The Journal of Laryngology & Otology
April 2004, Vol. **118,** pp. 263–266

Early experience with the Mills sleeve prosthesis for reconstruction of the incus long process

Robert Mills, M.S., M.Phil. F.R.C.S. (Eng) F.R.C.S. (Ed.), Alun Williams, F.R.C.S. (Orl-hns)

Abstract

This paper describes the Mills sleeve technique of ossicular reconstruction for defects of the incus long process and reviews the results of 27 procedures. A retrospective review of operations was performed by eight otologists. The results are compared with those from three other reconstruction techniques (cortical bone graft, cortical bone sleeve and incus autograft).

Prostheses were supplied to surgeons who expressed an interest. Pre- and post-operative audiological data forms were analysed for each case along with a questionnaire about use of the prosthesis. The mean post-operative air bone gap (ABG) was compared with results from cortical bone sleeve, incus autograft and simple cortical bone graft reconstruction cases previously performed by the senior author.

Twenty-seven procedures were performed. Closure of the ABG to within 10 dB was achieved for 44.4 per cent of Mills sleeve cases compared with 44.7 per cent for the cortical bone sleeve, 52.9 per cent for ossicular and 26.9 per cent for cortical bone grafts. The responses to a questionnaire sent to participating surgeons are discussed.

For the current follow-up period (three months to three years) the Mills sleeve prosthesis appears to be safe and easy to use with audiological results at least as good as other reconstructive techniques.

Key words: Ear Ossicles; Prostheses and Implants; Surgical Procedures, Operative; Treatment Outcome

Introduction

In the early days of ossiculoplasty, attempts were made to reconstruct the incus long process using a polythene tube.[1,2] The use of bone chips between the incus tip and the stapes head was also described.[1–3] No results for these techniques were reported and it appears they were abandoned at an early stage. More recently a number of methods have been developed to deal with partial loss of the incus long process. Appelbaum[4] has designed a prosthesis made of hydroxylapatite which sits on the stapes head with the stump of the incus long process resting on its upper surface. Plester[5] has devised a metal prosthesis (titanium or gold) which attaches to the incus by means of a double claw. A cup-shaped lower end attaches to the stapes head.

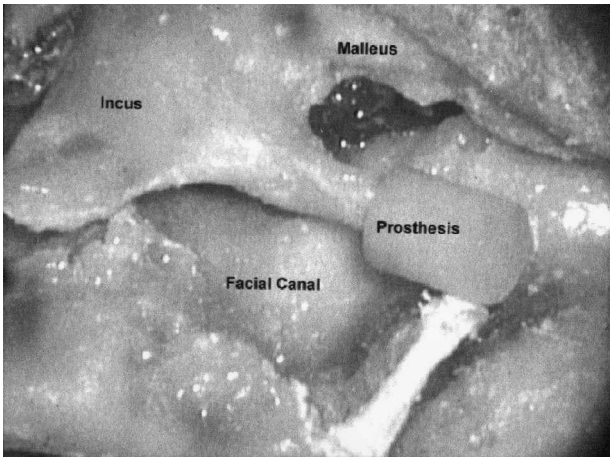
The principal author began by reconstructing the incus long process with a cortical bone autograft.[6] A hole was drilled down the centre of the graft so that the stump of the long process of the incus could be encircled by it, while its body rested on the stapes head. This was named the 'sleeve' technique. At first grafts were harvested with a conventional burr. A calculation based on the additional time required for the graft to take indicated that the cost compared favourably with that required to purchase a conventional ossicular prosthesis.[7] Histological examination of one of the cortical bone grafts used in this way showed new bone formation within its substance.[8] In order to simplify the process of graft harvesting a core cutter burr was developed.[9] This proved very satisfactory, but it has not been possible so far to make the device available commercially.

In order to eliminate the need to harvest a graft, a hydroxylapatite prosthesis shaped like the grafts produced by the core cutter burr has been developed by Exmoor Plastics (Figure 1). Two sizes, 2 mm in length for minimal incus defects and 3.5 mm for cases with more extensive erosion, are available. Initially Exmoor made a number of prostheses available free of charge so that they could be evaluated. This paper reports the early experience with the prosthesis, which has now been tried by a number of surgeons.

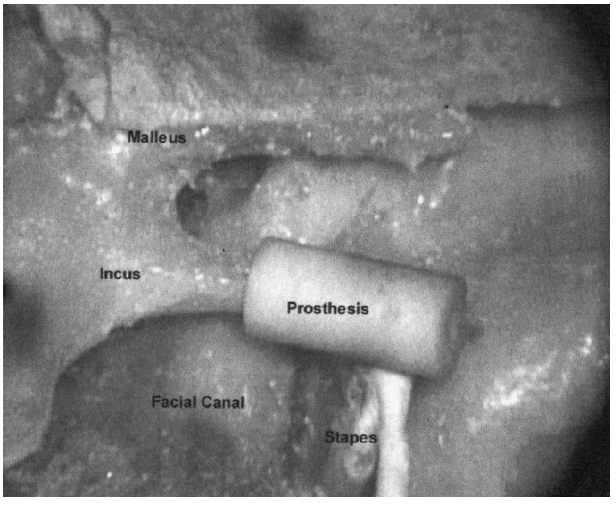
Materials and methods

Surgeons who expressed an interest in the sleeve prosthesis were supplied with a sample free of charge. These surgeons were asked to report on the use of the prosthesis and the outcome of surgery. Additional operations were carried out by the authors in Dundee and Edinburgh. Data forms were provided to record pre-operative and post-

From the Otolaryngology Unit, University of Edinburgh, Edinburgh, UK.
Accepted for publication: 8 January 2004.



(a)



(b)

FIG. 1

(a) 2 mm Mills sleeve prosthesis *in situ* in the 'middle-ear surgery trainer'.[11] (b) 3.5 mm Mills sleeve prosthesis *in situ* in the 'middle-ear surgery trainer'.[11]

operative data. Hearing outcomes were calculated using the frequencies 500, 1000 and 2000 Hz. Pre-operative bone conduction thresholds were used to calculate the post-operative mean air-bone gaps. The mean post-operative air-bone gaps have been divided into 5 dB bins to give a picture of the overall pattern of the results. The results have been compared with three other patient cohorts, those who have had an incus repaired with a cortical bone 'sleeve' and those who have conventional reconstructions of an incus defect in association with an intact stapes arch with either an incus graft or a cortical bone graft. All these operations were carried out by the first author, or by a trainee working under his close supervision.

All surgeons who were sent prostheses were sent questionnaires two years after the start of the study in an attempt to obtain their views about the prosthesis and its use (Appendix).

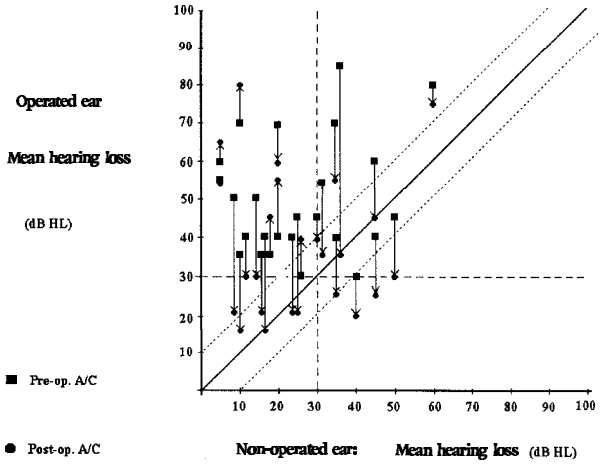


FIG. 2

Hearing results for the Mills sleeve prosthesis displayed using the Glasgow Benefit Plot[10]

Results

Prostheses were sent to a total of 22 surgeons. Of these, seven have reported using the prosthesis and have returned hearing data for analysis. Hearing results are currently available for 27 cases. The results are summarized in Figure 2 using the Glasgow Benefit Plot.[10] The proportions of patients with closure of the air-bone gap to within five and 10 dB for the four patient groups are presented in Table I. The distribution of the mean post-operative air-bone gaps for the various cohorts are presented in Figure 3, using 5 dB bins. So far two cases of extrusion of the prosthesis have been reported. One of these occurred in the early post-operative period while the other was noted three years after surgery. In a third case the prosthesis became displaced from the incus long process, but remained within the middle ear. Eleven questionnaires were returned. Six respondents had not used the prosthesis, four because no suitable case had yet been found, one because ossicular grafts were preferred and one because the prosthesis was desterilized before it could be used. Of the five who used the prostheses, all found them easy to use and none reported extrusion. Four surgeons said they would use the prosthesis again and one was still awaiting the outcome of their initial procedure.

Discussion

The concept of repairing the incus long process is appealing because it restores the mammalian three ossicle pattern, rather than creating an alternative (columella) arrangement. Results using cortical bone[6] and the Plester prosthesis[5] suggest that

TABLE I

POST-OPERATIVE CLOSURE OF MEAN AIR-BONE GAPS (%)

	<10 dB	<5 dB
Mills sleeve prosthesis	44.4	29.6
Cortical bone 'sleeve' graft	44.7	31.6
Autograft incus	52.9	31.4
Cortical bone autograft	26.9	19.2

https://doi.org/10.1258/002221504323011987 Published online by Cambridge University Press

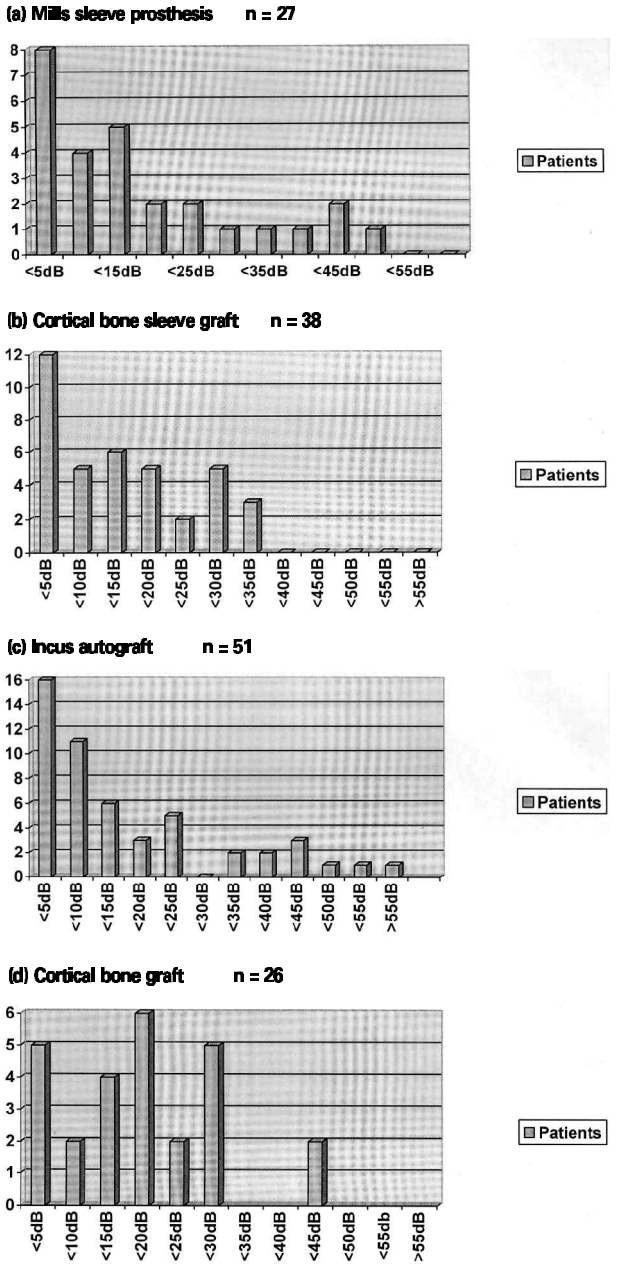


FIG. 3

Mean post-operative air-bone gaps for the Mills sleeve prosthesis, cortical bone 'sleeves', conventional reconstructions using an incus graft and those using a cortical bone graft.

superior hearing results can be achieved with this approach. Analysis of hearing results from a larger number of cases in which a cortical bone 'sleeve' has been used, using mean post-operative air-bone gaps as the measure of technical success, does not indicate superior outcomes to conventional reconstructions using ossicular grafts. However, the present study is under-powered and data from a variety of surgeons in one group (Mills sleeve prosthesis) have been compared with that from a single surgical team using other techniques.

The Mills sleeve prosthesis has proved easy to insert, provided that only ears with an appropriate ossicular defect are selected. When the short prosthesis became available the principal author attempted to use it in cases where the incus defect was too large, with disappointing results. This 2 mm prosthesis is only suitable for minimal incus defects (<1 mm). With the introduction of the longer (3.5 mm prosthesis) it has become possible to extend the technique to larger incus defects, as has been done with the cortical bone grafts. There must, however, be a large enough stump of the incus long process (preferably at least 2 mm) for the prosthesis to be stable.

The principal author has also used the Appelbaum prosthesis in the past and found it more difficult to insert than the Mills prosthesis.We have no experience of the Plester prosthesis. With all three devices the possibility exists that the tympanic membrane will retract down onto the prosthesis and become adherent to it. This means that sound transmission may occur directly from the tympanic membrane as well as via the ossicular chain. However, this can also be said of ears in which a retracted drum attaches to an intact incus. In the case of the Appelbaum prosthesis the stump of the incus rests in a 'tray' on the upper surface of the prosthesis. This appears to be a less stable arrangement than that produced by the Mills prosthesis which encircles the incus stump. The Plester prosthesis attaches to the incus and stapes head by means of claw-like elements. This appears to be a very stable arrangement, but might lead to further necrosis of the incus long process.

At present the longest follow-up period for patients with the Mills prosthesis is only three years. More long-term data are required before a full assessment of the effectiveness of the technique can be made. The longest follow-up available for cases in which a cortical bone 'sleeve' was used is five years. In the group treated with the Mills prosthesis, early extrusion of the prosthesis has occurred in only one case so far. In another the prosthesis was extruded three years after surgery, following an initial good hearing outcome, which was maintained for more than two years. Extrusion has always been a potential problem with artificial prostheses and long-term follow up is essential to properly quantify the extent of the problem. Extrusion of a cortical bone 'sleeve' graft has only occurred in two cases so far, despite much longer experience with this technique. Both these occurred in the early post-operative period. Another cortical bone 'sleeve' graft became displaced from the incus long process but remained within the middle ear during the first year of follow up.

The evidence presented above indicates that hearing outcomes with the Mills prosthesis and a cortical bone 'sleeve' are comparable to those obtained with conventional reconstructions using the patient's incus. Our survey of surgeons who have used the prosthesis indicates that the technique is simple and easy to perform. It is certainly much less demanding than a malleus-stapes assembly using a sculptured graft. The surgery can be carried out permeatally and takes very little time to complete, making it suitable for day cases. We are continuing to accumulate data on the prosthesis and plan to report a larger series with longer follow-up in due course.

https://doi.org/10.1258/002221504323011987 Published online by Cambridge University Press

- **Many methods have been described for ossicular reconstruction in patients with erosion of the long process of the incus**
- **A new prosthesis has been developed by the senior author and this paper presents the outcome of using his technique in 27 cases**
- **The ease of use of this technique and results are compared to those obtained using an incus autograft and reconstructions using cortical bone**

Acknowledgements

We would like to thank Exmoor Plastics for providing the prostheses used in this study and all the participating surgeons for their cooperation.

References

1 Guilford FR. Repositioning of the incus. *Laryngoscope* 1965;**75**:236–41
2 Armstrong BW. Experiences with the ossicular chain. *Ann Otol Rhinol Laryngol* 1969;**78**:939–49
3 Hough JVD. Tympanoplasty with the inferior fascial grafting technique and ossicular reconstruction. *Laryngoscope* 1970;**80**:1385–413
4 Appelbaum EL. An hydroxylapatite prosthesis for defects of the incus long process. *Laryngoscope* 1993;**103**:330–2
5 Maassen MM, Zenner HP. Tympanoplasty type 2 with ionomeric cement and titanium prosthesis. *Am J Otolaryngol* 1998;**19**:693–9
6 Mills RP. Physiological reconstruction of the incus long process. *Clin Otol* 1996;**21**:499–503
7 Mills RP. Heaton JM, Gray IG. The use of cortical bone grafts in ossiculoplasty 3: Audit of costs. *J Laryngol Otol* 1993;**107**:695–6
8 Mills RP, Cree IA. Histological fate of cortical bone grafts in the middle ear. *Clin Otol* 1995;**20**:365–7
9 Mills RP, Drew T. Core cutter burr for harvesting cortical bone grafts for reconstruction of the ossicular chain. *Ann R Coll Surg Eng* 1999;**81**:124–6
10 Browning GG, Gatehouse S, Swan IRC. The Glasgow Benefit Plot: A new method for reporting benefits from middle ear surgery. *Laryngoscope* 1991;**101**:180–5
11 Mills RP, Lee P. Surgical skills training in middle-ear surgery. *J Laryngol Otol* 2003;**117**:159–63

Address for correspondence:
Dr R. P. Mills,
Otolaryngology Unit,
Lauriston Building,
Royal Infirmary of Edinburgh,
Lauriston Place,
Edinburgh EH3 9YW, UK.

Fax: +44131 536 3417

Dr R. Mills takes responsibility for the integrity of the content of the paper.
Competing interests: None declared

Appendix

Mills 'sleeve' prosthesis, Exmoor Plastics, Surgeon's questionnaire

Section A: (Please circle 'yes' or 'no')

Have you used the prosthesis which we sent you?

Yes/No

If **No,** please go to **Section B**
If **Yes,** please go to **Section C**

Section B: Prosthesis Not Used (Please circle a, b, c, or d)

a I have not been able to find a suitable case

b I did not feel that the prosthesis would be as effective as the one I use at present

c I prefer to use ossicular grafts whenever possible

d Other (please specify) .....

.....

Section C: Prosthesis Used (Please circle 'yes' or 'no')

1 Did you find the prosthesis easy to use? ***Yes/No***

2 Has the prosthesis extruded? ***Yes/No***

3 Did the patient report subjective improvement in hearing? ***Yes/No***

4 Are you likely to use the prosthesis again? ***Yes/No***

Do you have any comments? .....

.....

.....