SerenoCem™-glass ionomeric granules: a 3-year follow-up assessment of their effectiveness in mastoid obliteration

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Keypoints

- A chronically discharging cavity is a complication of canal-wall down mastoidectomy procedures.
- Mastoid obliteration can reduce this otorrhoea, with many techniques and materials for obliteration described.
- This study assesses the effectiveness of SerenoCem™ granules in providing successful obliteration, by recording the need for subsequent aural care and patient satisfaction using the Glasgow Benefit Inventory.
- All ears were made dry by the procedure (three after revision). Aural care visits reduced [down 9.2 (95% CI 4.7–13.8) over 2 years] and quality of life benefited [total postoperative Glasgow Benefit Inventory score 21.8 (95% CI 10.1–33.6)] significantly, suggesting that SerenoCem™ granules are a useful biomaterial to consider in mastoid obliteration.
- Postoperative infection can prevent osseointegration of the SerenoCem™.

A common potential problem with canal-wall down mastoidectomy procedures is the long-term morbidity associated with a discharging cavity. This can result in offensive discharge, resultant perichondritis of the pinna, an inability to wear a hearing aid, the need for water precautions with avoidance of water sports and a potential lifetime of visits to outpatients for aural care with significant socioeconomic impact. Various factors can contribute to a problematic cavity, namely a large cavity, high facial ridge, narrow meatus, dependent mastoid tip, residual disease and an open middle ear space. Each of these is amenable to surgical correction, and techniques for mastoid obliteration to reduce the cavity size have been in place since the beginning of last century. Various autologous materials have been used, such as muscle, fat, cartilage, musculoperiosteal flaps, bone chip and bone pate. Whilst success has been recorded, there are technical problems with each, most commonly the variable resorption that occurs postoperatively leading to an unpredictable final cavity size. There is also the theoretical risk of reimplanting cholesteatoma using bone pate. Different biomaterials have been tried on the basis that they should be non-resorbable, non-reactive and integrate. This study aimed to assess the long-term effectiveness of SerenoCem™ granules, a glass ionomeric cement, as a suitable biomaterial for mastoid obliteration.

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Methods

Patients

Sixteen patients with chronically discharging mastoid cavities were selected for mastoid obliteration [12M, 4F, aged 14–80 years (mean 43 years)]. The subsequent procedures were performed between January 2001 and December 2003, on eight right and eight left ears, at the Radcliffe Infirmary, Oxford. SerenoCem™ granules are an established product licensed for use in this procedure, so no specific ethical considerations were made.

Outcome measures

The two main outcome measures were the number of attendances for aural care and the Glasgow Benefit Inventory (GBI). A secondary measure was the comparison of pre- and postoperative hearing thresholds.

The need for aural care was taken as a measure of cavity morbidity. Attendances were calculated by a retrospective analysis of the patient records. Most visits were to the Aural Care nurses. The number of visits in the 2 years prior to the operation was recorded. The number of visits in the first 6 months after the procedure was excluded as an increased number was planned to care for the healing cavity. The 2-year period, after this initial 6 months, was analysed to compare with the preoperative data.

The GBI was used to measure change in health status following mastoid obliteration. It is a validated post-

intervention questionnaire comprising 18 questions that assess how an intervention alters the quality of life of a patient.[1] It gives a total score and also general benefit, social support and physical health subscales. Each score ranges from −100 (maximal negative benefit), to 0 (no benefit), to +100 (maximal benefit). The *operation/intervention* on the template GBI form was completed with 'mastoid obliteration'. Questionnaires were completed by telephone interview, at least 3 years after the obliteration procedure, by an independent assessor blinded to any other patient procedural or follow-up details.

As a secondary outcome, the pure tone average (0.5, 1, 2, 4 kHz) was calculated before and after each operation. A calibrated audiometer was used with BSA-recommended procedures. The subsequent change in hearing was calculated.

Operative technique

The senior author performed all operations. Via a postauricular incision, a large superiorly based periosteal flap was elevated and a large temporalis fascia graft harvested. The mastoid epithelium was elevated as far forward as the facial ridge and tympanic membrane. Care was taken to keep the epithelium intact, particularly laterally, to help prevent the granules extruding. The mastoid bowl was cleaned of all mucosa and polished with a diamond burr. The facial ridge was preserved to help retain the granules. SerenoCem™ granules (Corinthian Medical Ltd, Nottingham, UK) were mixed with cefuroxime and blood and packed into the cavity. The fascia graft, positioned under the tympanic membrane, extended the full height of the cavity to contain the granules and form a new posterior wall of the external auditory canal. The granules were compressed down with a sucker on a neuropatty and sealed, with the fascia graft, using Tisseel fibrin glue. The periosteal flap was replaced to cover the SerenoCem™ laterally. The mastoid epithelium was positioned back against the temporalis fascia graft to give extra support to the new posterior wall of the external auditory meatus. The external auditory meatus was then packed with BIPP or more latterly, Merogel sponge (Medtronic Xomed UK Ltd, Bristol, UK). Postoperatively if Merogel was used, patients were discharged on ciprofloxacin drops twice a day for 2 weeks, and all were allowed home on the same or following day on oral ciprofloxacin 500 mg bd for 2 weeks. Dressings were removed in outpatients after 2–3 weeks.

Results

All ears were made dry by the procedure, although in three cases revision surgery was required. The postoperative otoscopic appearance resembled that seen with an atticoantrostomy (Fig. 1).

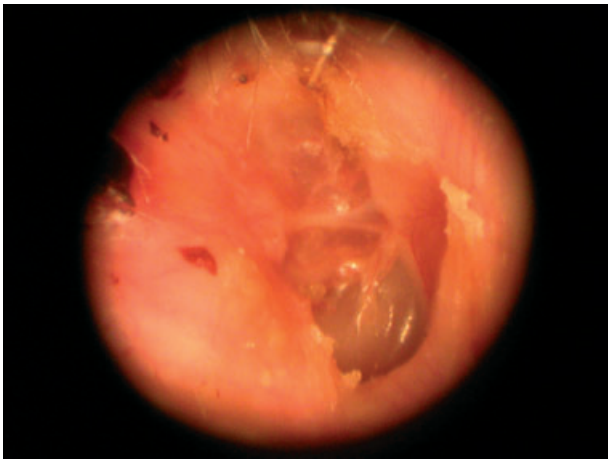

Fig. 1. Post-operative appearance of a right mastoid cavity obliterated with SerenoCem™ granules.

Statistics

The normality of all variables was assessed both formally (using the Shapiro–Wilk test) and informally (looking at the distribution in a histogram). The data did not deviate greatly from the normal distribution, hence mean values and standard deviations were used to summarise the data, and *t*-tests were used for all comparisons.

Aural care

The number of aural care appointments were obtained for 14/16 patients and were reduced in all but one. There was in general a significant difference in the number of aural visits pre- and post-operation. On average there were 9.2 less visits after the operation compared to before (95% CI 4.7–13.8) (Table 1).

Patient satisfaction

Benefit in quality of life was assessed using the GBI. In only one patient was there a negative total score indicating that they were worse off after the obliteration. The mean values

Table 1. Comparison of the number of aural care visits before and after the obliteration

No. aural visits	*n*	Mean	95% CI	*P*-value*
Pre-operation	14	17	12.4–21.6	
Post-operation	14	7.8	5.2–10.4	
Difference (pre–post)	14	9.2	4.7–13.8	0.0007

*Paired *t*-test.

Table 2. Glasgow Benefit Inventory (GBI) scores after obliteration

GBI	*n*	Mean	95% CI	*P*-value*
Total	16	21.8	10.1–33.6	0.001
General benefit	16	25.3	11.5–39.0	0.001
Social support	16	9.4	1.5–17.3	0.02
Physical health	16	20.8	−2.0 to 43.6	0.07

*Single sample *t*-test, comparing to 0.

and 95% confidence intervals for the total score and three subscales are given (Table 2). The mean values indicate that there has been a positive benefit in quality of life, the total score being highly significant ($P = 0.001$).

Linear regression was used to determine if there was a relationship between total GBI and the change in the number of aural care visits post-operation. The coefficient from the linear regression indicates that for every one unit increase in total GBI, the number of aural care visits reduces by 0.04 (95% CI −0.25 to 0.17). The *P*-value of 0.68 suggests that there is no significant correlation between the variables (Pearson's correlation coefficient = −0.04). Similar results were found for the subscales.

Pure tone average

Complete pure tone average results were available for 13/16 patients. In 8/13 patients, the hearing was improved, as intended by additional ossiculoplasty procedures. Of importance, a reduction of hearing was noted in only five patients, the worst of which was 7.5 dB for the 4-tone average. This can be considered insignificant and within expected inter-test variation.[2]

Complications

One patient had an infection in the first 6 weeks after surgery, which resolved with oral antibiotics. In three patients, the initial procedure did not make the ear dry. These required revision surgery due to persistent infection. In one the fascia graft was considered too small and an infection arose almost immediately. After revision with further SerenoCem™, the ear became dry and the obliteration was a success. The other two revisions were with bone pate. In each the SerenoCem™ had failed to osseointergrate, confirmed histologically by the presence of fibrosis rather than osseointegration between bone and SerenoCem™.

Discussion

The literature contains many examples of both autologous and synthetic materials being used to obliterate the mastoid cavity, each aiming to restore the original architecture of the external auditory meatus to as near normal as possible and reduce otorrhoea. An ideal cavity filler would stimulate growth of new bone at the surgical site and reabsorb at a rate equal to the deposition rate of new bone or become incorporated as an inert filler. It would not stimulate an inflammatory response and have no unwanted systemic or local effects, should be easily handled and relatively inexpensive.[3]

A study at the House Ear Institute allowed histopathological analysis of cadaveric mastoid obliteration cases. Despite small numbers the conclusion was that bone pate in conjunction with the Palva (musculoperiosteal) flap seemed best at long-term obliteration rather than muscle flaps on their own or the use of subcutaneous tissue.[4] Ramsey *et al.*[5] reviewed 60 cases where a periosteal- pericranial flap in conjunction with bone pate, produced a dry, trouble-free cavity in 90% of cases in cases of obliteration at primary surgery. The need for coverage of the pate was emphasised to prevent its dissolution. Dornhoffer[6] described the use of autologous cartilage chips, claiming cartilage resorption was less than that for bone. However, obtaining an adequate quantity was sometimes an issue such that a number of cases had mastoid contouring rather than obliteration.

Minatogawa *et al.*[7] reported on a variety of techniques utilising both autogenous material and hydroxyapatite (HA). Short-term failure relating to the HA granules seemed to be due to displacement of the fascial covering. Exposed granules showed inflammatory granulation with uncontrollable secretions despite apparent good unity with surrounding bone. Long-term follow-up showed that both the cortical bone chips and Palva flaps atrophied with a resultant increase in the size of the cavity. Bagot d'Arc *et al.*[8] reported on using a composite of biphasic ceramic granules and fibrin sealant with a covering of temporalis fascia. At 1 year, 19% experienced persistent discharge, correlating to partial resorption of the material forming crevices in which infection resided. Some partial resorption of the material was noted in up to 35% of cases, occurring less frequently when the material was carefully compacted after setting.

Yung reported on using HA granules and an inferiorly based periosteal flap. Due to a supply problem he also used HA cement for some time and so was able to make a comparison. After at least 1 year, half the patients obliterated with cement had infections sufficient to require revision surgery, whilst the granule patients were relatively trouble-free.[9] It was suggested that the cement failed in areas of bacterial contamination of the discharging cavity, and that the granules fared better as they are mixed with antibiotic solution at the time of placement.

SerenoCem™ granules are pre-packaged. This reduces operating time and the risk of introducing infection or

cholesteatoma from bone pate is avoided. The granules are composed of glass ionomeric cement based on the glass LG26, available in two sizes of granule. It is also available in cement form for use in fixing cochlear implants, reconstructing canal walls and in repair of an eroded long process of incus. Comparison has been made between HA granules and SerenoCem^{TM} granules, *in-vivo* using the rat femur, a well-established bone-healing model.[3] This showed SerenoCem^{TM} granules to integrate into the bone without eliciting a chronic inflammatory response or fibrosis, with increased osteoid formation adjacent to the granules as compared to the HA granules where new bone was mineralised. Similar work on baboon tibias confirmed that a similar glass ionomer (Ionogran) was both biocompatible and biofunctional (i.e. caused an appropriate tissue response).[10] A slow, sustained release of fluoride from the glass-ionomer material may provide the stimulus for sustained osteoblastic activity, enhancing the process of bone bonding and new bone formation. The essential difference between the two biomaterials seems to be the presence of a reactive fibrovascular response to the surface degradation products of the HA, stimulating a low grade, persistent irritation associated with active bone formation.[11] Whilst this new bone forms there is simultaneous resorption by osteoclast and macrophage activity. In comparison the glass ionomer is stable and promotes a well-organised osteoid formation, and the lack of inflammatory response may help the survival of grafted material (i.e. fascia) that is in contact with its surface. The lack of inflammation, fibrosis and resorption should make the obliterated cavity stable and the size predictable in the long-term. The lack of altered cochlear thresholds seen postoperatively, supports the fact that there is no toxic effect on the cochlea. Other glass ionomer products have been used in the past. There was concern about the thermal effects, but SerenoCem^{TM} is non-exothermic. Aluminium toxicity was also recorded and led to products being withdrawn from the market. SerenoCem^{TM} granules contain only a trace of aluminium that cannot leach out as the setting phase is complete when they are inserted, so this is not an issue with this product. They can safely come into contact with the dura, though we advocate placing a fascial graft over any defects in the tegmen prior to granule placement.

One might expect that as the GBI score increases, so the number of aural care visits after the operation decreases, in an individual. The results failed to show such a correlation. All ears were made dry, which should account for the improved GBI scores. However, attendance to aural care is not necessarily a sign of illness. Regular attendees may prevent cavity ill-health, wax may still need removal for effective hearing aid usage, and some patients simply like the reassurance of a check-up. So whilst both an improved GBI score and a reduction in aural care visits would imply successful outcomes of surgery, the relationship between the two is not clear.

Using the technique described, SerenoCem^{TM} was considered reasonable to handle. Success of the operation was felt to partly rely on having both a large periosteal flap and temporalis fascia graft to prevent extrusion of the granules and facilitate epithelialisation of the newly obliterated cavity. With such attention to detail, the findings of this study suggest that SerenoCem^{TM} granules provide a useful adjunct for mastoid obliteration, significantly reducing the subsequent number of outpatient aural care visits, with resultant dryer ears and improved quality of life as assessed by the GBI.

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Conflict of Interest

None to declare.

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