INTRODUCTION

Cochlear implantation (CI) has proven to be a safe and effective procedure to rehabilitate severe-to-profound sensorineural hearing loss in adults and children. In some patients, hearing loss is caused by or associated with chronic otitis media or following its surgical treatment. Cochlear implantation is still challenging, especially in patients with an open mastoid cavity after canal wall down (CWD) surgery since infection of the implant and/or extrusion of the array has been reported.

Cochlear implantation was previously contraindicated in the case of chronic otitis [1]. Then several techniques were described in the case of CI in previously performed CWD mastoidectomy. Covering the array with autologous material in the cavity [2-6], subtotal petrosectomy with blind-sac closure of the external auditory canal (EAC) and fat obliteration [7-9] or with a temporalis muscle flap [4,10,11] have been reported. These techniques can lead to donor-site complications and the material used for obliteration can be gradually resorbed. Moreover, subtotal petrosectomy is contraindicated in the case of residual hearing still being suitable for electroacoustic stimulation (EAS).

S53P4 bioactive glass (BG) is a bioactive material that elicits a specific biological response at the interface between material and tissue. It is a mixture of oxides composed of 53% SiO₂, 23% Na₂O, 20% CaO, and 4% P₂O₅ with the property of being antibacterial against many aerobic and anaerobic bacteria [12]. It can suppress Staphylococcus aureus and Pseudomonas aeruginosa biofilm formation on a titanium alloy disc in vitro [13-15] These properties make it particularly attractive when dealing with a cochlear implant in a potentially infected environment.

The use of BG has been reported for the rehabilitation of CWD mastoidectomies with good outcomes and very few complications [16-18]. We started to use this material for the rehabilitation of CWD mastoidectomies together with a cochlear implantation in the case of an open cavity.

The aim of this study was to review our cases which included such a procedure to investigate whether this might be an alternative to existing techniques.
MATERIALS AND METHODS

Population

This retrospective study was conducted in a tertiary referral center on 20 patients (10 male, 10 female) operated on for CI and mastoid obliteration with BG granules between January 2015 and December 2016. All patients gave their consent to the use of their personal clinical data.

Medical charts were analyzed for demographic data and medical history. Preoperative pure tone thresholds (mean at 0.125, 0.25, 0.5, 0.75 and 1 kHz) were evaluated for all patients especially with regard to residual hearing. A missing value at 0.125, 0.25, 0.5, 0.75 and 1 kHz due to severe hearing loss was replaced with 120 dB for calculation of the pure tone average (PTA). If a relevant residual hearing was expected, postoperative pure tone thresholds were analyzed.

If there was an indication of infection of the mastoid cavity preoperatively, a bacteriological scrub was taken and treatment with local antibiotics was started according to the antibiogram.

Surgery

Surgical reports were analyzed to identify the surgical approach (endaural/retroauricular), the route of insertion (round window/cochleostomy) and any intraoperative complications.

All operations were undertaken under general anesthesia by two senior surgeons and with facial nerve monitoring (NeMo NeuroMonitor by Medizintechnik Kuttner, Germany). The skin lining the preexisting mastoid cavity was elevated, the cavity carefully cleaned and overlying bone was drilled and any rough edges were smoothed. If possible, a bony canal at the edge of the cavity was formed for fixation of the array (Figure 1). Tissue glue (fibrin glue) was used to fix the array in place. To reconstruct the posterior wall, the elevated skin from the mastoid cavity was consolidated with cartilage and/or temporalis fascia. If necessary, the tympanic drum was reconstructed with cartilage. The external ear canal skin was lined with silicone sheets and Gelaspon® Strip (Bausch & Lomb, Dr Gerhard Mann chem.-pharm. Fabrik GmbH, Germany) cut into pieces and soaked in a local antibiotic solution (Doxycycline) was applied to the canal. In addition, an expandable tampon (Ivalon®, First Aid Bandage Company, New London, CT, USA) was placed in the external ear canal to ensure that it retained its form and volume. Afterwards, the mastoid cavity and, if possible, the former region of the attic were filled with S53P4 BG granules of 0.5/0.8 mm diameter (BonAlive® Biomaterials Ltd, Turku, Finland) moistened with physiological saline solution (Figure 2). All patients received one single intravenous shot of Ceftriaxone (1.5 g) during the operation. If there was no sign of infection with a clean cavity and/or otorrhea, no antibiotic was given postoperatively.

Postoperative assessments and complications

After surgery, digital volume tomography [19,20] was performed to check the correct positioning of the array (Figure 3).

The patients came to the outpatient clinic at about 10 to 14 days postoperatively and the expandable tampon and silicone sheets were removed. The external ear canal was checked for defects of the posterior wall with leakage of BG granules or signs of infection. All patients were seen at least 4–6 weeks (before starting the first fitting of the CI), and at 1 and 2 years postoperatively.
RESULTS

Population

Twenty patients were included (10 male, 10 female). Their age was 65 ± 14 years (mean ± SD, range 33–80 years). There were 14 right-side and six left-side ears. The mean follow-up was 19 ± 7 months (range 4–30 months). All patients were adults with postlingual onset of deafness. The exact etiology of hearing loss was not always clear. Most patients described an impairment of hearing caused by chronic otitis media (COM) or following surgical treatment which deteriorated with progressing age (presbycusis). One patient had a mumps infection as a child which caused the hearing loss, and one patient described a congenital hearing impairment with extended hearing loss after surgical treatment of COM.

All but two patients had undergone previous CWD mastoidectomy. One patient showed a very wide external ear canal with the clinical appearance of a radical cavity with nearly no mastoid cells left but with no previous ear surgery that they could recall. The second patient underwent a previous canal wall up cholesteatoma surgery and, due to an extensive recurrent cholesteatoma, he developed a spontaneous mastoid cavity.

Five patients had already undergone cochlear implant surgery. Two of them had failure of the implant, and the other three patients presented with electrode extrusion. In all five cases, cartilage had been used in the original operation to cover the array and reconstruct the posterior wall of the EAC.

Surgery

In all cases, surgery was uneventful and performed in a single stage apart from one. The latter patient underwent a tympanoplasty with mastoid cavity obliteration with BG granules due to a persistent otorrhea from a large mastoid cavity in preparation for cochlear implantation. Six months later, the cochlear implantation was carried out.

A retroauricular approach was used in three cases, an endaural approach in four cases and an extended endaural approach in 13 cases (Table 1). A cholesteatoma was found in four patients and removed during the operation. The array was positioned in the bony canal and inserted via the round window (eight cases) or cochleostomy (12 cases). The type of cochlear implant used is presented in Table 1. Reconstruction of the tympanic drum with cartilage was performed in five cases due to a mesotympanic perforation (one patient), atelectasis (three patients) and an epitympanic perforation with cholesteatoma (one patient).

Postoperative assessments and complications

The postoperative digital volume tomography scan showed correct placement of the array in all cases. All but two patients were discharged in the immediate postoperative period; two

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<th>Table 1: Details of patients operated on with cochlear implantation and mastoid cavity obliteration.</th>
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Array ext. = array extrusion; WEAC = wide external auditory canal; E = endaural incision; EE = enlarged endaural incision; mo = month; MS = mid-scala electrode; OMC = open mastoid cavity; R = retroauricular incision; RS = revision surgery array covered with cartilage; SMC = spontaneous mastoid cavity; Std = standard electrode.
patients suffered from dizziness that necessitated longer hospitalization.

After removing the ear dressing 2 weeks postoperatively, the posterior wall and ear drum were intact in all patients. There was no sign of infection or leakage of BG granules. One month after the operation, three patients showed minor granulations at the posterior wall of the external ear canal and otorrhea. All three patients were successfully treated with local antibiotics.

All but four patients had a well-healed EAC with no sign of infection and/or extrusion of the array in the follow-up period. One patient had infection of the CI 6 months after surgery and underwent explantation 6 months after primary surgery and reimplantation 10 months after primary surgery. During the follow-up period, this patient developed a retraction pocket that needed further revision surgery. After the latter operation, otoscopy showed a healed EAC with no sign of extrusion/infection. Three patients developed a retraction pocket that needed revision surgery. Two of them showed an extruded array located in the mastoid part in the EAC. The array was relocated again and covered with BG granules to prevent infection and extrusion. These three patients had a well-healed EAC at the last follow-up.

The analysis of preoperative pure tone thresholds showed that only one patient matched the criteria for EAS. Unfortunately, the attempt to preserve his residual hearing failed.

**DISCUSSION**

Cochlear implantation in patients with an open mastoid cavity is still challenging even for an experienced ear surgeon. Different surgical techniques can be used to avoid array extrusion, recurrent cholesteatoma and infection. Following the classification of Szymański and colleagues, the techniques for CI can be summarized in three groups.

“Covering” technique: The electrode array is located in the open mastoid cavity and is covered by some sort of autologous material [2-6, 21] (coverage with alloplastic material has not been described before).

“Bypass” technique: The surgeon uses an alternative route for electrode insertion away from the diseased middle ear. Colletti et al. [22], described electrode insertion via a middle fossa approach. Due to high surgical risks and effort, this technique has only been used in a few cases.

“Radical” technique: This includes a subtotal petrosectomy with blind sac closure of the EAC and obliteration of the cavity with fat [7,8, 23-25].

Patients operated following the “covering” technique using autologous materials such as fat [5] or cartilage and fascia [6] are at risk of electrode array extrusion into the EAC leading to revision surgery. Among our patients, we had three cases that needed revision surgery due to an electrode extrusion after cartilage had been used in the original operation to cover the array and reconstruct the posterior wall of the EAC. Muscular flaps seem to be more stable and offer better protection of the array [3,4, 10] but array extrusions into the EAC have been described [2,3,21]. Alloplastic materials have been used for mastoid obliteration but not in combination with cochlear implantation.

The “radical” technique was first described by Fisch and Mattox in 1988 [26]. Issing et al. (1998) [25] were among the first to use it in combination with cochlear implantation. The favored obliteration material is abdominal fat due to its easy availability, low metabolic rate, good biocompatibility and resistance to necrosis. Many studies have been published showing good results and few complications [7,8, 23-25]. Nevertheless, closure of the external ear canal leads to some disadvantages that the surgeon has to be aware of before deciding on this technique. The first major disadvantage of the “radical” technique is the limited clinical postoperative control over residual cholesteatoma. The only postoperative control is repeat HRCT scans since a diffusion-weighted MRI scan is not useful due to the artifacts from the electrode array and the magnet. The radiation exposure of recurrent CT scans could be an issue especially for young patients and a long follow-up period. Furthermore, the presence of fat makes interpretation of HRCT scans and the detection of a residual cholesteatoma more difficult, since the average density of fat and cholesteatoma is similar [27, 28]. The second major disadvantage is the impossibility of electroacoustic stimulation due to closure of the EAC.

Minor drawbacks are the limited availability of fat in thin patients, and its tendency to resorb over time, which can lead to retroauricular retraction or even fistulae [9,25].

A reconstruction of the anatomic structures by obliterating only the mastoid cavity thus forming a new external ear canal using a material with a good biocompatibility that inhibits bacterial growth would avoid the previously described disadvantages.

Our retrospective analysis of 20 cases is the first study investigating the short- and long-term outcomes of patients supplied with a CI in combination with mastoid cavity obliteration with BG granules in a one-stage surgery. Our results showed a good outcome for almost all patients.

Revision surgery was needed in four cases. One case (5%) of infection of the cochlear implant needed explantation and reimplantation. The other three patients developed a retraction pocket that led to array extrusion. The original surgical approach used in all three cases was an endaural incision and the extrusion was found in all cases in the area of the original incision leading to the assumption that the endaural incision might be a weak point facilitating this complication. Following this observation, we changed our surgical approach to use a retroauricular incision.

During the revision surgery, the removal of the BG granules was straightforward and the separation of electrode array from the BG granules was easily possible without damaging the array, thus allowing us to reuse the implant.

With regard to residual hearing, we had only one patient matching the criteria for EAS preoperatively. We tried to preserve his hearing by performing mastoid obliteration with reconstruction of the external ear canal and using a round window approach. Unfortunately, he lost his residual hearing during the operation and acoustic stimulation was not possible. Anyway with this technique, an attempt to preserve hearing and benefit from EAS is theoretically possible even though we did not have any other cases matching this condition.
Our study had some limitations: first, its retrospective nature implies some bias that is difficult to overcome. Moreover, we did not present a control group with patients operated on with another technique.

CONCLUSION

In conclusion, mastoid obliteration with S53P4 BG in combination with CI seems to be a safe and effective procedure in the case of cochlear implantation in a previously performed CWD mastoidectomy with acceptable postoperative complications.

However, cochlear implantation in patients with COM and open mastoid cavities is still rare, the number of patients treated with either the “radical” technique or the “covering” technique with alloplastic material is very limited, and very few long-term results have been published. A comparison between the different techniques with recommendations on which surgical approach should be used for which patient would be helpful in the future.

REFERENCES