Allograft tympanoplasty

ALLOGRAFT TYMPANOPLASTY

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ABSTRACT

Allograft tympanoplasty was once widely used across the world, but is currently only performed by a limited number of surgeons in Belgium and Germany. Allograft tympanic membranes and ossicles are procured endoscopically nowadays and are processed in specific tissue banks subject to European Union regulations on human allograft tissue to ensure the receptor will receive quality-controlled tissue. The surgical procedure via retroauricular approach can teach us how we can manage difficult cases with total, subtotal and marginal perforations, but also cases of isolated pars tensa cholesteatoma.

INTRODUCTION

Currently, the most widely used materials for tympanic membrane closure are autografts, including cartilage and temporalis fascia. Because these autograft materials rely on the support of a certain margin of the tympanic membrane remnant and/or fibrous annulus, which is not sufficiently available in total or subtotal perforations, they sometimes fail and reperforate. Implantation of tympano-ossicular allografts does not depend on remaining tissue as it can replace the entire tympanic membrane in cases with sufficient epithelial migration.

HISTORICAL PERSPECTIVE

The precise chronology in the development of allograft tympanic membrane transplantation remains unclear. The first report in literature dates back to 1964, when Ned Chalat (a Detroit-based physican) reported using pars tensa allografts for myringoplasty as early as 1960. (1) He was not very successful yet, as of the 3 reported cases, 2 grafts failed to incorporate; the third reperforated 2 years after surgery. Chalat reported his findings in the soon to be discontinued Harper Hospital Bulletin, a journal unfamiliar to most otologists at that time. In 1982, Christian Betow reported the implantation of allograft tympano-ossicular tissue since 1959, 1 year earlier than Chalat's procedure. (2) Like Chalat, Betow encountered similar challenges when his early fresh, dry allografts resorbed a few weeks after surgery. It was the introduction of the 5% buffered formaldehyde solution at pH 5.6 by Rodney Perkins in 1970 that allowed a major breakthrough with one reperforation in 24 grafted tympanic membranes. (3) These results prompted Jean Marquet to change his preservation technique in 1971 to 5% buffered formaldehyde fixation and Cialit 0.02% preservation, where he observed a progressive improvement of success rate from 73% in 1964 to 96% in 1973. (4) Sequential reports of successful outcome with buffered formaldehyde solution confirmed its feasibility and formaldehyde is currently still in use for preservation of allograft tympano-ossicular systems. For a more detailed historical perspective of the early history of tympanoplasty and allograft tympanoplasty, please read the papers by Albert Mudry (5) and Van Rompaey et al. (6)

PATIENT SELECTION

Allograft tympanoplasty can be indicated in subtotal or total perforations of the tympanic membrane, in marginal perforations, in revision tympanoplasty after failure of an autologous graft, in case of isolated pars tensa cholesteatoma, etc. The present case is a total perforation of the left tympanic membrane (figure 1).

INFORMED CONSENT

Patients should be informed preoperatively about the use of allograft tissue when the surgeon will potentially use an allograft tympanic membrane for myringoplasty or tympanoplasty. Potential risks that should be discussed are quite similar as to regular tympanoplasty in chronic otitis media, i.e. reperforation, blunting, myringitis, residual conductive hearing loss or even deafness, facial nerve injury, loss or alteration of taste sensation. Care is also taken to also the nature of chronic otitis media and the impact of aeration in the middle ear on functional outcome.

Postoperative instructions are discussed and are similar to regular tympanoplasty: keep the ear dry, avoid removing the external auditory canal dressing, visit outpatient clinic for evaluation and treatment when the dressing has fallen out, avoid strenuous activities that could increase pressure in the middle ear, etc.

SURGICAL TECHNIQUE

Perioperative setup and positioning

The setup for allograft tympanoplasty is identical to routine tympanoplasty via retroauricular incision. Instruments used during this procedure are displayed in figure 2.

Procurement of the allograft tympanic membrane (with malleus attached)

The endoscopic procurement technique was described earlier (7, 8) and involves a 30° angled rigid Hopkins rod nasal endoscope and a portable Tele Pack X with telecam camera head (Karl Storz, Tüttlingen, Germany). The meatal cuff is incised 360° using a Rosen knife and the meatal skin is elevated circumferentially from the bony canal using a Rosen knife or using a Marquet

decollator in case of a more curved meatus. The fibrous annulus is released from the bony annulus using a Rosen knife or Marquet decollator. After disarticulation of the incudostapedial joint, the incus is procured separately, while the allograft -consisting of a 360° meatal cuff, the fibrous annulus, the tympanic membrane and the malleus- is procured by clenching the malleus neck or head with a microforceps and gently pulling the allograft through the external auditory canal. The cuff is manually unfolded using a Marquet decollator or microforceps and then further unfolded in saline water using a Marquet decollator. When the allograft has retrieved its natural form, it's fixated in a buffered 2,7-4,0% formaldehyde solution with pH 5-6.

Preparing the external auditory canal for allograft tympanoplasty

The implantation procedure of tympano-ossicular allografts has been meticulously described in a book edited by Bernard Ars and Nicole Ars-Piret. (9) Before surgery, the surgeon should verify that a suitable allograft is available. The patient is on an operating table under general anesthesia. The surgery usually starts with a standard retroauricular skin incision producing a Palva flap to reach the lateral aspect of the bony ear canal. This approach enables the option of a canal-wall up mastoidectomy in case aggressive eradication of middle ear disease is necessary and provides a microscopical view to the external auditory canal.

The tympanomeatal flap is elevated until the annulus is reached. The remnants of the tympanic membrane are gently removed from the manubrium so the fibrous annulus can be released from the bony annulus safely in 360° (figure 3). Now the tympanomeatal flap, including the fibrous annulus, can be dissected from the anterior wall of the bony ear canal in a medial to lateral direction (figure 4). By doing so, the tympanomeatal flap can be everted and the diseased part of the tympanic membrane, annulus and meatal skin are cut and removed (figure 5). It is of utmost importance that no residual disease or remnants of removed tissue is left behind, as this would induce an iatrogenic cholesteatoma. This concludes the total myringectomy in preparation for the allograft tympanic membrane. The surgeon can now visualize the bony ear canal, tympanic cavity and ossicular chain optimally and assess whether further removal of mucosa, mastoidectomy, ossiculoplasty, etc. are

needed. In a next step, the tympano-ossicular allograft can be implanted, in order to allow a complete reconstruction of the tympanic membrane with or without the ossicles.

Handling of the allograft in the operating room

The allograft is taken out of its container filled with buffered formaldehyde solution and is rinsed extensively in sterile saline water to wash out the formaldehyde for at least 30 minutes (figure 6). The devitalized squamous epithelium on the inside of the allograft is removed by the surgeon before implantation using a Rosen knife. If needed, the malleus is removed from the allograft tympanic membrane by using a Rosen knife to release the periosteal layer from the manubrium (figure 7). The periosteal cuff can be modified and cut with scissors until the allograft has the right dimensions to fit the receptor site.

Implantation of the allograft tympanic membrane

The meatal skin of the allograft is folded gently to make it as narrow as possible, so it can easily be inserted into the appropriate position in the receptor's ear canal (figure 8). A sterile sponge or ball probe can be used to gently push the allograft medially towards the bony annulus (figure 9). Once the allograft is in the correct position, the remaining skin of the receptor's external meatus is replaced onto the surface of the allograft periosteal cuff. This will ensure vascularisation and epithelialisation. Fibrin glue is used to fixate the periosteal cuff on to the bony ear canal. The allograft manubrial periosteum should not be glued to the receptor's manubrium since this may inhibit adhesion and integration in the long term.

Ear packing

In order to keep the allograft periosteal cuff and tympanic membrane in its correct place postoperatively, a perforated silastic sheet, rolled up like a cigarette paper, is placed in the external auditory canal and is gently dilated so the periosteal cuff touches the bony ear canal. Sterile sponges soaked in a suspension of antibiotics and steroids (Terra-Cortril) are introduced into the canal. Finally, the retroauricular incision is closed using resorbable sutures. An external bandage is applied on the incision site. The compressive head bandage is

usually removed the morning after surgery, while the silastic sheet and sponges are removed from the external auditory canal after 12-16 days.

POTENTIAL COMPLICATIONS

Canal skin misalignment. Correct introduction of the ear packing is essential to ensure that the ear canal skin will migrate over the allograft periosteal cuff and towards the allograft tympanic membrane. In case of doubt, the allograft periosteal cuff can be cut with microscissors and/or a new silastic sheet packing should be introduced.

Fibrous strands. In case a fibrous strand is observed, it can be removed using microscissors and a butterfly-shaped silastic sheet can be used to introduce in the anterior tympanomeatal angle and dilate the sheet with non-resorbable sponges soaked in antibiotic-steroid suspension.

Infection. Can occur when exposed to water. Topical antibiotic treatment should be considered after culturing the secretion.

Myringitis. Can occur intermittently, spontaneous or after exposure to water, and very difficult to manage. In case of narrowing of the external auditory canal, meatoplasty can be considered.

Blunting. Can occur when ear packing has moved or removed too early due to fibrosis in the anterior angle of the external auditory canal.

Keratine cyst formation in the ear canal. Usually asymptomatic and observed at 1-year follow-up or later, this keratine cyst can be marsupialized and removed easily.

FUNCTIONAL OUTCOME

A retrospective cross-sectional study was performed on allograft tympanoplasties on grafts procured endoscopically between May 2013 and July 2018 (Ethics Committee approval (19/24/292). The tympanoplasty procedures were performed by 12 different surgeons in the Antwerp University Hospital from September 2013 to September 2018 using the same surgical technique in patients without cholesteatoma. Patients were only included if there was a follow-up visit at least 75 days (~2,5 months) after the surgery. The 12 months follow-up visit

was only considered if it was at least 270 days (~9 months) after the surgery. The graft take rate and hearing outcome was evaluated during the follow-up visit at three months after the surgery and at one year after the surgery. Male/female ratio was 67/62. Median age was 19 years (5-78 years). At 3 months after surgery, in 85,3% of the cases (110 patients), an intact tympanic membrane was found without myringitis or anterior blunting. Median period between surgery and 3 months follow-up was 106 days (75-918 days). Only 62 patients (48,1%) had a 12-month follow-up visit. Of these 62 patients, 83,9% (52 patients) had an intact tympanic membrane without myringitis or anterior blunting at 12 months. Median period between surgery and 12 months follow-up visit was 406,5 days (295-1828). Audiological data were available for 82 patients (63,6%) at 3 months postop and for 60 patients (46,5%) at 12 months postop. The mean difference in air-bone gap (ABG) before (preop) and after (postop) surgery decreased by 5,8 dB at 3 months postop and by 3,3 dB at 12 months postop (both compared to preop ABG). The distribution of ABG difference is plotted in figure 10. The difference of preop and postop bone conduction is shown in figure 11.

SUMMARY

Although national legislations on human allografts have made transplantation of tympano-ossicular tissue cumbersome, EU regulations are offering a legal framework to create a quality management system for tympano-ossicular tissue banking and allow allograft tympanoplasty to retain its place in the armamentarium of the otologist. Whether allograft tympanoplasty will have a place in the future of otology remains to be seen, but an understanding of the history of this technique is essential in evaluating its merit.

DISCLOSURE

The authors report no proprietary or commercial interest in any product mentioned or concept discussed in this article.

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Figure legends

Figure 1. Microscopic evaluation of the present case with left-sided total perforation of the tympanic membrane.

Figure 2. Instruments used during allograft tympanoplasty.

Figure 3. The remnants of the tympanic membrane are gently removed from the manubrium so the fibrous annulus can be released from the bony annulus safely in 360° (figure 3).

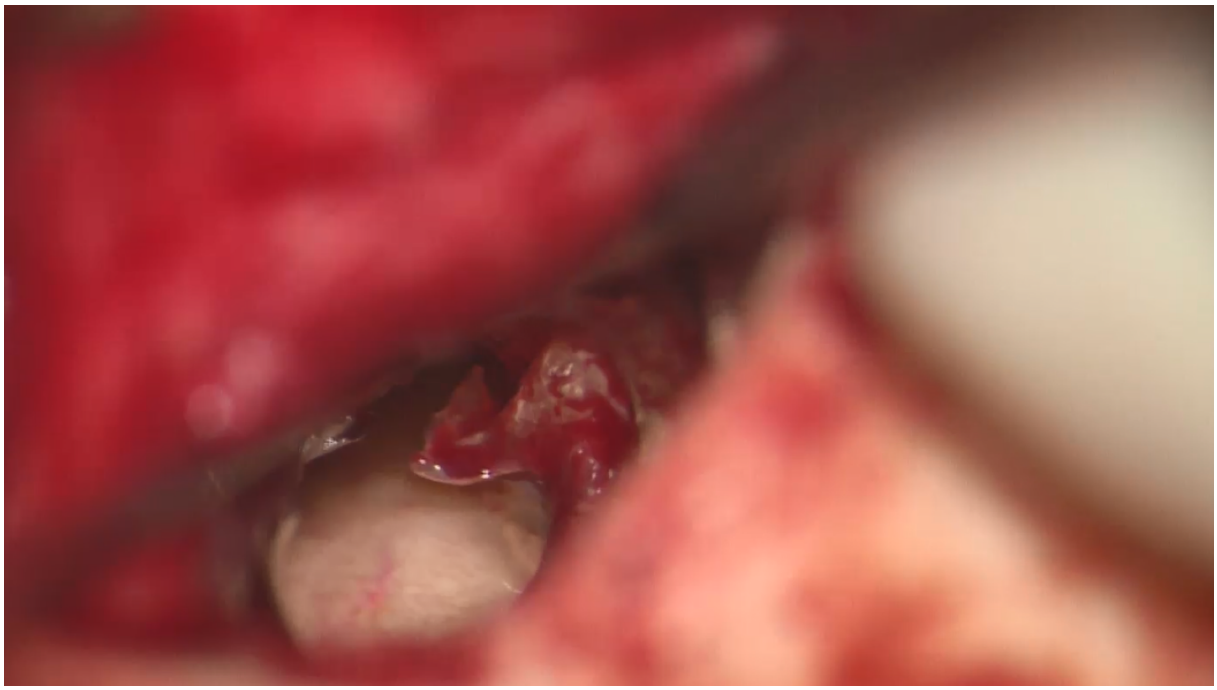


Figure 4. The tympanomeatal flap, including the fibrous annulus, can be dissected from the anterior wall of the bony ear canal in a medial to lateral direction.

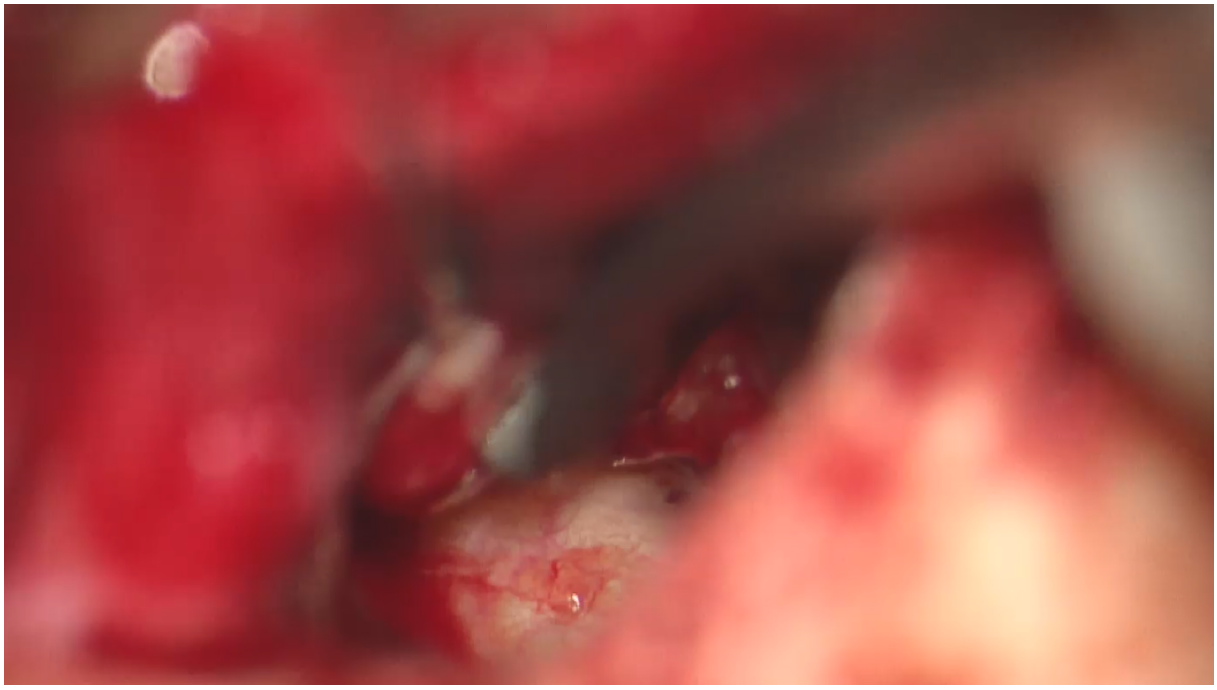


Figure 5. The tympanomeatal flap is everted and the diseased part of the tympanic membrane, annulus and meatal skin are cut and removed.

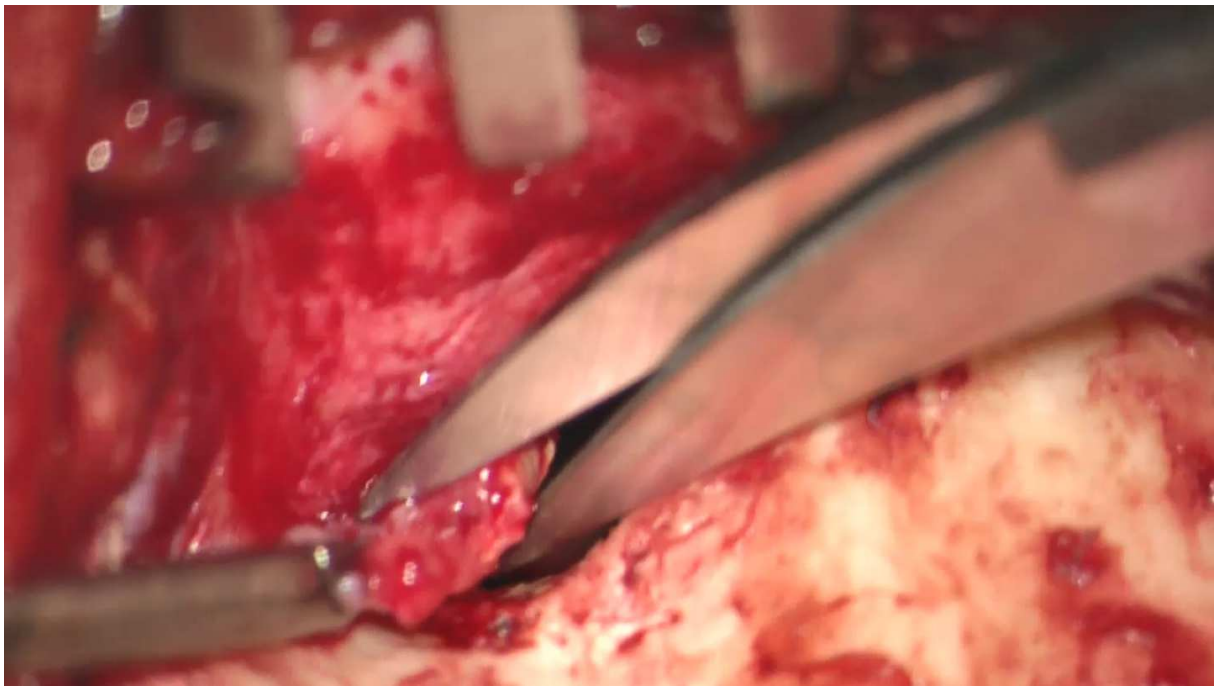


Figure 6. Tympano-ossicular allograft with malleus attached. The keratin is removed from the periosteal cuff.

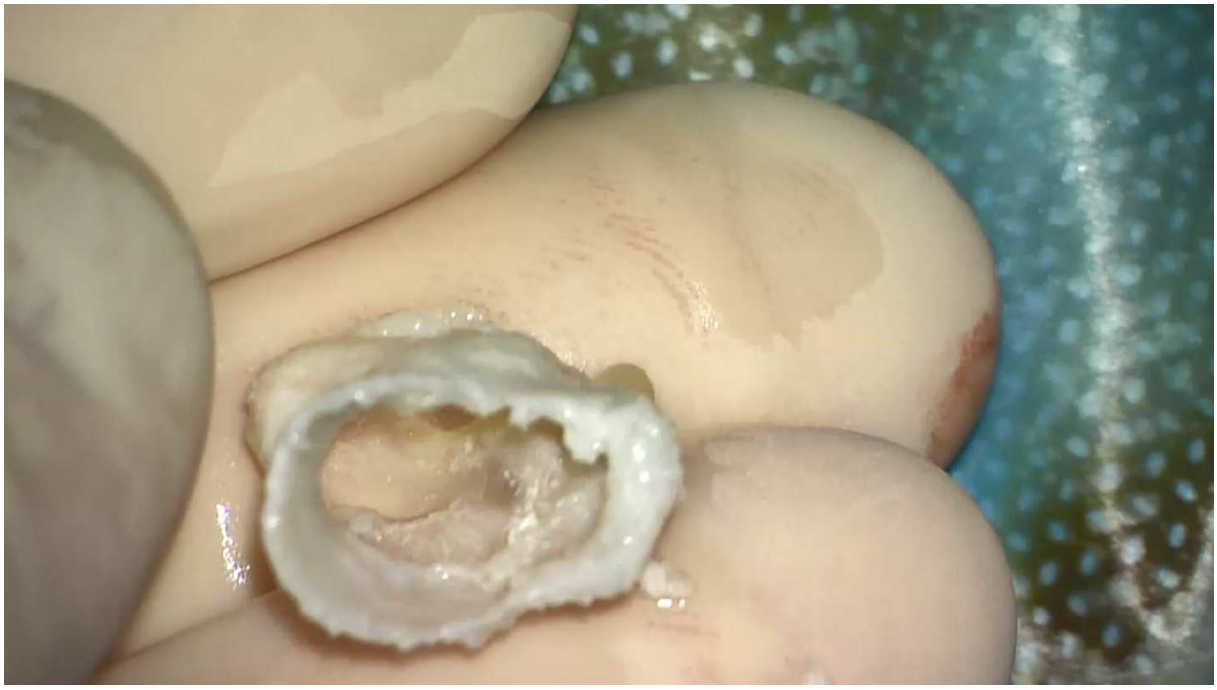


Figure 7. The malleus is removed from the tympano-ossicular allograft by subperiosteal dissection of the manubrium.

Figure 8. The meatal skin of the allograft is folded gently to make it as narrow as possible, so it can easily be inserted into the appropriate position in the receptor's ear canal.

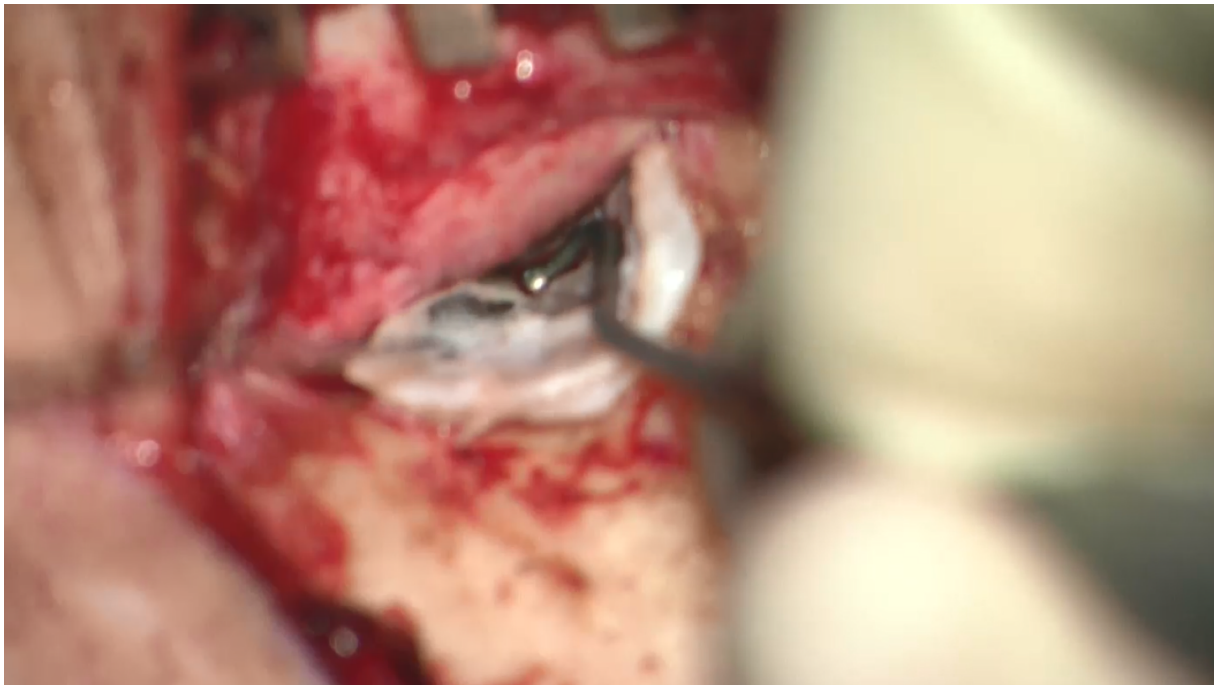


Figure 9. A sterile sponge or ball probe can be used to gently push the allograft medially towards the bony annulus. Once the allograft is in the correct position, the remaining skin of the receptor's external meatus is replaced onto the surface of the allograft periosteal cuff.

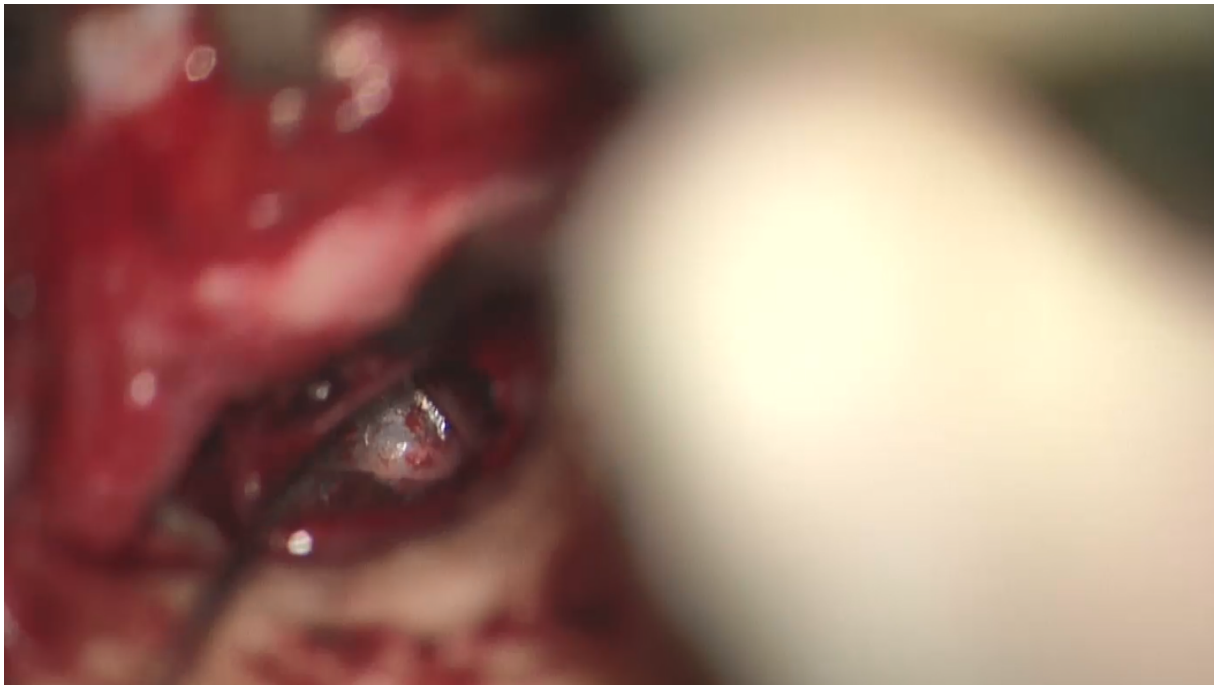


Figure 10. Amsterdam Hearing Evaluation Plot, comparing preoperative ABG (air-bone gap) and 3 months postoperative ABG (A) / 12 months postoperative ABG (B).

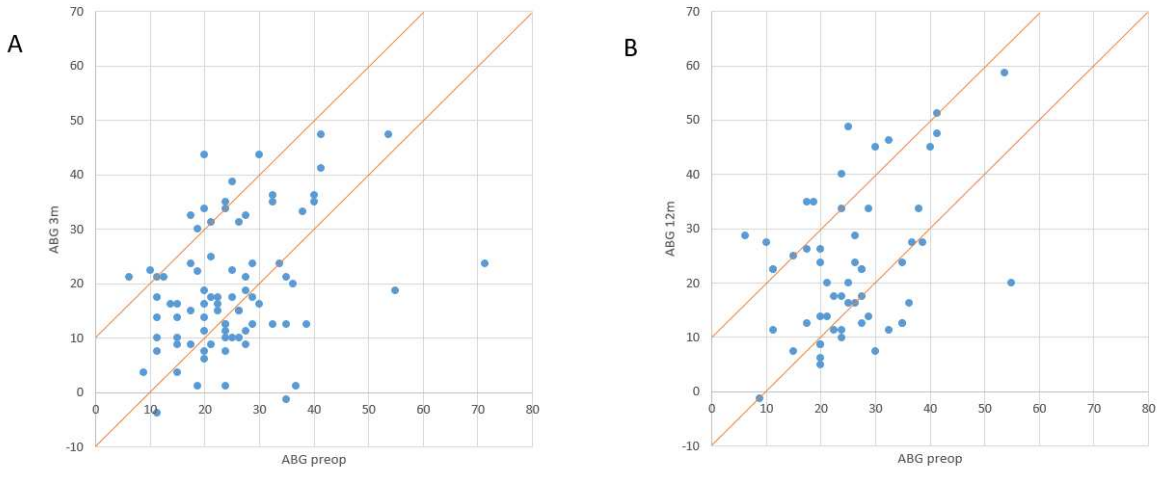
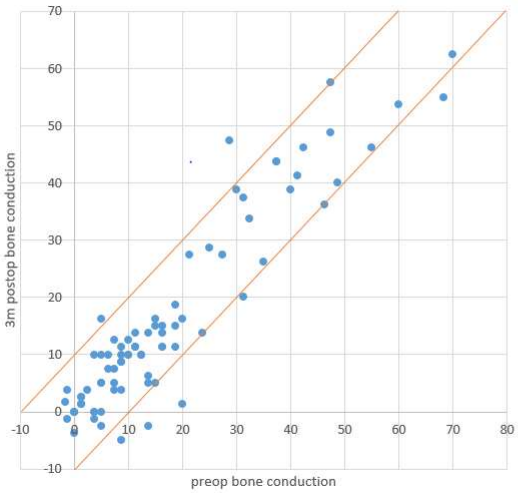


Figure 11. Amsterdam Hearing Evaluation Plot, comparing preoperative bone conduction and 3 months postoperative bone conduction (A) / 12 months postoperative bone conduction (B)

A



B