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A comparison of the user-friendliness of hydroxyapatite and titanium ossicular prostheses

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Abstract
Both hydroxyapatite (Ha) and titanium (Ti) are well-accepted alloplastic materials for ossicular prostheses. Many different designs of Ha and Ti prostheses are presently available. Fourteen surgeons of different seniority and surgical experience were asked to 'test-drive' four different types of ossicular prostheses in cadaveric temporal bones to investigate the user-friendliness of these protheses. The Goldenberg design Ha incus prosthesis and the Dusseldorf design Bell Ti prosthesis were used as partial ossicular replacement prostheses (PORP). The Richards design Ha incus-stapes prosthesis and the Dusseldorf design Aerial Ti prosthesis were used as a total ossicular replacement prostheses (TORP). Nine out of 14 surgeons found the Ha PORP to be more user-friendly because of the notch design in the head. The Ti prosthesis was found to be more difficult to manipulate because it was too light. Half of the surgeons preferred the Ti TORP because of the open design of the top-plate. The Ha TORP was thought to be too top-heavy and to have a tendency to fall over.

Key words: Ossicular Replacement; Titanium; Hydroxyapatite; Surgical Procedures, Operative

Introduction

For the last 40 years, there has been an almost obsessive desire among otolaryngologists to find the perfect prosthesis for ossicular reconstruction.[1] Since it is not always possible or even desirable to re-use the remaining ossicles in the middle ear, most research and development in ossicular reconstruction has been on the bio-compatibility and bio-functionality of various alloplastic materials.[2] Many alloplastic materials have been tried before and abandoned because they did not withstand the test of time. Plastic materials such as Proplast or Plastipore were found to have a higher extrusion rate in long-term clinical studies.[3] Ceravital, a bio-compatible ceramic, was found to become re-absorbed with time.[4]

The alloplastic materials that have best stood the test of time so far are hydroxyapatite (Ha) and titanium (Ti). Both materials have been subjected to vigorous animal experiments.[5,6] They have been shown to be not just bio-compatible, but also to be suitable for use in an infected environment.[5] Most importantly, these materials have been used in implantology for many years.[7,8] Whereas Ha has been used in ossicular replacement since 1984, Ti has only been introduced for the purpose of ossicular reconstruction since 1994.[9] To date, virtually all long-term clinical studies on these two alloplastic materials in ossicular reconstruction have been favourable. Migration or slippage of the ossicular prosthesis has replaced extrusion as the commonest cause of failure besides host factors.[10]

The main area of development in ossicular reconstruction in the last few years has been in the prosthetic design of both Ha and Ti prostheses. In general, Ti is more versatile than Ha in allowing various shapes and sizes of prosthesis to be produced by machines because of its strength. New research methodology in middle-ear mechanics such as laser doppler vibrometry and finite element analysis also helps in the design of both the incus replacement and incus/stapes replacement prosthesis to allow maximum transfer of sound energy from the ear-drum to the inner ear.[11,12] However, one aspect of the design of ossicular prostheses that cannot be studied by these scientific methods alone is the user-friendliness of the prosthesis. The present study is designed to compare the user-friendliness of some of the commercially available Ha and Ti ossicular prostheses, in the hands of both experienced, and less experienced, surgeons.

There are many aspects of the design of an ossicular prosthesis that can influence its user-friendliness. Some prostheses can be trimmed to the desired length by scalpel rather than by drill e.g. a Ha prosthesis with a Hapex shaft. Some prostheses are supplied in pre-measured sizes and can be used without further trimming e.g. the fixed-length tita-

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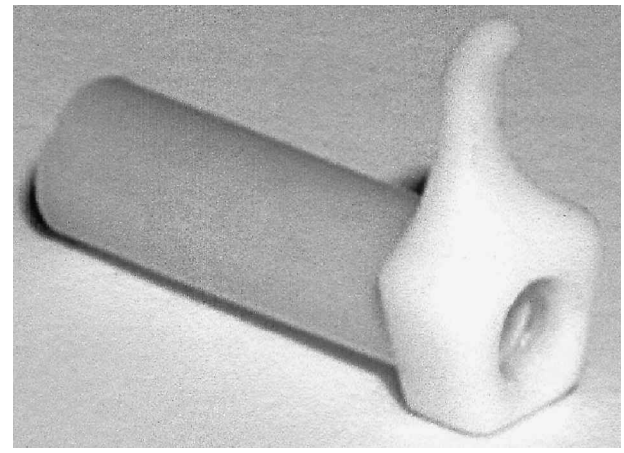
nium prosthesis. In order to compare like with like between the Ha and Ti prosthesis, the present experiment only examined the user-friendliness of the prosthesis during the implantation of the prosthesis into its desired position in the middle ear, as this is regarded as the more critical and difficult part of the operation.

Methods and methods

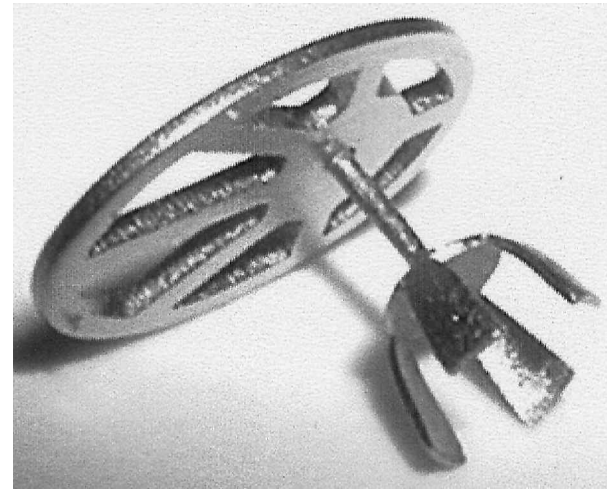
Fourteen temporal bones with two different types of ossicular defects were created. Seven had the incus removed to allow a partial ossicular reconstruction (POR) to be performed. Another seven had the incus removed and the stapes supra-structure removed by laser to allow a total ossicular reconstruction (TOR) to be performed. For each temporal bone, the distance between the malleus and the stapes capitulum or between the malleus and the footplate was then measured using a measuring gauge (Xomed, U.S.A.) and confirmed using an ossiculoplasty sizer (Kurz, Germany). Hence, the length of the ossicular prosthesis required for the ossicular reconstruction on each temporal bone was pre-determined.

The studied was carried out at the temporal bone laboratory at the Ipswich Hospital NHS Trust during the Regional Temporal Bone Dissection Course in 2000. Seven specialist registrars (trainees) and seven consultant surgeons (trainers) took part in the study. Their previous experience in ossiculoplasty ranged from none for some surgeons to over 400 ossiculoplasties for one of the surgeons. Each surgeon was asked to reconstruct the ossicular defect in the temporal bone using a pre-measured ossicular prosthesis. Two different types of PORP were used for the malleo-stapes assembly: the Goldenberg design Ha incus prosthesis (Ha PORP) with a solid Ha head, a notch for the malleus and a hollow Hapex shaft for the stapes capitulum (Smith and Nephew, U.S.A.; Figure 1(a); the Dusseldorf design Bell Ti prosthesis (Ti PORP) with an open head or top-plate and a bell at the bottom to fit onto the stapes capitulum (Kurz, Germany; Figure 1(b)). Two different types of TORP were also used for the malleo-footplate assembly; the Richards design Ha incus-stapes prosthesis (Ha TORP) with a solid Ha head, a groove for the malleus and a solid Hapex shaft (Smith and Nephew, U.S.A.; Figure 2(a)); the Dusseldorf design Aerial Ti prosthesis (Ti TORP) with an open head or top-plate and a thin shaft (Kurz, Germany; Figure 2(b)).

Each participating surgeon was given two temporal bones to work on, each with a different ossicular defect created as described previously. All the participating surgeons were asked to perform the tasks of implanting separately the Ha PORP and the Ti PORP between the stapes capitulum and the malleus at the mid-point between umbo and the neck. On the second temporal bone, they were asked to implant the Ha TORP and Ti TORP between the footplate and the malleus (again at the mid-point between the umbo and the neck of the malleus). Each surgeon was therefore required to perform four tasks. To reduce the effect of the 'learning factors' in using one particular type of prosthesis immediately following another type, each surgeon was given the Ha or the Ti prosthesis randomly to start with. They were also allowed to practise the reconstructions initially under the direct supervision of the senior author using both the Ha and Ti prosthesis before the actual task began. The time taken for each surgeon to perform a successful ossicular reconstruction using a particular type of prosthesis was recorded using a stopwatch. The task was regarded as failed if it could not be completed within 10 minutes. Any damage to the prosthesis, subluxation of the footplate or damage to the crura or eardrum was documented. Hence all the surgeons had the chance to use and compare the user-friendliness of four different types of prosthesis: Ha and Ti PORP and Ha and Ti PORP. They were then asked as to their preference of ossicular prosthesis for each type of reconstruction. The reasons for their preference were documented.



(a)



(b)

FIG. 1

Two different types of partial ossicular reconstruction prosthesis used for the malleo-stapes assembly in the present study. Figure 1(a) is the Goldenberg design hydroxyapatite incus prosthesis. Figure 1(b) is the Dusseldorf design Bell titanium prosthesis.

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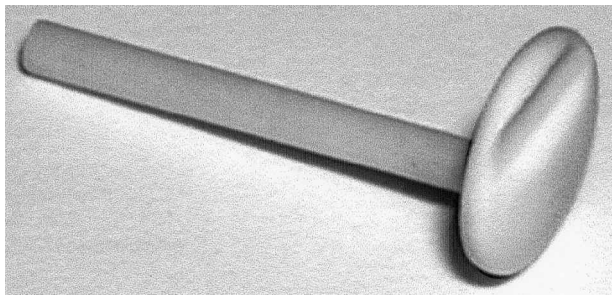
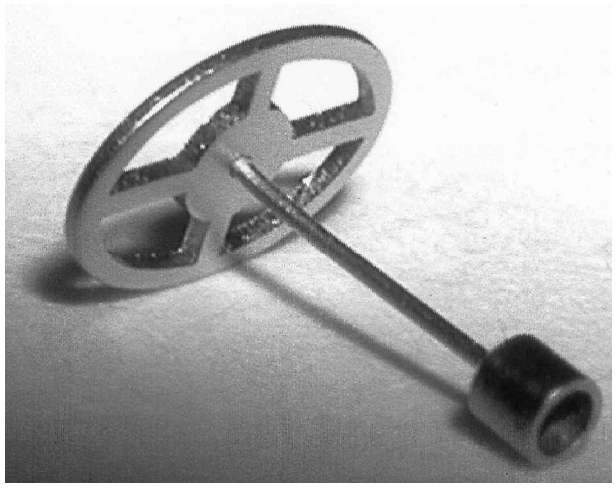


(a)



(b)

FIG. 2

Two different types of total ossicular reconstruction prosthesis used for the malleo-footplate assembly in the present study. Figure 2(a) is the Richards design hydroxyapatite incus-stapes prosthesis. Figure 2(b) is the Dusseldorf design Aerial titanium prothesis.

Results

There were big differences in the level of surgical experience among the specialist registrars (SpRs) and the consultant surgeons in the present study. Only one out of the 14 surgeons had had experience of using both the Ha and Ti prosthesis before. The others had either no experience in ossiculoplasty or had only used Ha prostheses before. The seniority of the surgeons and their previous ossiculoplasty experience are listed in Table I.

After having tried both the Ha PORP (Goldenberg design) and the Ti PORP (Dusseldorf design), nine out of 14 surgeons preferred the Ha prosthesis, four preferred the Ti prosthesis and one did not have a particular preference. For the total ossicular prosthesis, seven out of 14 surgeons preferred the Ha TORP (Richards design) and the other seven preferred the Ti TORP (Dusseldorf design). The breakdown of the preference of the surgeons among the specialist registrars and consultants is shown in Table II.

Most of the ossiculoplasty tasks were successfully completed within the time limit. One SpR failed to complete the task of partial ossicular reconstruction within 10 minutes using both the Ha and the Ti prosthesis but was successful in completing the task of total ossicular reconstruction. One consultant surgeon failed to complete the task of total ossicular reconstruction using the Ti prosthesis because of damage to the prosthesis during implantation. All the other surgeons managed to complete every task within 10 minutes without causing damage to the footplate or stapes. Table III compares the time taken to perform the ossiculoplasty using the Ha and the Ti prosthesis by the specialist registrars and the consultant surgeons. Most specialist registrars took longer to complete the task of partial and total ossicular reconstruction using the Ti prosthesis. Hence, this seems to support their overall preference for the Ha prosthesis. The time taken for the consultants to perform the ossicular reconstruction using the Ha or the Ti prosthesis was more even, for both partial and total ossicular reconstructions. This also seems to support the more even preference among the consultants for the Ha and the Ti prosthesis, for both partial and total ossicular reconstructions.

TABLE I

THE SENIORITY AND PREVIOUS EXPERIENCE IN OSSICULOPLASTY OF THE 14 SURGEONS WHO PARTICIPATED IN THE STUDY

Surgeon Number	Seniority (years)	Previous ossiculoplasty experience		Previously experience of ossicular prosthesis
		POR	TOR	
1	SpR (1)	0	0	–
2	SpR (2)	0	0	–
3	SpR (3)	0	0	–
4	SpR (3)	0	0	–
5	SpR (4)	20	2	Autologous incus
6	SpR (5)	2	0	–
7	SpR (6)	3	0	Ha; smooth head (i.e. without notch or groove)
8	Con (1)	6–10	0	Ha; single notch Wehr design
9	Con (3)	20	20	Ha; single notch Wehr design
10	Con (7)	20	3	Autologous incus or Ha
11	Con (10)	40	30	Ha; single notch Wehr design
12	Con (12)	15	8	Ha; single notch Wehr design for PORP; smooth head for TORP
13	Con (12)	200	200	Both Ha and Ti for PORP and TORP; smooth head
14	Con (15)	100	100	Ha; single notch Wehr design

SpR = specialist registrar; Con = consultant; Ha = hydroxyapatite prosthesis; Ti = titanium prosthesis

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TABLE II
THE PREFERENCE FOR THE TYPE OF PROSTHESIS FOR OSSICULOPLASTY AMONG SPECIALIST REGISTRARS (SPR) AND CONSULTANTS

Type of ossicular prosthesis	Preference among surgeons			
	SpR (n = 7)		Consultants (n = 7)	
	HA	Ti	Ha	Ti
PORP	4*	2*	5	2
TORP	4	3	3	4

*1 specialist registrar did not have any preference for the type of PORP
Ha = hydroxyapatite prosthesis; Ti = titanium prosthesis.

TABLE III
COMPARISON OF THE TIME TAKEN TO COMPLETE THE TASK OF PARTIAL AND TOTAL OSSICULAR RECONSTRUCTION USING DIFFERENT PROSTHESES

Grade of surgeons	Time taken to complete task			
	POR		TOR	
	Ha faster than Ti	Ti faster than Ha	Ha faster than Ti	Ti faster than Ha
SpR (n = 7)*	5	1	7	0
Con (n = 7)	3	4	2	5

*One SpR failed to complete the task of using both Ha and Ti for partial ossicular reconstruction.
Con = consultant surgeons; SpR = specialist registrar; POR = partial ossicular reconstruction; TOR = total ossicular reconstruction; Ha = hydroxyapatite prosthesis; Ti = titanium prosthesis.

Perhaps the most important information collected in the present study is the comments made by the surgeons on the user-friendliness of the different prostheses. All the relevant comments are listed in Tables IV and V. The main reasons given for Ha being the preferred prosthesis were the notch design in the head of the prosthesis making it easier to slide under the malleus and its slightly heavier weight making it easier to manipulate inside the middle ear. The cannulated hapex shaft of the Ha PORP (Goldenberg design) was felt to fit more tightly over the stapes capitulum than the cup design of the Ti PORP (Dusseldorf design). The main reason given for Ti being the preferred prosthesis was the open design in the head (top-plate) of the prosthesis allowing the bottom end of the shaft to be seen and making it easier for the head of the prosthesis to be manipulated by micro-instruments. Although this superiority in the Ti head design was agreed by almost all the surgeons, it was not sufficient to swing the vote for every surgeon. Also the Ti TORP was thought to be less top-heavy than the Ha TORP and therefore less likely to fall over after it is placed on the footplate.

Discussion

Surgeons of a wide range of seniority and ossiculoplasty experience were included in the present study as it was felt that a well-designed ossicular prosthesis should be user-friendly to both experienced surgeons

TABLE IV
REASONS GIVEN FOR THE HA OR TI PORP BEING THE PREFERRED PROSTHESIS

Reason for Ha being the preferred PORP (4 SpRs; 5 Con)	Commenting surgeons
Heavier weight and bigger head size making it easier to manipulate inside the ear with larger suction ends	3 SpRs; 1 Con
Notch in the head making it easier to slide under the malleus	1 SpR; 3 Con
Cannulated shaft fits on stapes capitulum better than the Bell design of Ti PORP	2 SpRs
Fine surgical hooks would not get caught as it may on the open head of the Ti PORP	1 SpR
Previous experience of using Ha PORP: confessed bias	1 Con
Reason for Ti being the preferred PORP (2 SpRs; 2 Con)	
Open head allowing bottom end of the shaft to be seen	1 SpR; 1 Con
Open head allowing easier manipulation with fine instruments	2 Con
Lighter weight allowing easier manipulation with thumb-controlled fine suction ends	2 SpRs

SpR = specialist registrar, Con = consultants; Ha = hydroxyapatite; Ti = titanium.

TABLE V
REASONS GIVEN FOR THE HA OR TI TORP BEING THE PREFERRED PROSTHESIS

Reason for Ha being the preferred TORP (4 SpRs; 3 Con)	Commenting surgeons
Heavier weight making it easier to manipulate inside the ear	4 SpRs; 2 Con
Fine surgical hooks would not get caught as it may on the open head of the Ti TORP	1 SpR
Previous experience of using Ha TORP: confessed bias	1 Con
Reason for Ti being the preferred TORP (3 SpRs; 4 Con)	
Open head allowing bottom end of the shaft to be seen	1 SpR; 4 Con
Open head allowing easier manipulation using fine instruments	3 Con
Ti TORP less top-heavy than the Ha TORP making it less likely to fall over after it is placed on the footplate	2 Con

SpR = specialist registrar; Con = consultants; Ha = hydroxyapatite; Ti = titanium

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and beginners. In fact, it is probably the less experienced oto-surgeons who appreciate the user-friendliness of the prosthesis most. Up to now, most UK otolaryngologists have been more familiar with the Ha ossicular prostheses because they have been on the market longer. It is therefore not easy to ask the consultants to compare the user-friendliness of the Ha prosthesis that they are more familiar with against that of the Ti prosthesis. Only one surgeon in the present study had used the Ti prosthesis before. However, all the consultants involved in the present study were aware of the problem of bias and promised to be as objective as they could.

It was encouraging that most of the SpRs completed the various tasks of ossiculoplasty without causing damage to the footplate, stapes or prosthesis. The authors strongly feel that such temporal bone exercises, on either cadaveric or plastic temporal bones, are the best way to prepare SpRs before they are allowed to operate on patients.

Ha is already a well-established biomaterial in otology. It has a low rate of extrusion even when placed against the eardrum.[13] Over the last 15 years, many designs of Ha prostheses with different shapes and sizes have been produced. The main ones include changes to the shape of the Ha head or notches machined onto the head to accommodate the handle of the malleus. Many modifications have also been made to the shaft of the prosthesis. While keeping the Ha head for bioactive stability against the eardrum, different materials have been used for the shaft, such as Hapex, polycel, fluoroplastic-coated stainless steel wire or FLEX HA, a hybrid material combining Ha and silicone. These materials enable the shaft to the trimmed with knife rather than drill, making the prosthesis easier to handle. A cannulation has been made in the shaft of the PORP for easier positioning over the stapes capitulum. The Goldenberg design for the Ha PORP and the Richards design for Ha TORP were chosen for the present study as they are among the more popular prostheses in the Ha range produced by one of the main manufacturers of Ha implants. (Smith & Nephews, verbal communication).

Ti is another well established biomaterial used in many medical devices and surgical implants.[8] Although Ti ossicular prostheses have been on the market for six years, titanium has shown great potential in allowing even prostheses of complicated designs to be made by machinery. It is stiffer and less brittle than Ha and hence allows the shaft to remain very slender. More importantly, it allows windows to be created in the top-plate of the prosthesis so that the surgeon can see the bottom of the shaft during the implantation of the prosthesis onto the stapes capitulum or the footplate. The Ti prosthesis is supplied in fixed sizes although there are also some designs that allow the prosthesis to be trimmed using special cutting devices. Although Ti has not been used for ossicular reconstruction for as long as Ha, many more designs and developments are already on the way to improve its mechanical stability within the middle ear. (Kurz, Germany, verbal communication). The Dusseldorf designs of Ti PORP and TORP were selected for this study as they are one of the more popular designs in the Ti range of prosthesis produced by one of the main manufacturers of Ti implants. (Kurz, Germany, verbal communication)

Only seven of 14 surgeons in the present study had personal experience of over 10 cases of partial ossicular reconstruction. On the whole, most of the surgeons (nine out of 14) found the design of the Goldenberg Ha PORP more user-friendly than the Dusseldorf Ti PORP. It took most of them a shorter time to complete the partial ossicular reconstruction using the Ha prosthesis. They liked the slightly bigger head size and the heavier weight of the Ha prosthesis because they felt more confident using a larger suction end to manipulate the prosthesis in the middle ear. Some surgeons found the Ti implant too light and difficult to control except using very find suction tips. Many surgeons found the notch design of the Goldenburg Ha prosthesis particularly useful and easy to rotate under the handle of malleus. Two SpRs found the 'bell' at the lower end of the Dusseldorf Ti PORP slightly too big for the stapes capitulum and the implant had a tendency to fall over even after it had been placed on the stapes capitulum. There was no obvious discrepancy between the consultants and the SpRs in their choice of PORP.

The previous experience in total ossicular reconstruction among the surgeons was even more limited. Only four out of 14 had performed over 10 total ossicular reconstructions previously. The preferences between the Richards Ha TORP and the Dusseldorf Ti TORP among the surgeons were more even. There was also no obvious discrepancy between the consultants and the SpRs in the choice of the TORP. Most of the surgeons appreciated the benefit of the open head design of the Ti prosthesis. As in the case of Ha PORP, many surgeons (six out of 14) found the weight of the Ha prosthesis more user-friendly. However, two consultants also commented that the Ti TORP has a more evenly-distributed weight whereas the Ha TORP was too top-heavy in its weight distribution. Hence it was felt that the Ha TORP has a tendency to fall over during the implantation of the prosthesis. It is interesting that out of the four consultants who preferred the Ti TORP, three had been using the Ha prosthesis exclusively before and were exposed to the Ti implants for the first time in the present study.

It must be recognized that user-friendliness is one of several considerations in the design of an ossicular prosthesis. The aim of the present study is not to identify which type of prosthesis is the best. It is very possible that all the four designs of ossicular prosthesis used in the present study may be superseded by better designs in the near future. It is hoped that the aspects of user-friendliness identified from each of the four designs will be taken into consideration in future prosthetic designs. The authors also recommend that any newly-designed prosthesis should first be 'test-driven' by surgeons of

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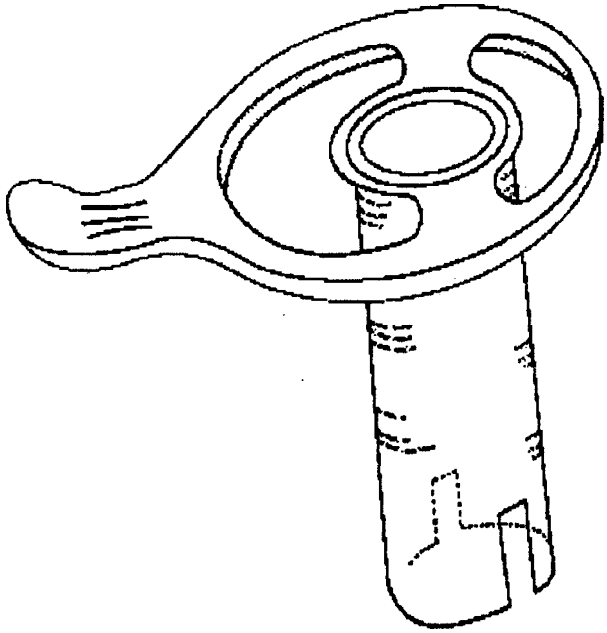
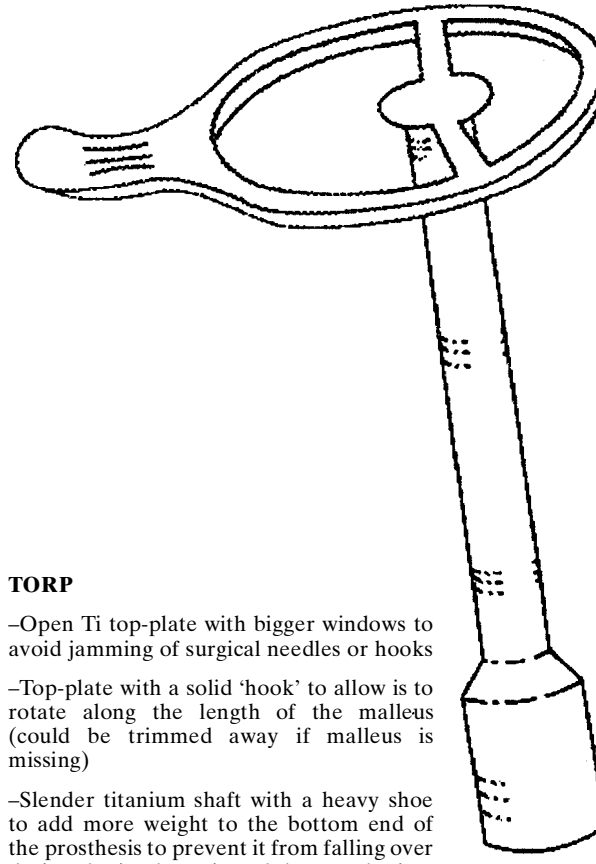


PORP

–Open Ti top-plate with bigger windows to avoid jamming of surgical needles or hooks

–Top-plate with a solid 'hook' to allow it to rotate along the length of the malleus

–Cannulated Ha or Ti shaft to sit on the stapes capitulum; cannulated shaft instead of slender shaft to add more weight to the lower end of the prosthesis



TORP

–Open Ti top-plate with bigger windows to avoid jamming of surgical needles or hooks

–Top-plate with a solid 'hook' to allow is to rotate along the length of the malleus (could be trimmed away if malleus is missing)

–Slender titanium shaft with a heavy shoe to add more weight to the bottom end of the prosthesis to prevent it from falling over during the implantation of the prosthesis

FIG. 3
A theoretical 'user-friendly PORP and TORP'.

different levels of surgical experience to find out its user-friendliness before it is put into commercial production. Figure 3 combines the favourable comments on the four types of ossicular prosthesis from our panelists to produce what we regard as a user-friendly PORP and TORP.

Acknowledgement

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Mr M. Yung takes responsibility for the integrity of the content of the paper.
Titanium prosthesis used for this study was supplied by Kurtz, Germany.