

# Erosion of the long process of the incus with incomplete ossicular discontinuity in simple chronic otitis media: Should we reconstruct or leave it be?

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**Objective:** To determine whether patients with simple chronic otitis media and incomplete ossicular discontinuity should undergo ossicular reconstruction.

**Design:** Prospective, randomised surgical trial comparing no intervention with incus interposition over a 5-year period.

**Setting:** Tertiary referral hospital.

**Participants:** Seventy-six participants with simple chronic otitis media and erosion of the long process of the incus but apparent good transmission throughout the ossicular chain as tested intra-operatively. Forty-four patients had partial erosion of the incus but still bony contact with the stapes head (Group A—Type I), and 32 had mainly connective tissue binding the incus and stapes (Group B—Type II). Each of these groups was randomised to either leaving the ossicular chain as it was (A1 and B1) or performing an incus interposition (A2 and B2).

**Main outcome measures:** Average postoperative air-bone gap and the degree of ABG closure. A postoperative air-bone gap under 20 dB was considered a successful result.

**Results:** In group A, there was no significant difference between no intervention and incus interposition. In group B, patients in the no reconstruction subgroup had a significantly worse hearing result than the incus interposition subgroup (postoperative air-bone gap of 27.5 dB and 31% closure within 20 dB vs 15 dB and 75% closure).

**Conclusions:** For Type I patients, the postoperative hearing results were similar for the reconstruction and no reconstruction groups. For Type II patients, the results clearly favour reconstruction.

## 1 | INTRODUCTION

Chronic otitis media with or without cholesteatoma may lead to erosion of the ossicles and discontinuity of the ossicular chain.<sup>1,2</sup> This discontinuity may be complete, with no contact between the disconnected ends, or incomplete, with normal contact replaced by soft tissue or by contact between opposing bones.<sup>3</sup> Preoperative findings may suggest either a complete or an incomplete ossicular discontinuity, but the status of the ossicular chain can only be truly identified intra-operatively.<sup>4</sup>

Very few reports in the literature have addressed the issue of incomplete ossicular discontinuity (IOD), in which some degree of erosion of the ossicles is observed (especially the long process and the lenticular process of the incus) but inspection and palpation during surgery still show good transmission of movements.<sup>3,5,6</sup> In such cases, the surgeon is confronted with the dilemma of either removing the incus and performing an incus interposition or trusting that the current status will result in an equally good or better sound transmission than a reconstruction and leaving the ossicular chain as it is. Most surgeons base this decision on the preoperative

audiogram, choosing reconstruction if the air-bone gap is larger than expected for the tympanic perforation (over 30 dB on average, for instance). The notion that preoperative hearing thresholds can accurately predict the ossicular chain status, however, has been disputed.<sup>4</sup> In both cholesteatomatous disease and simple chronic otitis media (SCOM) cases, inflammatory tissue can serve as transmission bridges and reduce the air-bone gap, mimicking an intact ossicular chain.

Furthermore, if the sound transmission in IOD is partially due to the presence of granulation (or fibrous) tissue, once the tympanic membrane perforation is closed and inflammation subsides, it is unclear to what extent this will lead to a regression of the tissue around the ossicles and eventually a weaker bridge, greater discontinuity and the deterioration of hearing.

To address these questions, we conducted a randomised controlled surgical trial comparing the audiological results of incus interposition reconstruction vs no ossicular intervention in patients with IOD who underwent tympanoplasty for SCOM.

## 2 | PATIENTS AND METHODS

### 2.1 | Ethical considerations

All patients were treated according to the protocol approved by the hospital's medical ethical committee. Patients gave their written informed consent to participate in the study.

### 2.2 | Preliminary study

To help determine the feasibility and the best design for a prospective surgical trial, we first looked retrospectively at a series of 42 cases that underwent surgery over a 4-year period at our hospital. The series consisted of type I tympanoplasties in which hyperplastic mucosa or granulation tissue surrounded the long process of the incus and the incudostapedial joint (ISJ), but the palpation of the ossicular chain showed good transmission of movements from malleus to stapes. These cases, at the surgeon's discretion, were treated only with the closure of the tympanic perforation. No effort was made to clean the granulation tissue surrounding the ossicular chain, and, consequently, the degree of erosion was not properly observed.

The main results of the preliminary study are shown in Table 1. The perforation closure rate was 83% (35 of 42 cases). We

**TABLE 1** Main results of the preliminary study

N	35
Preop ABG (SD)	31.5 dB ( $\pm 8.4$ )
Postop ABG (SD)	16.1 ( $\pm 13.3$ )
Mean ABG closure (SD)	15.4 ( $\pm 11.7$ )
ABG $\leq$ 20 dB	71%
ABG between 20 and 35 dB	9%
ABG $\geq$ 35 dB	20%

### Keypoints

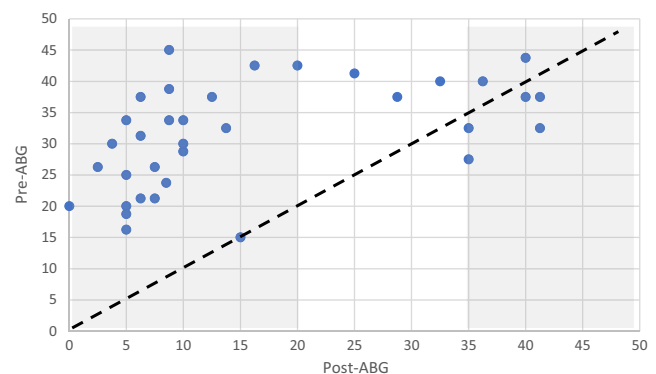
- Incomplete ossicular discontinuity (IOD) can be divided in two types, according to whether or not there is still bony contact between ossicles.
- In type I cases, reconstruction is not mandatory. In type II IOD, functional results clearly favor reconstruction.
- One should always explore the ossicular chain until the two types of IOD can be differentiated.

excluded cases with unsuccessful closure of the perforation from further analysis. Of the 35 successful cases of graft take, the mean preoperative ABG was 31.5 dB ( $\pm 8.4$  SD), and the mean postoperative ABG was 16.1 ( $\pm 13.3$  SD). The mean ABG closure was 15.4 ( $\pm 11.7$  SD), and 71% of the patients had a postoperative ABG of 20 dB or less.

Despite the overall good outcome, a closer look revealed a rather unequal distribution of hearing results. Figure 1 shows a scatter plot of the pre- and postoperative ABGs. The postoperative ABG results are particularly interesting as they seem to concentrate at the extremes, being either very good or very bad with few in between. It is worth mentioning 6 cases (17%) in which, despite closure of the perforation, the ABG remained the same or even worsened.

We interpreted these findings as if there were a factor or event that determined a turning point for the ossicular chain integrity, causing the incomplete discontinuity to either stabilise and sustain ossicular transmission or to destabilise, weaken and result in worse sound transmission.

We hypothesised that this factor could be the lack of bone contact between incus and stapes; in other words, the point at which the incus and stapes became connected only (or mainly) by soft (granulation or fibrous) tissue.



**FIGURE 1** Pre- and postoperative functional results of the preliminary study. Hearing outcomes concentrate in extremes with very few intermediary results, suggesting a “turning point” after which there is deterioration of the ossicular chain and hearing. The dashed line divides ABG increase (below line), decrease (above line) or unchanged (on line) after surgery

## 2.3 | Study design

To test this hypothesis, we conducted a prospective, randomised, controlled trial over a 5-year period at the same tertiary reference hospital. The inclusion criteria were (i) adult patients (ii) who had SCOM (iii) with hyperplastic mucosa or granulation tissue surrounding the long process of the incus and the ISJ, as observed intra-operatively, and (iv) good transmission of movements upon palpation of the ossicular chain, characterising an IOD. Patients with previous otologic surgery on the same ear and with unsuccessful graft uptake were excluded.

Contrary to the preliminary study, all patients underwent careful dissection of the tissue surrounding the incus and the ISJ until the degree of bony erosion was clear. The subjects were then divided into two groups as follows: cases that still had bony contact between the incus and stapes (group A) and cases in which the incus and stapes were thought to be connected mainly by soft tissue (group B). We classified the situation found in group A as type I IOD and the situation in group B as type II IOD.

Each of these groups was then randomised for the intervention. In groups A1 and B1, no further action was taken regarding the ossicular chain, and the surgeon proceeded to perform a type I tympanoplasty. In groups A2 and B2, an incus interposition was performed.

## 2.4 | Sample size and randomisation

The sample size for a continuous outcome superiority trial at  $\alpha = 0.05$  and power = 0.90, with a 10-dB difference in the main outcome measure between groups, was calculated to be 30 patients, 15 in each group. Consecutive sampling continued until there were at least 16 patients in each subgroup. SAS v. 9.1 software was used to randomise patients.

## 2.5 | Surgical techniques

In all patients, the surgeon carefully dissected the tissue surrounding the long process of the incus, starting superiorly, where it was still intact, and moving towards the ISJ. The dissection was just enough to determine the extent of erosion while maintaining the bridge connecting the incus and stapes.

In the no intervention subgroups, no further action was taken regarding the ossicular chain, and the surgeon proceeded to perform a type I tympanoplasty.

In the incus interposition subgroups, interposition was performed using autologous incus, as described by Fisch.<sup>7</sup> Briefly, the incus was removed from the middle ear, and the distance and angle between malleus handle and the head of the stapes were measured using the Fisch microraspatory as a reference. The incus was held with a parotid clamp, and the remaining long process was drilled out with a diamond bur. A groove for the malleus handle was made at the previous incudomalleolar joint area. An indentation for the stapes head was made opposite the malleus groove, within the posterior process of the incus, using a 1.0-mm diamond bur. The proper length of the remodelled incus—estimated by the measurements—was

confirmed by repeatedly placing the incus in its position. A slim (but still solid) remodelled incus was preferred to a bulky one.

The tympanoplasty also followed the technique described by Fisch and May.<sup>7</sup> In short, either an endaural or a retroauricular incision was made (no cases were treated through a transmeatal approach). The skin of the external auditory canal was removed circumferentially with a spiral meatal skin flap, and a canalplasty was made, until the whole tympanic membrane could be observed with one position of the microscope. The underlay technique and a temporalis fascia graft were used in all cases.

## 2.6 | Outcome measures

Pre- and postoperative audiograms were obtained in every case. Air conduction and masked bone conduction levels were obtained in each test. An average air-bone gap was calculated over four frequencies (0.5, 1, 2 and 4 kHz). We considered a postoperative air-bone gap of 20 dB or less to be a successful result.

Follow-up time was measured according to the last audiogram available, but a minimum of 12 months after surgery was required. The air-bone gap closure was also considered as an outcome measure.

Other relevant data recorded in all cases were gender, age, the size of the tympanic membrane perforation and episodes of otorrhea in the 3 months prior to surgery. The size of the tympanic perforation was determined from schematic drawings in the patients' records. We categorised the size of the perforation as less than 12.5%, between 12.5% and 35% and more than 35%, following the classification of Lerut et al<sup>8</sup>

We also analysed groups A and B for the presence of high-frequency conductive hearing loss (hfCHL), defined as a mean preoperative ABG at 0.25 and 0.5 kHz that was lower than the preoperative ABG at 4 kHz by 10 dB or more. This was done to allow comparisons of our results with findings by Sim et al<sup>5</sup> concerning IOD.

## 2.7 | Data analysis

The Chi-square ( $\chi^2$ ) test was used to compare categorical variables between groups. Student's *t* test was used to compare numerical variables between groups and subgroups in independent samples.

The Mann-Whitney test (non-parametric test) was used to compare numerical variables between groups that showed a non-Gaussian distribution.

The significance criterion adopted was  $\alpha = 0.05$ . Data were processed using SAS 6.11 software (SAS Institute, Inc., Cary, North Carolina).

# 3 | RESULTS

## 3.1 | Participants

After excluding cases with residual and recurrent perforations, group A had 44 subjects (22 in each subgroup—A1 and A2) and group B had 32 (16 in each subgroup—B1 and B2). Therefore, in this

consecutive series of patients with IOD due to incus erosion, approximately 58% of patients still had bony contact between the incus and stapes, and 42% had only soft tissue connecting the two ossicles.

Age varied from 18 to 62 years in group A and from 22 to 58 years in group B, with mean ages of 35.7 ( $\pm 12.4$  SD) and 35.9 ( $\pm 10.3$  SD) years, respectively. There was a homogeneous distribution of genders in all groups and subgroups. The mean follow-up time was 18.9 ( $\pm 7.1$ ) months overall, 19.2 ( $\pm 7.4$  SD) for group A and 18.5 ( $\pm 6.8$  SD) for group B, with no significant differences among the groups and subgroups. There were also no significant differences between the groups in the size of the tympanic perforation or in episodes of otorrhea before surgery. These findings are summarised in Table 2.

### 3.2 | Functional results

The preoperative ABG was significantly higher in group B ( $37.8 \pm 7.1$  dB) compared with group A ( $33.2 \pm 7.9$  dB), but no difference was found between the randomisation subgroups within each group (A1/A2 or B1/B2).

The other functional results are summarised in Table 3. In group A (bony contact between the incus and stapes), the postoperative ABG was 16.1 ( $\pm 8.2$ ) dB in the no intervention subgroup (A1), with a gain of 18 ( $\pm 5.4$ ) dB. In the incus interposition subgroup (A2), the postoperative ABG was 14.5 ( $\pm 8.3$ ) dB, with 17.7 ( $\pm 5.9$ ) dB of ABG closure. An ABG below 20 dB was achieved in 68% of the cases in subgroup A1 and in 77% of subgroup A2. None of these parameters differed significantly.

Conversely, in group B (soft tissue bridge between incus and stapes), there was a significant difference between subgroups B1 and B2 in all hearing outcomes (except for the postoperative ABG  $\leq 10$  dB parameter). The postoperative ABG was 27.5 ( $\pm 14.4$ ) dB in the no intervention subgroup (B1) and 15.0 ( $\pm 8.5$ ) dB in the incus interposition subgroup (B2). ABG closure was 10.5 ( $\pm 10.2$ ) and 22.5 ( $\pm 12.5$ ) in B1 and B2, respectively. A successful result (postoperative

ABG  $< 20$  dB) was obtained in 75% of cases in subgroup B2 but only 31% in subgroup B1.

Figure 2 shows the scatter plots of the individual pre- and post-operative hearing results in both groups. All cases in which there was no improvement of hearing are in group B (type II IOD). Size of the tympanic perforation was not associated with better or worse hearing improvement in either group.

The hearing results of subgroups A2 and B2 were very similar, reflecting comparable results for incus interposition regardless of the initial ossicular chain configuration. ABG closure, however, was significantly higher in subgroup B2 because the preoperative ABG in subgroup B2 was higher than that in subgroup A2.

High-frequency conductive hearing loss (hfCHL) was found in 27% of the patients in group A and 81% of the patients in group B before surgery.

## 4 | DISCUSSION

Ossicular discontinuity is a separation of the middle ear ossicles, which can be either complete or incomplete. IOD is characterised by partial erosion of the ossicles but with good transmission of movements throughout the ossicular chain.

There are various classifications for the ossicular defects that can be found in chronic otitis media, such as the Fisch and the Austin-Kartush classifications<sup>7,9</sup>, but none of them mention IOD. To facilitate communication, we created an IOD classification: type I occurs when there is still contact between opposing bones, and type II occurs when there is only (or mainly) soft tissue connecting the ossicles.

### 4.1 | Synopsis of key findings

The type of IOD may not be immediately clear during surgery and may require dissection of the tissues involving the ossicles. In our series, the proportions of type I and II IOD were approximately 60%

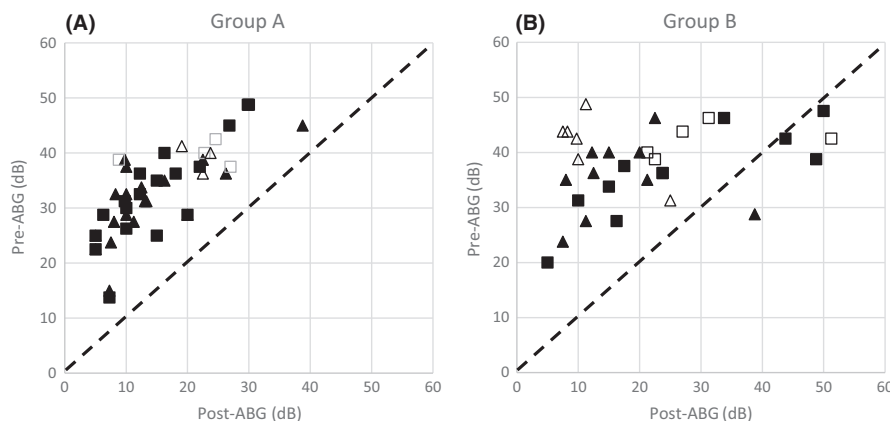
**TABLE 2** Participants characteristics in groups and subgroups

	Group A		P value A1/A2	Group B		P value A/B B1/B2
	A1 (No further action)	A2 (Incus interposition)		B1 (No further action)	B2 (Incus interposition)	
N	44			32		
	22	22		16	16	
M/F	22/22		.55	17/15		.79
	10/12	12/10		8/8	9/7	.72
Mean age (SD)	35.7 ( $\pm 12.4$ )		.97	35.9 ( $\pm 10.5$ )		.80
	35.4 ( $\pm 12.6$ )	36.0 ( $\pm 12.4$ )		33.9 ( $\pm 10.6$ )	37.9 ( $\pm 10.4$ )	.23
Mean follow-up	19.2 ( $\pm 7.4$ )		.96	18.5 ( $\pm 6.8$ )		.57
	18.8 ( $\pm 6.3$ )	19.7 ( $\pm 8.4$ )		18.8 ( $\pm 7.6$ )	18.2 ( $\pm 6.1$ )	.98
Size of perforation ( $< 12.5\%$ )/(12.5 - 35%)/( $> 35\%$ )	13/23/8		.99	7/14/11		.27
	6/12/4	7/11/4		4/7/5	3/7/6	.99
Otorrhea 3 months before surgery (Yes/No)	11/33		.73	10/22		.55
	6/16	5/17		4/12	6/10	.45

**TABLE 3** Functional results

	Group A		P value	Group B		P value
	A1 (No further action)	A2 (Incus interposition)		B1 (No further action)	B2 (Incus interposition)	
N	22	22		16	16	
Preop ABG (dB)	34.1 ( $\pm 8.7$ )	32.2 ( $\pm 7.1$ )	.44	38.0 ( $\pm 7.3$ )	37.6 ( $\pm 7.0$ )	.84
Postop ABG (dB)	16.1 ( $\pm 8.2$ )	14.5 ( $\pm 8.3$ )	.48	27.5 ( $\pm 14.4$ )	15.0 ( $\pm 8.5$ )	<b>.006</b>
ABG Closure (dB)	18 ( $\pm 5.4$ )	17.7 ( $\pm 5.9$ )	.67	10.5 ( $\pm 10.2$ )	22.5 ( $\pm 12.3$ )	<b>.003</b>
Postop ABG $\leq$ 20 dB	68%	77%	.54	31%	75%	<b>.013</b>
Postop ABG $\leq$ 10 dB	36%	45%	.50	13%	38%	.11

*p* values below 0.05 were marked in bold.



**FIGURE 2** Scatter plot of pre- and postoperative functional results of groups A and B. Squares are patients without ossicular reconstruction from groups A1 (Figure 2A) and B1 (Figure 2B). Triangles are patients who underwent incus interposition from groups A2 (Figure 2A) and B2 (Figure 2B). Black squares and triangles represent patients with small and medium perforations. Hollow squares and triangles represent patients with large perforations. The dashed line divides ABG increase (below line), decrease (above line) or unchanged (on line) after surgery

and 40%. The significantly different hearing results between these two types when no reconstruction is attempted are evidence of the importance of differentiating them. Identifying the type of IOD may be crucial to deciding what to do next with the ossicular chain.

In type I IOD, the results were similar for incus interposition and no reconstruction at all. In type II IOD, the results were unequivocally better when the patients were treated with ossicular reconstruction instead of no reconstruction.

In type I IOD, although the joint is compromised by the disease, there is still bone-to-bone contact. This is also the case when an incus interposition is performed; as no technique can reconstitute an ossicular joint, the surgeon can only aim for bony contact. Therefore, it is reasonable to assume that both situations may end in similar results.

## 4.2 | Comparison with other studies

We were not able to find any studies comparing different treatment options or reconstruction techniques in patients with IOD.

Sim et al<sup>5</sup> observed that IOD is associated with fluctuating hearing loss, improvement of hearing after the Valsalva manoeuvre and high-frequency conductive hearing loss (hfCHL), which occurred in 93% of their series. This is because in IOD, the connective tissue is believed to transmit low-frequency sounds better than high-frequency sounds, resulting in conductive hearing loss primarily at high

frequencies. In our series, we found hfCHL in 27% of patients with type I IOD and 81% of patients with type II. This suggests that our classification, which is based on the presence of bone-to-bone contact, can differentiate the cases of IOD that bear closer proximity to an intact ossicular chain from those with worse sound transmission. Nevertheless, hfCHL as an isolated parameter does not seem adequate to replace the role of intra-operative inspection in predicting a good functional result. The authors did not discuss treatment options as all cases in their series were submitted to incus interposition.

Farahmand et al<sup>3</sup> acknowledged there were two types of IOD, corresponding to what we classified as type I and type II. However, as their study was a retrospective one based on surgical notes, they did not attempt to separate the two types when reporting their results. They also used a slightly different and more complex definition of hfCHL and did not report on the ossicular reconstruction technique used to treat each case.

## 4.3 | Strengths of the study

Although a few studies have focused on the preoperative diagnosis of IOD, to our knowledge, this was the first study to address the management of such cases. This was also the first randomised controlled trial designed to determine whether IOD should be treated with ossicular reconstruction.

#### 4.4 | Study limitations

Although most of the patients underwent preoperative CT scans, our study did not include imaging data as a parameter. The ability of computed tomography to detect ossicular chain erosion, especially of the long process of the incus, varies greatly in the literature (from 7% to 83%).<sup>10,11</sup> There are no data regarding CT's sensitivity for detecting IOD in particular. The use of high-resolution CT and custom acquisition protocols may contribute to better results, but such methods are not readily available, even in tertiary hospitals. Further studies combining audiometry and imaging findings may aid the preoperative diagnosis of IOD.

Our study used autologous incus interposition as the ossicular reconstruction method. Some studies have found ionomeric cement to achieve superior results.<sup>12,13</sup> However, unlike autologous incus, ionomeric cement is not widely available, even in specialised centres.

Furthermore, to determine whether the IOD was a type I or a type II, the tissues were dissected until it was clear whether there was a bone-to-bone connection or just a soft tissue bridge between ossicles. This might have weakened the soft tissue connection and interfered with the hearing results obtained in the B1 subgroup.

It is also interesting to note that the bridge connecting the ossicles in type II IOD is partially made of inflammatory tissue, which may disappear over time (once the tympanic perforation is closed). Our mean follow-up time was 18.9 months (minimum of 12 months and maximum of 36 months). A longer follow-up (5 to 10 years) could show an even worse result in the B1 subgroup. Nevertheless, we were not able to identify a tendency of further hearing deterioration over time when comparing patients with shorter and longer follow-ups.

Finally, our study did not include cholesteatoma cases because the presence of matrix involving the incus could influence the decision to remove it and consequently interfere with the trial randomisation.

#### 4.5 | Clinical applicability of the study

Our study has direct clinical applicability. When a surgeon is confronted with inflammatory tissue around the long process of the incus and the incudostapedial joint in a patient with SCOM, we recommend proceeding with further dissection, even if the transmission of movements seems to be good or the preoperative audiogram does not show a large ABG.

Approximately 60% of cases will be type I IOD. In these cases, according to our data, reconstructing the ossicular chain with an incus interposition and leaving the chain will have similar hearing results.

On the other hand, if type II IOD is observed (approximately 40% of cases), we strongly recommend, based on our findings, that an ossicular reconstruction be performed.

### 5 | CONCLUSIONS

Ossicular reconstruction in patients with SCOM and IOD should be performed if there is no bone-to-bone contact between the incus

and stapes (type II IOD cases), regardless of the preoperative audiogram or the presence of a soft tissue bridge connecting the ossicles.

We did not find a significant difference between incus interposition and no ossicular reconstruction when there was still bony contact between the incus and stapes (type I IOD cases).

#### CONFLICT OF INTERESTS

None to declare.

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