Effectiveness of Stapedotomy with Inversion of Surgical Timing in the Treatment of Otosclerosis: Short-Term Results of a Prospective Study

L Livi[1], N Fagni[1], G M Fiori[1], L Salerni[1], M Mandalà[1]

1) Dept. of Medicine, Surgery and Neuroscience, University of Siena, Siena, Italy.
Corresponding Author: Niccolò Fagni – niccofagni93@gmail.com

Abstract. Over the last 30 years, stapes surgery has undergone notable changes, evolving from an initial stapedectomy operation to the more current stapedotomy and stapedotomy with reversed times. The aim of the study was to demonstrate how, through the choice of a reversed stapedotomy procedure, it is possible to improve the quality of life of patients suffering from otosclerosis, in terms of improvement of auditory perception and the more objective audiometric examination. The study analyzed patients operated on from December 2014 to March 2016, for a total of 81 operations (m25 f56). For each patient we researched the audiometric tests carried out the day before the operation and three weeks after. In the evaluation of each exam, analyzing the frequencies of 500-1000-2000 Hz, we calculated the average value of the VA and the ABG and, by comparing the pre-operative values with the post-operative ones, the gain or each patient's hearing loss. Finally, the 81 cases were divided into 4 classes based on the pre-operative air bone gap values.
The study carried out, in accordance with the data present in the literature, demonstrates that the reversed time technique guarantees an excellent improvement of the air bone gap. It also highlights how there is uniformity in hearing recovery for classes A, B and C quantifiable with an average improvement of 64.08% of the starting gap. As regards class D, due to the worse starting situation, a smaller decrease in the gap is calculated at around 52.05%.

Keywords: stapedotomy with reversed times, otosclerosis, air bone gap.

Introduction

Otosclerosis is an otological condition characterized by abnormal bone growth within the otic capsule, leading to progressive hearing loss. This pathology primarily affects the middle and inner ear, with a significant impact on the stapes, one of the three ossicles in the middle ear, which becomes immobilized due to the sclerotic process. This immobilization impairs the transmission of sound waves from the tympanic membrane to the cochlea, resulting in conductive hearing loss.

Anatomical and pathological lesions of otosclerosis have an incidence rate ranging from 6% to 12%, although the clinical manifestation of the disease occurs at a lower rate of 0.2% to 2%. This discrepancy is attributed to the site of the disease development, which can affect non-functional areas of the labyrinthine capsule, leading to silent otosclerosis.

The disease manifests within an age range of 10 to 48 years. Recent studies (Dejuan et al.) provide a more detailed description of the disease incidence, indicating that it develops in 28% of young individuals between 18 and 21 years, 40% of those between 21 and 30 years, and 22% of those between 21 and 40 years. Ethnicity and gender also provide indicators of the probability of developing otosclerosis: it is well-established that the Caucasian population is more predisposed to the

condition, with an incidence rate of 1%. The disease is bilateral in 70%-80% of cases and usually manifests symmetrically. Females are more affected than males, with a ratio of 2:1. This discrepancy between sexes is due to endocrinological and hormonal differences:

triggering factors for the pathology, especially in its bilateral form, include pregnancy, lactation, and estrogenic hormonal therapies.

Regarding its incidence among different populations, otosclerosis is the predominant cause of hearing loss in Europe and the USA, while it appears to be less frequent in the Japanese population. The causes of the disease are multiple, with new hypotheses continually emerging over the years. The diagnosis of otosclerosis is based on data obtained from the patient's medical history, including recent, remote, pharmacological, and family history, as well as information derived from otomicroscopic examination, which usually shows a normal tympanic membrane, audiometric tests, and especially impedance testing, which includes tympanometry and stapedial reflex testing.

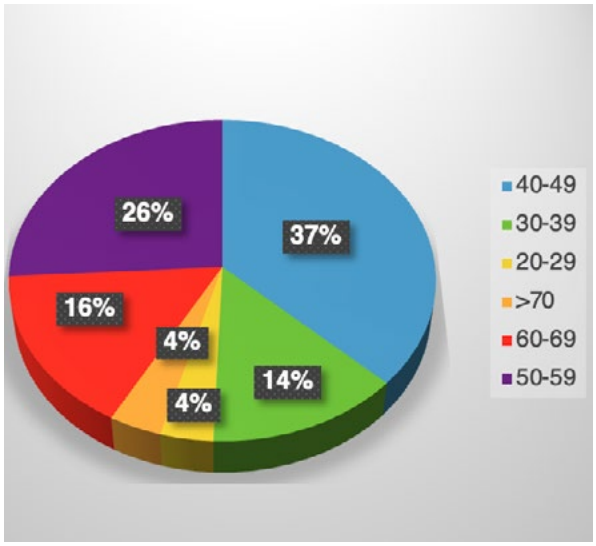
Starting from 1987, the stapedotomy technique with reversal of surgical times was introduced at our clinic as an elective procedure for otosclerosis treatment, reserving the classic stapedotomy only for those rare cases in which it is not feasible. This last type of operation was carried out on 2538 patients (1726 women, 812 men aged between 8 and 81 years) in the period between 1987 and 2014 and in another 81 cases (25 men and 56 women) starting from December 2014 to March 2016.

The aim of the study was to demonstrate how, through the choice of a reversed stapedotomy procedure, it is possible to improve the quality of life of patients suffering from otosclerosis, both in terms of improvement of auditory perception and optimization of audiometric test.

Case studies

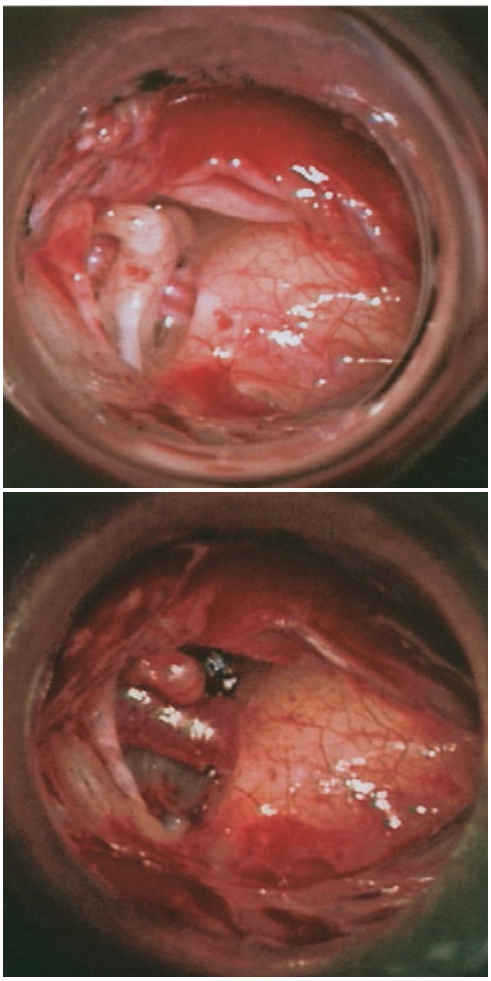
In this prospective follow-up study, we evaluated the short-term functional results of patients who underwent stapedotomy surgery in our Clinic with reversal of surgical times from 01/12/14 to 03/18/16. The population examined included 81 patients of which 26 were male and 56 were female; 3.70% of the patients were aged between 20-29 years, 13.58% between 30-39 years, 37.03% between 40-49 years, 25.92% were in the range between 50-59 years of the cases, in those between 60-69 years 16.04% and finally 3.70% were aged ≥ 70 years. (**Figure 1**)

Figure 1



In 6.17% of patients (5 out of 81) the operation was performed bilaterally with an average time interval between the first and second operation of one year and six months. In a single patient, due to an anatomical anomaly of the facial nerve, which was damaged, a classic stapedotomy was necessary. A second case, again due to the presence of a prociding facial nerve, received a stapedotomy operation only partially with reversed times characterized by the fracture of the crus posterior of the stapes and the maintenance of the crus anterior. 7 patients out of 81 (8.64%) went to our center to undergo revision surgery, 3 patients for disarticulation of the old prosthesis, 3 for the formation of fibrous tissue and one patient for necrosis of the long process of the incus . The remaining 72 cases, including those who presented anatomical anomalies [3 patients with protruding facial nerve, 2 patients with exposed facial nerve, one patient with persistence of the stapedial artery (**Figure 2**) and one patient with fusion of the branches of the stapes], were treated with a stapedotomy operation with reversal of surgical times.

Figure 2: Persistence of the stapedial artery that runs between the branches of the stapes and removal of the branches of the stapes with sparing of the stapedial artery.



Inclusion and exclusion criteria

Patients undergoing stapedoplasty had a normal tympanic membrane on otomicroscopic examination, a conductive or mixed hearing loss with the presence of gaps between VA and VO on audiometric examination, a normal tympanogram or with slightly reduced compliance, the absence of the reflex stapedial and good vocal discrimination. The contraindications to the surgery were divided into absolute, such as the presence of a single hearing ear, a gusher in the contralateral ear and endolymphatic hydrops, and temporary contraindications such as an ongoing infection or a perforation of the tympanic membrane. In the case of bilateral otosclerosis we operated on the worse ear first and, only in the case of recovery and stabilization of hearing values, we also operated on the contralateral ear after no less than a year. The study included all those patients who received stapedotomy surgery with reversal of surgical times, who were operated on by the same surgeon and to whom the same prosthesis was applied, who attended all check-ups and who did not have developed a pathology capable of causing conductive hearing loss.

Of the 81 total patients we therefore excluded the 7 patients who had received revision surgery and the two cases of classic stapedotomy and stapedotomy with partial surgical time reversal. In the follow-up three weeks after surgery we therefore studied 67 patients for a total of 72 ears as 5 patients (6.94%) were operated on bilaterally.

Description of the technique

The operation was performed in all cases under local anesthesia and as day surgery. Patients, after correct disinfection of the operating field, are infiltrated with 6-8 cc. of Marcaine in the retro-auricular sulcus and with 2 cc. of Marcaine with adrenaline in a ratio of 20.000:1 in the external auditory canal. Anesthesia of the external auditory canal is performed in four points, two of which are on the anterior wall and two on the posterior wall. This infiltration, in addition to having an anesthetic purpose, also helps to detach the skin of the duct from the bone plane and reduces bleeding by causing vasoconstriction. The position of the patient on the operating bed is of fundamental importance as it allows to increase the visible area of the tympanic cavity: the patient's head is rotated 20° to the opposite side of the operator and the operating bed must be inclined 30° towards the patient's head. After a correct cleaning of the ear canal, the surgeon positions an ear speculum of the largest possible size for that specific ear canal and this speculum will be kept in place throughout the operation by the index and middle fingers of the operator's left hand.

The endocanal access to the tympanic cavity is the one according to Rosen and is based on an incision with a Beaver scalpel approxi-

mately 8 mm from the tympanic membrane, proceeding from 12 to 6 o'clock. The meatal-tympanic membrane is raised and folded forward on the handle of the hammer thanks to the Sultan micro-detacher and a cottonoid. Once inside the tympanic cavity, the chorda tympani is located and dislocated downwards and if it adheres to the stapes it becomes necessary to section it. Very often the stapes is not perfectly visible as it remains covered by the postero-superior edge of the duct: in this case it is necessary to proceed with an atticotomy using a micro-drill or a House's spoon.

The main purpose of this step is to fully visualize the operating field which includes the II section of the facial nerve, the incudo-stapedial joint, the stapedial branches, platina, the pyramidal eminence, and promontory. Before starting the actual stapes surgery, it is advisable to touch the handle of the malleus to ensure that the sound transmission block is not at that level; once this has been established, using the Zini measurer, the distance between the long apophysis of the incus and the platina is calculated. The prosthesis is chosen and, after placing it on the appropriate measurer, it is cut to a length 0.2-0.5mm greater than the calculated distance. Finally, using a self-static clamp, it is hooked and positioned ensuring the right inclination. The platinotomy is performed with a 0.6 mm Shea "Skeeter" microdrill and a hole is created in the posterior third of the platen (at this level there is a greater safety margin between the platen and the saccule) with a diameter 0.1 mm greater than to that of the prosthesis. The use of the micro-cutter is of fundamental importance: it must be activated before contacting the platen and stopped only once it has left it since, by acting differently, it could hook the platen and "tear" it. Once the prosthesis has been positioned inside the platinar hole, the hook is anchored around the long process of the incus and fixed using Mc Gee forceps.

Carrying out these surgical steps on a rigid system, guaranteed by the presence of the platina branches and the incudo-stapedial ligament, ensures a lower incidence of platina fracture, easier measurement of the incudo-stapedial distance, reduction in labyrinthine trauma and easier anchoring of the prosthesis.

Subsequently, the stapedius tendon is cut with micro-scissors, the stapes is disarticulated with a House hook, the anterior and posterior branches are fractured with the same hook and finally the superstructure is removed (**Figure 3**). With a tip, the handle of the hammer is touched to verify the movement of the reproduced ossicular chain and a drop of blood is slid onto the platinar hole to keep the prosthesis in place. The chorda tympani is repositioned in place, the tympanomeatal flap is overturned, the patient's hearing is checked by asking a few questions in a low voice and the operation is concluded with the medication. This last step involves the use of a Merocel, which is an expandable sponge that inflates once positioned in the center of the duct and soaked in antibiotic solution, and small fragments of Gelfoam. The first swab is removed the day following the operation while the Gelfoam is removed approximately 20 days later.

Evaluation of results

For each of the 81 cases, audiometric tests carried out the day before the operation and those dating back to the follow-up visit held 21 days after the surgical procedure were searched for. Consulting the literature review on stapes surgery we found a variety of criteria used to establish surgical success rates. In various guidelines proposals, the average of the pure tone threshold (PTA) at the frequencies of 500-1000-2000 Hz has been considered the most important parameter as these frequencies are those most involved in speech discrimination (Williams 1963, Sakai 1994). In most studies, surgical success is evaluated with the improvement of the air-bone gap (ABG) induced by the restoration of the conduction system of the middle ear. Initially, post-operative VA and pre-operative VO values were used (Engel at al 1984, Bailey at al 1986) while nowadays, thanks to Carhart's discoveries, we prefer to use post-operative VO values.

For our study we chose the last analysis criterion: considering the frequencies of 500-1000-2000 Hz we calculated the average values of VA, VO and with these data we obtained the pre-operative and post-operative air bone gap. Taking into consideration the

results relating to the pre-operative GAP, the patients were divided into four populations each sharing the same interval:

GAP between 10-20 dB - GAP A – 22 patients
GAP between 21-30 dB – GAP B – 29 patients
GAP 31-40 dB – GAP C – 18 patients
GAP ≥ 40 dB – GAP D – 12 patients

For the sake of accuracy of the investigation we eliminated the 9 patients who had received an operation other than stapedotomy with reversal of surgical times and the values of the hearing gain expressed by the improvement in the GAP were indicated for the remaining cases.

Results

Examining the 72 patients treated with a stapedotomy with reversal of surgical times we found that 2.77% (2 cases out of 72) achieved a total hearing recovery compared to the pre-operative value, with a complete closure of the GAP; 4.16% (3 cases out of 72) did not benefit from the operation and maintained the same pre-operative gap value; 93.05% (67 cases out of 72) showed good hearing gain. In patients who had a pre-operative type A GAP, an average gain of 9.46 dB was calculated for a gain percentage of 63.12% (**Figure 4**). The subpopulation with a pre-operative type B GAP recovered on average 16.60 dB expressed with a percentage of 66.40% (**Figure 5**). Patients with a type C GAP post-surgery recovered on average 21.96 dB for a percentage of 62.74% (**Figure 6**). Finally, the class characterized by a type D GAP gained 27.59 dB in the post operative period for a percentage gain lower than the previous ones and calculated at around 52.05% (**Figure 7**).

Figure 3: Platinotomy, insertion of the prosthesis, cutting of the stapedius tendon, disarticulation and removal of the superstructure.

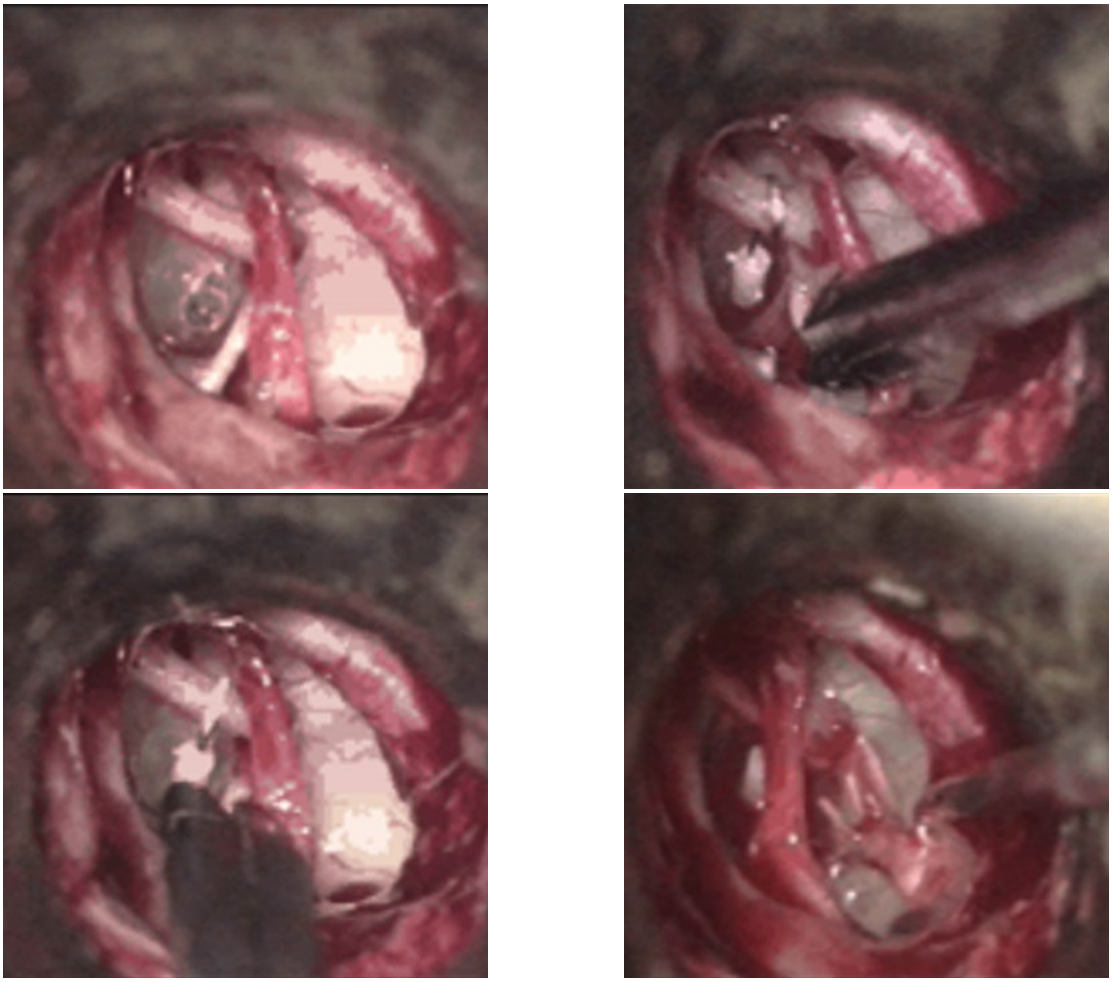


Figure 4: Class A

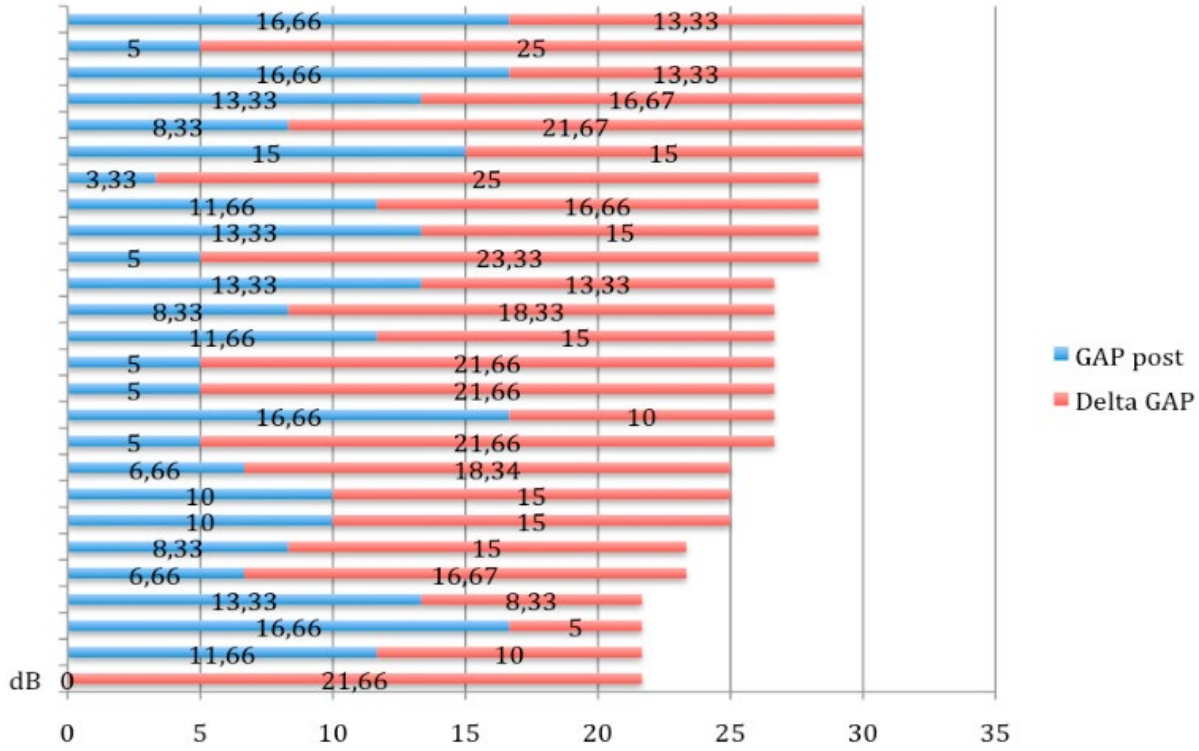


Figure 5: Class B

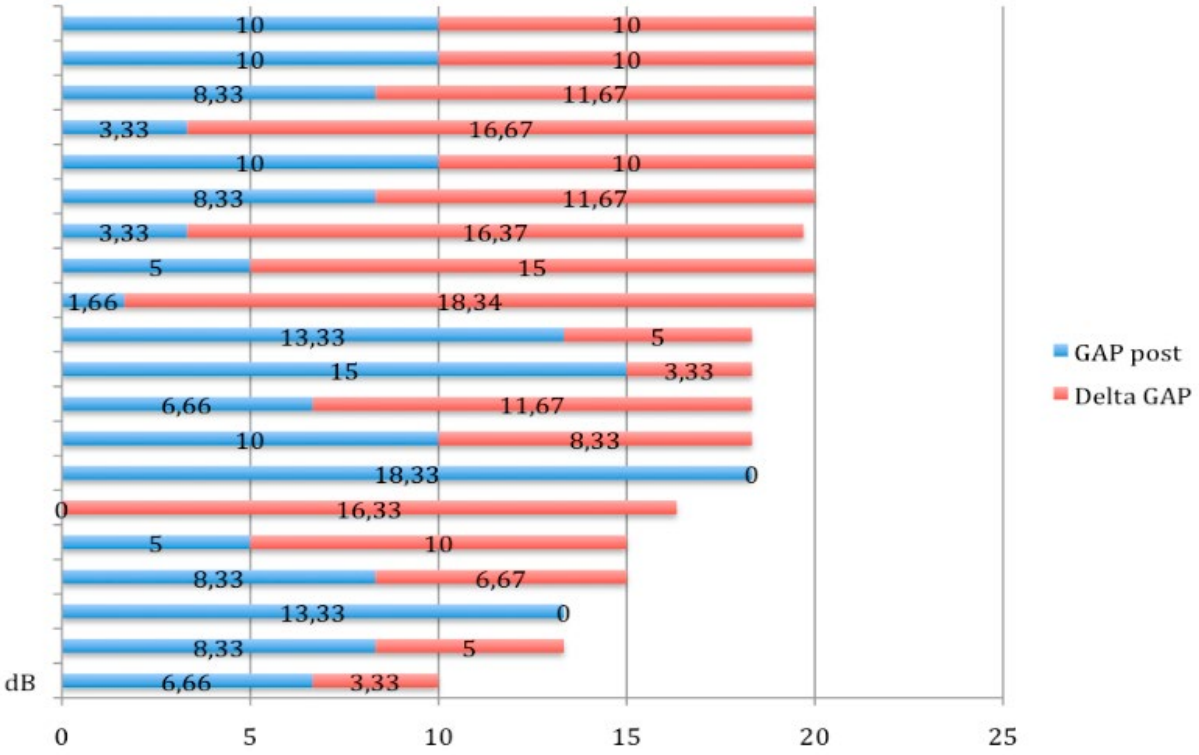


Figure 6: Class C

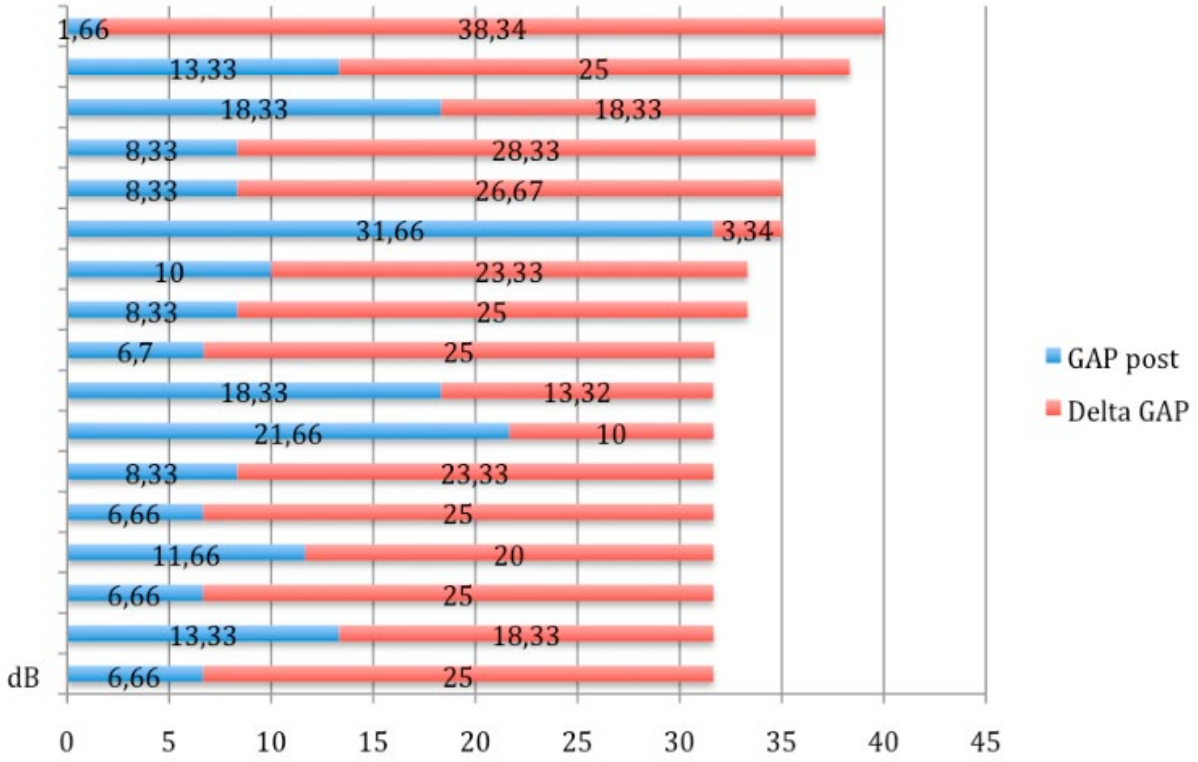
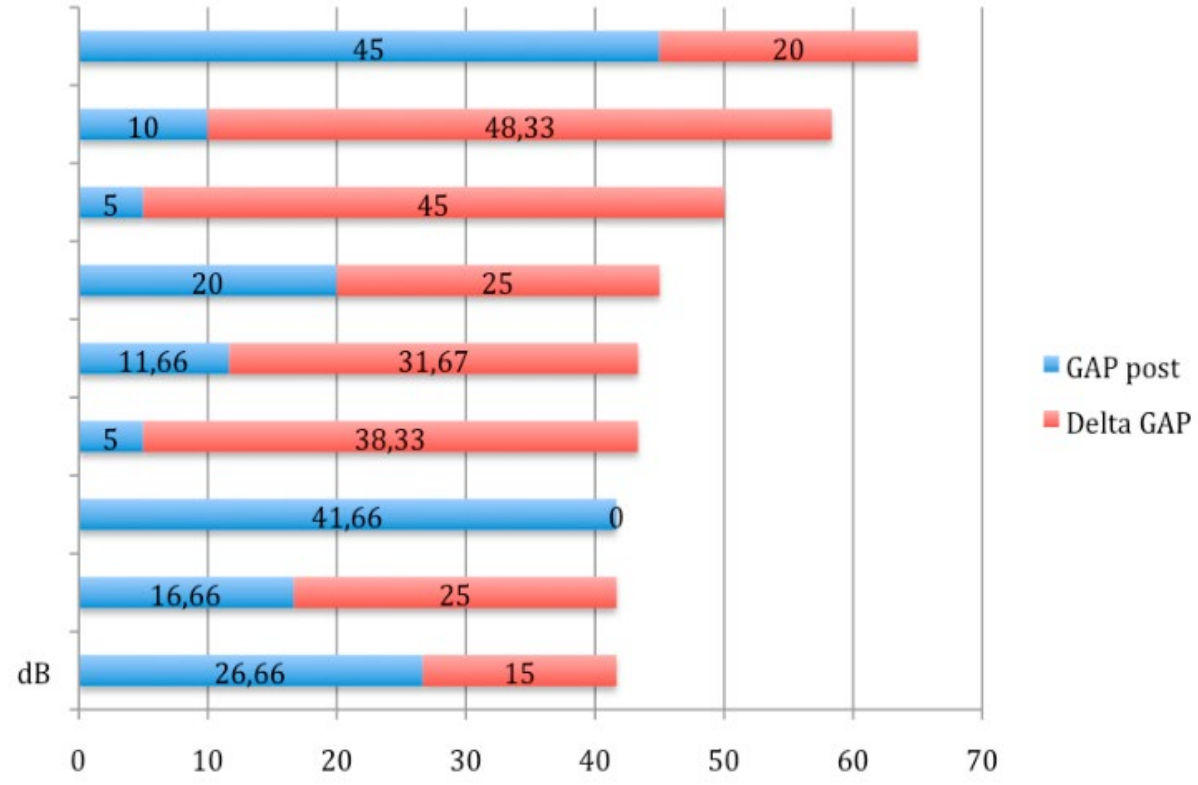


Figure 7: Class D



Furthermore, two statistical analyzes were carried out, the T-Test and the analysis of variance (ANOVA) using Prism - GraphPad software, detecting values both generic and divided by classes statistically significant with a *P-value* < 0.000037 (The result is significant at $p < 0,05$). (**Figure 8**, **Figure 9**).

Figure 8:

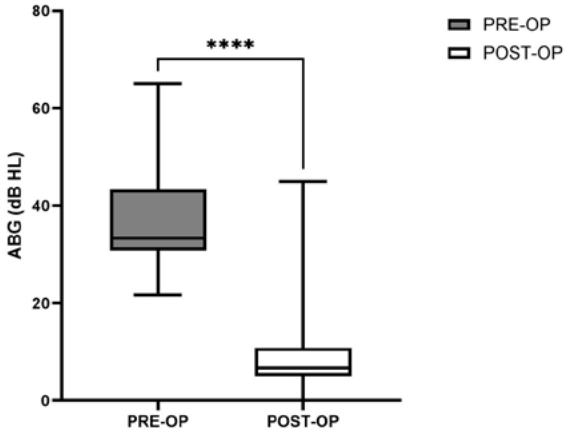
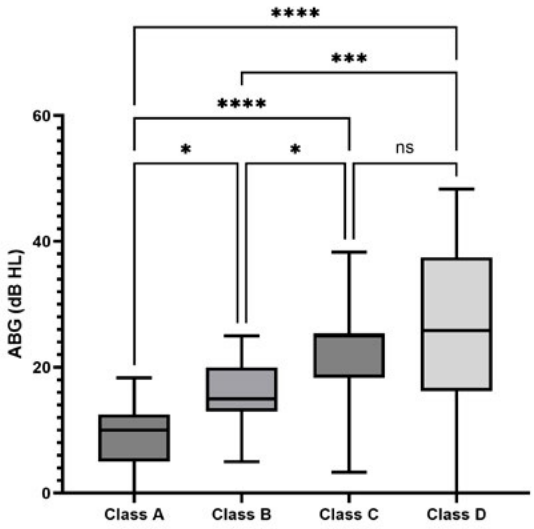


Figure 9:



Discussion

The choice of one surgical technique rather than another for the treatment of otosclerosis depends on three conditions: less development of post-operative complications, better hearing recovery, longer lasting results.

Many studies have compared the audiological results of stapedectomy and stapedotomy (Fisch 1982, Colletti at al 1994, Kürsten at al 1994, Sedwick at al 1997) and most demonstrate that there is no statistically significant difference between the two techniques in closure of the ABG. From these works it appears that only the skill of the surgeon could make the difference regardless of the procedure, the instrumentation, and the type of prosthesis.

The studies in the literature also state that excellent results are short-term ones while, over the years and regardless of the technique, there is hearing deterioration. The least significant part of the hearing loss is caused by a decrease in sound transmission due to fibrosis that has developed around the piston, on the articular ligaments or to a new otosclerotic focus. The largest part of the decay is instead due to the impairment of cochlear function. According to most authors (Smyth at al 1986, Birch at al 1986, Del Bo at al 1987, Bauchet at al 2008) this hearing loss would be linked partly to presbycusis and partly to the cochlearization of otosclerosis, due to the release of lytic enzymes from the otosclerotic focus or by direct invasion of the otosclerotic focus into the labyrinth. An etiopathogenetic alternative could be sought in the same surgery which could cause damage to the inner ear in the long term. Precisely by appealing to this last observation we could hypothesize that surgery with reversal of surgical times, thanks to the lower onset of labyrinthine trauma due to the fixity of the joint system during surgical maneuvers, could slow down long-term sensorineural hearing loss, less development of post-operative complications, better hearing recovery and ore durable long-term results.

Study Limitations

One of the main limitations of our study is the short duration of the follow-up, limited to three weeks post-surgery. Long-term studies are necessary to evaluate the stability of the hearing results and the duration of the benefit obtained from inverted timing stapedoto-

my. Additionally, our sample was treated by a single surgeon, which may limit the generalizability of the results. Future studies should include a larger sample size and multiple surgeons to further validate these findings.

Conclusion

Otosclerosis is considered one of the main causes of hearing loss and therefore a handicap for people's social life. In most cases this pathology is characterized by an ankylosis of the stapes and the oval window, conditions that cause a conductive and subsequently mixed hearing loss due to the damage that the otosclerotic foci induce in the labyrinth.

Stapes microsurgery, which aims to restore the movement of the ossicular chain damaged by the pathology, is certainly the most complex surgical technique of all otosurgery and requires great skill and experience of the operator. Since 1987, stapedotomy with reversal of surgical times has been performed as elective surgery in our Clinic; this technique is preferred over the others because it allows surgical maneuvers to be carried out when the stapedius tendon, the superstructure of the stapes and the incudo-stapedial junction are still in place. Working on a rigid system we obtain: a lower incidence of fracture of the platina, greater ease of measurement of the incudo-stapedial distance, facilitation in the insertion and crimping of the prosthesis, a reduction in labyrinthine trauma (dizziness and post-operative tinnitus) and reduction in cochlear damage.

Our study demonstrated that the surgical time reversal technique guarantees excellent post-operative hearing recovery indicated by an improvement in ABG. The research also highlights an important uniformity in the recovery of classes A, B, C quantifiable with an average improvement in ABG of 64.08%. For population D we calculated a lower improvement in ABG with average values of 52.05%; this worse result of the operation is certainly linked to the greater hearing deficit presented by patients before the operation.

In our experience, this type of surgery represents the best approach for patients suffering from otosclerosis, both for a reduction in the short-term complications of the operation and for the excellent hearing gain that results; furthermore we can state that the intervention is all the more effective the earlier it is practiced on patients suffering from otosclerosis and for this reason the timely diagnosis of conductive hearing loss is of primary importance.

Conflict of interest statement

All authors declare that they have no conflicts of interests.

References

Baguant, A., Schmerber, S., Baguant, K., & Quatre, R. (2022). Binaural squelch effect in unilateral otosclerosis surgery: comparison of speech intelligibility in noise before-after surgery. European archives of oto-rhino-laryngology : official journal of the European Federation of Oto-Rhino-Laryngological Societies (EUFOS) : affiliated with the German Society for Oto-Rhino-Laryngology - Head and Neck Surgery, 279(3), 1301–1310. https://doi.org/10.1007/s00405-021-06797-3

House, H. P., Hansen, M. R., Al Dakhail, A. A., & House, J. W. (2002). Stapedectomy versus stapedotomy: comparison of results with long-term follow-up. The Laryngoscope, 112(11), 2046–2050. https://doi.org/10.1097/00005537-200211000-00025

Hunter, J. B., & Rivas, A. (2016). Outcomes Following Endoscopic Stapes Surgery. Otolaryngologic clinics of North America, 49(5), 1215–1225. https://doi.org/10.1016/j.otc.2016.05.012

Luryi, A. L., Schettino, A., Bojrab, D. I., Babu, S. C., Michaelides, E. M., Bojrab, D. I., 2nd, & Schutt, C. A. (2021). Hearing Outcomes and Complications in Stapes Surgery for Otosclerosis Performed Under General or Local Anesthesia. Otolaryngology--head and neck surgery : official journal of American Academy of Otolaryngology-Head and Neck Surgery, 165(1), 157–162. https://doi.org/10.1177/0194599820972671

Meyer, T. A., & Lambert, P. R. (2004). Primary and revision stapedectomy in elderly patients. Current opinion in otolaryngology & head and neck surgery, 12(5), 387–392.

Nazarian, R., McElveen, J. T., Jr, & Eshraghi, A. A. (2018). History of Otosclerosis and Stapes Surgery. Otolaryngologic clinics of North America, 51(2), 275–290. https://doi.org/10.1016/j.otc.2017.11.003

Nitta, Y., Sano, H., Furuki, S., & Yamashita, T. (2023). Long-term outcomes of stapes surgery. Auris, nasus, larynx, 50(3), 337–342. https://doi.org/10.1016/j.anl.2022.08.001

Schwam, Z. G., Schettino, A., Babu, S. C., Bojrab, D. I., Michaelides, E. M., & Schutt, C. A. (2021). Outcomes in Revision Stapes Surgery. Otolaryngology--head and neck surgery : official journal of American Academy of Otolaryngology-Head and Neck Surgery, 165(5), 705–709. https://doi.org/10.1177/0194599821991479

Shapiro, S. B., Grojean, M., Hong, M., Lipschitz, N., Breen, J. T., Pensak, M. L., & Samy, R. N. (2022). Predictive Effect of Bone Conduction Pattern on Hearing Outcomes of Stapes Surgery. Otology & neurotology : official publication of the American Otological Society, American Neurotology Society [and] European Academy of Otology and Neurotology, 43(3), 289–294. https://doi.org/10.1097/MAO.0000000000003453

Vincent, R., Sperling, N. M., Oates, J., & Jindal, M. (2006). Surgical findings and long-term hearing results in 3,050 stapedotomies for primary otosclerosis: a prospective study with the otology-neurotology database. Otology & neurotology : official publication of the American Otological Society, American Neurotology Society [and] European Academy of Otology and Neurotology, 27(8 Suppl 2), S25–S47. https://doi.org/10.1097/01.mao.0000235311.80066.df