paper has dealt with this topic so far. The aim of the present study was an anatomic and histologic assessment of the durability of the bonding between GIC and the intact or denuded auditory ossicle in an experimental rabbit model.

Material and method

A total of 34 3-6-month-old Pannon White rabbits weighing 1220-2470 g were used in the study. The tympanic bulla was opened through the pars flaccida, the lateral attic wall was partially removed and the ossicles were identified. The pars tensa was maintained intact. In the left ears, the mucosa was gently denuded off the lateral side of the incus body with a diamond burr. The mucosa of the right incudi was preserved. The GIC paste was transferred with a fine curved otological pick onto the lateral surface of the body of the incus on both ears of 30 out of 34 rabbits. In groups of three, the animals were sacrificed by the intravenous injection of 1 g thiopental sodium on day 1, 3, 7, 14, 21, 30, 60, 90, 180 or 365 postoperatively. A total of 4 sham-operated animals served as controls and were sacrificed on day 1, 7, 30 or 365 after the surgery. Following sacrifice, the surgical field was reexplored bilaterally. The IS and the IM joints were disarticulated and the incus together with the covering GIC was carefully removed.

The bone samples were fixed in 6% formaldehyde for 2 days. After fixation, the materials were decalcified in a 15% solution of ethylenediaminetetraacetic acid for at least 3 days, during which the bones were checked daily. After perfect demineralization, the bone samples were dehydrated and embedded in paraffin with careful orientation according to the usual histopathological processing. Several 3-4- μ m-thick sections were cut from every sample with a microtome and stained with hematoxylin-eosin. The slides were examined under a standard light microscope for the presence/absence of GIC, changes in bone architecture, mucosal lining and signs of inflammatory changes or foreign body reactions, in part with the application of strong diffraction to facilitate the visualization of the glass particles. The related-samples Wilcoxon signed ranks test was used to determine the level of significance of differences.

Results

Exploration following sacrifice revealed a dry ME and an inflammation-free mucosa in all 68 ears. A whitish patch of GIC was still visible on the lateral surface of the incus in all 60 tympanic bullas in which the material had been applied. No fragmentation or displacement of the GIC was detected macroscopically. However, despite the careful manipulation, the GIC was found to be separated from the ossicle in 3 cases during the disarticulation of the IS and IM joints and the removal of the incus from the bulla. The subsequent histological processing revealed the separation of the GIC from a further five ossicles. All these 8 GIC samples separated in one intact piece, all 8 were from the right side and all 8 were found at least 60 days postoperatively. Separation of the GIC from the bone was detected in 8 of the 30 cases on the right side, but in none of the 30 cases on the left side. With the related-samples Wilcoxon signed ranks test, the difference between the two sides proved to be statistically significant ($p < 0.05$).

Days 1-7. The presence or absence of mucosa was evident on the lateral surface of the right and left-side ossicles, respectively. From day 1, neutrophilic granulocytes, lymphocytes or macrophages sporadically appeared within the cement or in the bone in its vicinity, but only in the left-side specimens. No inflammatory reaction was detected on the right side. The number of cellular elements of the acute inflammatory reaction gradually decreased during the first 7 days. By the end of the week, the neutrophils had completely disappeared and the numbers of lymphocytes and macrophages also underwent a significant decrease. No foreign

body reaction could be observed. Remnants of blood clots were visible on the surface of both the bone and the GIC. The vessels in the bone were dilated and congested with blood.

Days 14-30. During this period the most marked change was the appearance of epithelialization bilaterally. From the bone next to the edges of the GIC, the mucosa overgrew onto the surface of the GIC. It comprised nonsquamous epithelium and swollen submucosa containing fibroblasts and fibrocytes. No foreign body reaction and no pronounced inflammatory reaction was seen from this point on. In some specimens, a few macrophages were visible. The original mucosa was still visible on the bone-GIC border in the right-side specimens on day 14 and 21, but only in 1 out of the 3 specimens on day 30.

Days 60-365. The cavital surface of the GIC was overgrown by a delicate, viable, nonreactive mucosa. The mucosal coverage displayed a narrowing tendency to become thinner in time. The original epithelial layer between the bone and the GIC was no longer visible in the right-side specimens. The adjacent bone looked healthy, and newly formed bone was not observed in any specimen.

Controls. The specimens from the right ears of the sham-operated control animals did not exhibit any sign of inflammation; the incus from the right side was covered by a delicate layer of mucosa. On day 1, the bare bony surface of the left side incus was visible. The presence of neutrophils, lymphocytes and macrophages could only be detected in the left-side specimens from day 1 and 7. The ossicle was partly covered by mucosa by day 7, and had become fully overgrown by a thickened mucosal layer by day 30. On day 365, a normal-looking incus was present on both sides.

Discussion

Due to its connection through the Eustachian tube with the nasopharyngeal space, inhabited by potentially pathogenic microorganisms, the human TC poses a challenge for the implantation of any alloplastic material. Invasion and colonization with microorganisms can promote resorption and extrusion of an implant. The defensive reaction of the recipient organism involves the early mucosal overgrowth of the material, which prevents bacterial colonization in the vicinity of the implant. During the 1-year observation period, the GIC applied proved to be biocompatible, and the structure of the underlying bone remained healthy. Between days 14 and 60, the epithelialization of the material began, and by the end of this period the cement was fully overgrown by a layer of mucosa containing fibroblasts and fibrocytes, that was thicker than normally present in the tympanic bulla of the rabbit. By day 365, the mucosal envelope surrounding the GIC had become a delicate, thin layer. The denudation of the incus presented as a mechanical injury, and thus inflammatory cells, such as neutrophils, lymphocytes and macrophages, were detected only in the denuded group of animals in the first week. The substantial decrease in the inflammatory reaction by day 7 indicated a normal recovery from the tissue injury, the recipient bone adapted well to the GIC within a short time. During the one-year observation period, there was no evidence of any foreign body reaction at any point: no extrusion of the GIC was seen, and large numbers of giant cells or macrophages were never detected on the surface of the recipient bone at any of the sacrifice times.

The present study on rabbits has clearly demonstrated, that GIC adheres more strongly and more durably to a bare bone surface (denuded with a diamond burr) than to an ossicle covered with mucosa. GIC applied to the mucosa was significantly more likely to separate from the ossicle than was GIC applied to the denuded bone. The separation occurred either

during extremely careful removal of the ossicle from the bulla or when the specimen was cut into sections with the microtome. Of course, it is possible that, if such manipulations had not been performed on the incus, the GIC would have remained in place. Nevertheless, the GIC proved to adhere more strongly to the denuded bone than to the mucosa.

The mucosal lining under the GIC disappeared between days 30 and 60 in the right-side ossicles. Interestingly, the separation of the GIC from the ossicle covered with mucosa was first detected at day 60, and later became more frequent. The difference between the two groups of incudi was most evident when the specimens from 60 or more days postoperatively were compared: separation was observed in 8 of the 12 right-side (intact) cases (66.7%) and in none of the 12 left-side (denuded) cases. It may be speculated that the postoperative disappearance of the mucosa between the GIC and the bone possibly weakened the adherence of the GIC to the incus. The GIC appeared to integrate more durably with the ossicle when the mucosa was removed before the application of the GIC paste.

The denuding of an ossicle can be achieved with a prick, a hook or a needle, but complete removal can be attained more securely by means of a diamond burr or laser. Laser can be used for the denudation of the central part of a disrupted OC without the risk of causing an acoustic trauma to the inner ear. Clarification of the causes of failures related to a technique, and their prevention are of particular interest from a surgical aspect. The causes of unsatisfactory functional results of GIC ossiculoplasty could include the use of cement with expired validity or glass powder previously contaminated by humidity, the improper ratio of the mixture of powder and liquid, application of the material onto a wet or bloody bony surface, the lack of sterility, or unintentional fixation of the OC to the surrounding bony elements with GIC. Over rough manipulation within the TC or during the tamponade of the EAC, leading to breakage of the cement, and incomplete denudation of the recipient bony surface might also result in a lack of success.

Conclusion

During ossiculoplasty with GIC, the bone must be denuded by removal of the mucosa if the cement is expected to demonstrate durable adherence. Some unsuccessful GIC ossiculoplasty cases might possibly be due to omitted or incomplete denudation of the recipient bone. The GIC proved biocompatible in the rabbit ME.

IV.5. Laserstapedotomy – a modern surgical solution of stapes fixation

Introduction

The first domestic observations on the KTP laser assisted stapedotomy with a self-crimping, thermal shape memory Nitinol piston are reported hereinafter.

Material and method

The 14 surgeries with this technique were performed between March 2006 and April 2007 (operated on by *Prof. Imre Gerlinger*). The inclusion criteria were a normal-appearing TM and ME space, an absent stapedius reflex with at least 15 dB conductive HL in speech

frequencies and 60% discrimination loss. Multifrequency tympanometry showed an A type curve and the frequency of resonance was detected above 1 kHz characteristic to a rigid OC. In case of bilateral fixation, the second surgery was only performed 3 years after the first complication-free operation, after which the ABG had to be decreased.

Nitinol shape memory prosthesis (SMart Piston, Ghyrus Ltd., Germany) made up of nickel, titanium and fluoroplastic was used. The crimp itself contains 55.3% nickel and 44.7% titanium, its width is 0.11 mm. The fluoroplastic part of the piston is put adjacent to the perilymphe during surgery. The piston is shaped on 500 °C, then cooled in aseptic icy water. The cooled crimp of the piston is deformed, widened, without atomic structural damage. The metallic alloy prosthesis has a biomaterial memory allowing it to crimp itself to its original shape. The unique self-crimping capacity of the prosthesis linked onto the LPI and inserted into the hole on the stapedial footplate can be activated through the application of heat (laser or bipolar forceps). All patients underwent general anaesthesia, the transmeatal approach was applied. The fixation of the stapedial footplate was confirmed by the gentle touching of the stapedial arch with a bended otologic pick. The mobility of the IS joint was ensured by the gentle palpation of the neck of the malleus. The tendon of the stapedial muscle and the posterior crus of stapes were divided with KTP laser (Laserscope, Orion laser, United Kingdom, 2 W, 100 msec). The thin anterior crus was also cut with the laser with avoidance of harming the facial nerve. The produced smoke was suctioned continuously and the operating field was repeatedly rinsed with cold saline solution. The IS joint was separated with a small cross-cut scalpel. The stapedial superstructure was removed with a pair of alligator forceps. Mild bleedings were stopped by laser coagulation from a distance of 1 mm. The target point on the footplate was set by thinning the bone with the laser (6-12 shots, 1 W, 100 msec). To prevent the perilymphe from being overheated ample time was taken between shots. A hole at the border of the middle and posterior third of the footplate was created with a quiet microdrill (low rev, 0.6 mm in diameter, Xomed, United Kingdom). Care was taken not to direct the laser beam against the open vestibulum and not to suck perilymph out of it. After measuring the distance between the incus and the footplate a Nitinol SMart piston (Ghyrus Ltd., Germany) 4.5 mm in length and 0.6 mm in diameter was inserted into the hole. The crimp of the piston was hanged on the LPI. The shape memory of the hook was activated with one or two laser shots on the greater curve (1 W, 100 msec). The closure of hook and the mobility of the OC was confirmed and a thin strip of fascia was placed around the piston. The TM was repositioned, the EAC was filled with a gauze plug and dressing was put on the ear. The patients were emitted on the 1st or 2nd postoperative days. Gauze plugs and sutures were removed on postoperative day 5 and 10, respectively. Audiograms were assessed on the sixth week, sixth month and 1 year after surgery.

Results

The average decrease of the air conduction measured on 0.5, 1, 2 and 3 kHz frequencies was 21.5 dB. No increase in bone conduction PTA was detected. The postoperative ABG was below 10 dB in 85% and below 20 dB in 100% of the patients. An increase in the ABG values was not experienced during the postoperative follow up (9 months in an average), which is reassuring, as the necrosis of the LPI and the dislocation of the prosthesis took place within the first postoperative year. The postoperative air conduction PTA (averaged on frequencies 0.5, 1 and 2 kHz) was measured as lower than 30 dB.

Discussion

Meanwhile the number of surgeries for stapes fixation shows a decreasing tendency, the number of surgeons willing to perform this type of surgery is stable. Consequently, there will be more less experienced ear surgeons, that may lead to the worsening of the results of surgeries. The will to work out reliable surgical methods, that function even in unexperienced hands, is understandable. The usage of laser and Nitinol piston with shape memory provided ABG<10 dB postoperatively in 85% of the cases in our study. The time of hospitalization was shorter than after stapedectomies that had been performed by the same surgeon with other technique. This fact compensates for the price of the piston. The postoperative vertigo lasted shorter, the operating field was less bloody due to the usage of laser. Another advantage of the technique is its applicability even in the presence of persistent stapedia artery, obliterative otosclerosis, floating footplate and in revision cases. The safe anchoring due to the shape memory prevents from the consequences of either the loose or the too tight crimping: the dislocation and the necrosis. Doppler interferometry studies on the mechanics of the ME pointed out that the linkage between the piston and the LPI has a major role in sound transduction. Application of this technique eliminates manual crimping, the most critical step in conventional stapedotomy. In combination with the hand-held non-touch laser fibre, the extent of manipulation around the OC is much less, the degree of cochlear trauma is minimal and the surgical environment is comparatively bloodless. Application of the Nitinol piston seems to be ideal even for unexperienced surgeons. The hearing results appear comparable with those achieved with other prostheses.

IV.6. Myringoplasty for anterior and subtotal perforations using the KTP-532 laser

Introduction

The anterior and subtotal tympanic membrane perforation continues to be one of the greatest problems in middle ear surgery. It has been shown that one of the most important factors in the success of myringoplasty is the size and position of the perforation and it has been noted that the repair of anterior and subtotal perforations is less likely to be successful compared with the repair of small posterior perforations. It is generally accepted that the method used for the repair of posterior perforations may not be appropriate for either anterior or subtotal perforations.

Material and method

A retrospective analysis was performed by reviewing the case notes of 23 patients who underwent myringoplasty procedure during the years 1997-2004 in the Department of Otorhinolaryngology & Head and Neck Surgery, University of Pécs. No ossiculoplasty procedures were needed in any cases. The sites of perforations are demonstrated in Table II. All procedures were carried out by *Professor Imre Gerlinger*.

Surgical technique: Endaural incision was carried out in all but 3 cases. In these 3 cases retroauricular approach was preferred. A large temporalis fascia graft was harvested and dried. A "C" shaped posterior meatal skin incision 5 mm from the annulus was made from 12 o'clock to 5 o'clock on the right hand side and from 12 o'clock to 7 o'clock on the left hand side, in continuity with the medial end of the incision mentioned above. In all cases wide

canalplasty was carried out in order to gain good exposure to the anterior quadrants of the drum remnant. Using the Orion KTP-532 laser® (Laserscope, UK), the edge of the perforation was denuded of squamous epithelium. The KTP-laser was delivered to the operation site by means of fibre, 0,2 mm in diameter. Any tympanosclerotic plaque was excised with the laser applying 1 Watt power and continuous mode. Having raised the tympanomeatal flap the annulus was elevated off the tympanic sulcus and the malleus was exposed. Using the KTP-laser the flap was gently freed from the malleus handle and further elevated off the antero-superior part of the tympanic ring in order to gain more space for antero-superior graft fixation. At the border of the anterior quadrants a "pull-back" tunnel was created between the annulus and the bony ear canal, further improving the graft fixation. The dry graft was placed medial to the handle of the malleus and the drum remnant (underlay technique). The graft was made to a size which would at least completely cover the area enclosed by the tympanic ring and was fashioned with a split of 4-5 mm in the middle of one edge. Extra graft coverage outside the boundary of the tympanic sulcus should afford further anchorage. The tympanomeatal flap was replaced, gelfoam was placed around the edge of the perforation. The ear canal was packed medially with tiny gauze balls on gelfoam pieces and laterally with a gauze strip absorbed with jodoform powder. The latter was changed every other day. A piece of preformed silicon dressing was used to cover the endaural incision to further facilitate the healing process. Removal of the sutures and the gauze balls took place on the eighth day and the third week after surgery, respectively.

Table II. The sites of perforations.

Sites of perforation	Number
Subtotal	9
Anterior quadrants	8
Anterior quadrants and posteroinferior quadrant	4
Anterosuperior quadrant	2
Total	23

Results

Of the 23 anterior and subtotal perforations the graft-taking rate was 100 %. Only one case required reoperation due to a posterior marginal reoperation. In this case the graft dislocated in medial direction and sank into the TC. Reoperation resulted in continuous TM. Apart from this residual perforation no recurrent perforation was observed during the follow up period in any of the cases. Blunting or graft lateralisation was not experienced. Thorough canalplasty made post-operative follow-up very convenient. The ABG (averaged on 0,5-1-2 kHz frequencies) decreased 5-20 dB after surgery. There was no bone conduction threshold elevation in any of the frequencies.

Discussion

It is generally acknowledged that closure of both anterior and subtotal perforations is technically more difficult than the repair of a posterior perforation. One of the problems the surgeon has to face is the lack of anchorage and proper support for the graft, especially with the underlay technique. A further problem is the frequent presence of anterior bony overhang hindering access to the anterior margin of the perforation. Because of the poorer vascularity

of the anterior quadrants there is a greater risk that epithelization and healing may not occur in the anterior tympanic membrane prior to necrosis and reabsorption of the fascia graft. In this area of the tympanic membrane there is also a problem with fixation of the fascia graft. If the anterior angle is denuded, scar contracture or blunting may occur.

We think that our KTP-laser assisted technique has several advantages. The double fixation (antero-superior anchoring and anterior "pull-back") prevents blunting of the graft and provides good contact between the graft and the drum remnant and facilitates epithelization of the graft. Being medial to the malleus handle and underlaid position of the graft prevents lateralisation. The size of the graft and the thorough soft tissue and bony work contributes to the high percentage graft taking rate because of promoted revascularisation of the anterior TM. Wide canalplasty is necessary to make intraoperative manipulations and the postoperative follow up much easier. Our technique involves dissection of the drum remnant from the malleus handle which means manipulation around the intact OC. Using the KTP-laser no bone conduction elevation was observed during the postoperative follow up period in any frequencies which gave rise to the fact that dissection of the drum remnant from the intact OC did not cause cochlear damage. Less bleeding is also beneficial from the viewpoint of better intraoperative visualisation. Application of the KTP-532 laser in ME surgery requires proper training, effective team work, and thorough knowledge of laser physics in order to avoid unexpected iatrogenic complications such as facial nerve palsy, overheating of the perilymph etc. In reviewing the pre- and postoperative audiological results we have to emphasize that sole myringoplasty was carried out in every case. OC damage, tympanosclerosis or other ME pathology could contribute to the final outcome of the audiological result. These conditions will be addressed later in case of necessity. We suggest that annual evaluation of an individual surgeon's results is a necessary means for improving surgical outcome.

IV.7. Transmeatal excision of pars tensa retraction pockets with simultaneous ventilation tube insertion in children

Introduction

RPs of the TM are frequently encountered by otologists. The underlying disorder is a dysfunction of the Eustachian tube, leading to retraction and atrophy of the TM with loss of the organized collagenous layer and effusion formation. Children lacking this pressure-equalizing function are prone to recurrent episodes of acute suppurative otitis media, which additionally results in histological degeneration and atrophy of the lamina propria of the TM. In childhood, the tubal malfunction is caused by adenoid vegetation in most of the cases and is likely to resolve spontaneously over time. The RP can retract onto the medial wall of the TC and the incus, and may adhere to the underlying structure. Such adhesion gives rise to chronic pressure and may lead to erosion of the incus. Some RPs are stable and self-cleansing. In other cases, the produced keratin accumulates in the RP and cannot migrate toward the outer ear canal through the mouth of the RP, and a cholesteatoma develops.

The symptomatology includes earache, fullness of the ear, otorrhea, a HL and recurrent episodes of acute otitis media. Some cases of RPs are asymptomatic. Surgical procedures with the aim of improvement of the tubal function, such as adenoidectomy, may be helpful. The treatment of choice can include watchful waiting, nasal decongestants, excision of the RP with or without insertion of a VT, tympanoplasty with or without reinforcement of the eardrum, cortical mastoidectomy, and, in the event of a discontinuous OC, ossiculoplasty. Creation of a perforation by excision of the RP and appropriate aeration of the ME cleft via VT insertion, first described *Sharp and Robinson*, is considered to promote a spontaneous TM repair. The present study was conducted to determine the effect of certain factors (age, bilaterality, stage, extent) on the results of transmeatal excision of pars tensa RPs with simultaneous VT insertion.

Material and method

According to the classification of the pars tensa RPs of *Sadé*: grade I - mild retraction of the TM; grade II – retraction onto the IS joint with or without erosion; grade III – retraction onto the promontory without retraction; grade IV – adhesion to the promontory; grade V – spontaneous TM perforation. Thirty children presenting with grade II or III pars tensa RPs during a 30-month period were included in this prospective study. Bilateral retractions, present in 10 children, were operated upon simultaneously. A detailed preoperative history was taken, including symptomatology, predisposing factors and previous medical or surgical treatment. The ears were observed under an operating microscope. The site and grade of the RPs, the state of the underlying IS joint, and the presence of any TM or ME abnormality were noted. Retraction in the attic region, large RPs inaccessible by a transmeatal approach and the presence of a cholesteatoma were factors ruling out this procedure and the children were excluded from the study.

VTs (10 Aesculap and 30 Shah grommets) were inserted into the anterior quadrants of the TM. Gentle suction was applied to the retracted TM area to lift off the medial wall of the TC and/or the IS joint, and the pars tensa RPs were then excised with a sickle knife and microscissors through a transmeatal approach. The operations were performed under general anesthesia by four surgeons, in two tertiary pediatric otolaryngology centers. The procedure was carried out as a day case. The postoperative healing of the eardrum was followed and any persistent perforations, scars, tympanosclerosis, cholesteatoma formation or further developing RPs were noted. When necessary, repeat excision of the retracted areas was considered. Pre- and postoperative pure tone audiometry (air and bone conduction thresholds at 0.5, 1, 2 and 3 kHz) and preoperative tympanometry were performed on all 30 children. The results were assessed by means of microscopic examination, together with audiometric evaluation, 1, 3 and 6 months postoperatively and then at 6-monthly intervals. Statistical analysis (Mann-Whitney test, Fischer's exact test) was carried out to elicit whether age, or the extent and severity of the retraction had any influence on the final outcome of the procedure. A staging system was introduced for patient selection for this procedure: *Sadé* grade II. and III. situations were awarded scores of 1 and two, respectively. An additional score was given if the RP affected more than one quadrant. The rate of success was evaluated in different stages.

Results

RPs were excised in a total of 40 ears in 30 children (14 male and 16 female). The average age at operation was 7.2 years (range 3-14 years). The follow-up ranged from 6 to 29 months, with a mean of 16.1 months. The severity of the retraction was grade II in 28 and grade III in 12 cases. In 22 ears the postero-superior quadrant alone, in 1 case the postero-inferior quadrant alone, and in 15 cases both posterior sites were affected. In 2 ears, both the anterior-inferior and posterior quadrants were affected. The LPI was partially eroded, but still in contact with the head of the stapes in 4 cases. No ossicular discontinuity was noted. In 25 ears, a concomitant middle ear fluid was aspirated. The retracted area was successfully excised and the VT could be inserted in all the ears. No ossicular reconstruction procedures were attempted. Thirty-eight of the 40 surgically created perforations healed completely in a mean of 1.9 months (range 2 weeks to 6 months); the remaining 2 decreased in size, but failed to close (Picture 1). The edges of the residual perforations were carefully wounded with microinstruments and VTs were inserted into the holes under general anesthesia 7 and 15 months postoperatively. One of the tubes remains in place, whereas the other was extruded 6 months later, leaving a continuous eardrum behind. Six severe RP recurrences were noted postoperatively, all in the same quadrants as before surgery. A second excision of the RPs with grommet (5 Shah, 1 Aesculap) insertion was performed in all 6 cases. No residual perforations were detected and 4 TMs became free of RPs. The other 2 patients underwent a tympanoplasty procedure with reinforcement of the newly retracted posterior quadrants. No cholesteatoma formation, scarring or tympanosclerosis was noted. The average pre- and postoperative ABGs (averaged at four frequencies) were 22.4 dB and 9.7 dB, respectively (Table III). The bone conduction thresholds remained in the normal range in all children.

A successful outcome was defined as an intact TM following the initial surgery, with no retraction or merely the development of a stable, grade I RP of the pars tensa, that required only observation. With these criteria, the procedures proved successful in 32 ears (80%). The success rate was 75% (15 of 20 ears) in the bilateral and 85% (17 of 20) in the unilateral group. The 8 unsuccessful cases comprised 2 residual perforations and 6 grade II RP recurrences in the pars tensa region. The average ages of the patients who exhibited grade II recurrence of the retraction and those with a successful outcome were 6.75 years (4-10 years) and 7.0 years (3-14 years), respectively. There was no significant difference between the two groups ($P=0.842$; Mann-Whitney test). Significantly higher success rates were achieved in the grade II than in the grade III group (26/28 vs 6/12 ears; Fischer's exact test, $p<0.01$) and in the ears with retractions involving only one quadrant compared to those with retractions extending to more than one quadrant (22/23 vs 10/17 ears; Fischer's exact test, $p<0.01$). The overall success rate increased from 80% (32 of 40) to 95% (38 of 40) after the second surgery.

Discussion

In contrast with the pressure of the ambient air, the pressure in the ME is continuously decreasing because of absorption of the gases by the mucous membrane of the ME cleft. Meanwhile, equalization of this difference through the Eustachian tube takes place in stages. Low pressure may develop due to the elastic resistance of the TM. In the case of a partially or totally atrophied, relaxed TM, the absorption of the gases only results in reduction of the volume of the air in the ME cavity without the development of a lower pressure, since the relaxed membrane moves in medial direction without resistance. As the air pressure is equal

on both sides of the relaxed drum, the membrane keeps its medial position. Considering that absorption of the gases is a continuous process and opening of the tube does not alter the position of the relaxed TM, the retraction goes on with all its well-known consequences. Atrophy of the TM caused mainly by prolonged tubal malfunction, which may improve. The period of improvement is critical. After its development, atrophy itself will cause a progression of the pathological process independently of normal function of the tube. This fact explains why patients with a RP might show normal tympanogram.

Picture 1. The change in the number of RPs, intact TMs and residual perforations due to surgeries.

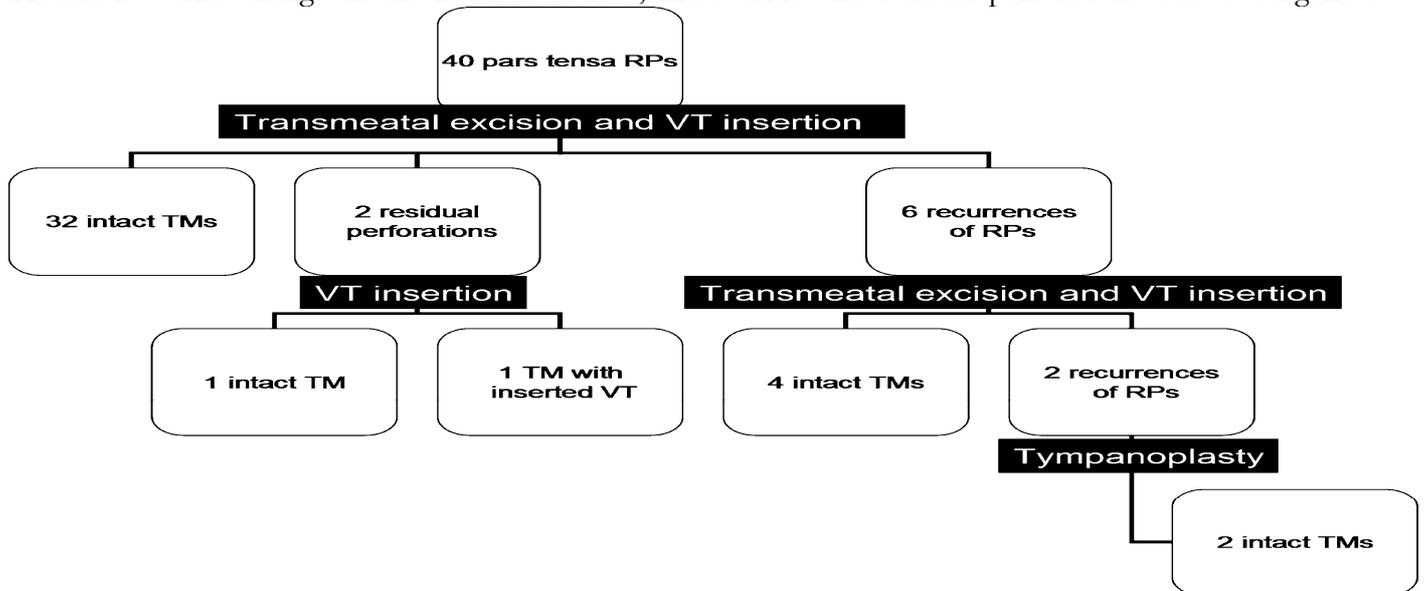


Table III.

Number and percentages of ears in different air-bone gap (ABG) decibel (dB) ranges before and after initial surgery.

ABG (dB)	Number (percentage) of ears	
	preoperative	postoperative
0 – 10	0	19 (47.5%)
10 < ≤ 20	16 (40%)	18 (45%)
20 < ≤ 30	19 (47.5%)	2 (5%)
30 <	5 (12.5%)	1 (2.5%)

Table IV.

Number and percentages of the successful cases and the prognosis in relation with the given scores.

Score	Ears	Successful cases	Prognosis
1	21	21 (100%)	Excellent
2	9	6 (66.7%)	Good
3	10	5 (50%)	Acceptable

The RP may disappear, remain unchanged, continue to grow, or in a minority of the cases, form a cholesteatoma. There does not appear to be any predictive sign that indicate which of these courses will occur. A progressive process can be distinguished from a stable one only through regular follow-ups. We achieved similar success rate in ears with previously undertaken adenoidectomy to those with no adenoidectomy carried out in the past. Adenoidectomy has a beneficial effect on the ET function in the majority of the children with adenoid hypertrophy. It is not uncommon to notice the disappearance of a RP after adenoidectomy. However, if the adenoidectomy was performed when the TM had already atrophied, the atrophy itself caused the progression of the pathological process independently of

the normal function of the tube. The reduction of volume, caused by the resorption of gases, was not followed by the reduction of pressure in the tympanic cavity, as the atrophied TM had already lost its elasticity. The deterioration of the RP went on in the atrophied region. One may speculate that the improvement in ET function caused by the adenoidectomy in a well selected child with a RP and partial TM atrophy may indicate a turning point and the weakened, yet still existing elasticity makes the intratympanic pressure decrease, air enters into the middle ear as the ET opens and the TM hopefully restores its original normal position. Hence, any surgeries aiming at the restoration the tubal function should be performed *before* part of the TM loses its elasticity.

In the current material, the postero-superior site was affected in all but one ear (98%). There is merely poor elastin in this area, leaving a weaker TM once this mesenchyme finally disappears. The postero-superior is the largest of the quadrants, which justifies its greater deflection due to the lower intratympanic pressure. In this region, the fiber distribution of the lamina propria is less able to withstand pressure differences, the tympanic sulcus decreases in depth until it practically no longer exists and the annulus is also reduced in caliber, which explains a less resistant insertion of the TM. Unfortunately, due to the close proximity to the LPI, which is the most vulnerable part of the OC, postero-superior RPs may result in bone erosion.

Nevertheless, cartilage reinforcement of the TM leads to obscuring opacity, which may conceal any evidence of cholesteatoma pearl should it develop behind the eardrum. In cases of grade I-III RPs reinforcement tympanoplasty appears to be unnecessarily aggressive in childhood, when ME aeration tends to become more efficient spontaneously over time. Previously reported closure rates after tympanoplasty and permeal excision were reasonably comparable, in the intervals 54-96% and 87-97%. Transmeatal excision has several advantages over tympanoplasty: it is quicker, simpler, less invasive, is associated with less morbidity and can be performed as a day case. Bilateral RPs can be transmeatally excised in the same sitting, while major ear surgeries with extensive manipulations in close proximity of the ossicles are not recommended to be performed bilaterally. The postponement of the operation of the other ear is time-consuming or might be even depressive for the patient and, not irrelevantly, the additional general anaesthesia contributes to the risks. The healed eardrums showed no sign of scarring or tympanosclerosis in the regenerated area. This suggests that even large traumatic perforations extending to 2 or even 3 quadrants can be treated conservatively. It is not uncommon that the transparency of the drum decreases after tympanoplasty in the grafted region. If an epithelial pearl develops from squamous remnants in the TC due to incomplete removal of the RP, it would be easier to identify it through a transparent TM. Should the excision fail, tympanoplasty can still be performed afterwards. Nevertheless, RPs adhering to the medial wall are extremely difficult to remove completely transmeatally; there is a high risk of tearing of the exceedingly thin TM that may lead to epithelial pearl formation. We do not consider transmeatal excision suitable for grade IV or V situations.

In principle, the excision of RPs in pediatric ears does not require grafting, as the vast majority of the cases will heal spontaneously. Intact TMs following initial surgery with no retraction or with development of a stable, grade I RP of the pars tensa were found in 32 of 40 ears (80%), which is comparable to the findings of others (67-91%). We achieved a mildly higher success rate in cases of unilateral vs bilateral RPs (85% vs 75%), and significantly higher rates in ears with lower vs higher grade RPs (93% vs 50%) and in cases involving one quadrant vs those extending to more than one quadrant (96% vs 59%). Thus, a higher grade

of RP, and the involvement of more than one quadrant of the TM are presumed to indicate a more severe pathology in the background. Recurrence was more likely in patients with bilateral disease. Eustachian tube dysfunction is presumed to resolve in time due to stiffening of the tubal cartilage, widening and lengthening of the tube itself and development of the palatal muscles. In our study, however, similarly as experienced by other authors, the rate of a successful outcome after the initial surgery was independent of the average age of the children. Consequently, it may be speculated that the eardrum might respond similarly in adulthood.

For lack of histological evidence it is only hoped that the newly formed TM in the previously excised area has the classical three layer structure. After transmeatal excision the rate of recurrence of RPs is between 15-20%. This observation suggests that the majority of the eardrums regenerated to at least a certain degree and became a more or less stable membrane. Nevertheless, this part of the TM represented a weaker point; all the six RP recurrences we observed reoccurred in the same quadrant, where the original RP was excised. One may speculate that, in the long run, the rate of RP recurrence in this weaker area would show an increase. The hearing improvement was acceptable, as the average pre- and postoperative ABGs (averaged at 4 frequencies) were 22.4 dB and 9.7 dB, respectively.

Though unsuccessful in many cases, reestablishment of the function of the Eustachian tube is of key importance, as a persistent tubal malfunction may lead to recurrence of the disease postoperatively. After a period of malfunction, the re-improved ET function itself will not make the atrophied, retracted TM to restore the normal position but with autoinsufflation the children may achieve this aim. However, in case of tubal malfunction, autoinsufflation can only present a temporarily solution and has no long-term beneficial effect on the ventilation of the ME cleft as the absorption of gases remains continuous. Nevertheless, a properly inserted VT successfully substitutes the missing tubal function. According to our staging system children with grade II RPs localised within one quadrant may have an excellent, while those with grade II RPs spreading to more quadrants or grade III RPs within the border of one quadrant may have a good prognosis after the transmeatal excision and simultaneous VT insertion. The treatment of pars tensa RPs remains a controversial area, but in well-selected cases this procedure can be performed with high chances of a good surgical and functional outcome.

IV.8. Long term audiological follow up of childhood tympanoplasties

Introduction

Tympanoplasty is performed both in adulthood and childhood. Creation a closed, air-filled TC requires the reconstruction of the TM. The graft can be placed above (overlaid technique) or under (underlaid technique) the fibrocartilagenous ring and the middle, fibrous layer of the TM. According to the nomenclature of the Otorhinolaryngology & Head and Neck Surgery Department of Pécs University, type I reconstruction is to be performed in the presence of intact OC and TM perforation. Type II reconstruction is needed when the incus is missing and the implant is placed between the stapes head and the TM (i.e. short columella,

PORP). The absence of both the incus and the stapes superstructure requires type III surgery, and the implant is positioned between the mobile footplate and the TM (i.e. long columella, TORP). In case of fixation the footplate must be removed and an implant is inserted between the TM and the fascia covering the oval window (type OH). In most of the cases two-stage tympanoplasty is performed in childhood cholesteatoma. During the first stage (sanation) the cholesteatoma is removed and the TM is reconstructed to achieve a closed, air-filled TC without the attempt to reconstruct the disrupted OC (type IV). The OC is only reconstructed in the second stage after ensuring the absence of residual cholesteatoma.

During the aftercare of patients the surgeon gains an impression on the efficacy of the applied technique, mostly influenced by the level of success of the very last cases. However, this subjective opinion might be changed by the complete process of the data regarding to sanation and hearing of all the patients operated on by the same method. Should a surgeon keep on using a certain technique for years the information became especially useful. Such a long term follow up may help to judge the durability in a surgical technique. So far, *Professor József Pytel* has been reconstructing discontinuous OCs in children with the same method of using ACBCs for nearly three decades. The operator developed a windows-based software that eased the data processing.

Patients and method

The data of 328 tympanoplasties have been performed in 202 ears of 176 children under 18 years of age during 29 years (between 1 September 1975 and 30 September 2004) was processed. The audiograms gained in adulthood related to patients being operated on first in their childhood were integrated into the pool of data, too. Twenty-one of that kind of second or third surgery took place after the age of 18.

Table V. The number of different types of tympanoplasties.

	Type I	Type II	Type III	Type IV	Type OH	Exploration	Total
The types of first surgeries	68	30	5	85	0	14	202
The types of further surgeries	2	72	33	11	4	4	126

Table VI. The number of different tympanic membrane repair techniques.

	Intact eardrum	Types of reconstruction of the eardrum								Total
		A	B	C	D	E	F	FC	AD	
Number of cases	17	1	167	3	8	0	0	0	6	202

Results

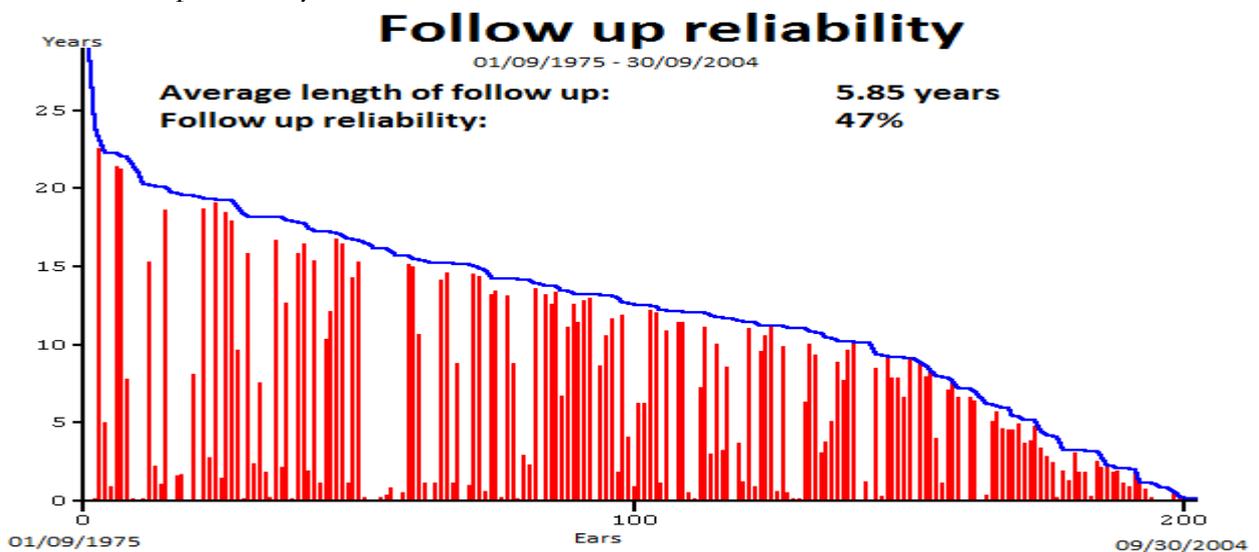
The average age was 11.7 years (ranged between 4.3 and 17.7 years) at the time of the first ear surgery. The number of types of surgeries are demonstrated in Table V. The first stage of a planned two-stage operation (type IV) has been performed in 85 cases, out of these ears the second stage took place in only 67 cases. The number of unplanned second or third stage surgeries was 59. TM repair was required 185 cases (Table VI), performed with underlaid method in 93.2% (167 operation) and with overlaid technique in 16.8% (18 cases). Temporal fascia was used as TM graft in all but one ear: in the lack of ample residual temporal fascia due to graft-takings of previous surgeries a piece of the periosteum covering

the squama temporalis was excised and applied as reconstructive material to the eardrum. The taking rate was as high as 100%, four reperforations (2%) developed during follow-up. 1.86 surgeries (328/176) have been performed per patient and 1.62 (328/202) per ears.

1095 audiograms were available. Due to the young age of 11 children subjective hearing thresholds could not be measured, brainstem electrical response audiometry was gained instead.

Only the hearing results of surgeries of 178 ears were comparable in the sporadic lack of postoperative audiograms. In speech frequencies bone conduction thresholds remained constant and the the air conduction PTAs decreased by 9.1-14 dB. The higher the frequency was the greater decrease of the air conduction PTA was detected. In other words the efficacy of the technique was higher in low frequencies. The decrease of ABGs showed similar pattern and reached at least 11 dB on the speech frequencies. Postoperative $ABG > 20$ dB, $10 \text{ dB} < ABG \leq 20$ dB and $ABG \leq 10$ dB were regarded as unsuccessful, acceptable and good results, respectively. After type I, type II, type III and type OH surgeries the ABG, based on the last audiograms, was evaluated as good or acceptable in 76%, 68%, only 33% and surprisingly high of 80% of the cases, respectively. According to the best audiograms type I, type II, type III and type OH operations were followed by an $ABG \leq 20$ dB in 83%, 80%, 49% and 80%. The rate of best and last postoperative ABGs were compared in different types of surgeries. The rate of cases of good results decreased from 41% to 36%, meanwhile the acceptable group remained almost the same, changed from 33% to 32%. Regarding type III surgeries the acceptable group shrank from 38% to 22%. The rate of postoperative $ABGs \leq 20$ dB decreased from 80% to 68% in the type II and from 49% to 33% in the type III group.

Picture 2. The follow up reliability curve.



The "audiological history" of an ear is well described on the *individual follow up curve*. , Nearly all the important audiological information (the changes in hearing thresholds during even decades, the short and long term effect of surgeries on hearing) is immediately visible on this curve for practised eyes. The *follow up reliability curve* is a summary graph (Picture 2). The follow up reliability percentage value (47% in the present study) is the rate of square filled up by columns proportioned to the total square underneath the curve. The longest follow up and the average length of follow up was 22.5 and 5.85 years, respectively. The *studying curve* helps

to judge the effect of experience on results. The *long term follow up graph* attempts to summarize the hearing results of all the operations ever performed by the given ear surgeon.

Discussion

Unsurprisingly, the best hearing result was achieved in the type I surgeries, as the OC remained intact in these ears. Out of the surgeries with ossicular reconstruction type III were followed by the worst hearing results. It seems as the long type ACBC cannot substitute efficiently enough the three missing ossicles. Additionally, the stapedial footplate might not remain completely mobile after the destruction of the superstructure by the COM in at least certain cases. This incomplete fixation of the annular ligament could not be recognised during intraoperative palpation. The partial fixation could be already present at the time of surgery or could develop only later. Of course, this explanation is clearly speculative as no instrument being capable of detecting intraoperatively even a very mild fixation of the OC was not available.

Moreover, this hypothesis would provide us an explanation on the background of the unpredictably good hearing results of type OH surgeries, as according to this method the presumably partially immobile footplate was removed. In adulthood the hearing results of the type OH procedure is less outstanding. The removal of the footplate results in an open vestibulum that can lead to the inflammation of the inner ear in the presence of COM. Although, it is a very rarely reported complication, it jeopardises even a complete hearing loss. The *studying curve* may require additional earlier data, since prior to the first ear surgery on a child the surgeon had been performing tympanoplasties on adults for approximately 5 years. The *long term follow up curve* demonstrates that the reconstruction with ACBC provided stably good hearing results even in the long run, which fact is against the often cited critique that predicts the shrinkage of the implanted ACBC. Due to the early age of patients audiologists had to face difficulties in taking subjective audiogram. Thus, objective audiological methods were required to determine the hearing thresholds. The 500 Hz and 2-3 kHz frequency range could be examined with middle latency response and brainstem electrical response audiometry, respectively.

The process of the postoperative data of children being operated on with the same technique of reconstruction using autogenous materials for nearly 30 years confirmed that the method provided good results.

V. Novel findings

1. No extrusion was observed after the reconstruction of the LPI with GIC. The ABG averages significantly decreased postoperatively. An $ABG \leq 20$ dB was observed in 79% and 74% one year after surgery and at the time of the last audiological test, respectively. The reconstruction of the LPI with GIC was proved to be successful both anatomically and functionally. Connection was suspected between the prolonged setting time of GIC and the loss of quality of the material. The application of a new package of cement is recommended when the setting is too long. Keeping a spare set of GIC in the operating theatre is advisable. The existence of incomplete fixation of the annular ligament undetectable intraoperatively by palpation is assumed to be the cause of a postoperative ABG of 10-20 dB in case of good aeration of the TC and intact TM.
2. Scarcely, the function of the TTTM, to maintain the proper position of the malleus and to prevent the malleus and the TM from excessive displacement in lateral direction, is required to the success of the reconstruction of the OC. In the described case the measuring of the ACBC was only possible after the reconstruction of the TTTM with GIC and a suturing material, as a novel technique. Usually the ear surgeon has a concern in the reconstruction of the TM and/or the OC and not too much attention is paid to the TTTM. The importance is preserving the tendon is emphasized. The described case illustrates the fact that even the neglected function of the TTTM can be necessary to the success in special cases. In this special case, however, the silastic sheeting prevented the adhesions not only between the medial wall of the TC and the graft, but between the upper end of the malleus handle as well. It seems advisable to keep in mind this possibility during tailoring the silastic sheeting after cutting the tendon.
3. An experimental ME surgery animal model on Pannon white rabbit was worked out by the author. The steps of the exploration of the tympanic bulla was described in detail. The application of the animal model is recommended in the assessment of different ME reconstruction techniques.
4. During the 1-year observation period, the GIC implanted into the ME of rabbits proved to be biocompatible, and the structure of the underlying auditory ossicle remained healthy. Between days 14 and 60, the epithelialization of the material began, and by the end of this period the cement was fully overgrown by a layer of mucosa containing fibroblasts and fibrocytes, that was thicker than normally present in the tympanic bulla of the rabbit. By day 365, the mucosal envelope surrounding the GIC had become a delicate, thin layer. The denudation of the incus presented as a mechanical injury, and thus inflammatory cells, such as neutrophils, lymphocytes and macrophages, were detected only in the denuded group of animals in the first week. The substantial decrease in the inflammatory reaction by day 7 indicated a normal recovery from the tissue injury, the recipient bone adapted well to the GIC within a short time. During the one-year observation period, there was no evidence of any foreign body reaction, extrusion of the implant or bone neo-formation at any point. The present study on rabbits has clearly demonstrated, that GIC adheres more strongly and more durably to a bare bone surface (denuded with a diamond burr) than to an ossicle covered with mucosa. GIC applied to the mucosa was significantly more likely to separate from the ossicle than was GIC applied to the denuded bone. The GIC appeared to integrate more durably with the

ossicle when the mucosa was removed before the application of the GIC paste. The missed or unsatisfactory denudation of the recipient bony surface may play a role in the lack of audiological success after OC reconstructions with GIC. The mucosal lining under the GIC disappeared between days 30 and 60 in the right-side (not denuded) ossicles. Interestingly, the separation of the GIC from the ossicle covered with mucosa was first detected on day 60, and later became more frequent. It may be speculated that the postoperative disappearance of the mucosa between the GIC and the bone possibly weakened the adherence of the GIC to the incus. The denuding of an ossicle can be achieved with a prick, a hook or a needle, but complete removal can be attained more securely by means of a diamond burr or laser.

5. The first domestic observations on the KTP laser assisted stapedotomy with a self-crimping, thermal shape memory Nitinol piston were reported. The average postoperative ABG was still lower than 10 dB after 9 months in the majority of patients (85%) and no increase in bone conduction thresholds was experienced. Less bleeding in the operative field and less cicatrization in the TC was found with this technique. Compared with the traditional stapedotomy this method is less invasive, the postoperative dizziness is less severe, the hospitalization is shorter, thus the technique is cost-effective. Even in less experienced hands, the method is capable of providing permanent and significant decrease of the ABG.
6. The method of KTP laser assisted myringoplasty used for the repair of anterior and subtotal TM perforations, first applied in Hungary, was described in detail. Taking rate was measured as high as 100%. Reperforation was observed in one ear requiring reoperation. The postoperative ABG based on the best audiograms and averaged on four frequencies has been decreased with more than 10 dB compared to the preoperative value. Using the KTP-laser no bone conduction elevation was observed during the postoperative follow up period in any frequencies which gave rise to the fact that dissection of the drum remnant from the intact OC did not cause cochlear damage. Less bleeding is also beneficial from the viewpoint of better intraoperative visualisation. Wide canalplasty is recommended to ease the manipulation around the anterior edge of the TM and the postoperative follow up.
7. In the first domestic publication on the transmeatal excision of pars tensa RPs and simultaneous VT insertion the removal of 40 grade II and III RPs of 30 children was reported. In 80% (32/40) of the ears intact TM or only mild retraction developed on the pars tensa that did not require treatment. The ABG decreased to 9.7 dB after surgery from the preoperative value of 22.4 dB. Residual perforations were noticed in two ears and grade II RPs developed in six cases. Reoperations were performed in all the eight ears that resulted in continuous eardrums, but grade II RP development was observed again in two ears. The age of children did not influence the results. Recurrence was more likely in bilateral pathology, higher grade and greater extent of the RP. A new staging system was introduced to facilitate the selection of candidates with good prognosis for this procedure.
8. The results of reconstruction of TM and/or OC in 328 childhood cases using the same technique and autogenous materials for 29 years were evaluated and proved the good functional and anatomical efficacy of the method in the long run. 9.1-14 dB decrease in air conduction thresholds was achieved between 250 and 2000 HZ while the bone conduction values remained almost constant. The ABG showed a decrease of at least 11

dB on speech frequencies regarding the whole patient material postoperatively. The efficacy of bettering hearing was higher in low frequencies. The taking rate was 100% and the reperforation rate was only 2%. Based on the best postoperative audiogram an $ABG \leq 20$ dB was detected in 83%, 80%, 49% and 80% after type I, II, III and OH techniques, respectively. According to the last postoperative data this value altered to 76%, 68%, 33% and 80% in type I, II, III and OH surgeries, respectively. Out of type I, II, III and OH tympanoplasties the best hearing results were achieved with type I technique, since the OC was intact in these cases. The less favourable results were gained with type III method (TORP). It seems as the long type ACBC cannot substitute efficiently enough the three missing ossicles. Additionally, the stapedial footplate might not remain completely mobile after the destruction of the superstructure by the COM in at least certain cases. This incomplete fixation of the annular ligament could not be recognised during intraoperative palpation. This observation may furnish explanation for the unexpectedly good results of type OH surgeries, as according to this technique the partly fixed footplate was removed. The *individual follow up curve* has been introduced to facilitate the demonstration of the "audiological history" of the examined ear. Nearly all the important audiological information (the changes in hearing thresholds during even decades, the short and long term effect of surgeries on hearing) is immediately visible on this curve for practised eyes. The herein introduced *follow up reliability curve* is a summary graph that describes the level of monitorization, the regularity of check ups and the length of follow up.

VI. Publications

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The impact factor of citable abstracts and publications related to the theses:

5.512

Cumulative impact faktor:

10.087

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VII. Acknowledgement

My grateful thanks go to my teachers and masters, Professor Miklós Bauer, Professor József Pytel and Professor Imre Gerlinger, who always provided professional and scientific guidance when I was in need. For the completion of my work, I hereby express my thanks to the Topic Supervisor Professor Imre Gerlinger, who always monitored my work with care, guided me with constant encouragement and aided me. I owe many thanks to Professor Dénes Molnár for his support, László Kereskai for the hystological examination of the specimens, Ildikó Fábián for her kind and reliable assistance during surgeries on animals and László Pótó and Sára Jeges for their valuable help in statistical analysis.

Herein, I wish to thank everyone providing me encourage, help and support in the Departments of Otorhinolaryngology & Head and Neck Surgery, Surgical Research and Techniques and Pediatrics in Medical Faculty, Pécs University. I owe the utmost gratitude to my parents, my sister, my friends, my wife and our sons for their understanding patience and the loveful, supportive atmosphere I could work in.