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Systematic Preservation of the Ossicular Chain in Cholesteatoma Surgery Using a Fiber-Guided Laser

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Objectives: 1. To investigate whether systematic preservation of the intact ossicular chain in cholesteatoma surgery provides better hearing than dismantling the chain and reconstructing it. 2. To determine whether systematic preservation of the ossicular chain in cholesteatoma surgery can be performed safely.
Study Design: Longitudinal parallel group study.
Setting: District general hospital and private hospital.
Patients: Adults and children who underwent primary intact canal wall cholesteatoma surgery.
Interventions: Group A: Laser-assisted cholesteatoma surgery resulting in an intact ossicular chain. Group B: Laser-assisted cholesteatoma surgery resulting in a disrupted chain and an ossiculoplasty onto an intact stapes superstructure.
Main Outcome Measures: 1a. Conductive hearing loss (four frequency air-bone gap). 1b. Patient-orientated outcome (Belfast Rules of Thumb). 2a. Change in bone conduction threshold (four frequencies). 2b. Residual cholesteatoma rate. 2c. Rate of facial palsy.
Results: There were eighty ears in Group A and sixty-nine in group B. The median hearing loss for Group A is 11.44 dB HL.The median hearing loss for Group B is 15.63 dB HL. ($p = 0.001$). Seventy out of eighty ears in Group A and forty-six out of sixty-nine ears in Group B fulfilled the Belfast Rule of Thumb. ($p = 0.002$). The null hypothesis is rejected for both of the hearing outcome measures. The two groups did not significantly differ in respect of any of the risk assessment measures.
Conclusion: The fibre-guided laser allows the cholesteatoma surgeon to preserve the ossicular chain in a systematic manner which is both safe and of benefit to the patient. **Key Words:** Cholesteatoma—Hearing—Laser assisted surgery—Patient related outcome measure—Risk assessment.
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Of all the aims of cholesteatoma surgery, the preservation of hearing is the most difficult. Not only does such symptom control need to be considered within the context of the more fundamental need to adequately remove pathology but the surgeon also is aware that careless handling of those ossicles linked to the cochlea can lead to permanent cochlear damage. Judicious management of the intact ossicular chain in cholesteatoma surgery has usually required that the chain be dismantled to allow both complete removal of the disease and protection of the inner ear, with later reconstruction to restore an acoustic conductor between the tympanic membrane and the cochlea (1).

In 1999, a survey of a large series of patients who had undergone cholesteatoma surgery revealed that hearing in the operated ear was significantly better in the long-term when the ossicular chain was preserved rather than dismantled and reconstructed (2). At the same time, a trial of fiber-guided laser was undertaken, during which it was realized that this technology made possible the removal of cholesteatoma from the ossicles without movement, thereby overcoming concerns about cochlear injury (3). Following the fortuitous coincidence of these events, a conscious effort was made by the author to minimize the number of cases in which the intact chain was dismantled in the course of cholesteatoma surgery.

The objectives of this study are 2-fold: 1) to investigate whether preservation of the intact ossicular chain in cholesteatoma surgery provides better hearing than separating the chain and then reconstructing it and 2) to determine whether systematic preservation of the intact ossicular chain in cholesteatoma surgery can be performed safely.

MATERIALS AND METHODS

Inclusion and Exclusion Criteria

Ears were included in this study provided they underwent primary cholesteatoma surgery using a staged intact canal wall technique with the use of a fiber-guided laser and provided that the stapes superstructure was intact.

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In this study, *cholesteatoma* was defined as the presence of accumulating keratin debris within the middle ear (4). Therefore, ears with retracted tympanic membranes but no accumulating keratin were excluded.

Ears that did not have an intact stapes superstructure at the conclusion of surgery were excluded. Excluded also were ears in which the tympanic membrane was simply draped over the intact stapes at the end of surgery.

Treatment Groups and Allocation

Ears were categorized into 2 groups on the basis of the state of the ossicular chain at the end of surgery.

Patients with a continuous ossicular chain were allocated to group A.

Patients with a disrupted chain and an intact stapes superstructure onto which an ossiculoplasty had been performed were placed in group B. Patients with a disrupted chain so that a remnant of the lenticular and long process of the incus was retained on an intact stapes superstructure were included in group B.

The size of the treatment groups was calculated on the estimate that the treatment effect would be 5 dB HL and the standard deviation of each treatment group would be 10 dB HL. The power of the study was set at 0.8, and the significance level was set at 0.05. The required size for each treatment group was 60 cases.

Source

Appropriate patients were included in the study between November 1999 and December 2007. Patients were selected from both the otology operating list at a District General Hospital and from a similar list in a private otology clinic.

In most cases from the District General Hospital, a supervised trainee surgeon contributed to the operation but did not perform the ossicular surgery, whether intact or reconstructed. The author was the principal surgeon in all cases.

Baseline Measures

At the time of surgery, the following baseline characteristics were recorded: the year of the study in which the surgery was undertaken, the age and sex of the patient, the preoperative status of the ossicular chain, the preoperative bone-conduction threshold in the operated ear, the degree of mucosal inflammation, the extent of the cholesteatoma, the approach used to gain access to the cholesteatoma, the technique used to reconstruct the lateral attic wall, and the presence or absence of a surgical assistant.

Outcome Measures

Hearing after surgery was assessed with the air-bone gap (according to standard format [5]) and the Belfast rules of thumb (6,7). The air-bone gap is a good measure of the residual conductive hearing loss after surgery. This is a simple and reproducible measurement of the effect of surgery on the conductive hearing mechanism. It can be treated as a continuous measure, which maximizes the information available to distinguish the 2 groups. The Belfast score is a validated measure of the patient's experience of the hearing benefit after surgery.

Members of the audiology department at the District General Hospital performed the audiograms for all of the patients in this trial from which these measures were derived. The audiograms were all performed at 1 year after surgery.

A risk management assessment was undertaken to establish the likelihood of any patients coming to harm: 1) the preoperative to postoperative change in bone conduction threshold assessed the effect of surgery on the cochlea, 2) the risk to the facial nerve was assessed by measuring facial movement after surgery (8), and 3) the impact of the procedure on the complete

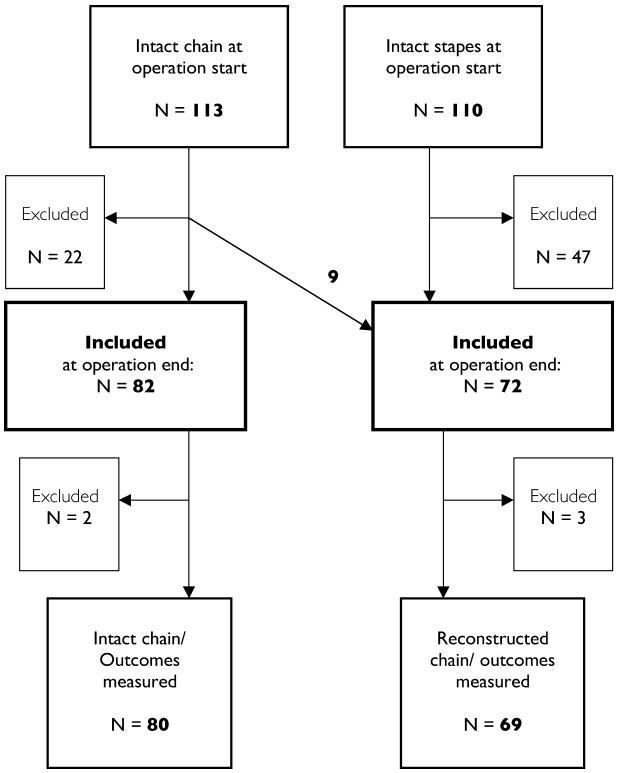

FIG. 1. Process of trial: 113 patients commenced intact canal wall cholesteatoma surgery with an intact ossicular chain. Of these, 22 did not fulfill the inclusion criteria: 13 ears with retraction pockets with no accumulating infected keratin debris, 6 ears with immigration of keratin through a tympanic membrane perforation without involvement of the ossicles, and 3 cases in which the cholesteatoma was in minimal contact with the ossicles and was removed easily without the use of the laser. In 9 cases, the cholesteatoma fully enveloped the ossicular chain, and access could not be gained to remove all the cholesteatoma without significant movement of the chain. In these cases, it was preferable to dismantle the chain. These cases were subsequently included in the "reconstruction" group. Thus, 82 ears were enrolled into group A. Of these, 2 were lost to follow-up without audiometric assessment after 6 months: 1 patient moved away without notice, and 1 patient died of unrelated causes. As a result, 80 ears in group A were assessed audiometrically in keeping with the protocol. Seventy-seven patients underwent intact canal wall cholesteatoma surgery and ossiculoplasty onto the stapes head during the recruitment period. Nine of these presented with an intact chain that could not be preserved because access to all the disease deep to the chain could not be safely obtained. Of these 77 patients, 5 did not fulfill the inclusion criteria because they were actually associated with retraction pockets that contained no accumulating infected keratin debris. Note that 37 patients who otherwise fulfilled the inclusion criteria but who underwent no ossiculoplasty onto an intact stapes were excluded after an interim assessment results indicated that hearing in these ears was discernibly poorer than in ears with any sort of ossiculoplasty onto the intact arch. Thus, 72 ears were enrolled into group B. Of these, 2 did not attend for audiometric assessment after 6 months, and 1 patient was excluded because she developed a false fundus, thus rendering audiometric assessment of her ossicular reconstruction meaningless. Accordingly, 69 ears in group B were adequately assessed audiometrically.

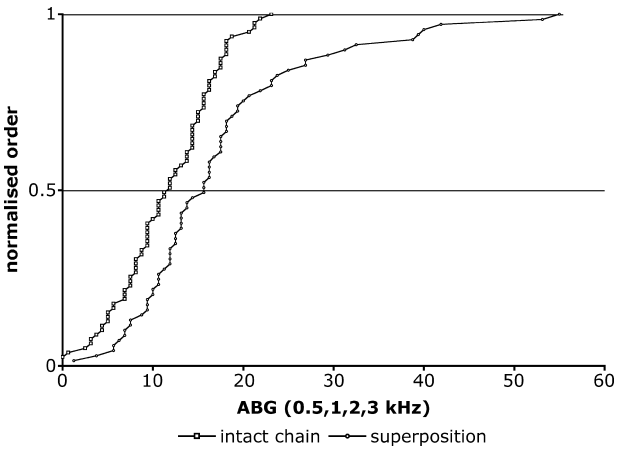

FIG. 2. Comparison of ordered distributions of conductive hearing results after cholesteatoma surgery: results of procedures resulting in intact chains compared with those in which the chain was reconstructed. The comparison of the conductive hearing loss of the 2 groups in this study indicates 2 features: 1) as a group, the air-bone gap in the "intact chain" group is generally smaller than that in the "reconstructed" ears. The 2 groups are justifiably considered distinct. 2) The spread of results in the intact chain group is smaller than that of the reconstructed ears. The reconstruction group seems to contain 2 distinct subgroups: that with smaller air-bone gaps, the distribution of which parallels that of the intact ears; and a second with larger air-bone gaps, the distribution of which is dissimilar to both the intact ears and the former subgroup of reconstructed ears. The likely reason for this is that the "reconstructed" group contains some ossiculoplasties that do not function as the surgeon intended. The intact group contains no such surgical failures.

removal of disease was assessed by measuring the presence of residual cholesteatoma at a second-stage procedure. This was undertaken in all cases at 1 year to 18 months after the original operation.

The proportion of cases in which the intact chain was dismantled despite the use of the laser also was recorded.

Analysis

The null hypothesis was that the distributions of the hearing results of the 2 groups should be the same.

The distributions of the hearing results as measured by the air-bone gap were assessed by the Mann-Whitney *U* test.

The distributions of the hearing results as measured by the Belfast rules (the "Belfast score") were assessed by the χ^2 test.

To investigate the confounding influence of other baseline factors, multiple logistic regression was performed. The dependent variable was the dichotomous Belfast score.

The distributions of the presence of residual cholesteatoma were assessed by the χ^2 test. The distributions of change in bone conduction threshold were assessed by the Mann-Whitney *U* test.

A hospital-based clinical statistician performed all statistical tests using SPSS (version 17) software (SPSS, Inc., Chicago, IL, USA).

RESULTS

Response Rate for Each Group

Of the 113 patients with intact chains at the start of surgery, 80 were suitable for outcome measurement. Of the patients with an intact stapes and reconstruction of the ossicular chain, 69 were suitable for measurement after surgery (Fig. 1). The age of included patients ranged from 4 to 82 years, with a mean of 34 years.

Analysis

Conductive Hearing Loss

The cumulative distributions of the conductive hearing loss for each group are shown in Figure 2.

The median hearing loss for group A is 11.44 dB HL.The median hearing loss for group B is 15.63 dB HL. Comparison of the distributions using the Mann-Whitney *U* test indicates a discernible difference between the two ($p = 0.001$). On the basis of this measure, the null hypothesis is rejected.

Patient-Related Outcome

The distribution of ears satisfying the Belfast rule of thumb is shown in Figure 3.

Seventy of the 80 ears in group A fulfilled the criteria of the Belfast rule of thumb. Of ears that retained an intact ossicular chain after cholesteatoma surgery, 78 had useful hearing in that ear a year after surgery.

Forty-six of 69 ears in group B fulfilled the criteria. Two-thirds of ears that underwent an ossiculoplasty on top of an intact stapes after cholesteatoma surgery had useful hearing in that ear 6 months after surgery.

The results of the intact chain group are significantly different to those of the reconstructed group ($\chi^2 = 9.33$, $\nu = 1$, $p = 0.002$).

Adverse Effects

Comparison of adverse effects did not identify any discernible difference between the distribution of these outcomes between the 2 groups of ears (Table 1). In 9 cases, the cholesteatoma so completely enveloped the intact

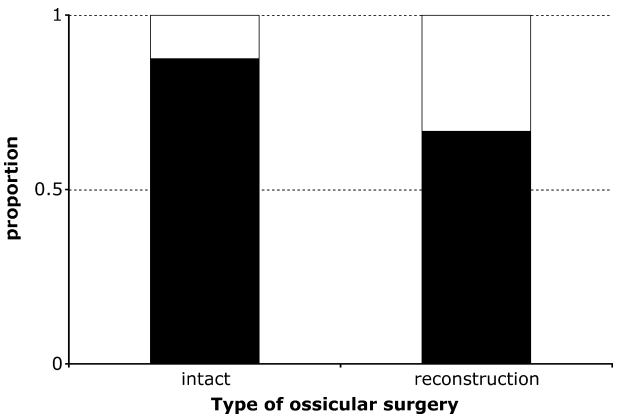

FIG. 3. Comparison of hearing results after cholesteatoma surgery of operations resulting in intact chains and those with reconstruction onto the intact stapes: hearing measured by the Belfast rule of thumb. Seventy of 80 patients with intact ossicular chain and 46 of 69 patients with a reconstructed chain fulfilled the requirements of the Belfast rule of thumb.

TABLE 1. *Outcomes of risk assessment of ossicular preservation with the fiber-guided laser*

	Group A (intact chain)	Group B (reconstructed chain)	*p* value
Residual disease	9	8	0.88
Deterioration in cochlear function mean (preoperative bone conduction – postoperative bone conduction)	+1.5 dB HL	−0.6 dB HL	0.16
Postoperative facial nerve palsy (House-Brackmann grades II to VI)	0	0	1

Assessment of harm to patients caused by preservation of the intact ossicular chain with the fiber-guided laser. There was no greater rate of unwanted outcomes compared to the control group. With regard to residual disease, it should be noted that in all cases, residual disease was merely a tiny pearl. Removal of this disease did not require any ossicular chain or reconstruction to be dismantled. One patient in each group underwent a third-look procedure, and in each case, there was no residual disease.

ossicular chain that it was felt prudent to disarticulate the ossicles rather than place the cochlear function at risk.

Analysis of Prognostic Factors

Multiple logistic regression was performed to seek sources of bias between the 2 groups. The only predictive factors were the status of the ossicular chain after surgery and the preoperative bone conduction threshold. The odds ratio was 2.73 (95% confidence interval, 1.13–6.59; $p = 0.03$) in favor of the intact ossicular chain. The odds ratio per unit increase in bone conduction is 0.934 (95% confidence interval, 0.895–0.975; $p = 0.002$). This means that for every 10-dB increase in bone conduction threshold, the likelihood of success is approximately halved.

DISCUSSION

When performing cholesteatoma surgery, the surgeon's priority is the correction of the disease affecting the ear. The patient, by contrast, measures the success of the operation according to the correction of symptoms (9). The need to remove disease is facilitated by a radical surgical technique, whereas the intention to minimize symptoms benefits from a more conservative strategy. In this conflict, the history of cholesteatoma surgery, which reflects first the need to remove disease and, only later, a desire to treat symptoms as well, is manifested (10).

Although preservation of the chain has been performed *ad hoc* in the past (11–14), this is the first study investigating the efficacy and safety of preserving the chain in a systematic manner. This study demonstrates that improvement in hearing because of systematic preservation of the ossicular chain does not come at the cost of increased morbidity because of a higher rate of residual cholesteatoma, an increased rate of sensorineural hearing loss, or a higher rate of facial palsy. The duration of follow-up in this study is inadequate to provide an authoritative assessment of the effect of the 2 types of surgery on the rate of recurrence of cholesteatoma, a time-dependent phenomenon (15).

This study confirmed that, when the ossicular chain is intact at the start of the operation, preservation of the chain results in better and more reliable hearing than the conventional approach, which has been to dismantle the chain and afterward to reconstruct it.

There was a significant difference in satisfaction between the intact (87.5%) and reconstruction groups (66.7%). The odds of success in the intact group were 7:1, compared with 2:1 in the reconstructed ears. The odds ratio of success of the 2 groups on this univariate analysis was 3.5:1.

After correction for other factors, the odds ratio for intact chain surgery, compared with ossicular reconstruction, dropped to 2.73. This extra analysis also revealed that bone conduction threshold also was an independent predictive factor. This result is not entirely surprising, given that the outcome measure is dependent, in part, on the air conduction threshold in the operated ear, which is the sum of the postoperative bone conduction threshold and the conductive hearing loss. As noted in Table 1, surgical intervention in this study did not significantly affect bone conduction threshold, so there is a close relationship between preoperative bone conduction threshold and the outcome measure.

This relationship also helps to explain why 2 treatment groups that seem to differ so little when measured by the difference of the medians of the conductive hearing loss are poles apart when measured by patient satisfaction: The preoperative bone conduction threshold constrains the maximum conductive loss that will satisfy the Belfast criteria. Within a group of results, the spread of the bone conduction thresholds necessitates that not only the mean but also the spread of the conductive hearing results be minimized to maximize the proportion of the group meeting the Belfast criteria. Patients benefit from ossicular chain preservation not only because it provides better hearing but also because it also is more consistent than reconstructive surgery.

With the current technique, approximately 10% of cases still require the intact chain to be dismantled to fully remove cholesteatoma without jeopardizing cochlear function. In the remaining 90% of cases, the fiber-guided laser allows the cholesteatoma surgeon to preserve the ossicular chain in a manner that is both safe and of benefit to the patient.

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