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Original article

Radiological-audiological correlation in type II tympanoplasty with glass ionomer cement

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ABSTRACT

Aim: To assess the CT scan aspect of cement bridges used to repair incudostapedial joint discontinuity (ISD) and correlate these observations to audiometric data over time.
Material and methods: A retrospective study in 12 patients with cement rebridging for ISD compared pre- and post-operative pure-tone average thresholds, Hounsfield units (HU), and bridge size and position on postoperative CT scans.
Results: Mean pre- and post-operative air-bone gap (ABG) was 24.5 and 16 dB, respectively. HU did not vary over time post-surgery, with no significant correlation between HU and time to postoperative CTnscan up to 24 months ($p = 0.219$). However, a "suggestive" correlation was found between postoperative ABG and HU ($p = 0.004$, $r = -0.7$). High cement density correlated with good functional outcome: HU < 500 indicating functional failure and > 1000 indicating ABG closure.
Conclusion: Immediate cement polymerization quality (high HU) was stable over time and a marker of ossiculoplasty success, correlating with good functional outcome. Particular care should be taken in preparing the cement, and solidification needs to be on dry mucosa-free ossicles.

1. Introduction

Lenticular process lysis or incudostapedial joint discontinuity (ISD) is the most frequent ossicle pathology in chronic otitis media [1]. It is a weak link, being thin and fragile and highly sensitive to local inflammatory, traumatic or ischemic effects, and thus often the site where the ossicular chain breaks under chronic otitis media, leading to conduction hearing loss.

Columellar effect rehabilitation techniques in this pathology are numerous:

- cartilage interposition;
- incus interpositioning;
- partial ossicular replacement prosthesis (PORP) or;
- more recently, cement bridge [2,3].

Glass ionomer cement was first used by dentists [4], and otologists progressively came to take an interest in this biocompatible material. There are now various indications in middle-ear surgery: in stapedectomy revision surgery to stabilize the prosthesis, middle-ear implant fixation, reconstruction of canal-wall-down tympanoplasty, and ISD [5–8]. In type II ossiculoplasty (with intact stapes) for ISD, many studies compared audiometric results between ossiculoplasty techniques [9–16]. A 2015 literature review [17] concluded that no particular technique demonstrated superiority. Cartilage interposition ossiculoplasty gives good results (air-bone gap [ABG] ≤ 20 dB) in 47–85% of cases, incus interpositioning in 45–65%, PORP in 75–86%, and cement rebridging in 74–95% [3,18–20].

Cement rebridging is useful in ISD, as the ossicular chain is sufficiently well conserved for it not to need replacing. The cement restores functional anatomy, without risk of mechanical trauma to the ossicular chain as it is easy to apply and does not require moving the chain. However, as in all ossiculoplasties, results are variable, with failure rates ranging from 25% to less than 10% [18]. Some studies reported that the most significant factors for failure of type II ossiculoplasty concerned preoperative middle ear status (polyps, cholesteatoma, humidity) and the extent of ossicular chain lysis [10]. Ossicular cement is used in case of lenticular process lysis or distal ISD, which is thus not very extensive, and no studies have found a correlation between auditory outcome and the extent of ISD [16]. On the other hand, the middle-ear environment can be more or less stable or progressive. Ossicular cement involves a chemical reaction within the middle ear; progression of density and stability

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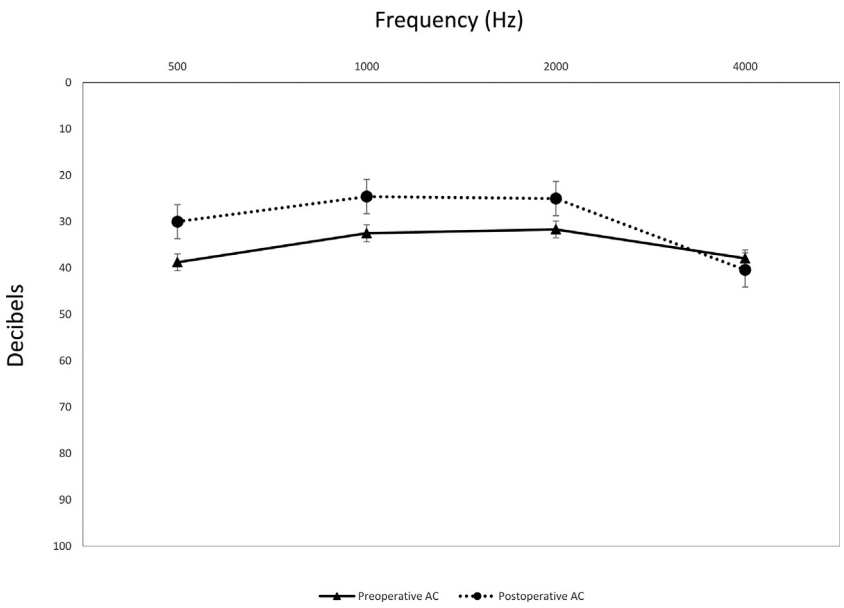

Fig. 1. Audiogram showing preoperative (full line) and postoperative (dotted line) air conduction at the study frequencies (mean ± standard deviation).

are unknown and are in theory subject to middle-ear status. To our knowledge, no previous studies have addressed these factors.

The aim of the present study was to assess the radiologic aspect of glass ionomer cement and postoperative progression in its density (Hounsfield units [HU]), and to correlate findings with functional results.

2. Material and methods

A retrospective study included patients undergoing type II ossiculoplasty using glass ionomer ossicular cement, between March 2015 and July 2017 in a center employing surgeons experienced in otology.

Twelve patients were included, presenting incudostapedial joint discontinuity (ISD) secondary to severe retraction pocket or cholesteatoma. Postoperative CT scan was performed at a median 5 months (range, 1–24 months). Other indications for cement rebridging, such as stapedectomy revision surgery or malleus fracture, were excluded. The cement used in the center at the time of study was SerenoCem® (Invotec®, Jacksonville, FL, USA).

Mean pre- and post-operative bone- and air-conduction (BC, AC) pure-tone hearing thresholds and ABG were measured at 500, 1000, 2000 and 4000 Hz [21]. Median time to audiometry was 6 weeks (range, 4–72 weeks).

Pre- and post-operative imaging was interpreted by a radiologist specializing in otology. As a preliminary to the in-vivo study, radiologic cement density was assessed for a 5-mm fragment of glass ionomer ossicular cement, polymerized as under final middle-ear conditions. By way of reference, bone shows density of > 1000 HU and facial bones, including ossicles, show about 1500 HU [22], while cartilage shows 60–150 HU. Density was 2000 HU in a cement fragment much larger than needed for lenticular process reconstruction.

On the available postoperative CT scans, cement visible in anatomic position, density (HU) at the intended ossiculoplasty site (and any displacement of the fragment) and fragment length (mm) were assessed.

Audiometric data were reported as mean ± standard deviation. The correlations of density (HU) to CT-to-surgery time, postoperative ABG and fragment length were assessed on Pearson test on Xlstat® software, with the significance threshold set at $p < 0.005$ and p values 0.05–0.005 considered suggestive [23].

3. Results

The study comprised 12 patients: 8 female, 4 male (sex ratio = 0.5); median age, 49 years (range 13–63 years). Fig. 1 shows mean pre- and post-operative AC thresholds at the study frequencies. Mean ABG was 24.5 ± 11 dB pre-operatively, and 16 ± 7 dB postoperatively, for a gain of 8 ± 10 dB. There was 1 case of mean 13 dB sensorineural hearing-loss at the study frequencies, and no other complications during follow-up.

All patients showed aerated tympanic cavities on postoperative CT scans. HU values were available for all patients. One patient showed a cement fragment that was well-polymerized but dislocated, failing to bridge the chain (HU −500, indicating defect). Cement density showed no significant relation to time to postoperative CT scan ($p = 0.219$, $r = 0.4$) (Fig. 2). Fig. 3, however, displays a suggestive negative relation between postoperative ABG and HU values ($p = 0.004$, $r = -0.75$) and a suggestive positive relation between fragment length and HU ($p = 0.002$, $r = 0.71$). One patient (Fig. 3, empty circle) showed intermediate density in a long (3 mm) fragment and absence of ABG closure; discounting this subject, the significance levels are higher for both ABG ($p < 10^{-3}$, $r = -0.9$) and fragment length ($p < 10^{-3}$, $r = 0.76$). Discounting the same subject, the correlation between fragment length and final ABG remained suggestive ($p = 0.016$, $r = -0.73$; $n = 11$): the higher the HU value, the longer the fragment and the smaller the postoperative ABG.

Postoperative results distinguished 3 groups:

- density < 500 HU, associated with failure ($n = 4$, ABG > 20 dB);
- density 500–1000 HU ($n = 6$), associated with intermediate functional outcome: 1 patient with ABG < 10 dB, 4 with 10–20 dB and 1 with 26.25 dB (marginal case);
- density >1000 HU ($n = 2$), associated with success (ABG < 10 dB).

4. Discussion

There are several type II tympanoplasty techniques, with overall success rates (final ABG, < 20 dB) ranging between 60% and 94% depending on the cohort [17]. The present study aimed not to

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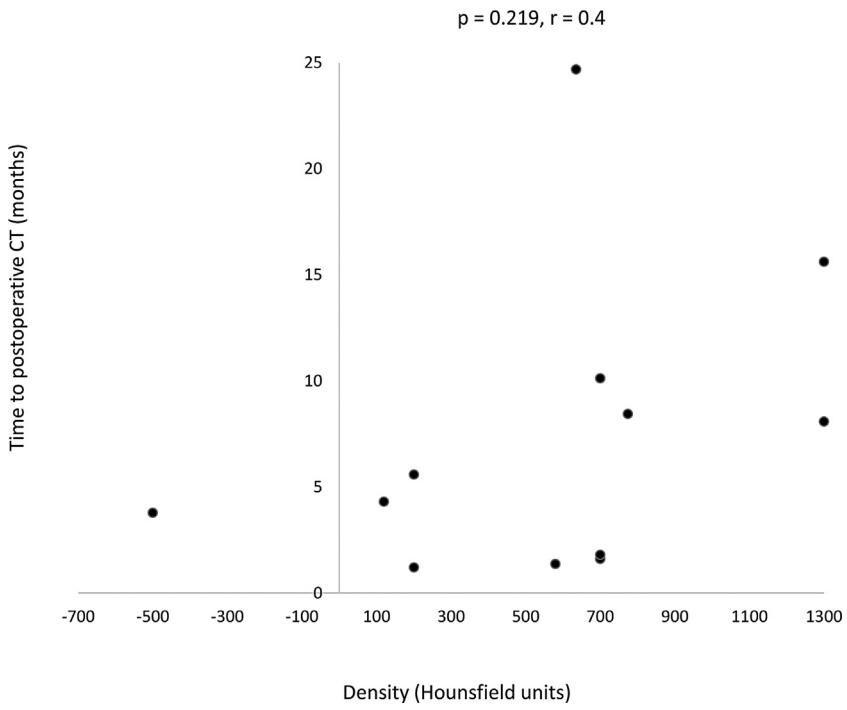

Fig. 2. Cement fragment density in Hounsfield units according to interval between surgery and postoperative CT scan for each patient. No significant correlation.

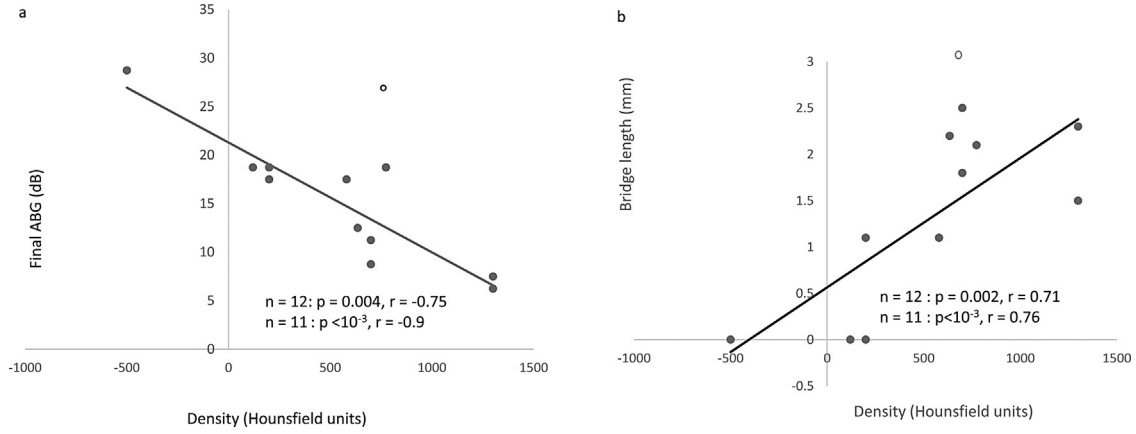

Fig. 3. a: correlation between postoperative air-bone gap and cement density (HU); b: correlation between bridge length (mm) and cement density (HU). Correlations were significant (regression curve for $n = 11$). Empty circle designates a poorly polymerized long fragment, resulting in poor functional outcome. Results are reported with ($n = 12$) and without this marginal case ($n = 11$).

demonstrate superiority for glass ionomer cement rebridging but to shed light on immediate and long-term functional results, in correlation with postoperative CT data.

To our knowledge, this was the first study of glass ionomer cement from this point of view, taking account of progression, HU density and bridge length.

The small number of inclusions was due to the high cost of this technique, compared, for example, to autologous graft such as cartilage, without functional superiority [20]. Moreover, given the retrospective design, only patients with postoperative CT scan as part of contralateral ear monitoring were included. The sample was, however, representative in terms of age (13–63 years) and hearing loss (mild to moderate).

The results showed cement density to be stable over time in postoperatively aerated tympanic cavities.

Functional success appeared directly related to intraoperative polymerization quality, indicated by high HU values. Logically, the longer the fragment, the higher the density; but equally, the higher the density, the smaller the postoperative ABG. There were thus 3 outcome groups:

- density < 500 HU was associated with failure. Cartilage shows density < 500 HU, and this value can probably be attributed to the tympanic membrane reconstruction cartilage covering the IS joint. Cement may have been insufficient in quantity, or else drying time had not been respected;
- density 500–1000 HU gave intermediate or variable results, probably due to suboptimal polymerization resulting in an insufficiently rigid chain;
- density > 1000 UH was associated with postoperative ABG < 10 dB.

The longer and more dense the fragment, the better the functional outcome, with optimally physiological anatomy. The case of the marginal patient confirms this hypothesis, with a long fragment the density of which was insufficient for the length,

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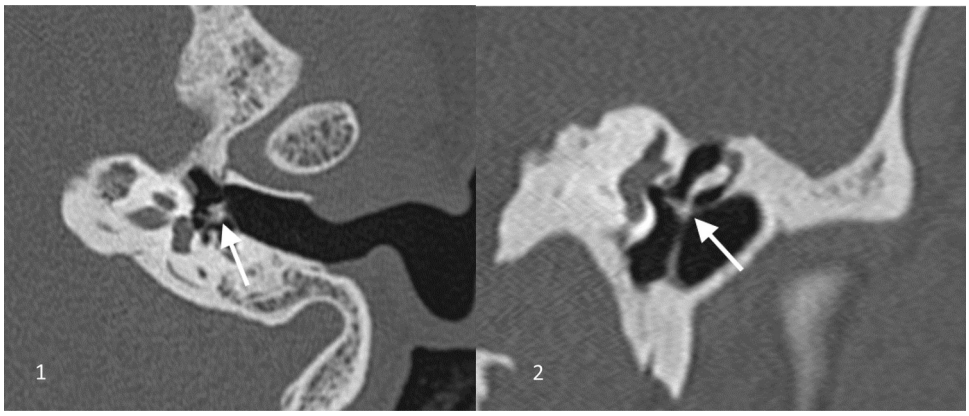

Fig. 4. Postoperative CT scan showing bone cement ossiculoplasty (white arrow) 1) on axial slice in contact with the stapes, and 2) on coronal slice in contact with the incus long process. Good functional outcome, with ABG < 10 dB.

impairing conduction. Low density was probably due to poor polymerization. According to Elsheikh et al., bone defect does not correlate with functional outcome in cement ossiculoplasty [16]; even so, it may be the case that large ISD, requiring a bridge longer than 2.5 mm, represents a limit to successful cement ossiculoplasty.

The key to success is thus an optimally dense bridge, anatomically positioned. The technical pitfall is to manipulate the cement before the chemical reaction is optimal. Firstly, the ossicles must be completely free of blood and mucosa [24]. In our center, no specific instrument, such as laser or coagulation needle, is used. Residual mucosa is removed by needle or micro-hook. The ossicles are cleaned and dried using cotton buds impregnated with adrenalin. There is a theoretic risk of sensorineural hearing-loss in manipulating the stapes. As the chain is discontinuous, mobilizing the incus long process is not risky. In the present series, only 1 patient showed deterioration of the bone-conduction pure-tone average, related to resection of the retraction pocket. Secondly, in vivo, drying time is long (10 min) without a moistening agent to soften the fragment. Thirdly, tympanic membrane reconstruction should precede ossiculoplasty, to avoid fragment dislocation under excessive manipulation. Only when the cement has fully hardened can the tympanomeatal flap be folded back in contact with the polymer. Polymerization may be impaired by a problem with the cement itself, according to our experience in our own center, where the chemical reaction has been defective once.

In conclusion, functional outcome depended on good polymerization of the cement bridge restoring functional anatomy between the healthy incus long-process and the head of the stapes, without blocking the chain on the canal wall, thus ensuring reliable conduction (Fig. 4).

5. Conclusion

The SerenoCem® ossicular cement was visible on CT scan, and showed high HU values at more than 1 year post-surgery. Functional outcome depended directly on fragment length and polymerization quality. Particular care should thus be taken in preparing the cement and making sure it solidifies on ossicles completely free of blood and mucosa. It would be useful to pursue the present study by comparing several types of cement in a larger sample: ease of polymerization, drying time, ease of manipulation by needle.

Disclosure of interest

The authors declare that they have no competing interest.

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