Usage of Homograft Bone in Stapedectomy: KHMC Experience

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Objective: The objective of this study is to show the efficacy, safety and feasibility of using homograft bone prostheses in middle ear reconstruction.

Material and Methods: Twenty subjects (12 males, 8 females) with a mean age of 32.6 years (age range15-47 years) presented with unilateral 3 (15%) or bilateral 17 (85%) conductive hearing losses and were diagnosed as having otosclerosis. Stapedectomy was performed on each. In each case a homograft bone, prepared and sculptured at the Hough Ear Institute in Oklahoma, USA by the author, was then used as a prosthetic device to replace the diseased ossicle after its removal.

Results: The donated homograft bone proved to be safe with no transmission of disease; long lasting without infection, rejection, or resorption; and a good transmitter of sound with good closure of the air-bone gap. Of the 20 cases, 11 had complete closure of the air-bone gap (55%), 7 had closure air-bone gap within 10 dB (35%) and 2 showed no improvement (10%).

Conclusion: Homograft human bone is the most logical choice for ossicular reconstruction because it is the closest transplantation material to the host histologically. Current fixatives and storage materials remove the immunogenicity and so do away with the host versus graft reaction.

Keywords: Stapedectomy, Homograft.

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Introduction

Various types of artificial prosthetic materials such as plastics, ceramics, metals and porous plastics have been used to replace the gap between the ossicles after stapes removal in cases of otosclerosis and in cases of ossicular erosion caused by middle ear infections or trauma. Homograft bone is another option that can be used to replace diseased or missing ossicles. The efficiency, functionality and biocompatibility of this method is excellent since it more closely approximates the patient's own bone.

This study describes the efficacy, safety and feasibility of using homograft bone as prostheses in middle ear reconstruction.

Materials and Methods

The bone grafts used in this study were prepared and sculpted by the author at the Hough Ear Institute in Oklahoma, USA. Sculpturing was done according to a special protocol developed by Institute personnel. [1] With this method donor bone graft material (human femur) is obtained from the American Red Cross Bone Bank.

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It arrives packed in dry ice and is transferred to a 10% formaldehyde solution and where it is stored for 3 days. After 3 days, the large piece of bone is removed from the formaldehyde and cut into smaller specimen blocks. These small bone specimens are stored in alcohol until sculpted into ossicles. The bone to be sculptured (Figure 1) is mounted on a Dremel rotary tool and then microlathed using the Dremel rotary tool and a hand drill (Figure 2).

Three types or shapes of ossicles can be created from the bone as follows:

1. **S** type which connects the perichondrial graft in the oval window to the long process of the incus,
2. **FPM**, which connects the footplate of the stapes to the handle of malleus, and
3. **SHM**, which connects the head of the stapes to the handle of the malleus (Figure 3).

Figure 1.

Figure 2.

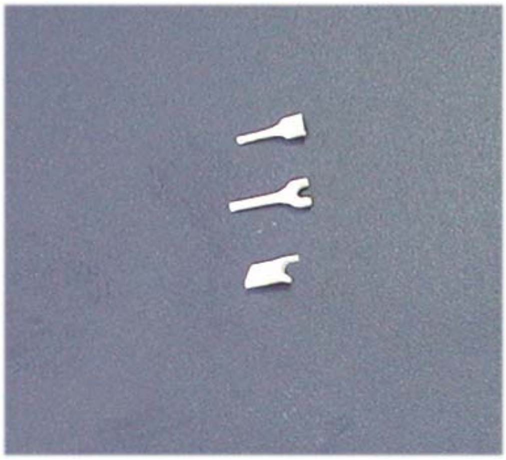

Figure 3.

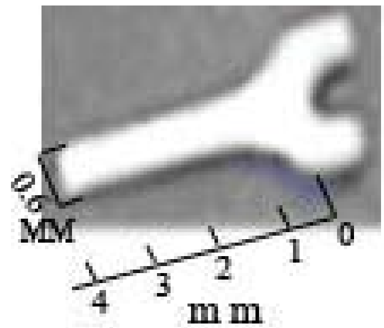

Figure 4.

Each type of bone is prepared in several different lengths and in 0.6 MM in diameter (Figure 4) to allow for anatomical variations. These sculptured bone grafts are stored individually in the bone bank in small bottles of alcohol, which are labelled with the type, and length of the bone.

While at the Institute, the author sculpted several of these small blocks of bone into the various prostheses types with several lengths of each. These were then transported to Jordan to be used in his middle ear surgeries.

The 20 patients (12 males, 8 females) with a mean age of 32.6 years (age range 15-47 years) presented with unilateral 3 (15%) or bilateral 17 (85%) conductive hearing losses and were diagnosed with otosclerosis. The diagnosis was built on history, clinical examination and hearing evaluation. The standard measure of hearing acuity is pure tone audiometry, sensitivity to pure tone stimuli were measured for air and bone conduction from (250 to 8000 Hz). In each case, middle ear exploration under general anesthesia disclosed a fixed stapes. The stapes footplate was punctured and the stapes superstructure removed. The footplate was then elevated and in most of the cases removed.

A perichondrial graft taken from the tragus of the patient was placed over the oval window to seal that opening. A bone graft was placed between the oval window and the long process of the incus. The tympanomeatal flap was replaced and the external auditory canal filled with Gelfoam.

Results

The 20 patients presented with different levels of hearing loss. Stapedectomies were performed on each using homograft bone. Following surgery, no infection or rejection was observed in any of the patients. Fourteen of the patients underwent surgery in the right ear and 6 patients had surgery in the left ear. Patients with smaller gaps of conductivity had better results.

Eighteen patients had closure to within 15 dB of the preoperative bone score. Of these 18, 7 closed to within 10 dB (35%) and 11 had complete closure of the air-bone gap (55%). Two patients showed no improvement (10%) in their conductive loss, but neither suffered a cochlear loss. (Table 1)

Study Results.

Number of Patients	Results
11	Complete closure Air-Bone Gap
7	Closed to within 10 dB of Air-Bone Gap
18	Closed to with 15 dB
2	No improvement

The two patients who showed no improvement had very thick footplate, with excessive whitish otosclorotic lesions in the medial wall of the middle ear, and neither suffered a cochlear loss. In each case, only fenestration of the footplate was performed. The homograft Stapedectomies failed in these two cases.

Discussion

Ossicular reconstruction is one of the challenging problems in middle ear surgery. Many materials have been used to reconstruct the ossicular chain, which has been destroyed due to trauma, infection or by otosclerosis. Ossicular bone grafts are one of the treatment choices.

Ossiculoplasty using autograft bones was first performed as a stapes replacement in the late 1950s by Hall and Rytzner. [2] In 1958, J. Hough first used autogenous cortical bone for repair of the incudostapedial joint. [3] The graft was taken from the bony canal wall of the patient's ear and placed between the head of the stapes and the lenticular process of incus. In 1966, House, et al. proposed using autograft ossicular transplants as a replacement for incudes. [4] Since the mid-1960s, numerous authors have reported favorably on the use of both allograft and homograft transplants. [5-10]

In 1990, M. McGee et al. used non-ossicular homografts taken from otic capsule bone as a prosthetic material or device in stapedectomy. [11] Before this time, no homograft bone had been used for stapes replacement. Plastic, [12] titanium wire, [13, 14] ethylene tubing [15] and stainless steel [16-17] (and other materials) had been used instead.

In 1992, the same author M. McGee et al. began to use donor femur as a replacement source in all types of Ossiculoplasty including tympanoplasties, tympano-mastoidectomies and Stapedectomies, and about the same time he started to use a microlathing technique. This technique has drastically reduced the amount of time spent in the bone laboratory manufacturing ossicles and has decreased the cost of Ossiculoplasty. [1] Others have reported good results using cartilage and perichondrium in middle ear surgery. [18]

Comparing the homograft with the artificial prosthesis, the latter has several disadvantages. An artificial prosthesis is a foreign body and can be rejected by the body at any time. Due to an unnatural attachment of the artificial prosthesis to the remaining ossicles of the host, the host bone may undergo an inflammatory reaction causing necrosis.

In addition, artificial prostheses are more expensive. One donor femur, at a cost of approximately $700 USD, can produce up to 400 bone grafts, a significant saving.

At the Hough Ear Institute, a trained laboratory technician prepares the bones in order to save time for the surgeon. However, the author, who learned the technique during Fellowship training at the Institute, prepared all the bones used in this study.

A similar bone laboratory could be set up in almost any medical institution since the equipment needed is relatively inexpensive and the sculpturing technique is easily learned. [1]

Use of homograft prosthesis requires the removal of the entire footplate in order to get the best results. So, in stapedectomy you need to be careful while removing the footplate in order to prevent complications that might affect the inner ear which we consider to be less by doing stapedotomy. In some cases, if the footplate is deep with narrow access, removal of the footplate may be impossible. In these instances, it is better to fenestrate the footplate and use an artificial prosthesis instead.

When using donor bone, it is very important that first it has to be tested for hepatitis and HIV to eliminate the possibility of transmission of these diseases. In addition, the donor bone should be stored for 3 days in formaldehyde as a fixative since it also kills any viruses that might be present in the specimen. [1] A study done in 1998 showed that an ossicular allograft taken from an HIV positive patient within 6 hours post mortem and treated with formaldehyde resulted in no detection of proviral HIV-1 DNA in these ossicles. [19, 20] In this study the American Red Cross had tested the bone for hepatitis and HIV, and formaldehyde was used as prescribed.

Recently other authors have reported that they prefer autoclaving the bone at 135 degrees C temperature after immersing the ossicles in 4% formol solution at pH 5.6 for 3 days. [21]

However, Hotz et al., have suggested that autoclaving used to inactivate infectious agents produces material properties changes similar to the older treatment with formaldehyde/cialit, and they prefer using NaOH instead. [22]

Human histology of transplanted ossicles is similar to that of animals in that transplanted ossicle is covered by mucosa by the 14th postsurgical days. [23] Fibrous and blood vessel formation then follows directly into the transplanted ossicle via the old vascular channels. Osteogenesis occurs first on the external surface and later osteocytes form deeper into the bone. Remodeling of the transplanted bone mainly occurs in the first year, then minimally thereafter. [1, 11]

Bone banks now ship donor bones as freeze – dried bone as part of their normal protocol. Some histological studies in animals have shown that freeze – drying, as well as fixation with formaldehyde, retards the potential for new bone growth. [24, 25, 26] However, other authors have several specimens, all of which were freeze-dried and fixed in formaldehyde, that have demonstrated new bone growth. [1, 11]

Conclusion

Homograft human bone is the most logical choice for ossicular reconstruction because it is the closest transplantation material to the host histologically. The body accepts it without rejection. Current fixatives and storage materials remove the immunogenicity and so do away with the host versus graft reaction. Therefore, donor bone is long lasting without infection or resorption, and it is safe without disease transmission.

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