



COMPARISON OF HEARING OUTCOMES AFTER STAPES SURGERY DEPENDING ON PROSTHESIS TYPE: A RETROSPECTIVE ANALYSIS

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ABSTRACT – Stapes surgery is generally performed to treat otosclerosis, and there are numerous surgical techniques and prosthesis materials available. Critical evaluation of postoperative hearing outcomes is crucial for identification and further improvement of treatment options. This study is a non-randomized retrospective analysis of hearing threshold levels before and after stapedectomy or stapedotomy in 365 patients during a twenty-year period. The patients were classified into three groups depending on the prosthesis and surgery type: stapedectomy with Schucknecht prosthesis placement and stapedotomy with either Causse or Richard prosthesis. The postoperative air-bone gap (ABG) was calculated by subtracting the bone conduction pure tone-audiogram (PTA) from the air conduction PTA. Hearing threshold levels were evaluated preoperatively and postoperatively from 250 Hz to 12 kHz. The results showed air-bone gap reduction <10 dB in 72% patients, 70% of patients, and 76% of patients using Schucknecht's prosthesis, Richard prosthesis, and Causse prosthesis, respectively. The results did not differ significantly between three prosthesis types. Choice of prosthesis should be made individually for each patient, but surgeon competency is still the most important outcome variable, regardless of prosthesis type.

Key words: *Surgery; Stapedectomy; Stapedotomy; Prosthesis; Outcome; Hearing*

Introduction

The first stapes surgery was performed in 1876 by Johannes Kessel. In 1956, John Shea changed the course of modern otology by rediscovering and improving the surgical technique called stapedectomy.¹ Since then, procedures in stapes surgery have evolved from early fenestration attempts to minimal fenestra-

tion techniques. While a stapedectomy generally involves removing the entire stapes footplate and replacing it with a soft-tissue graft and a prosthesis, during stapedotomy a prosthesis is positioned within a limited fenestration opening that is created in the footplate of the stapes bone. A piston-like prosthesis is then put in place of the immobile stapes, allowing movement in a way that efficiently transfers acoustic energy to the inner ear. The size of the footplate fenestration into the vestibule defines the type of the surgical technique: stapedectomy or stapedotomy. Different types of prostheses were used in the course of the evolution of stapes surgery, and all of them needed to fulfill basic criteria of good transmission of vibration and absence

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of inflammatory response. Multiple studies compared the outcomes of stapedectomy and stapedotomy, and the results show minimal differences in postoperative hearing threshold level values, but most authors preferred stapedotomy.²⁻⁵ It has been shown that stapedotomy, previously called “small fenestra stapedectomy” causes less labyrinthine trauma and is associated with a lower incidence of sensorineural hearing impairment and lower incidence of perilymphatic fistula.³

Adequate stapedectomy and stapedotomy results can be achieved with numerous types of prostheses and surgical techniques. There many options have become available through the development of science and technology supporting stapes surgery.⁶ Constant evaluation is crucial for identification and further advancement of the current gold standard.

The objective of this study was to evaluate and compare the improvement of hearing threshold levels as a measure of surgery outcomes following stapedectomy/stapedotomy using three different types of stapes prostheses in patients with otosclerosis and conductive hearing loss.

Methods

This study was a non-randomized longitudinal consecutive retrospective analysis of PTA hearing

threshold levels in 365 patients during a twenty-year period (1995-2015). Inclusion criteria were met if the patients had undergone either primary stapedectomy or primary stapedotomy from January 1st, 1995 to May 1st, 2015 in a tertiary referral center, if the procedures were performed by the same otologic team, and if intraoperative data and preoperative and postoperative pure tone audiometry data were available. The patients were classified into three groups, depending on the type of prosthesis and surgery. The first group consisted of patients that underwent stapedectomy with stapes footplate removal and insertion of a Schuknecht hand-shaped prosthesis (Figure 1). The second group included patients that underwent stapedotomy with the replacement of stapes by the Causse prosthesis (Figure 2). The third group consisted of patients that had stapedotomy and Richard’s prosthesis implantation (Figure 3). Follow-up consisted of recording the postoperative PTA one year after surgery. The type of prosthesis used, surgery type, and audiometric data as pure tone average air-bone gap (ABG) values (dB) on the main speech discriminating frequencies; 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz, were entered into a comprehensive database in accordance with the guidelines of the Committee on Hearing and Equilibrium. The mean air-bone gap (ABG) was calculated as the sum of the mean bone conduction

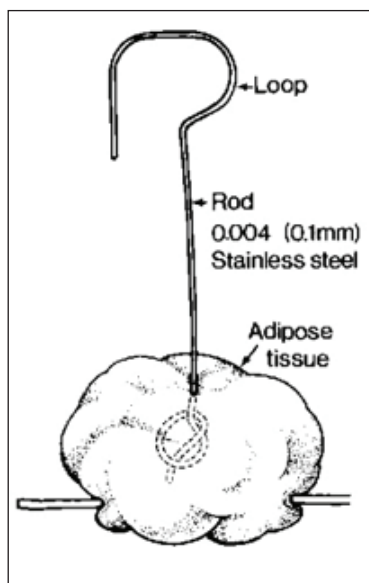


Figure 1. Schuknecht's wire-adipose prosthesis.

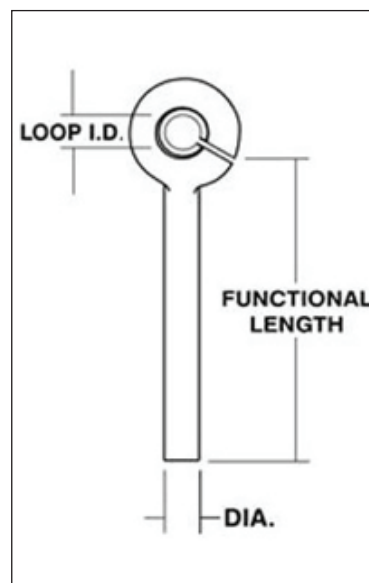


Figure 2. Causse fluoroplastic prosthesis with a 0.4 mm piston diameter.

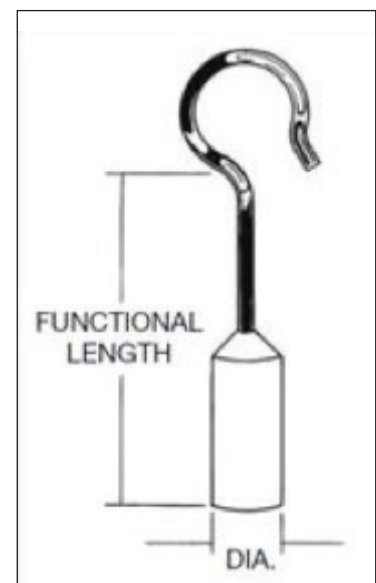


Figure 3. Richard's Teflon prosthesis with a 0.6 mm piston diameter.

Table 1. Demographic details in the patient cohort (age in years).

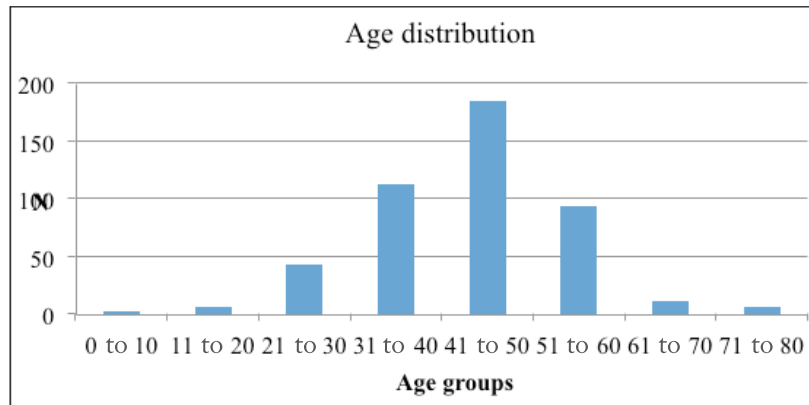


Table 2. Postoperative hearing results in the percentage of patients with <10 dB postoperative air-bone gap on speech-discriminating frequencies (0.5–4.0 kHz).

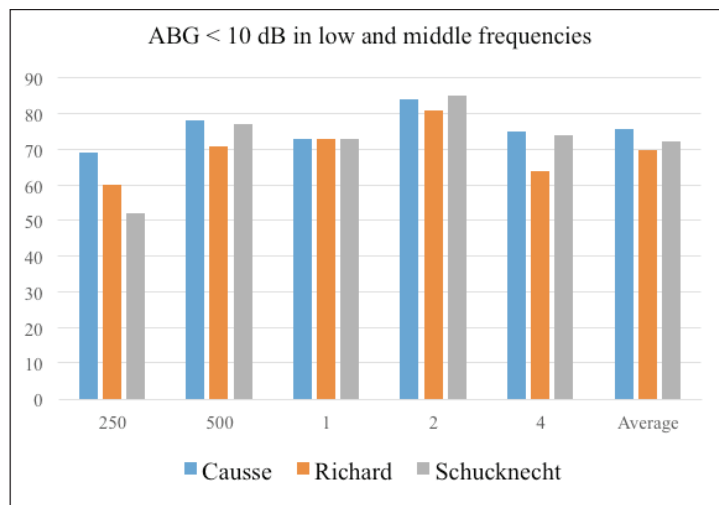
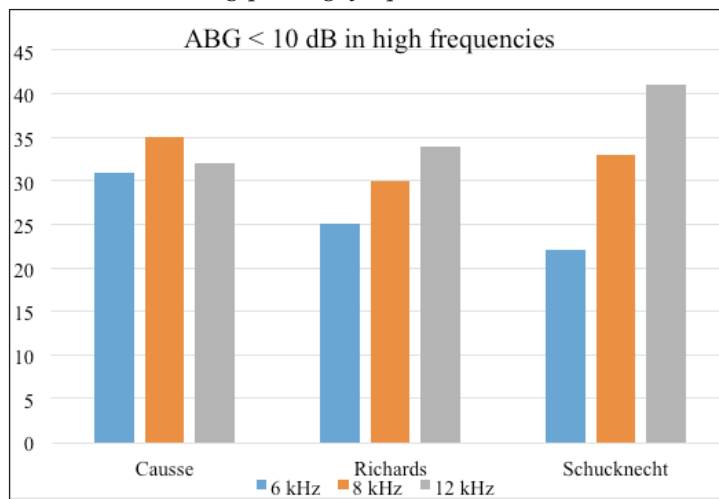


Table 3. Postoperative hearing results in the percentage of patients with <10 dB postoperative air-bone gap on high frequencies (6–12 kHz).



(BC) – air conduction (AC) difference at frequencies of 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz, according to the criteria of the American Academy of Otolaryngology, Head and Neck Surgery (AAO-HNS). An AC40 (Interacoustics, Middelfart, Denmark) audiometer with supra-aural TDH-39 earphones was used for the audiometric evaluation. Informed consent was obtained from all of the patients.

Exclusion criteria were insufficient intraoperative details and patients without available audiometric data. The primary endpoint was postoperative hearing gain, obtained by subtracting the postoperative ABG from the preoperative ABG. Statistical analysis was performed using SPSS software (Version 22.0 © 2013. IBM SPSS Statistics for Windows, Armonk, NY: IBM Corp), using standard descriptive statistics and frequency tabulation as indicated. Associations between variables were assessed using the Mann Whitney U test and binary logistic regression model with odds ratios (OR). All tests were performed using a two-sided 5% type I error rate.

Results

There were 365 patients in our study; 279 of them were women and 86 were men. The mean age was 55 years (Figure 1). The procedures were performed under general anesthesia (200), local anesthesia (161), and local potentiated anesthesia (4). An endaural approach was used in 159 patients, while a transmeatal approach was used in 206 patients. There were 109 patients in the stapedectomy group who received the Schuknecht prosthesis, whereas 164 patients in the stapedotomy group received a Causse prosthesis measuring 6x0.4 mm on average. The other stapedotomy group comprised 69 patients who received Richard's Teflon-piston prosthesis, measuring 4.25x0.6mm on average. The remaining 23 patients received other types of prostheses and were excluded from analysis to reduce sampling bias.

The number of patients with postoperative ABG <10 dB in mid and low frequencies (250 Hz–4kHz) divided into groups based on the prosthesis type are shown in Table 1. The number of patients with postoperative ABG <10 dB in high frequencies is shown in Table 2.

The average follow-up time was 15 months. The results show an air-bone gap reduction to <10 dB in 72% patients, 70% patients, and 76% patients using Schuknecht's prosthesis, Teflon piston prosthesis, and

Causse's prosthesis, respectively, without statistical significance regarding prosthesis type ($p > 0.05$, Mann Whitney U test and binary logistic regression model).

Discussion

Numerous studies have compared the outcomes of stapedectomy and stapedotomy since the introduction of both surgical techniques. Stapedectomy is considered more invasive due to greater mechanical manipulation during stapes footplate removal. Stapedotomy is a technically more advanced procedure and is currently preferred by most surgeons. However, certain surgical and anatomic conditions may still require stapedectomy.⁷

Stapedectomy is preferred over stapedotomy due to greater risk of complications. Literature reports show higher rates of sensorineural hearing loss in stapedectomy groups as a result of mechanical trauma, although some authors did not find such correlations.^{3,4,7 years}⁶

When comparing the short-term results of the two procedures, authors claim that both stapedectomy and stapedotomy provide excellent outcomes in addressing conductive hearing loss due to otosclerosis.⁶ However, some authors suggest there are frequency-specific differences in ABG correction. Cheng et al. and McGee et al. agree that stapedotomy provides superior high frequency hearing improvement compared with stapedectomy, which is related to better speech discrimination scores.^{5,6} Furthermore, Kos et al. have found that larger footplate perforations result in better correction of the ABG at the lower frequencies.⁷ Our study did not find significant correlations between frequency-dependent hearing improvement and surgery type. Therefore, we would argue that stapedectomy and stapedotomy are equally valuable procedures in terms of hearing improvement, and that prosthesis type is not a significant variable in assessing postoperative outcomes.

When comparing different prosthesis types, there are some general advantages and disadvantages based on the material, self-crimping properties, and piston diameter.^{8,9} It is believed that a larger piston diameter provides for a larger vibrating surface area, while a smaller diameter causes less trauma to the inner ear.¹⁰ Systematic analyses comparing postoperative hearing depending on the prosthesis having a 0.4 or 0.6 mm piston diameter have not provided a clear answer to the question whether diameter is a predictor

variable.^{11,12} Our results show slightly superior results compared with the results included in the systematic analyses, possibly pointing toward surgical technique rather than piston diameter as the main outcome variable.

Achieving a post-operative ABG equal or lower than 10 dB was most successful in the group of patients who received a Causse prosthesis, measuring 76%, followed by 72% in the group with the Schuknecht prosthesis and 70% in the group with Richard's prosthesis. Causse prosthesis has some technical advantages compared with others. It does not require crimping, which is the most delicate part of the procedure. Over-crimping around the long process of the incus may result in avascular necrosis, while under-crimping can lead to piston displacement and erosion of the incus.^{7,8} Causse Loop Piston prosthesis was used in 76 ears and the Big Easy Piston prosthesis in 72 ears. The main outcomes were preoperative and postoperative pure tone audiometry and air-bone gap (ABG).¹²⁻¹⁷ Despite the potential dangers of manual crimping, many studies that compared hearing results between manual and self-crimping prostheses did not find significant differences.⁹⁻¹¹ A newly introduced piston prosthesis for stapedotomy, is a nitinol-based, heat-activated, self-crimping prosthesis. We review our hearing results and postoperative complications using this self-crimped piston prosthesis and compare them with those obtained using stainless steel or platinum piston prostheses. Hypothesis: Audiometric results using the SMart piston are identical to those obtained using a conventional piston prosthesis. Study Design: Retrospective chart review. Setting: Private neurotologic tertiary referral center. Patients: The 416 ears reviewed included 306 with a SMart prosthesis and 110 conventional prostheses. 61% were women. Mean follow-up time was 5.6 (standard deviation [SD], 6.3 mo⁴

Although the type of anesthesia does not influence the surgical outcome, each type has some advantages.⁴ Local anesthesia provides immediate feedback from the patient during the procedure, but general anesthesia allows a longer duration of surgery in difficult cases and ensures sedation and relaxation of the patient.⁹

Conclusion

The results of our study suggest that postoperative outcomes depend mainly on surgical technique, namely skill of the surgeon, but not on the type and

characteristics of the prosthesis employed. Currently, there is no clear evidence on specific advantages of prosthesis design regarding postoperative hearing outcomes.

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Sažetak

USPOREDBA POSTOPERATIVNOG PRAGA SLUHA NAKON STAPEDOTOMIJE OVISNO O TIPU PROTEZE: RETROSPEKTIVNA ANALIZA

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Stapedotomija ili stapedektomija su metode izbora za liječenje otoskleroze, a postoji velik broj proteza koje se koriste u obje kirurške tehnike. Konstantna evaluacija postoperativnih ishoda sluha ključna je za vrednovanje najboljeg tipa i materijala za korištenih u kirurškom liječenju otoskleroze. Ovo je istraživanje nerandomizirana retrospektivna analiza pragova sluha prije i nakon stapedektomije ili stapedotomije u 365 pacijenata tijekom desetogodišnjeg razdoblja. Pacijenti su na temelju tipa operacije i proteze svrstani u tri grupe; stapedektomija s postavljanjem Schucknechtove proteze, stapedotomija s Causse ili Richardovom protezom. Postoperativni ABG izračunat je oduzimanjem BC PTA od AC PTA. Tonskim audiogramom su evaluirani pragovi sluha prijeoperativno i postoperativno u rasponu od 250 Hz do 12 kHz. Rezultati pokazuju smanjenje zračno-koštanog prozora na <10 dB u 72% pacijenata s Schucknecht protezama, dok je u grupi pacijenata s Richardovim protezama takvih pacijenata bilo 70%, a u grupi pacijenata s Causse protezama 76%. Rezultati su bili slični za sve tri promatrane opcije. Odluka o tipu operacije i proteze trebala bi biti individualna za svakog pacijenta, a ishod operacije ne ovisi o tipu proteze.

Ključne riječi: *Kirurgija; Stapedektomija; Stapedotomija; Proteza; Ishod; Sluh*