Role of bone cement in stapedectomy

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Abstract

Background: Otosclerosis is a complex and progressive disease of bone of otic capsule.1 Mature lamellar bone is replaced by osteoblasts with the bone of more thickness, cellularity, and vascularity.2 It mainly affects the stapes footplate especially the fissula ante fenestram and can extend to the inner ear causing cochlear otosclerosis, which can be termed as mixed otosclerosis. With an incidence of 1–2% of the white population, otosclerosis is among the most common causes of acquired hearing impairment. **Aim:** in this study; we reviewed the Bone Cement Application in Patients with Otosclerosis, **Summary:** The use of hydroxyapatite bone cement in primary stapedotomy may have a role in providing stability for the procedure decreasing the incidence of recurrent conductive hearing loss in otosclerosis patients. This can provide a substitute for the problems of malcrimping of the prosthesis.
Keywords: Bone cement, Crimping, Long process of incus, Necrosis, Otosclerosis, Revision stapedotomy

Introduction

The middle ear cleft is anatomically divided in five parts: the epitympanum is located superiorly, and is interconnected by the antrum to the mastoid air cell system (MACS); the retrotympanum posterior is a system of bony bridges and more or less shallow sinuses; inferiorly lies the hypotympanum; anteriorly is the protympanum with its connection to the Eustachian tube; and in the center, lies the mesotympanum **(1)**.

The main advantages of the endoscope are the panoramic and wide-angled views of the middle ear. For instance, the otherwise hidden retro- and hypotympanum may be accessed using an exclusive endoscopic transcanal approach without a canaloplasty6. A recent study showed superior visibility of all middle ear compartments using the endoscope when compared to the microscopic technique **(2).** The use of angled endoscopes (30° and 45°) further improves visibility and allows dissection with a view of the most hidden areas of the middle ear.

In general, the gold standard for surgical training is considered to be cadaveric dissection. In cases of unavailability of cadaveric specimens or local ethical issues, an animal model for the training of endoscopic ear surgery has recently been described8. Surgical training is considered an important factor in the education of trainees in a novel technique **(3).**

Compared to the microscopic technique for middle ear dissection, the endoscope allows the observation and preparation of the delicate middle ear structures through a natural orifice, the EAC. Of course, the endoscopic approach does not teach mastoidectomy, which may be performed on the same specimen after endoscopic dissection. The endoscopic technique for ear surgery is internationally spreading and therefore the need for suitable surgical training will increase **(4)**.

Otosclerosis

With an incidence of 1–2% of the white population, otosclerosis is among the most common causes of acquired hearing impairment. The technique developed by Shea continues to be valid to the present day; however, the less invasive stapedotomy has its benefits. With this method, micro-drills or various lasers are used to perforate the stapes footplate **(5)**.

Incidence:

Caucasians are more commonly affected by otosclerosis than Asian, black, and Native American populations, with a prevalence of clinical otosclerosis of less than 1% among white individuals. Females are disproportionately affected in a variable ratio to males **(6)**.

Otosclerosis is a bilateral disease in approximately 80% of cases. Patients present with gradual Conductive Hearing Loss (CHL) and with tinnitus in approximately 65–92% of cases **(7)**.

Aetiology:

Otosclerosis is a disease of the otic capsule and middle ear ossicles, in which a new dense sclerotic bone is formed. The etiology of otosclerosis has not been fully elucidated despite numerous studies; however many theories have been suggested to explain it on the basis of genetic, viral, hormonal, and other factors. The inheritance of otosclerosis is believed to be predominantly autosomal with variable penetrance, but other modes of inheritance are possible **(8)**.

In response to viral or bacterial infections, the cells secrete pro-inflammatory cytokines, e.g. tumor necrosis factor-α (TNF-α) and interleukin-1β (IL-1β). TNF-α is secreted by activated monocytes, macrophages, lymphocytes B and T and osteoclasts. Thus, the activities of TNF-α, IL-1β and OPG lead to contrasting effects concerning the bone remodeling. Action of TNF-α and IL-1β leads to an increase in bone resorption, whereas osteoprotegerin inhibits its destruction **(9)**.

Clinical and histological otosclerosis:

Clinical otosclerosis is one of the most common etiologies of acquired hearing loss in the Caucasian population, affecting 0.5%. Clinical otosclerosis manifests as a progressive CHL. Otosclerosis may eventually evolve into a mixed hearing impairment if the lesion extends to the cochlear endosteum and involves the spiral ligament (SL), resulting in hyalinization **(10)**.

Surgical management:

Surgical management of stapedial otosclerosis began with stapes mobilization by Bousheron in 1890 and the modern operation of stapedectomy introduced by Shea in 1958. The concept of small fenestrum stapedotomy was proposed by Fisch in 1982. Using the piston type of prostheses, this procedure gained excellent hearing results and minimal complications **(11)**.

Treatment options for otosclerosis include medications, use of hearing aids, and surgery. Medical treatment is indicated in the early active stage of the disease, which usually goes unnoticed, while hearing aids tend to be indicated when patients refuse surgery. The surgical treatment of otosclerosis is the most commonly used and most effective treatment and includes either stapedectomy or stapedotomy. Shea first performed stapedectomy in 1956 and is considered the pioneer of the modern surgical treatment of otosclerosis **(12)**.

Over the years, stapedotomy fenestration techniques have evolved from the use of microinstruments to microdrills, and more recently laser. The main advantages of the laser include the high precision of its application and the low risk of footplate mobilization as a result of the no-touch principle of this technique. Even though inner ear damage as a result of mechanical trauma is less likely, the potentially harmful effects of laser use should not be underestimated **(13)**.

Bone cement

Bone cements have no intrinsic adhesive properties, but they rely instead on close mechanical interlock between the irregular bone surface and the prosthesis. Other types of commercially available bone cement like calcium phosphate cements (CPCs) and Glass polyalkenoate (ionomer) cements (GPCs) are successfully used in a variety of orthopaedic and dental applications. CPCs are bio resorbable and biocompatible, but are mainly used in cranial and maxillo-facial surgeries because of their low mechanical strength **(14)**.

Historical perspective

The first bone cement use in Orthopaedics is widely credited to the famous English surgeon, John Charnley, who in 1958, used it for total hip arthroplasty **(15)**.

In the 1970's, the U.S. Food and Drug Administration (FDA) approved bone cement for use in hip and knee prosthetic fixation. Since then, while bone cement has become widely used for fixation of prostheses to living bone, the trends of bone cement usage have evolved **(16)**.

Complications of bone cement in orthopedic surgery:

Hypotensive episodes and **cardiac arrest** have been reported during cement insertion.

The premature insertion of bone cement may lead to a drop in blood pressure, which has been linked to the availability of methyl methacrylate at the surface of the product, although this has not been proven. This drop in blood pressure, on top of hypotension induced either accidentally or intentionally, can lead to cardiac arrhythmias or to an ischaemic myocardium. However, according to a report, the possible risk of death associated with the use of cemented implant is confined to early postoperative and perioperative period **(17)**.

The most frequent adverse reactions reported with acrylic bone cements are: Transitory fall in blood pressure, elevated serum gamma-glutamyl-transpeptidase (GGTP) upto 10 days post-operation, thrombophlebitis, loosening or displacement of the prosthesis, superficial or deep wound infection, trochanteric bursitis, short-term cardiac conduction irregularities, heterotopic new bone formation and trochanteric separation.

Antibiotic bone cement

Bone cement has proven particularly useful because specific active substances, e.g. antibiotics, can be added to the powder component. This makes bone cement a modern drug delivery system that delivers the required drugs directly to the surgical site. The local active substance levels of bone cements are significantly below the clinical routine dosages for systemic single injections **(18)**. Various antibiotics have been successfully mixed and used with bone cements like Gentamycin, Tobramycin, Erythromycin, Cefuroxime, Vancomycin, Colistin etc. The basic requirement, being that the mixable antibiotic should be heat resistant and should last for longer duration of time.

Curing process

The curing process is divided into 4 stages: a) mixing, b) sticky/waiting, c) working, and d) hardening. The mixing can be done by hand or with the aid of centrifugation or vacuum technologies.

Bone cements are heat sensitive. Any increase or decrease in temperature (either ambient, and/or of the cement components and mixing equipment) from the recommended temperature of 73 °F (23 °C) affects the handling characteristics and setting time of the cement. Manual handling and body temperature reduces the final setting time. Variations in humidity affect the cement handling characteristics and setting time. It is recommended that the unopened cement components are stored at 73 °F (23 °C) for a minimum of 24 h before use. Vacuum mixing of cement can also accelerate the setting time of the cement **(14)**.

Methods of application

Various methods exist for the application of cement into the bone or joint surface **(19)**.

Digital: All antibiotic bone cements can be applied digitally. The cement is mixed thoroughly but carefully to minimize the entrapment of air. Once dough is formed the surgeon should wait until the cement no longer adheres to the glove and the surface has become dull as opposed to shiny. The cement can then be taken into gloved hands and kneaded thoroughly. It is vital that premature insertion of cement is avoided as this may lead to a drop in the patient's blood pressure. Importantly, this stage will occur at different times for different cement types.

The time of cement application and prosthesis insertion is at the discretion of the surgeon and will depend upon the surgical procedure used. In general, implant insertion should be delayed until the cement has developed a sufficient degree of viscosity to resist excessive displacement by the implant. However, implant insertion should not be delayed such that there is a risk that the procedure cannot be completed due to cement hardening.

Following introduction the implant must be firmly held in position to avoid movement and pressurization must be maintained until the cement finally hardens. Excess bone cement must be removed before the cement has completely hardened **(19)**.

Bone cement in otologic surgery:

Glass ionomeric cement, which is a type of bone cement, gained the United States Food and Drug Administration approval in 2001 for otological use **(20)**. Since then, it has been used in ossiculoplasties and revision stapes surgery.

Technique of application: Bone cement consists of powder and liquidmixed at certain ratios. This mixture hardens within minutes through an exothermic process. The mixing time is 2.5 minutes, and the hardening is completed in 5–10 minutes. Whenthe bone cement hardens, it no longer reacts with the surrounding liquids **(21)**.

Bone cement in primary and revision stapes surgery: Stapedotomy is considered the first-line management for cases of otosclerosis as it is a cost-effective safe option for these patients with progressive hearing loss. However, the need for revision surgerydue to recurrent conductive hearing loss is a major drawback of this type of surgery. In the situation of revision surgery for these cases, it has been found that prosthesis displacement and incus necrosis were the most common etiologies of recurring hearing loss **(22)**.

Many studies is in line with the proposed use of bone cement in primary stapedotomy such as made by Goebel and Jacob. In addition, it is more comprehensive than the study of Rompaey et al. who used the bone cement in the difficult cases of primary stapedotomy and proposed that its use will have a better impact on postoperative hearing as the prosthesis and the incus moves as one unit over the footplate **(23)**.

Bone cement in Long process of incus (LPI) necrosis in revision stapedectomy : It has been shown that bone cement provides many options for hearing reconstruction in cases of LPI necrosis **(21)**.

Many studies have discussed the recurrent conductive hearing loss after 1-year stapedotomy. House et al. studied 37 cases of previously treated otosclerosis patients where incus erosion was observed during revision stapedotomy. Moreover, Rouhani and Lavy managed 27 cases of revision stapedotomy who had incus necrosis using bone cement and had good closure of the air-bone gap. Stapedotomy with bone cement fixation of the prosthesis provides excellent hearing outcomes in both primary and revision treatment of otosclerosis. Results are consistent and stable through long-term follow-up. The use of bone cement should be incorporated into the surgical armamentarium of the otologist for the prevention and treatment of loose-wire syndrome and incus necrosis **(24)**.

Bone cement for ossicular chain defects: Ossiculoplasty with bone cement is a cheap and simple procedure. It is known to be safe and not affecting the inner ear functions, and there is also a proof of biocompatibility and osseointegration. Bone cement is cost-effective because it is cheaper than other ossiculoplasty materials **(25)**.

Bone cement is cost effective, because it is cheaper than other ossaiculoplasty materials, and this cost-effectiveness plays an important role in the decision the surgeon has to make, and bone cement has a promising role in this so, there is a rising interest in the otologic surgical field to use bone cement because of its biocompatible profile, its ease of application in difficult regions, its reasonable cost, and its low extrusion rate. Moreover, it seems to have a potentiality of neo-osteogenesis **(26)**.

Disadvantages include displacement. For some ossicular chain problems, bone cement can be used to restore these defects as a cost-effective option. Hoffmann et al., 2003 demonstrated already that bone cement could bind adequately to the ossicular bone with new bone growth and no inflammation occurring at the site of application, making a suitable solution as an agent to fix the sculpted autograft to the remaining ossicular chain **(27)**.

Drawbacks of bone cement

One of the major drawbacks of bone cement in joint replacement is cement fragmentation and foreign body reaction to wear debris, resulting in prosthetic loosening and periprosthetic osteolysis. The production of wear particles from roughened metallic surfaces and from the PMMA cement promotes local inflammatory activity, resulting in chronic complications to hip replacements. Histologically, a layer of synovial like cells which line the bone cement interface supported by a stroma containing macrophages and wear particles, has been described in loose prostheses **(28)**.

Complications of bone cement in otology surgery: Glass ionomer cement has been shown by Driscoll et al. to have adverse effects on soft tissues. According to Yazıcı et al., the GIC group had an intact graft rate of 78.6%. In our study, we had a 92.6% graft success rate with 2 cases that presented with granular myringitis, which improved with medical treatment later on. To avoid the undesirable effects of GIC, soft tissues should be avoided, the middle ear cavity should be kept dry, and enough time should be given for the GIC to harden **(29)**.

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