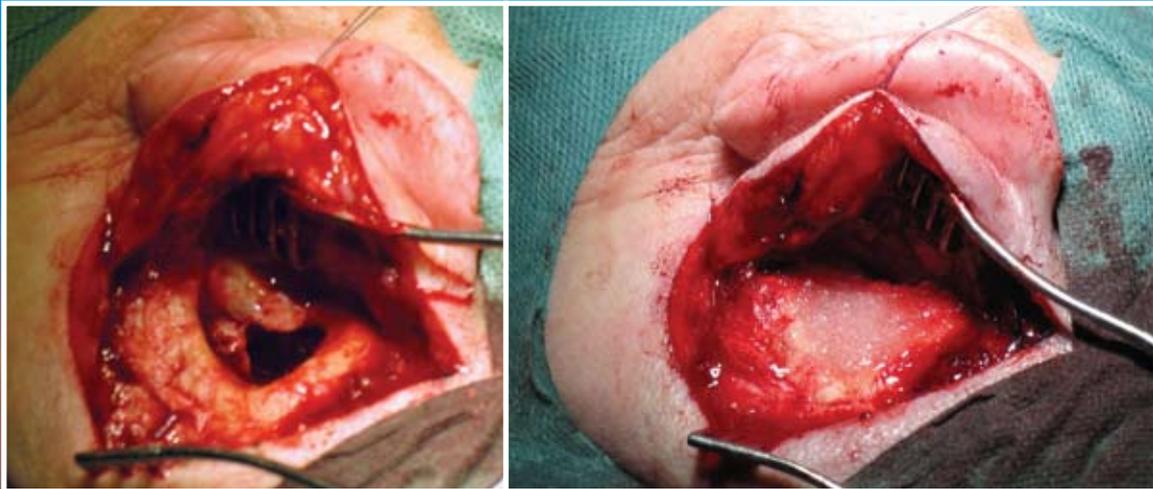


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Bioactive Glass S53P4 in the Filling of Cavities in the Mastoid Cell Area in Surgery for Chronic Otitis Media

Patricia Stoor, MD, PhD; Jaakko Pulkkinen, MD, PhD; Reidar Grénman, MD, PhD

Objectives: Chronic infection of the middle ear and cholesteatoma can be treated surgically by exenteration of the mastoid air cells behind the ear. After a procedure with the canal wall-down technique, a cavity remains that is sometimes difficult to clean, collects crust, and becomes repeatedly infected. Such problematic mastoid cavities can be eliminated by filling the created cavity surgically after thorough removal of mucous membranes and cleaning of the bone.

Methods: We treated 7 patients with cavities after canal wall-down surgery for the treatment of chronic suppurative otitis media or cholesteatoma by filling the difficult-to-clean cavity in the mastoid cell area with granules of bioactive glass (BAG) S53P4 to avoid further retraction formation. The area with BAG was carefully closed with a musculoperiosteal flap.

Results: After the canal wall-down tympanomastoidectomy, the mastoid cavities were successfully filled in all 7 patients. No biomaterial-associated infection was seen, and no disadvantages for the patients due to the BAG were observed. The cavity in the mastoid cell area decreased in size in all patients treated.

Conclusions: This BAG seems to be a promising material for filling mastoid cavities after canal wall-down tympanomastoidectomy.

Key Words: bioactive glass, otitis media, surgical treatment.

INTRODUCTION

Chronic infection of the middle ear is more common in people who have experienced ear disease in early childhood. Disease of the ear in infancy and early childhood may arrest the normal pneumatization of the mastoid cells. It is possible that the same process alters the mucosa of the middle ear so that it is more susceptible to recurrent infection than a normal ear. Chronic suppurative otitis media implies a permanent perforation of the eardrum. Cholesteatoma is known as a chronic condition of the middle ear. It occurs most often with a marginal perforation of the eardrum that allows squamous epithelium from the external auditory canal to grow into the middle ear or as a retraction pocket of the pars flaccida, causing an attic cholesteatoma. As squamous epithelium becomes infected and grows, it desquamates, and keratin and cellular debris collects inside the middle ear. Slow enlargement of the cholesteatoma and the infection leads to expansion into the mastoid antrum and possible complications outside the middle ear.¹

Patients with chronic otitis media can be treated surgically by exenteration of the mastoid air cells behind the ear. Cholesteatoma surgery often in-

volves canal wall-up or canal wall-down tympanomastoidectomy. Often, after a procedure with the canal wall-down technique, a cavity remains that is difficult to clean, collects crust, and becomes repeatedly infected. Such problematic cavities can be eliminated by filling the created cavity surgically, after thorough removal of mucous membranes and cleaning of the bone, with the patient's own tissue, such as fat or bone.²⁻⁴ However, autogenous tissue transplantation is associated with donor-site morbidity and new cavity formation after tissue retraction.⁵ Bioactive glass ceramic particles have previously shown promising results in an experimental mastoid cavity obliteration study.⁶

Our aim was to treat patients with cavities after canal wall-down tympanomastoidectomy for suppurative otitis media or cholesteatoma surgery by using a biomaterial to fill the difficult-to-clean radical cavity in the mastoid cell area to avoid further retraction formation. A smaller residual cavity collects less crust, the risk of infection in the area decreases, and the often unpleasant and painful cleaning of the cavity does not need to be performed frequently. As a filling material, we chose the bioactive glass (BAG) S53P4, which has been proposed for clinical use as a bone substitute for mastoid cavity obliteration and

From the Department of Maxillofacial Surgery, Helsinki University Central Hospital, Helsinki (Stoor), and the Department of Otorhinolaryngology-Head and Neck Surgery, Turku University Hospital, Turku (Pulkkinen, Grénman), Finland.

Correspondence: Reidar Grénman, MD, PhD, Dept of Otorhinolaryngology-Head and Neck Surgery, Turku University Hospital and University of Turku, PO Box 52, 20521 Turku, Finland.

seemingly has antimicrobial properties.⁷⁻⁹ Bioactive glass has been used for small implants, eg, in treatment of the middle ear¹⁰ and in reconstruction of defects of the facial bones.^{11,12} It has also been successfully used in areas potentially contaminated with microbial infections, such as in treatment of frontal sinusitis,^{13,14} repair of nasal septal perforations,¹⁵ and treatment of atrophic rhinitis or ozena.⁷

The BAG S53P4 is a surface reactive material that contains oxides of silicon, sodium, calcium, and phosphorus. It is biocompatible, bone-bonding,^{16,17} soft tissue-bonding,¹⁸ non-tissue-toxic,¹⁰ and osteoconductive.^{19,20} The chemical bond with tissue in vivo is reported to result from the leaching of sodium ions and the congruent dissolution of calcium, phosphate, and silica from the glass in an aqueous environment, giving rise to a silicon-rich layer on the material. The silicon-rich layer acts as a template for a calcium phosphate precipitation, which binds to bone and soft tissue.^{16,18} Obliteration with BAG of closed bone defects, which are not exposed to the external environment after the clinical procedure, has been shown to be successful even if these areas have been potentially contaminated with microbes.^{12,14} Discs and granules of BAG have been shown in vitro not to favor adhesion or growth of oral and nasal microorganisms.⁷⁻⁹ Even stronger antibacterial effects on oral microorganisms have been observed for a paste containing BAG. These effects are due to the high pH and the nonphysiological concentration of alkali ions leached out from the glass.²¹ Bioactive glass has also showed inhibiting properties on the colonization of *Pseudomonas aeruginosa* when incorporated in degradable composites, as compared to degradable composites used without BAG.²² So far, no clear BAG-associated infections have ever been observed in clinical studies. Bioactive glass has also shown primary successful results when used in treatment of osteomyelitis in orthopedic surgery (our data, submitted but not yet published).

MATERIALS AND METHODS

The BAG S53P4 used in this study was produced by Vivoxid Ltd in Turku, Finland, and has received the CE-mark in Europe (2004) and 510k clearance in the United States (2008) for use in head and neck surgery, among other indications. The composition of the BAG given in weight percentages is: silicon dioxide 53%, sodium dioxide 23%, calcium oxide 20%, and phosphorus pentoxide 4%. A description of the preparation of the glass has been published.²³ The mastoid cell area was reduced in size by filling the mastoid cavity with about 5 g of bioactive glass granules of the size 500 to 800 μm . The BAG was dry heat-sterilized at 150°C for 2 hours before use.

In 7 patients who had large cavities due to canal wall-down tympanomastoidectomy surgery for chronic otitis media and/or cholesteatoma, the difficult-to-clean cavity in the mastoid cell area was reduced in size by filling it with granules of the BAG S53P4. The surgery was performed by a retroauricular incision with a musculoperiosteal flap according to Palva.² A canal wall-down tympanomastoidectomy or revision of a previously created cavity was performed. The edematous cavities were opened, and the osseous surfaces were thoroughly cleaned by carefully drilling to reach vital bone surfaces without remnants of mucous membranes. In the patients with cholesteatoma, the cholesteatoma tissue was carefully eliminated from the middle ear cavity. The mastoid cell area was then filled with granules of BAG that were moistened with physiological saline solution to make a pasty mass that is easy to handle (Fig 1). The area containing the BAG was carefully closed with a musculoperiosteal flap and temporalis muscle fascia under the ear canal skin to keep the BAG in position and covered by tissue. In some cases, Lyoplant (14-mm, B. Braun, Aesculap, Melsungen, Germany) was also used. The surgery and follow-up were performed at the Department of Otorhinolaryngology-Head and Neck Surgery at Turku University Hospital, Finland. All subjects enrolled in this study gave their informed consent. The BAG study was approved by the joint Institutional Committee on Human Research at the University of Turku and Turku University Hospital.

In 4 patients, the auditory ossicular chains were reconstructed at the same time. After surgery, the patients were given antibiotics, usually amoxicillin 750 mg twice daily for 10 days, and Merocel (9 \times 15 mm, Medtronic, Xomed Inc, Jacksonville, Florida) and wicks were inserted into the outer auditory canals and removed about 1 week after surgery. The surgical area was cleaned and treated with boric acid powder, and boric acid-ethanol drops were administered after operation as necessary.

During the follow-up, symptoms suggestive of clinical inflammation, such as erythema, swelling, draining, or pain, were sought. In addition, we monitored whether there was any pain, bleeding, or any other abnormality in the operation area. Attention was also paid to whether the glass remained in place under the soft tissue reconstruction. Blood counts, inflammation values (C-reactive protein), and renal function (serum creatinine) were monitored as clinically indicated.

RESULTS

The patients were followed up for 36 to 98 months, except for 1 patient, who was followed for

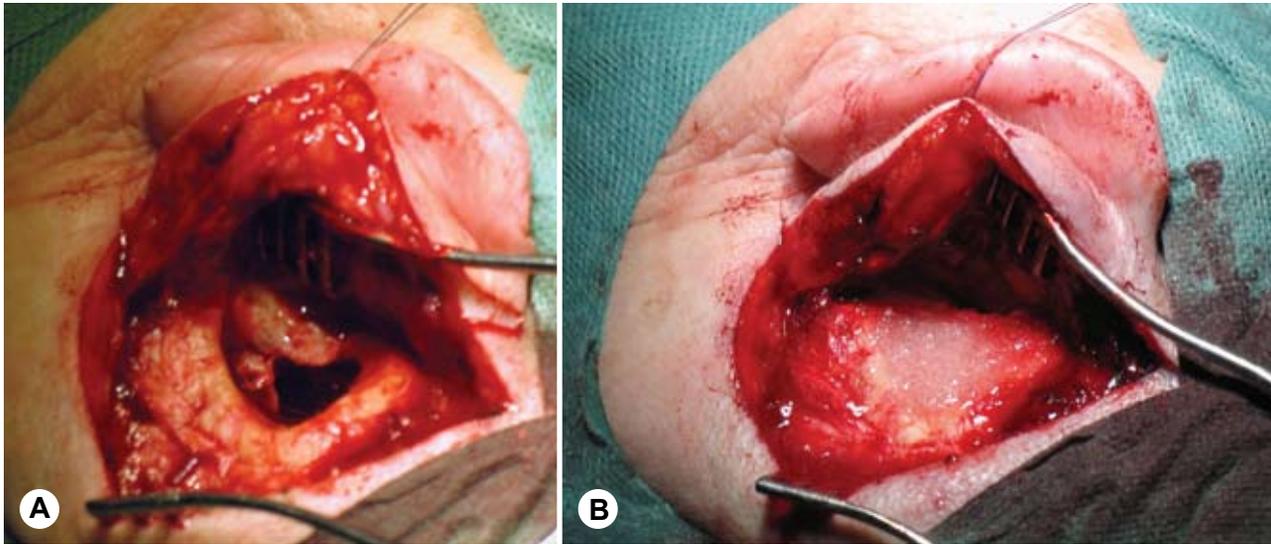


Fig 1. A) Canal wall-down tympanomastoidectomy was performed through retroauricular incision. B) After thorough cleaning of mastoid cell cavity, it was filled with granules of bioactive glass.

only 22 months because of recent surgery; the mean follow-up was 57 months. The cavities were clearly decreased in size in all patients after surgery. In 2 patients, the cavity was totally eliminated, and the posterior canal wall resembled a normal one. In 5 patients, only a small postoperative cavity remained. Despite the extensive surgery and the conservative treatment, such infection-related signs as a transient small fistula with granulation tissue formation and *Staphylococcus* growth were seen in patient 1 (see Table) for a period of several months. However, no extrusion of the BAG was seen in the area. Computed tomography scans were taken of this patient in order to evaluate the status of the middle ear and mastoid cavity (Fig 2). Because a complete obliteration of the mastoid cavity was seen, conservative treatment was continued, and since November 2006, the ear has remained asymptomatic and dry. The infection responded to conservative treatment in spite of the filling material, and thus, the infection was not shown to be associated with the BAG. One patient complained of pain in the area of the operated ear a couple of times in the first postoperative year in connection with symptoms of flu. However, no courses of antibiotics were required to treat the symptoms, and analgesics provided sufficient relief. The BAG remained well in place in the surgical area underneath the soft tissue reconstruction, and no extrusion of granules of the BAG was observed. After successful filling of the cavity, the number and frequency of visits for cleaning of the ears decreased. In 6 patients, the hearing improved after surgery (see Table). No tissue samples were obtained from our patient group during the follow-up, because the patients did not show signs of biomaterial-associated infection.

DISCUSSION

Many different materials, autologous as well as synthetic, have been described in the literature for obliteration of mastoid cavities. The surgery typically aims at reducing the size of difficult-to-clean radical mastoid cavities, thus restoring the original architecture of the external auditory meatus.

Autografts such as bone and fat are resorbed with time, in which case reoperation may be needed to place a new tissue substitute.²⁴ However, according to Linthicum,²⁵ the mucoperiosteal Palva flap used together with bone pate seemed to be a better choice than muscle flaps as such, or the use of subcutaneous tissue. A periosteal-pericranial flap in conjunction with bone pate has also shown very good results in cases of obliteration at primary surgery.²⁶ It has even been described that autologous cartilage chips are resorbed less than bone.²⁷ Obtaining an adequate quantity of autologous graft material is, however, sometimes the issue.

Reconstruction of the posterior canal wall with porous hydroxyapatite (HA), or a Grote canal wall prosthesis, has also been used for obliteration of the mastoid cavity with successful long-lasting results.^{28,29} Porous HA has also showed very promising results in experimental studies in dogs, in which the material appeared to become completely incorporated into host tissue, thus offering a great degree of fixation.³⁰

The short-term failure described with use of HA granules seems to be due to displacement of the fascial covering.²³ Studies with HA cement in obliteration of mastoid cavities have shown poor long-term results, which are suggested to be due to bacterial contamination of the obliterated area. This problem

DATA ON PATIENTS WITH CHRONIC OTITIS MEDIA TREATED WITH FILLING OF MASTOID CAVITY WITH BIOACTIVE GLASS S53P4

Pt No.	Sex	Age at Surgery (y)	Treatment and Disease History	Preoperative Bacterial Strains	Surgical Treatment	Hearing Level (dB)		Follow-Up (mo)	Postoperative Outcome
						Preop	Postop		
1	F	70	Surgery due to chronic mastoiditis in right ear 1950, radical surgery 1960, surgical revision 2002		Revision and bioactive glass S53P4 filling of right radical cavity	70	70	36	Granulation tissue and fistula in area of radical cavity, no residual cavity
2	F	63	Repeated episodes of chronic otitis media, radical surgery of right ear due to cholesteatoma 1999	<i>Proteus mirabilis</i> , <i>Alcaligenes faecalis</i>	Revision and bioactive glass S53P4 filling of right radical cavity, reconstruction of auditory ossicles, widening of outer auditory canal	80	65	64	Good, small cavity toward attic
3	F	50	Radical surgery of right ear due to chronic otitis media 1959		Revision and bioactive glass S53P4 filling of right radical cavity, reconstruction of auditory ossicles	80	55	71	Good, small cavity toward attic
4	M	41	Repeated episodes of chronic otitis media and cholesteatoma of left ear		Radical surgery and bioactive glass S53P4 filling of right radical cavity, reconstruction of auditory ossicles	30	20	98	Good, small cavity toward attic, mild otitis once per year relieved by nonsteroidal anti-inflammatories
5	M	35	Atticoantrostomy of right ear due to cholesteatoma 1978		Revision and bioactive glass S53P4 filling of right radical cavity	10	5	61	Good, small cavity
6	M	30	Tympanomastoidectomy of right ear due to chronic otitis media 1978, surgical revision due to cholesteatoma 1980 and 1983	<i>Staphylococcus aureus</i> , <i>Staphylococcus epidermidis</i> , <i>Enterobacter cloacae</i>	Revision and bioactive glass S53P4 filling of right radical cavity	55	29	49	Good, small cavity
7	M	50	Myringoplasty of left ear due to chronic otitis media 1970, emergency radical surgery due to Bell's palsy on left 1976		Revision and bioactive glass S53P4 filling of left radical cavity and ossiculoplasty	59	14	22	Good, no residual cavity

is rarer for HA granules, as they are mixed with an antibiotic solution at the time of placement.³¹ Very promising results in mastoid cavity obliteration have also been obtained with glass ionomeric granules.³²

In these 7 clinical cases, BAG appeared to be a functional and well-tolerated material that could be used to create favorable conditions for patients with difficult-to-clean radical middle ear cavities. The cavities decreased clearly in size in all patients treated, and in 2 patients there was no cavity-shaped area left after operation. A smaller residual cavity collects less crust, the risk of infection in the area decreases, and the cleaning of the cavity does not need to be done so frequently — advantages that are believed to improve the quality of life.³²

One patient had a postoperative infection that persisted for several months; however, no extrusion of

the BAG granules was seen. There was a good response to conservative treatment, and the ear has been asymptomatic and dry during a 3-year follow-up. In biomaterial-associated infections, extrusion of the infected material is often seen. The colonization of a biomaterial with microorganisms leads to the formation of a biofilm.³³ Neither conservative treatment nor the plasma concentration of antibiotics after normal dosage can eradicate bacteria in a biomaterial-associated biofilm; only surgical revision and removal of the infected biomaterial can. Thus, the infection in our patient is not believed to be associated with the biomaterial or with biofilm formation.

In 6 patients, the hearing improved, even though reconstruction of the auditory ossicles was performed in only 4 patients. This finding suggests that the decrease in the size of the cavity and in the in-

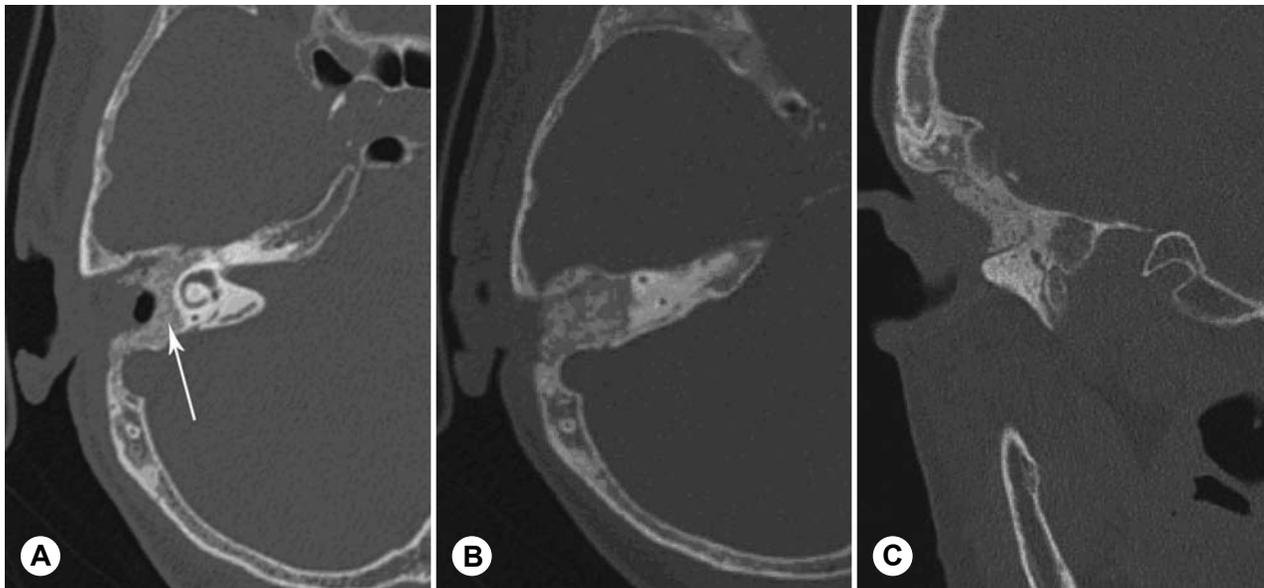


Fig 2. Postoperative **A,B)** coronal and **C)** axial computed tomography scans after filling of mastoid cell cavity with bioactive glass granules. Arrow shows site of bioactive glass.

fections causing mucosal swelling in the middle ear had an improving effect on the hearing. The lack of postoperative altered cochlear thresholds supports the fact that there is no toxic effect on the cochlea.

In addition to being a functional and well-tolerated material, the BAG granules were easy to apply once the technique had been mastered. There is no need for harvesting additional autograft material when using BAG — a feature that promotes overall recovery from surgery. Bioactive glass reduces both the time required for the operation and the postoperative discomfort of the patient. In principle, BAG is always available in sufficient quantity and can be used instead of tissue bank material, which has an inherent risk of infections such as with hepatitis or human immunodeficiency virus.^{34,35} In addition, synthetic BAG can be used instead of biomaterials of animal origin, thereby avoiding the risk of diseases carried by such material, such as prion diseases.

Because BAG is radiopaque, the implant can later be examined by radiography if necessary. Radiographic examinations in patients with septal perforations treated with BAG plates and granules showed the amount of glass to be nearly unchanged after a follow-up of 1 year.¹⁷ When granules are used alone instead of using both plates and granules together, the surface-to-volume ratio of the material increases

and thus the slow, gradual dissolution rate of the materials increases, and the BAG is replaced by cartilage, bone, or soft tissue, depending on the cells in close vicinity to the glass. The slow resorption of the material also provides a successful result as such, since it maintains a good obliteration of the cavity. Despite a potentially infected environment, no clear inflammation associated with the BAG was seen. The success of our operations was partly due to use of a large periosteal flap and temporalis fascia graft; Lyoplant can also be used if needed to prevent extrusion of the granules. Good tissue compatibility and low susceptibility to infection are advantages of BAG that might ensure a long-lasting therapeutic solution.

The BAG S53P4 granules, as a reconstructive material, have not shown any disadvantages for the patients during the follow-up. The cavities that resulted from canal wall-down tympanomastoidectomy were either clearly decreased in size or totally absent in all patients treated, and remained so for the whole follow-up period.

However, for us to be able to draw any definite conclusions about the superiority of BAG compared to other existing grafting alternatives or cortical bone, larger numbers of patients are needed in subsequent prospective studies.

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