Total Ossicular Replacement Prosthesis: A New Fat Interposition Technique

Issam Saliba[1,2,3], Valérie Sabbah[1] and Jackie Bibeau Poirier[1]

[1]Division of Otorhinolaryngology—Head & Neck Surgery, University of Montreal, Montreal, QC, Canada. [2]Department of Otolaryngology, Sainte-Justine University Hospital Center (CHU SJ) Otology and Neurotology section, Montreal, QC, Canada. [3]Department of Otolaryngology, University of Montreal Hospital Center (CHUM) Otology and Neurotology section, Montreal, QC, Canada.

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ABSTRACT:

OBJECTIVE: To compare audiometric results between the standard total ossicular replacement prosthesis (TORP-S) and a new fat interposition total ossicular replacement prosthesis (TORP-F) in pediatric and adult patients and to assess the complication and the undesirable outcome.

STUDY DESIGN: This is a retrospective study.

METHODS: This study included 104 patients who had undergone titanium implants with TORP-F and 54 patients who had undergone the procedure with TORP-S between 2008 and 2013 in our tertiary care centers. The new technique consists of interposing a fat graft between the 4 legs of the universal titanium prosthesis (Medtronic Xomed Inc, Jacksonville, FL, USA) to provide a more stable TORP in the ovale window niche. Normally, this prosthesis is designed to fit on the stapes' head as a partial ossicular replacement prosthesis.

RESULTS: The postoperative air-bone gap less than 25 dB for the combined cohort was 69.2% and 41.7% for the TORP-F and the TORP-S groups, respectively. The mean follow-up was 17 months postoperatively. By stratifying data, the pediatric cohort shows 56.5% in the TORP-F group (n = 52) compared with 40% in the TORP-S group (n = 29). However, the adult cohort shows 79.3% in the TORP-F group (n = 52) compared with 43.75% in the TORP-S group (n = 25). These improvements in hearing were statistically significant. There were no statistically significant differences in the speech discrimination scores. The only undesirable outcome that was statistically different between the 2 groups was the prosthesis displacement: 7% in the TORP-F group compared with 19% in the TORP-S group ($P = .03$).

CONCLUSIONS: The interposition of a fat graft between the legs of the titanium implants (TORP-F) provides superior hearing results compared with a standard procedure (TORP-S) in pediatric and adult populations because of its better stability in the oval window niche.

KEYWORDS: TORP, PORP, ossicular chain, ossicular replacement, hearing loss, conductive, total, partial

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CORRESPONDING AUTHOR: Issam Saliba, Department of Otolaryngology, Sainte-Justine University Hospital Center (CHU SJ), 3175 Côte Sainte-Catherine, Montreal, QC H3T 1C5, Canada. Email: issam.saliba@umontreal.ca

Introduction

Chronic diseases affecting the middle ear, such as cholesteatoma and chronic otitis media, or acute pathology, such as trauma, may damage the ossicular chain that is essential for sound transmission from the tympanic membrane (TM) to the inner ear. When performing middle ear surgeries, 2 main objectives are sought: (1) the eradication of the primary disease and (2) restoration of normal hearing.[1] In these cases, associated ossiculoplasty may be necessary. Ossiculoplasty differs between adult and pediatric populations, particularly regarding its underlying pathology. Cases requiring ossicular reconstruction in a setting of serous otitis media or congenital anomalies are more frequent in children than in adults.[2] There is a controversy in the recent literature regarding the progression of pediatric cholesteatomas compared with those in the adult population.[3–5] According to the work by Cushing and Papsin,[2] cholesteatomas are contained in a more restricted anatomical space in children that makes their eradication more difficult.

Even though the first ossiculoplasties date back to the 1950s, the first ossiculoplasty using a titanium prosthesis was realized by Stupp in 1993.[1,6] Since then, titanium has become a privileged material for use in ossiculoplasty. Some of its main advantages include an excellent biocompatibility, lightweight, and a good rigidity.[1,7] During surgery, it is necessary to interpose cartilage between the TM and the prosthesis to minimize the risk of prosthesis extrusion.[1] With this procedure, the extrusion risk is evaluated, according to initial studies, between 1% and 2% with a follow-up of up to 3 years. Audiometric results seem to be equivalent or slightly superior to those obtained with bioactive materials such as hydroxyapatite.[8–12] Operative success with ossiculoplasty is defined as an air-bone gap (ABG) closure inferior to 20 dB. Operative success after total reconstruction with a total titanium ossicular prosthesis is between 40% and 60% according to some reports.[11,13–15]

Our study is based on Medtronic Universal Titanium Prosthesis (Medtronic Xomed Inc, Jacksonville, FL, USA) that can be assembled in 2 ways. If we keep the cup with the 4 legs, it is designed to fit on the stapes' head and constitutes a partial ossicular replacement prosthesis (PORP). If we cut the cup and keep only the fluoroplastic end, it is designed to reach the footplate and constitutes a standard total ossicular replacement prosthesis (TORP-S). Similar to every TORP, the end surface is small, difficult to place properly and may move during and after surgery. Displacement of the prosthesis from the footplate can often be the cause of suboptimal surgical outcomes. We believe that the use of titanium prosthesis keeping its 4 legs but with interposing a piece of fat between the legs of the prosthesis provides better stability of the prosthesis on the footplate when used as a TORP. The objectives of this study were to compare hearing results for TORP with a new fat interposition method (TORP-F) with a standard method (TORP-S) and to assess the stability of the ossicular reconstruction type and the complication rate.

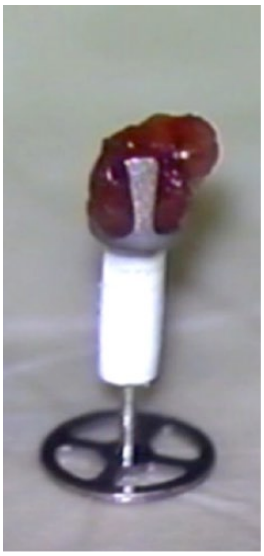

Figure 1. Total ossicular replacement prosthesis with a fat interposition between the 4 legs.

Methods

Population

We conducted a retrospective study by chart review of patients who underwent total ossicular reconstruction surgery in our tertiary care center between 2008 and 2013 by the senior author (I.S.). The study was approved by the institutional research ethics board and followed the standards of our institutional ethics committee.

Basic conditions for which patients had undergone ossiculoplasty were divided into 6 categories: (1) ossicular chain pathology: congenital anomalies, fixation, or dislocation of the ossicular chain; (2) TM retraction with ossicular chain erosion; (3) cholesteatoma; (4) revision of prior ossiculoplasty for fixation or dislocation; (5) chronic otomastoiditis; and (6) hypoacusis from other causes.

The total number of ipsilateral otologic procedures undergone by each patient in the past was counted. Ossiculoplasties performed during a scheduled second stage were also noted as well as the presence or the absence of the malleus.

We collected all prosthesis-related complications such as prosthesis displacement, extrusion or fixation, middle ear fibrosis, vertigo, and total hearing loss.

Surgical technique

The surgical technique consists of interposing a piece of fat between the 4 legs of the prosthesis, normally designed to be used as a PORP. The 4 legs are therefore slightly crimped together to trap the fat piece. The fat bulges slightly between the legs (Figure 1). Then, the prosthesis is placed directly on the footplate. The fat piece can be harvested through the surgical incision or through a pretragal or lobule incision, large enough to fill the space between the 4 legs of the prosthesis. Cartilage as a disk covering the prosthesis shaft or a total cartilage replacing the entire TM surface was placed between the shaft of the prosthesis and the TM to prevent extrusion. Ossiculoplasty was done with tympanoplasty only or with canal wall up or canal wall down tympanomastoidectomy.

Only the first ossiculoplasty surgery for each patient performed by our department was analyzed to avoid statistical biases between the groups. All subsequent surgeries were excluded. All patients had to have a replacement of the stapes' superstructure without removal of the footplate that had to remain intact and mobile.

Functional results

The audiometric results consisted of 1 preoperative and 2 postoperative ABG measurements (less than 8 months and more than 8 months). The frequencies measured were as follows: 500, 1000, 2000, 3000, and 4000 Hz. An ABG of less than 20 dB is considered as a postoperative success. Near success is assigned to ABGs between 21 and 25 dB, acceptable is assigned to ABGs between 26 and 30 dB, and failure is assigned to ABGs more than 30 dB.

Pure-tone average (PTA) are reported on the level II of the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) guidelines for reporting hearing loss, which was endorsed by the Hearing Committee of the AAO-HNS in 2012.[16] The reported PTA, calculated using 500, 1000, 2000, and 3000 Hz air conduction thresholds and rounded to the nearest whole number, is plotted on the *y*-axis of the scattergram in increasing 10-dB intervals from 0 to >91 dB from top to bottom.

Statistical analysis

Statistical analysis was performed by a professor Miguel Chagnon from the Department of Statistics, University of Montreal. Categorical variables (sex, side, preoperative diagnosis,

Table 1. Cohort data of the patients.

	TORP-F (N = 104), %	TORP-S (N = 54), %	*P* VALUE
Mean age, y	32.3	27.2	.14
Gender (female/male)	49.4/50.6	40.7/59.3	1.00
Pediatric/adult	32.0/68.0	53.7/46.3	.01
Side (right/left)	44.2/55.8	61.1/38.9	.07
Malleus presence	32.0	51.9	.02
Total cartilage	24.5	25.0	1.00
Procedure			
MT/T	84.3/15.7	90.4/9.6	.33
CWU/CWD	88.2/11.8	55.3/44.7	<.001
Second-look surgery	48.1	23.1	.003
Mean no. of procedures	2.4	1.8	.0003
Diagnosis			
1. Ossicular chain pathology	16.4	3.7	.02
2. TM retraction	12.6	35.2	.002
3. Cholesteatoma	70.0	55.6	.08
4. Revision surgery	28.2	1.9	<.001
5. Chronic otomastoiditis	15.7	16.7	1.00
6. Other causes	14.4	18.5	.50

Abbreviations: CWD, canal wall down; CWU, canal wall up; MT, mastotympanoplasty; T, tympanoplasty; TM, tympanic membrane; TORP-F, total ossicular replacement prosthesis with fat; TORP-S, standard total ossicular replacement prosthesis.

presence or absence of malleus, and procedure performed) were compared using χ^2 test. Continuous variables (age, follow-up, number of procedures, and diagnosis) were compared using *t* test. Audiograms were analyzed using analysis of variance with 2 factors: intergroup factors and interindividual frequencies. A *P* value less than .05 is considered statistically significant.

Results

Demographic data, preoperative diagnosis, and procedure type are presented in Table 1. No statistically significant difference was noted at the level of age, sex, or side of the ossicular replacement. In total, 54 patients underwent a total reconstruction using the standard universal prosthesis (TORP-S) and 104 patients underwent an ossiculoplasty using the modified universal prosthesis with fat interposition (TORP-F). There are relatively more pediatric patients in the TORP-S group (54% versus 32%) leading to a subanalysis separating the adult and pediatric cohorts. There were a significantly higher number of cases operated for revision of prior ossiculoplasty in the TORP-F group ($P < .001$). The patients from the TORP-F group had a significantly higher number of procedures than patients from the TORP-S group ($P = .0003$) in the operated ear.

Hearing results

Preoperative and postoperative ABG results are reported in Table 2. The first postoperative hearing tests were performed at an average of 5.38 and 5.63 months in the TORP-F and TORP-S groups, respectively. The second hearing tests were performed at an average of 17.1 and 18.9 months in the TORP-F and TORP-S groups, respectively. No statistically significant differences were noted in mean first and second follow-ups ($P = .72$ and $P = .40$, respectively). To evaluate postoperative audiometric results, average total ABG was calculated for 500, 1000, 2000, 3000, and 4000 Hz frequencies and classified according to 4 categories. For the combined adult and pediatric cohort at second postoperative follow-up, there was a 44% success rate in the TORP-F group compared with only a 25% success rate in the TORP-S group. In the ABG >30 category, which corresponds to the worst outcome, 53% of the TORP-S fit in this category compared with 19% in the TORP-F group. By stratifying data, the pediatric cohort shows a 30% success rate in the TORP-F group compared with a 15% success rate in the TORP-S group. However, the adult cohort shows a 55% success rate in the TORP-F group compared with 38% in the TORP-S group.

Table 2. Second postoperative follow-up ABG results.

	ABG, DB	TORP-F (N = 52), %	TORP-S (N = 36), %
Combined cohort			
Success	<20	44.2	25.0
Near success	20-25	25.0	16.7
Acceptable	26-30	11.5	5.56
Failure	>30	19.2	52.8
Adult cohort			
Success	<20	55.2	37.5
Near success	20-25	24.1	6.25
Acceptable	26-30	10.3	12.5
Failure	>30	10.3	43.8
Pediatric cohort			
Success	<20	30.4	15.0
Near success	20-25	26.1	25.0
Acceptable	26-30	13.0	0
Failure	>30	30.4	60.0

Abbreviations: ABG, air-bone gap; TORP-F, total ossicular replacement prosthesis with fat; TORP-S, standard total ossicular replacement prosthesis.

Table 3. Differences in mean ABG for combined cohort.

	TORP-S	TORP-F
	MEAN ABG, DB	MEAN ABG, DB
1. Preoperative	37.44	39.02
2. First postoperative follow-up	29.44	23.32
3. Second postoperative follow-up	26.37	26.29

Abbreviations: ABG, air-bone gap; TORP-F, total ossicular replacement prosthesis with fat interposition; TORP-S, standard total ossicular replacement prosthesis.

We also compared the postoperative average differences in mean ABG between the first postoperative follow-up and the second postoperative follow-up (Table 3, Figure 2). To do so, the mean postoperative ABG was subtracted from the postoperative ABG for the 2 follow-up durations. We notice that the differences increase with time in TORP-F group, from 12.7 to 15.7 dB, and decrease with time in TORP-S group, from 11.1 to 8.0 dB. The improvement in hearing results at second postoperative follow-up is highly significant in TORP-F ($P < .001$).

Speech discrimination scores (SDSs) were also compared between the 2 groups. There were no significant differences in discrimination postoperatively in TORP-F or TORP-S groups ($P > .05$). Preoperative average SDS was 90.9% and 93.1% in the TORP-F and TORP-S groups, respectively. At the first postoperative follow-up, average SDSs were 94.2% and 89.9%, respectively. At the second postoperative follow-up, average SDSs were 93.3% and 87.8%, respectively. There were no statistically significant differences between preoperative and postoperative SDS scores ($P > .05$).

A scattergram of pretreatment and posttreatment for patients hearing results of the TORP-F and TORP-S groups is represented in Figure 3.

Postoperative complications

Results are reported in Tables 4 and 5. The only undesirable outcome that was statistically different between the 2 groups was the prosthesis displacement: 7% displacement in the TORP-F group compared with 19% in the TORP-S group. No major complications were noted in the TORP-F group. However, 2 cases of sensorineural hearing loss

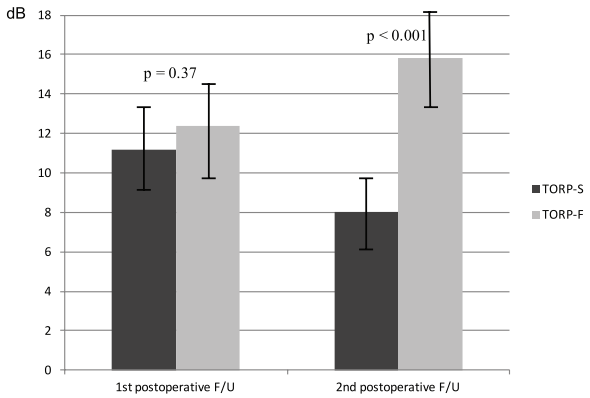

Figure 2. Average differences in mean air-bone gap for combined cohort. F/U indicates follow-up; TORP-F, total ossicular replacement prosthesis with fat interposition; TORP-S, standard total ossicular replacement prosthesis.

(SNHL) were noted in the TORP-S group (loss of 27 and 17.5 dB).

Discussion

The goal of ossicular chain reconstruction is to restore middle ear acoustic properties by matching air to cochlear fluid impedances. To achieve this and also to provide better prosthesis stability on the footplate, we modified the original design of the Medtronic Universal Titanium Prosthesis by keeping the 4 legs and interposing fat between them. This modification facilitates the positioning of the TORP-F in the oval window niche. The presence of the bulging fat helps to keep the total prosthesis in place and stable.

Differences were found in patient baseline characteristics between TORP-S and TORP-F groups. Separate statistical analyses for adult and pediatric cohorts were done to control for these differences. The other statistically significant differences observed in patient data such as canal wall up versus canal wall down procedures, second-look procedures, total number of procedures, tympanic pathology, ossiculoplasty, and revision surgeries were not identified as prognostic factors for audiometric outcome in our study.

It is important to mention that patients in the TORP-F group had more severe disease. This is reflected by the fact that they had more comorbidity at the time of surgery: 28.2% of the cases were revisions of previous ossiculoplasties. Several authors have demonstrated that revision cases have worse outcomes than primary cases.[15,17] In the series by Woods et al, improvement in mean ABG and average of PTA were better in the group undergoing their first surgery compared with the group undergoing a revision procedure. Despite this fact, we have observed better hearing results with the fat interposition technique than with the standard technique.

The rate of dislocation of the prosthesis reported in literature varies between 10.8% and 12.1%[13,18] which is slightly higher than that reported with the new fat interposition technique (TORP-F). Moreover, as nearly no patients (except one) with prosthesis displacement achieved satisfactory hearing results, we believe that the stability of the prosthesis is a necessary component to surgical success. This is consistent with previously cited studies, which stated that prosthesis or cartilage displacement is one of the prime causes of failure.[18,19] The higher rate of prosthesis fixation in the TORP-F group is not statistically significant because of the short distance between the fallopian canal and the promontory at the level of the oval window niche resulting in friction between the bone and the titanium ring holding the legs of the TORP and this is not due to the fat interposition. This can be countered by a slight curettage to enlarge the niche of the oval window.

Adult success rates (55% TORP-F versus 38% TORP-S) were comparable with those found in literature (40%-60%).[11,13–15] However, pediatric success rates (30% TORP-F versus 15% TORP-S) were inferior to those seen in pediatric TORP literature (51%-80%).[20–22] There are few studies available in the literature, which are done exclusively with titanium implants on a pediatric population.[20–23] Michael et al[20] obtained an 80% success rate with a small cohort of 14 patients. Nevoux et al[23] obtained a 56% success rate with TORP (n = 116), with all procedures being second-look postcholesteatoma surgeries. However, other factors can contribute to a less hearing improvement, such as the postoperative complications, including external auditory canal or mastoid cavity infection, middle ear fibrosis, prosthesis extrusion, TM thickening or retraction, and prosthesis fixation as well. Moreover, more than 50% of our cohort had a diagnosis of cholesteatoma. There is actually a controversy in the literature regarding the aggressiveness of pediatric cholesteatomas when compared with adult cases.[22] Many authors have published a recurrence of cholesteatomas in the pediatric population which are 2 to 3 times superior than the adult population with the same diagnosis.[3,24,25] Another study published by Palva et al[4] suggests that pediatric cholesteatomas have a growth pattern that is more aggressive and extensive than in adult population. A more recent study demonstrated that pediatric specimens of cholesteatomas are characterized by an epithelial matrix which is thicker, that they express a higher level of metalloproteinase at the matrix level, and that they have a higher and more exaggerated inflammatory profile demonstrating that these biological factors are in favor of a more aggressive behavior in pediatric cases when compared with adult cases.[5]

Operative success with TORP-F is more significant among the pediatric cohort because most of the pediatric complications or undesirable outcomes were linked to prosthesis displacement. About 20% of complications or undesirable outcomes in the TORP-F pediatric group and 75% of pediatric complications or undesirable outcomes in the TORP-S group were due to prosthesis displacement. These differences can be explained by the increased stability

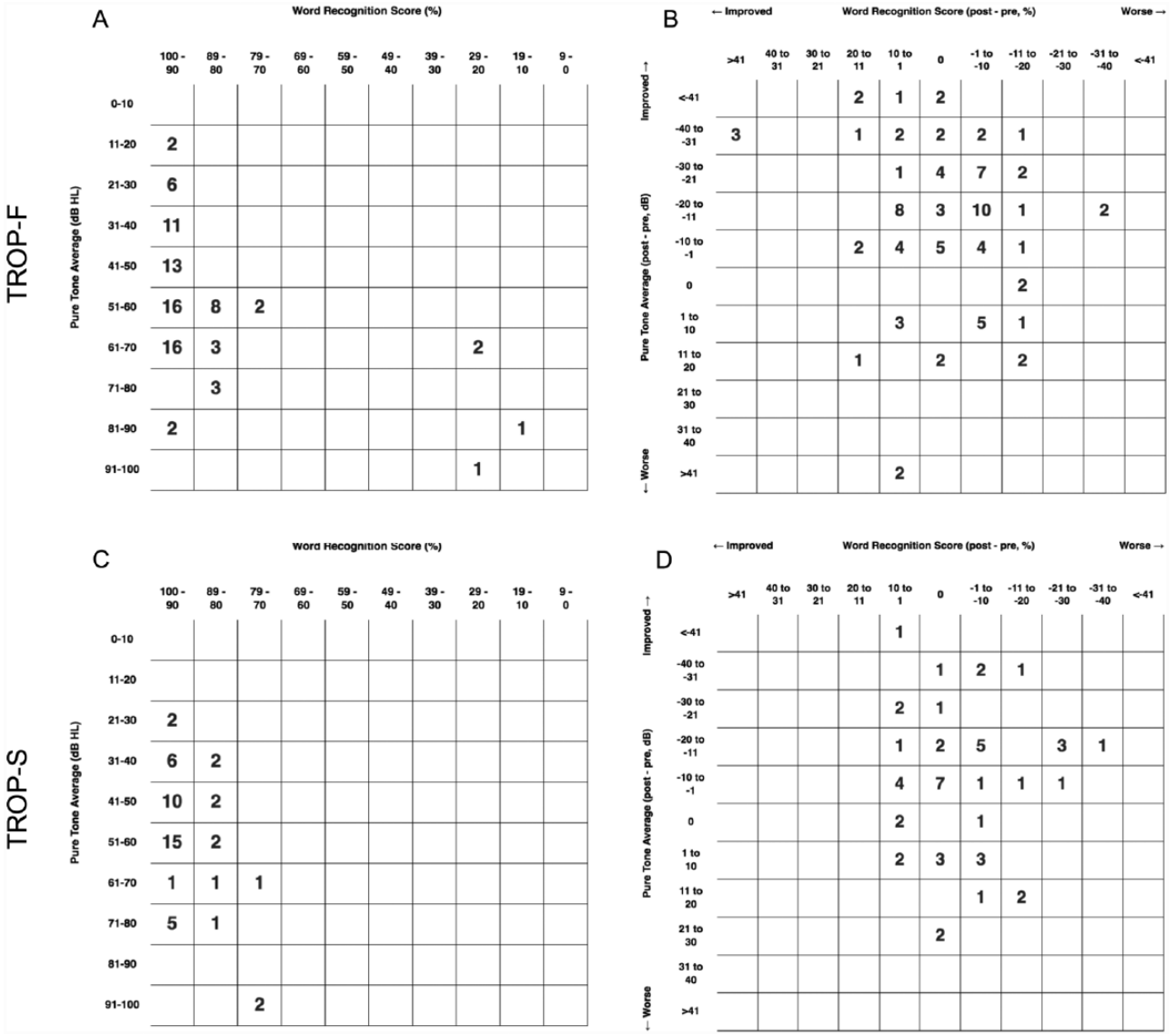

Figure 3. Scattergram of pretreatment hearing results of the (A) TORP-F group and (B) TORP-S group. Pure-tone averages (PTAs) are represented on the *y*-axis and word recognition scores (WRSs) are represented on the *x*-axis. Each number represents the number of patients whose audiometric data place them into a certain square. Posttreatment scattergram for (C) TORP-F patients and (D) TORP-S patients. Most patients have improvement in their hearing, predominantly in their PTAs. In TORP-F group, most of the WRSs vary from +20% to –20%, which is not clinically significant. The number of patients who improved their WRS more than 40% is represented in the boxes of the left upper quadrant of the scattergram. In the TORP-S group, most of the WRSs vary from +10% to –20%, which is not clinically significant. The number of patients who worsen their WRS more than 20% is represented in the boxes of the right upper quadrant of the scattergram.

rendered by the new TORP-F technique compared with the TORP-S technique, which would be able to minimize prosthesis displacements.

An important aspect of this technique is that the prosthesis is easier to place on the footplate. It is immediately stable permitting cartilage manipulation and TM repositioning with a low risk of displacement. The open platform of the prosthesis allows the surgeon to observe the position of the bottom end of the prosthesis during placement, and the claw-like design of the prosthesis prevents it from tipping or moving. The interposition of fat provides lasting contact between the prosthesis and the footplate. This contact prevents displacement of the prosthesis despite the TM healing in addition to the sealing effect of any potential leakage of perilymph created during the procedure. It also protects the footplate by avoiding penetration of the shaft of the prosthesis into the inner ear.

This demonstrates the security of this technique supported by the fact that bone conduction and SDS in TORP-F patients were not different postoperatively from the preoperative data. No cases of SNHL or intralabyrinthine displacement were noted in the TORP-F group. In addition, no cases of vertigo or sinking of the prosthesis in the inner ear are visualized on the postoperative scan performed in the failure cases.

When we started to use fat between the legs of the prosthesis, we were afraid that the piece of fat would be resorbed and that there would be an increase in TORP-F displacement rate. This

Table 4. Postoperative complications for combined cohort.

	TORP-F (N)	TORP-S (N)	*P* VALUE
Complications			
EAC infection	1	0	1.00
Vertigo	1	0	1.00
Sensorineural hearing loss	0	2	.12
Mastoid cavity infection	1	0	1.00
Otitis media	0	1	.34
Middle ear fibrosis	2	0	.55

Abbreviations: EAC, external auditory canal; TORP-F, total ossicular replacement prosthesis with fat interposition; TORP-S, standard total ossicular replacement prosthesis.

Table 5. Postoperative undesirable outcomes for combined cohort.

	TORP-F, %	TORP-S, %	*P* VALUE
Undesirable outcomes			
Prosthesis extrusion	4.2	5.6	.70
TM thickening	4.8	1.9	.66
Prosthesis displacement	6.8	18.5	.03
Prosthesis fixation	5.8	0	1.00
TM retraction	1.0	1.9	1.00
TM atelectasis	1.9	1.9	1.00

Abbreviations: TM, tympanic membrane; TORP-F, total ossicular replacement prosthesis with fat interposition; TORP-S, standard total ossicular replacement prosthesis.

was not the case. We identified on the revision cases of the 6.8% displaced TORP-F that the fat and the legs were covered by a new mucosa, increasing its stability and remained in the oval window niche; however, the axis of the TORP-F was displaced.

Limitations

The limitations of our study include loss of long-term follow-up. Loss of follow-up can be attributed to the fact that the hospitals in which the study was conducted were tertiary care centers, and many long-term follow-ups may have occurred out of these hospitals, in local clinics or in primary care settings. The nonrandomized and retrospective nature of this study is also a limitation. Moreover, statistically significant differences remain between cohort patient data.

Conclusions

Fat interposition technique is safe and easy to perform. Fat interposition between the 4 legs of a partial ossicular reconstruction prosthesis (TORP-F) compared with the TORP-S provides better postoperative audiometric results at 17 months follow-up in both pediatric and adult populations.

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Author Contributions

IS: Protocol design, data collection and analysis, manuscript review, Final approval; VS: data collection and analysis, manuscript writing; JBP: data collection and analysis, manuscript writing and review.

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