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Stapes-replacing prosthesis (S.R.P.)

by

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Any chronic inflammatory condition of the middle ear may bring about bone destruction. Today, in the antibiotic era, this destruction concerns mostly the ossicular chain. Any one of the ossicles or all of them together may be partially damaged or completely destroyed (Sadé *et al,* 1981). Hearing is usually impaired if the stapes or the incus or both of them are damaged. To overcome the resulting hearing deficit, various surgical techniques, using various materials, have been introduced, with various degrees of success. The most problematic situation encountered surgically is the one in which the stapes is missing, and it is with this situation that the present study deals.

The surgical solution so far advocated has been in the form of a surgical bridge or columella between the mobile footplate and the drum. The columella (Fig. 1) is made out of bone or some non-organic biocompatible material. Often, however, this solution is not very successful, for two reasons:

A. Instability of the columella (prosthesis) is often unavoidable because of its slim attachment to the footplate;

B. Biologically, an incompatibility between the drum and the prosthesis is all too often present, when the latter is made of plastic materials. These columellas have been found, sooner of later, to extrude.

It is the purpose of this communication to report a new technique and a new concept, which tries to overcome the above shortcomings, using a different type of stapes-replacing prosthesis.

Method, i.e., The Tabor Prosthesis (Figs. 2, 3, 4 and 5)

The new stapes-replacing prosthesis (S.R.P.) is made of two parts: A. The lower part, which is in contact with the footplate, is made of a plastic material. Teflon, Plastipore, Poroplast, ceramics, stainless-steel, or any other biocompatible material may be used. We have made it of Teflon*. The base of the Teflon part is not pointed; in fact, it has an oval, slightly convex, shape and covers most of the footplate. The advantage of this configuration is its stability and relative ease of placement; B. The upper part of the prosthesis is made of bone. So far, we have used malleus heads, either as homografts and as autografts. The use of bone is a safe way to counteract the extrusion of the prosthesis. In fact, I have seen them well tolerated for up to 14 years (Figs. 6, 7 and 8).

I have termed this prosthesis 'Tabor'—as it requires a name and its configuration

* The actual primary preparation of the Teflon was done with the active participation of the Department of Plastics at the Weizmann Institute of Science, which furnished us with special Teflon sheets, from which the final carvings were easy to perform.

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* the Plastic Research Department, Weizman Institute of Science.

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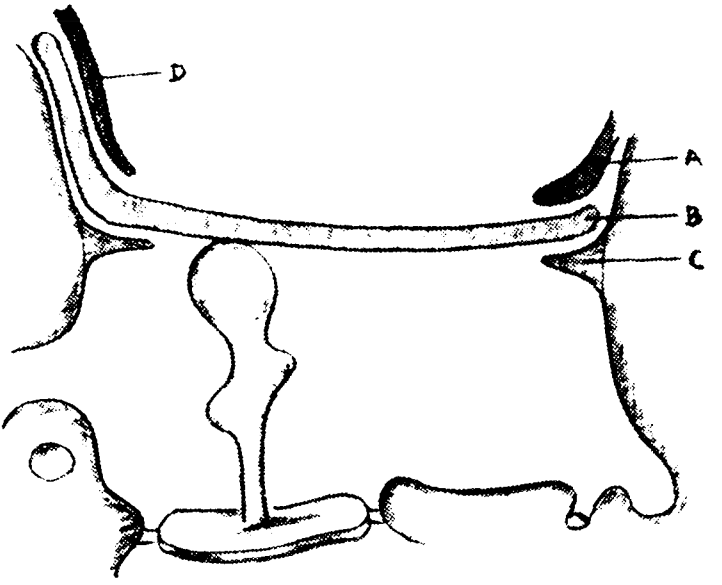


FIG. 1.

Old time columella—made of a malleus. Note the graft was placed over the annulus—a technique not used any more.

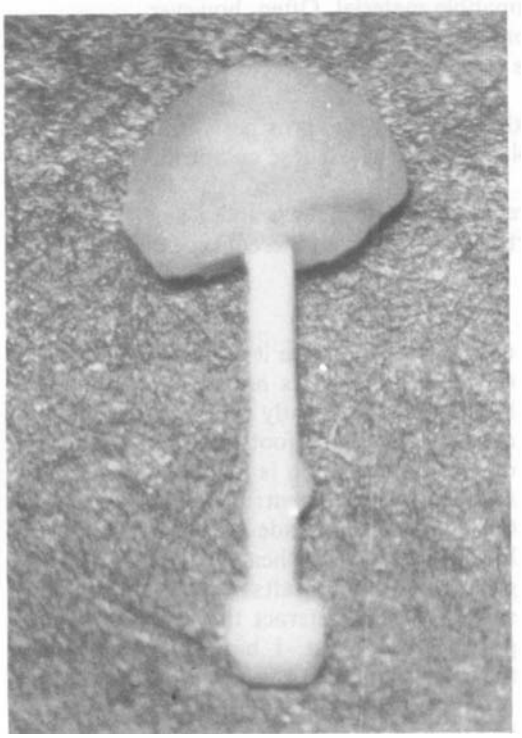


FIG. 2.

The S.R.P.—side view.

reminded me (with a bit of imagination) of a small mountain.

Material

Eight ears, previously operated on for various chronic inflammatory conditions of the middle ear, which were found to have their stapes missing, as well as the incus, were re-operated upon to improve the hearing. In none of these ears had an ossiculoplasty been attempted previously. All these ears were found to be well aerated. Each patient underwent a tympanotomy and a mobile footplate was looked for. Most ears presented, over the footplate, some fibrosis which had to be removed. Two ears presented so much fibrosis, as well as bony growth over the footplate, that the procedure was abandoned. These two ears are not included among the eight reported herewith, as no prosthesis was introduced into the middle ear.

Once the footplate has been cleaned and found to be mobile, the prosthesis is placed over it and stabilized with Gelfoam, and the drum is then reclined back over the Tabor's

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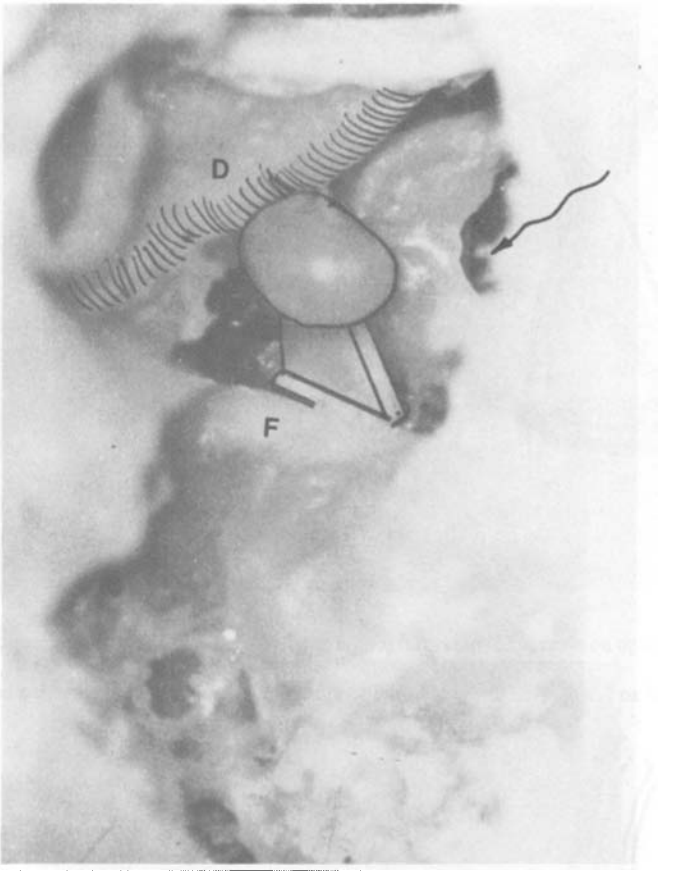


FIG. 3.

The S.R.P. in place in the middle ear. D = drum: F = facial nerve. Arrow—round window.

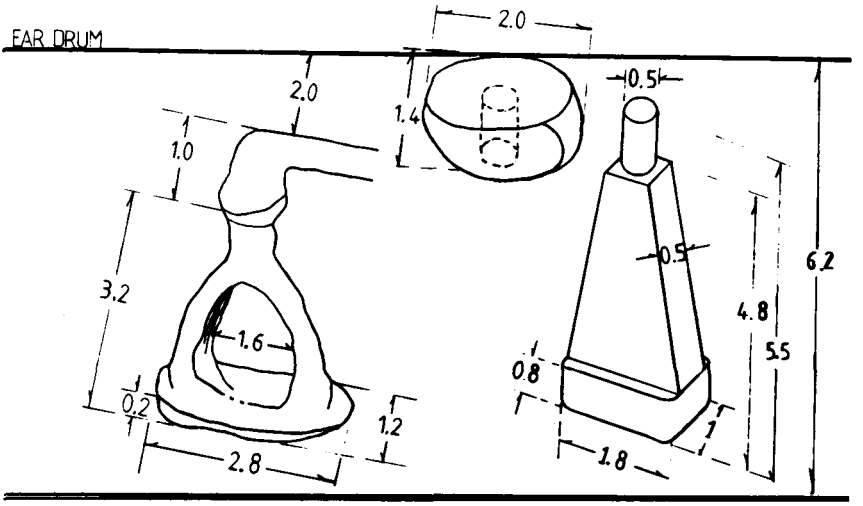


FIG. 4.

Measurements of stapes and S.R.P.

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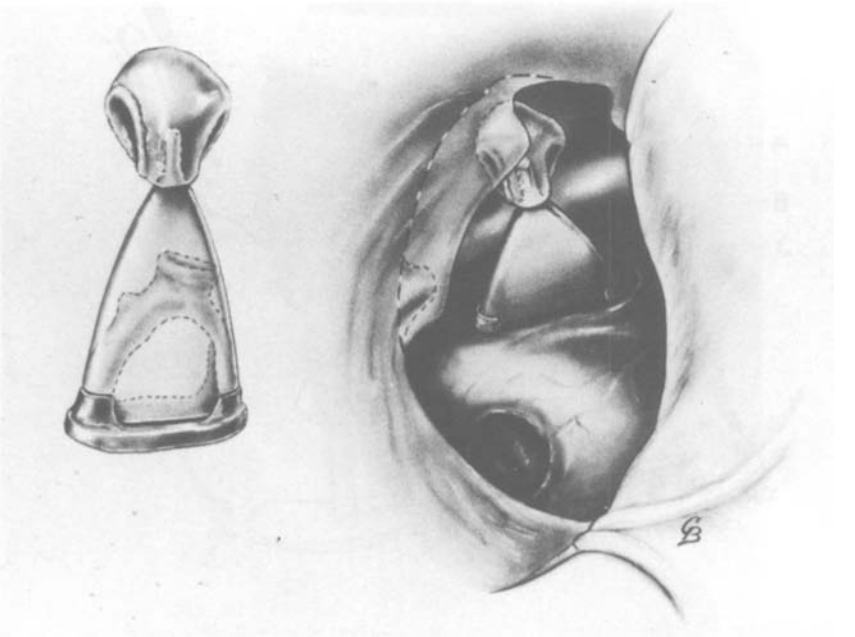


FIG. 5.

Drawing of an S.R.P. Note the part of the scutum to be removed is marked with a broken line.

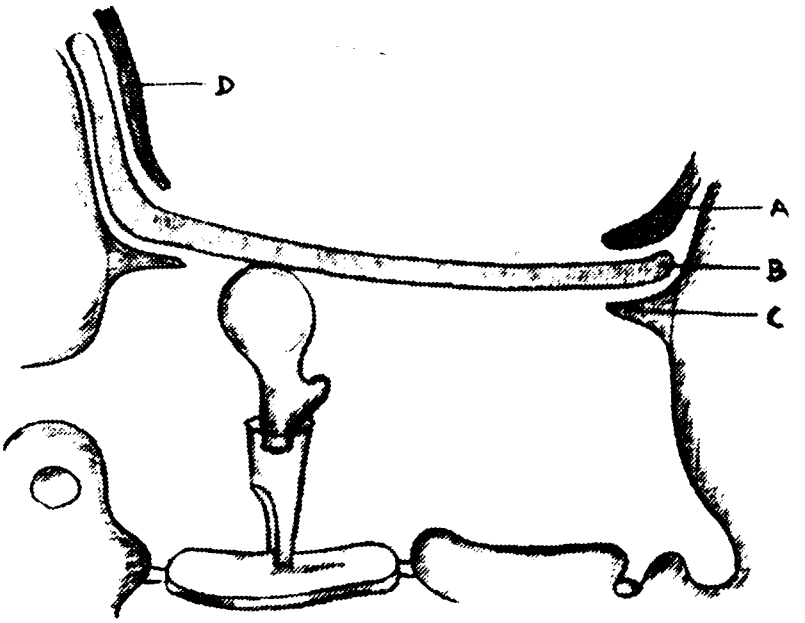


FIG. 6.

A columella made of malleus head and polyethylene—the malleus head was found intact 14 years after initial surgery at a revision operation.

Figures 1 and 6 are by courtesy of the Ear, Nose and Throat Journal.

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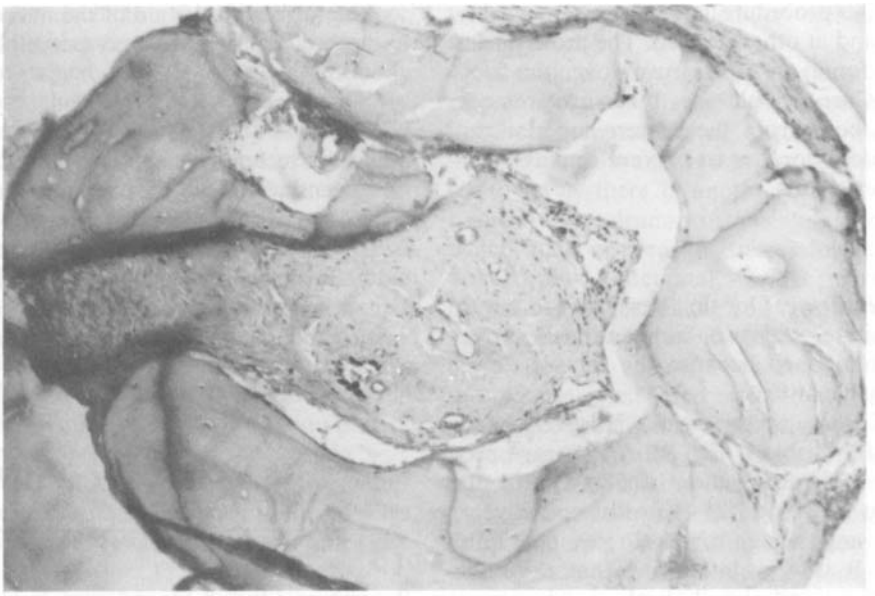


FIG. 7.

Cross-section through a 14 year old viable homograft removed at revision operation.

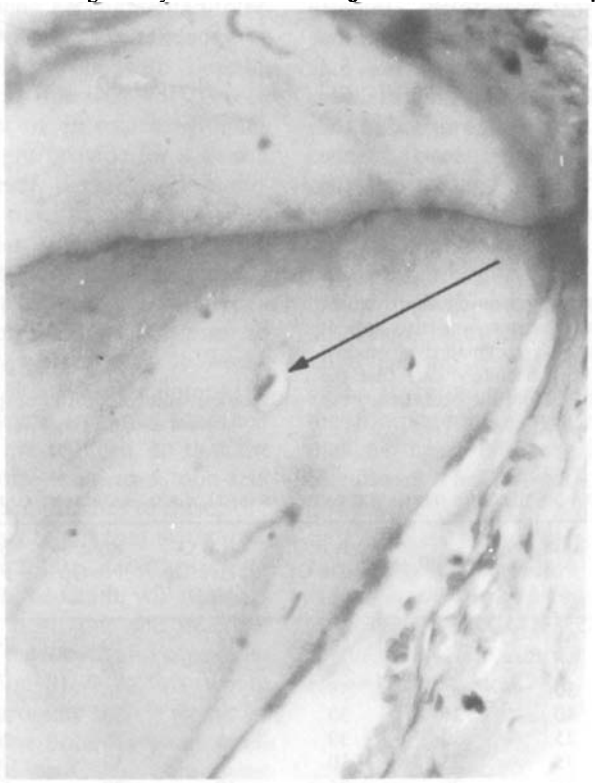


FIG. 8.

Higher magnification of Fig. 7. Note bone is alive with osteocyts (arrow).

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head. The procedure is at times remarkably simple and at others less so. The prosthesis is mostly found to sit very well over the footplate. Care should be taken to remove enough bone from the postero-superior rim of the deep meatus to prevent impingement of the prosthesis.

Results

The Hearing: Our first case* turned out to be a failure, and two, as mentioned above, were abandoned because the footplate was inaccessible or fixed.

The other seven cases, however, were successful (Table I, Fig. 9). An average pre-operative air conduction of 58 (45–70) db. went up to 30 db. (25–40) post-operatively, leaving an average air-bone gap of 12 db. (5–20). It is very interesting that the bone conduction itself also showed some improvement, from 23 db. (10–30) pre-operatively to 18 db. (also 10–30) post-operatively.

The State of the Drum: The average time since these ears were operated upon was 5.2 months at the time that this report was written; this is too short a time to judge the final outcome, yet all these cases show the head of the malleus to be in contact with the drum in the absence of any inflammation. Looking at it with the aid of the microscope, the contact region looks 'very peaceful'.

Discussion

Several techniques and various materials have been introduced to overcome a missing part of the ossicular chain, a condition often seen as a sequel of some types of chronic middle ear infection (Sadé *et al.*, 1981). However, when non-organic materials such as plastics and metals are used, a tendency to be extruded through the drum becomes appar-

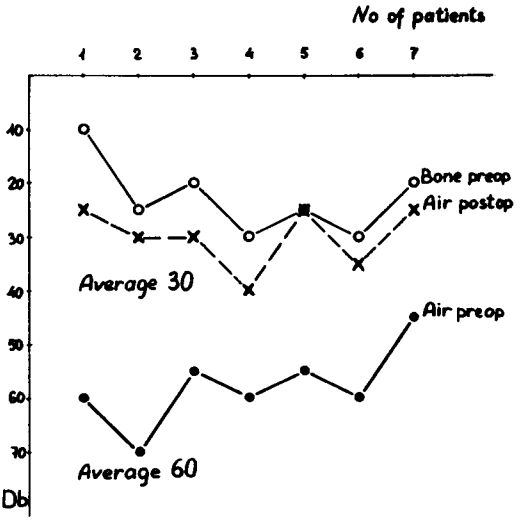


FIG. 9.
Diagram showing SRT of pre-operative and post-operative hearing level in seven patients.

* This case did present some hearing improvement post-operatively, yet some dizziness was also present and on exploration I found a very small oval window fistula. I am, however, not absolutely sure that the fistula was not also present before the operation. I did not replace the prosthesis again.

TABLE I
DETAILS OF SEVEN OPERATED PATIENTS (SRT). A.B.G. – AIR BONE GAP.

Patient	Air Pre-Op dB	Air Post-Op dB	Gain dB	A.B.G. Pre-Op dB	A.B.G. Post-Op dB	Bone Pre-Op dB	Bone Post-Op dB	Follow up months
No. 1	60	25	35	50	15	10	10	4
No. 2	70	30	40	45	15	25	15	5
No. 3	55	30	25	35	15	20	15	7
No. 4	60	40	20	30	20	30	20	7
No. 5	55	25	30	30	5	25	20	4.5
No. 6	60	35	25	30	5	30	30	2
No. 7	45	25	20	25	10	20	15	7
Average	58	30	28	35	12	23	18	5.2

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ent sooner or later. This is so even with materials which are indisputibly biocompatible and which do not provoke antibody formation, such as Teflon. At the same time, Plester and Januke (1981) maintain that they have obtained good short-term results with ceramics. On the other hand, when ossicular grafts have been used, the drum-ossicle relationship has usually withstood the test of time. There are two amazing facts concerning the body's tolerance towards ossicular implants:

(a) Both autografts and homografts are well tolerated by the middle ear and the tympanic membrane, i.e., no rejection phenomenon occurs;

(b) Whether the ossicles are live autografts or denatured homografts, the ossicles do show signs of revitalization with time (Fig. 8).

At first, it was thought that the middle ear behaves immunologically differently from the rest of the body, having an augmented tolerance and being devoid of the tendency to reject homografts. However, with time, it became apparent that this was not correct. The minimal contact of an ossicle with the tissue of the host might provide for a slower rejection rate. However, once a fresh *homograft* is used, it will nevertheless be rejected sooner or later, like any other 'non-self- graft. At the same time, a homograft will not be rejected *if denatured* by boiling or by treatment with alcohol, formalin or Cialit prior to implantation in the middle ear. It would seem, therefore, that denaturing a homograft alters its proteins to such an extent that their antigenic properties are reduced, so that the host does not recognize them as a 'non-self' and does not produce antibodies to them.

The second amazing fact is that denatured, i.e., homografts which are *dead* owing to treatment with alcohol or Cialit, will not only be accepted by the host, but will in effect begin to present new osteocyts and some new bone remodelling (Fig. 8). This fact would indicate that those proteins which signal or induce bone to become bone have not been destroyed by alcohol or Cialit. New bone formation is also seen in fresh autografts, but not in ossicles (homografts or autografts) which have been boiled or treated with formaldehyde.

All ossicles, denatured by whatever means, as well as autografts, will also show in most instances penetration of vascular elements into the vascular and Haversian spaces.

However, there is another crucial factor, besides the drum-prosthesis relationship, which may prevent a successful surgical, acoustically functional, bridge formation between the footplate and the drum: a narrow contact between whatever (plastic or bony) pointed end of a columella and the footplate is often lifted up or deviated from its desired position by adhesive processes, and even the best initial surgical result will fail. Ossicles, whether autograft or homograft, are usually not extruded through the drum and are truly biologically compatible yet, if their contact with the footplate is narrow or pointed, this may end with unsatisfactory results (Fig. 6). Thus my initial attempts to overcome extrusion were successful from this point of view, yet the slim contact with the stapes remained a problem. The purpose of the broad base of the Tabor prosthesis is obviously to overcome the problem created by the pointed end of a prosthesis. When I used stapes homografts for the same purpose, so much fibrosis was formed around the stapes that I abandoned this method.

The S.R.P. prosthesis, i.e., the Tabor, described herewith, has given initial very good hearing results in seven out of eight cases. Its broad base allows it to be placed on the footplate in a stable position while its malleus head ensures that it will not be extruded. The air-bone gap does not, however, close completely and has amounted to 12 db. on the average. This is not really surprising, as the lever mechanism with a factor equalling 1.3 is abolished once the clever physiological device of three ossicles is converted into a simpler collumelar type of sound transmission.

Summary

This is a description of a new stapes

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replacement prosthesis (S.R.P.), which we term 'Tabor'. The prosthesis has two parts: the lower part is made of a broad non-organic, biocompatible material (Teflon) base, which fits and covers most of the footplate, ensuring maximal stability; the upper part of the prosthesis is made of autograft or homograft bone, usually a malleus head, its contact with the drum preventing extrusion. Seven out of eight ears operated upon with this prosthesis were successful, the average post-operative hearing by air conduction going up to 30 db. (25–40), leaving an average of 12 db. (5–20) air-bone gap. The bone conduction also improved, from average of 23 db. (10–30) to an average of 18 db. (10–30).

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