

Our experiences with revision stapedotomies: The role of periprosthetic fibrosis formation in the development of unsatisfactory hearing results after stapedotomy.

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Abstract

KEY POINTS: - Our goal was to identify the most common and most influential postoperative reasons causing persistent ABG. Our focus was concentrated on the mechanical dysfunctions in the middle ear, with special regard to postoperative fibrosis formation. - Periprosthetic adhesion formation was seen in 64% of the cases, and it was the primary cause behind the unsatisfactory hearing result in 32% of all cases - There was no significant difference in the level of persistent ABGs across groups of fibrosis and surgical failure after primary surgery - Periprosthetic fibrosis is the most common reason for compromised audiological outcomes after stapedotomy, and has the same negative effect on ABG development as any other surgical failure, while the revision could be more challenging in these cases - The use of the most atraumatic surgical technique and preservation of intact intratympanic mucosa is a key factor during middle ear surgery.

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KEY WORDS: fibrosis, stapedotomy, revision stapedotomy, stapes surgery, audiological results, hearing, microsurgery, middle ear surgery, stapes prosthesis,

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- Periprosthetic fibrosis is the most common reason for compromised audiological outcomes after stapedotomy, and has the same negative effect on ABG development as any other surgical failure, while the revision could be more challenging in these cases
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Abbreviations:

TM- tympanomeatal

ISJ-incudostapedial joint

AC-air conduction

BC-bone conduction

ABG-air-bone gap

PTA-(extended) pure tone average

LPI-long process of incus

TOST- two-one-sided t-tests

Introduction

Stapedotomy is considered as an efficient and safe surgical option in the treatment of stapes fixation. It has been shown that the postoperative ABG of 10 dB or less (which is defined as surgical success according to AAO-HNS guidelines(1)) could be achieved in 87-97% of the cases(2). Although this number has to be considered as a high success rate, it means that at least one revision is needed in 13-3% of the surgeries. According to the available data, revision surgeries are generally more difficult to perform and their audiological results are inferior to primary surgeries(3). The prevention of primary failure seems to be the most favorable option to achieve superior results. Revision surgeries offer the opportunity to recognize the exact reasons behind unsatisfactory results. According to previous data, intratympanic adhesion formation is one of the most common findings during revisions(4, 5), but its influence on the hearing results is not clear yet. Our goal was to identify the most common and most influential postoperative reasons during our revision surgeries, causing persistent ABG. We focused on the mechanical dysfunctions in the middle ear, with special regard to postoperative fibrosis formation. Our hypothesis was that postsurgical inflammation and scar tissue formation in the middle ear could be the main reason behind compromised ABG gain.

Materials and methods:

Compliance with Ethical Standards:

Conflict of interest

The authors declare that they have no conflict of interest.

Ethical approval

This research was approved by '[removed for blind peer review]'. For this type of study, formal consent is not required.

Patients: A retrospective case series study of 25 revision stapedotomy was performed. The surgeries were carried out between 2013-2020, at the Department of Oto-Rhino-Laryngology, Head and Neck Surgery [removed for blind review]. The indication for revision was 10 dB or higher persistent ABG-PTA. The presumed preoperative clinical diagnosis of stapes fixation before primary intervention was made by PTA testing, tympanometry, stapedius reflex, and physical examination, and was confirmed with palpation during the surgery. Out of the 25 cases, 7 patients were male and 18 were female, with an average age of 50.52 (SD 11.5) years.

Surgical technique: In all of the cases, the same standardized surgical approach was applied and performed by the same senior surgeon. After an endaural approach, the posterior TM flap was lifted, and the cause of failure was verified by the palpation of the ossicular chain and with microscopic examination. According to the intratympanic findings, prosthesis replacement or repositioning was performed, and adhesions were removed. In five cases, malleovestibulopexy was performed. Stapedectomy was performed in one case only, otherwise, small fenestra technique was preferred.

The prosthesis loop was bridged with a small connective tissue to prevent the slipping and necrosis of the long process. The TM flap was restored, meatal incisions were overlaid with sterile silicone sheets, and the

ear canal was stuffed with ofloxacin-impregnated absorbable hemostatic gelatin sponge (Spongostan) pieces. The incision was closed with sutures.

The length of the applied prosthesis was 4.5mm in 56%, 5mm in 8%, and 6mm in 20% of the cases, with a diameter of 0.4mm in 32% and 0.6mm in 52%. The majority (52%) of the applied pistons were Schuknecht fluoroplastic, stainless, slim shaft wire pistons (Gyrus Acmi, USA), Richards Platinum Fluoroplastic Pistons (Olympus, Japan) were applied in 32% of the cases. In the remaining surgeries the original pistons were used (16%).

Methods:

In all the cases, the exact reason behind the unsatisfactory primary results and the surgical solution was noted. Intratympanic problems were classified based on whether the failure was related to scar tissue formation (periprosthetic adhesion, ossicular chain fixation) or any other specific surgery-related complication (LPI necrosis, prosthesis dislocation, ossicular luxation etc.). Fibrosis was considered as the main reason if it was the only finding during surgery.

The average postoperative follow-up time was 147 days (SD 155.7; range 28-614), which could be considered as a reliable indicator of the long-term results (6).

The AC levels were measured at 0.125; 0.25; 0.5; 1; 2; 4; 8 kHz, and the BC were registered at 0.25; 0.5; 1; 2; 4 kHz. Evaluation was done according to the Committee on Hearing and Equilibrium guidelines of the American Academy of Otolaryngology Head and Neck Surgery (AAO-HNS) (1). The thresholds were reported, and the extended pure tone average was calculated from 0.5; 1; 2; 3 kHz frequencies. The 3 kHz values were considered as the mean of 2 and 4 kHz (7). The ABG was calculated from same-time measurements. These data were retrospectively analyzed statistically (IBM SPSS v. 25., Armonk, New York, USA) to define descriptive data and the difference between types of surgical failure. Bootstrapped Independent Samples t-test was used for analyzing group differences, while intervention success was examined with Paired Samples t-test. TOST test with the effect size of '1' was used to determine equivalence and non-inferiority (TIBCO Statistica). The statistical significance level was $p < 0.05$.

Results:

Fig1. The average postoperative AC-PTA was 46.4dB, which is significantly better compared to the 61.5dB preoperative value. ABG-PTA also significantly improved after the surgical intervention: 15.9dB vs 31.1dB. No significant difference could be seen between pre- and postoperative BC-PTAs, 30.4dB vs 30.5dB. The minimum of 30dB AC-PTA was achieved in 44% of the cases. In 56%, at least 10 dB ABG gain was achieved, while the 10dB or better ABG closure was 44%, ABG closure between 10-20dB prevailed in 20%. Fig2 Intratympanic fibrosis was the most common finding during revision; with a prevalence of 64%, in 32% it was the main reason behind compromised ossicular chain mobility. In the remaining 36%, the main problem was due to surgical failures. The most common prosthesis-related complication was the disconnection between the piston loop and the LPI. Both fibrosis and surgical failure was noticed in 32% (fig2). According to fig2, the highest hearing gains were accomplished in cases where the cause of failure was LPI-prosthesis disconnection, while in the cases with adhesions as the primary cause of failure, the hearing gains were the lowest. Fig3

Although in the presence of intratympanic fibrosis mean ABG gain and hearing gain was lower compared to other cases (fig3a), no statistically significant difference could be found ($p = 0.087$; $p = 0.095$). On this basis, TOST test was performed to determine equivalence. Concerning hearing gain and ABG gain, equivalence was rejected, and the non-inferiority of the intratympanic fibrosis associated negative effect was shown compared to the other group ($p = 0.94$ upper tailed; $p = 0.037$ lower tailed and $p = 0.94$; $p = 0.03$ respectively).

There was no statistically significant difference between preoperative (after primary stapes surgery) ABG and AC PTA levels across 'fibrosis' and 'no fibrosis' groups (fig3b) ($p = 0.44$ and $p = 0.96$ respectively).

Discussion: (4)

Primary findings: Revision stapedotomy is a valuable treatment option in case of unsatisfactory hearing results after primary stapedotomy. However, our results – in consensus with other data – show that audiological outcomes in these cases are still inferior to primary surgeries. From this standpoint, the efficacy of the first operation is extremely important in stapes surgery.

The experience during revision surgeries could be helpful in understanding the reasons behind unsatisfactory results. In our series, periprosthetic adhesions were the leading cause behind mechanical failures. Adhesive processes were not only very common, their negative impact on hearing results was the same as that of any other prosthesis-related complication. Furthermore, after revision surgery, in the presence of intratympanic adhesions, audiological results were not superior compared to the remaining cases. The difficulty of managing patients with adhesions was described previously in the literature (4).

This finding highlights the importance of the most atraumatic surgical technique, the preservation of intact intratympanic mucosa, and the prevention of post-surgical scar tissue formation.

Using perioperative corticosteroid treatment to prevent postoperative fibrosis is already a topic of discussion (8). Our group was the first to describe that the above adjuvant treatment contributes to a significantly better ABG closure after primary CO₂ laser stapedotomy compared to the control group (9). Our assumption was that this contribution is manifested through the prohibition of scar tissue formation.

Limitations:

Due to the retrospective setting and the low number of cases, the statistical power of this study is limited, which could explain why no statistical difference, but non-inferiority was demonstrated.

The data represents the results of a single institution and a single surgeon. Evaluation is based exclusively on subjective hearing tests, however, pure-tone audiometry is still considered as the gold standard for monitoring hearing outcomes after middle ear surgery.

Conclusion: In our experience, revision stapedotomy is an efficient treatment option in case of persistent ABG after primary surgery. Periprosthetic fibrosis is the most common reason behind compromised audiological outcomes after stapedotomy. We also concluded that fibrosis formation itself has at least the same negative effect on ABG development as any other surgical failure, although revision could be more challenging in such cases. According to these findings, the exclusion of postoperative inflammatory reactions in the middle ear are mandatory for optimal results. The role of perioperative corticosteroid treatment could play a major role in this process. Further investigation is recommended concerning this topic.

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