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Malleomyringoplasty using a silicone prosthesis

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Abstract
Successful replacement of the sound conducting mechanism of the ear has been hampered by infection, perforation, prosthesis instability and extrusion. In this animal study on thirty rats a silicone prosthesis was inserted between two layers of fascia as a total replacement of the tympanic membrane and ossicular chain. After four months the graft was found to be intact without evidence of infection or extrusion in all but one of the 30 rats. These results justify a trial of a similar silicone prosthesis in humans.

Introduction

Reconstruction of the sound conducting mechanism of the ear in those cases in which the handle of the malleus has been destroyed has taxed otologists since the concept was first introduced by Wüllstein (1956) and Zoellner (1956). Because of the absence of this vital connecting link reconstituting a stable ossicular chain in permanent continuity with the tympanic membrane has become a major problem (Farrior, 1960; Hall and Rytzner, 1960; Jansen, 1963; Sheehy, 1965, Goodhill, 1967). Previously described methods include:

1. Malleus by-pass procedure (Wüllstein, 1956; Zoellner, 1956).
2. Homograft and ossicle procedure (Marquet, 1966; Glasscock and House, 1968).
3. Malleo-myringoplasty procedure (Schiller, 1968, 1971).

1. Malleus by-pass procedure

This relies on reconstituting the ossicular chain by interposing either a cartilage, bone or synthetic strut directly between the fascia graft and the stapes superstructure or footplate in the hope that a fibrous union will become established between these structures. Unfortunately the sound conducting mechanism assembled in this way tends to be unstable (Schiller, 1971). Lateralization of the graft causes disruption of the fibrous union and retraction may lead to extrusion of the prosthesis.

2. Homograft procedure

This was developed by Glasscock and House (1968) but there are problems related to the laws governing the removal of these grafts from cadavers and the incidence of spontaneous perforation of the homograft tympanic membrane is excessively high (Smyth and Kerr, 1969).

3. Malleo-myringoplasty procedure

Schiller (1968) described this method of reconstructing

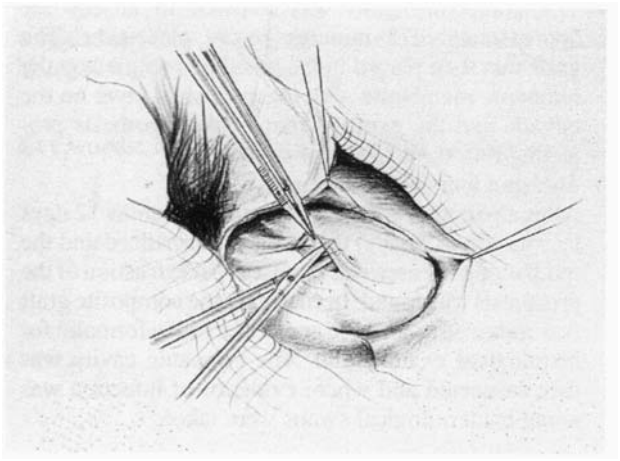

FIG. 1
Elevation of the superficial connective tissue layer.

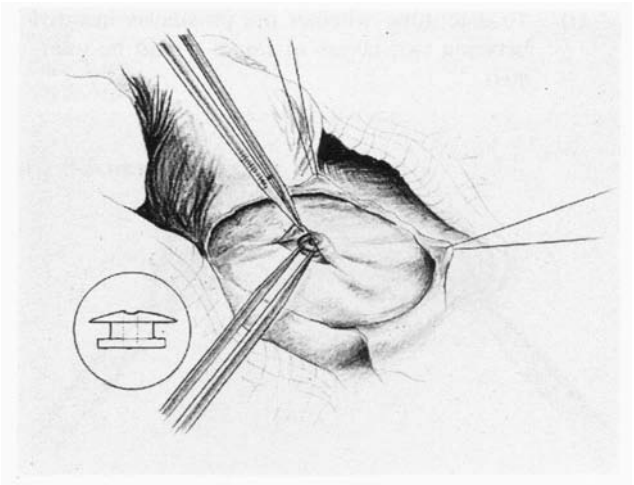

FIG. 2
Insertion of the prosthesis between the two layers.

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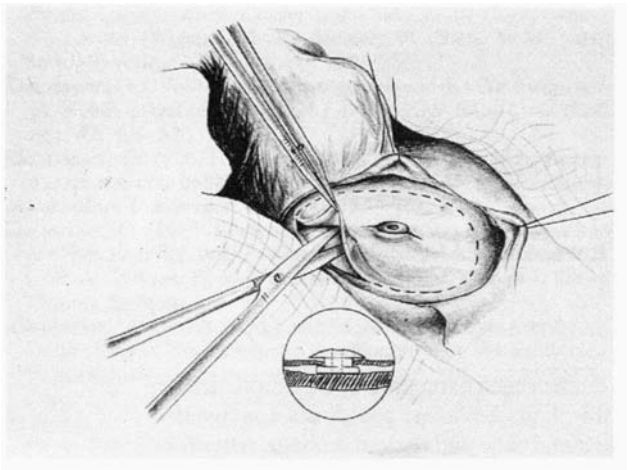


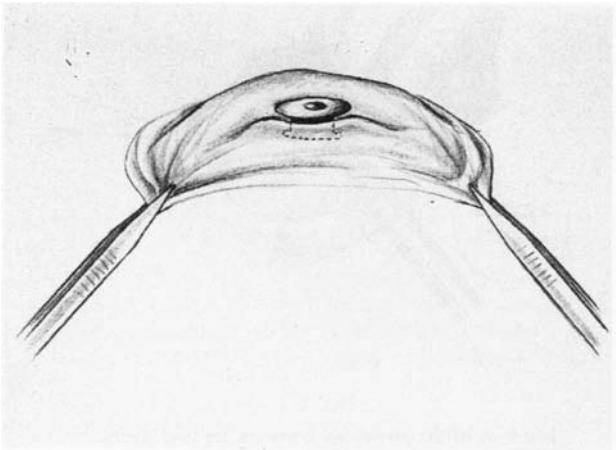
FIG. 3
After button-holing the fascia the composite graft is elevated.

the tympanic membrane and the handle of the malleus as a unit by incorporating a malleus replacement bone graft between two layers of temporalis fascia. Subsequently an attempt was made to reconstruct the ossicular chain in permanent continuity with the tympanic membrane. This was a one stage procedure executed with the aid of a wireclip prosthesis attached to the malleus replacement bone (Schiller, 1971). This composite graft took successfully without extrusion of the prosthesis in 29 out of a series of 32 cases. However, the wireclip prothesis proved to be inadequate for ossicular reconstruction and the long-term hearing results proved unsatisfactory.

In order to overcome this mechanical problem, the possibility of substituting the malleus replacement bone by a suitably designed silicone prosthesis was considered. Silastic medical grade elastomere was chosen because in previous studies it has shown to be well tolerated for prolonged periods of time without evidence of rejection (Paparella and Sugiura, 1968). If successful this could establish a more effective method of connecting the prosthesis to the stapes superstructure of its footplate in a one or two stage procedure.

The objectives of the study were:

(i) To determine whether the prosthesis inserted between two layers of fascia would be tolerated.



(ii) To establish whether the prosthesis predisposed to increased risk of infection.

(iii) To determine whether the composite graft would survive as a integrated unit.

Materials and methods

Rats were selected for this study because the middle ear is readily accessible and rats have been used in several previously reported studies (Hack, 1971; Borg, 1982; Anniko *et al.*, 1989).

Operations were performed in accordance with standard laboratory animal management protocols. The rats were anaesthetized with intra-muscular Ketamine (2 mg/kg). The sequence of the operation was as follows:

(1) Construction of the composite graft.
A post auricular incision was made and extended across the top of the skull in a T-form so as to expose the loose connective tissue layer covering the periostium on top of the skull. This was done because there is no temporalis fascia in the rat. Under magnification, a piece of loosely woven areolar tissue was elevated and a tunnel created between the connective tissue and the underlying periosteal layer with a pair of sharp pointed scissors (Fig. 1). The silicone prosthesis (umbria minor silicone grommet) was inserted into the tunnel so that it was completely buried between the two layers of tissue (Fig. 2). A button-hole was made in the connective tissue layer immediately overlying that section of the prosthesis which would project into the tympanic cavity and be used for reconstructing the ossicular chain (Fig. 3). The required area of the composite graft consisting of the prosthesis interposed between the loose connective tissue and the periosteal layer was excised and set aside to dry (Fig. 4).

(2) Preparation of the middle ear.
At the same operation, both the tympanic membrane and the malleus were removed and the bony canal at the entrance to the middle ear cavity was widened with a bone nibbler so that the composite graft could be easily accomodated.

(3) Placement of the composite graft.
The composite graft was allowed to air-dry for approximately 25 minutes before placement. The graft was then placed in the position occupied by the tympanic membrane with the periosteal layer on the outside and the exposed part of the prosthesis projecting into the middle ear cavity.

(4) The skin incision was sutured.
After a period averaging 4 months (3 months 12 days to 5 months 17 days) the rats were sacrificed and the tympanoplasty area was exposed. No extrustion of the prosthesis was found. In each case the composite graft was removed as a whole and preserved in formalin for histological examination. The tympanic cavity was then inspected and where evidence of infection was noted bacteriological swabs were taken.

TABLE I
CLINICAL INFECTION AND EXTRUSION

Total number of cases = 30.
Clinical extrusion of the prosthesis = nil
Clinical evidence of middle ear infection = 1

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TABLE II
HISTOLOGY OF 20 CASES

(1) No significant host response = 11
(2) Mild histiocytic response = 6 (not indicative of rejection)
(3) Foreign body giant cell response = 3 (2 mild and 1 severe)

Results

The results are summarized in Tables I and II. Histology was performed on twenty cases. In the remaining ten cases the histopathologist was unable to comment owing to a lack of a visible prosthesis or owing to insufficient tissue present on the slide. Our technician had difficulty sectioning the silastic in these specimens due to the silastic being distorted in the paraffin block by the sectioning blade. This resulted in either a lack of sufficient tissue or silastic for the pathologist to comment accurately. Bacteriological contamination was only evident in one specimen where gram negative bacilli were cultured. The other 29 rats showed no evidence of infection.

Discussion

These results indicate that this experimental trial has achieved its aims. Contaminants on the silastic at the time of insertion may have contributed to the foreign body response seen in three of the specimens. Our operations were clean but not surgically sterile and adverse tissue reactions have been noted to contaminants on silicone implants (Paparella and Sugiura, 1968). However, our results show conclusively that in all cases the silicone prosthesis was accepted by the tissues used in construction of the composite graft without causing significant infection or becoming extruded. Thus the use of a silicone prosthesis to reconstruct the ossicular chain appears to be a viable alternative to Schiller's bone graft in the malleomyringoplasty method. It is now planned to develop a suitable silicone prosthesis which could be used clinically to reconstruct the ossicular chain as a primary of secondary procedure.

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