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ORIGINAL ARTICLE

A New Golden Wire Prosthesis Technique Between the Malleus and Stapes: Our Preliminary Results

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Objective: Ossicular chain reconstruction in chronic otitis media is still a matter of investigation. Many types of prostheses have been defined. We present biocompatibility-tested golden wire prosthesis used in the presence of a damaged or missing incus and the functional results of chain reconstruction.

Materials and Methods: This report describes a prospective case review from a tertiary referral center. The study was approved by ethics committee of İzmir Atatürk Training and Research Hospital.

Ossiculoplasty between the malleus and stapes was performed on a total of 20 patients, including 14 intact-wall tympanoplasty and 6 canal-wall-down tympanoplasty (CWDT) procedures. Wire prostheses were inserted between the malleus and stapes and the stapedial tendon. Pure tone average thresholds were calculated at 500, 1000, 2000, and 3000 Hz. Preoperative and postoperative air–bone gaps (ABGs) and air-conduction gains (ACs) were compared. An ABG ≤20 dB and AC ≥20 dB were accepted as successful hearing gains.

Results: The placement of the prosthesis was successful in all patients. The mean follow-up period was 11.9 (3–24) months. The preoperative average ABG was 38.25 ± 11.98 dB, and the postoperative average ABG was 17.25 ± 9.92 dB. The preoperative average AC was 53.90 ± 14.99 dB, and the postoperative average AC was 34.05 ± 18.50 dB. These results were statistically significant (P = 0.001). We reached the goal of an ABG <20 dB in 9 (64.3%) of 14 patients who underwent canal-wall-up tympanoplasty (CWUT) but in only 2 (33.3%) of 6 patients who underwent CWDT. This difference was statistically significant (P = 0.033).

Conclusion: Despite the limited number of patients, this study demonstrated the effectiveness of the golden wire prosthesis in reconstructing the ossicular chain in the presence of a damaged or missing incus. Biocompatibility, easy accessibility and application of the golden wire, and low cost are the advantages of this technique.

Key words: golden wire, prosthesis, ossiculoplasty

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Introduction

Chronic otitis media is a disease that is characterized by irreversible pathological changes in the epithelial mucosa of the tympanic cavity and mastoid air cells. The most vulnerable part is the long arm of the incus due to the relatively poor blood supply of this area, and the stapes suprastructure is affected secondarily [1].

Reconstruction techniques continues to develop since the last 50 years [2]. Initially, polyethylene tubes were used for reconstruction; however, biocompatibility-tested materials were later used to improve results. Today, autograft ossicles are the preferred material if present and synthetic materials are preferred otherwise.. As being involved most frequently many prostheses have been created to be used to reconstruct the defects between malleus and the stapes. The task is to allow stable integration with the stapes and malleus to allow the anteroposterior and piston movements in speech frequencies [3]. Reestablishing continuity by placing a strut prosthesis between the stapedial head and malleus handle minimizes the possibility of extrusion and displacement.

The success reconstruction is directly related with the coupling of the prosthesis with the remaining ossicles

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[4]. A new golden prosthesis is created to be placed with a hook on the handle of the malleus and with spirals on the stapedial capitulum and tendon. In this paper, we describe the design of our prosthesis, the operative technique, and outcomes, including the audiological results.

Materials and Methods

Ossiculoplasty was performed on 20 patients by inserting a wire prosthesis between the malleus and stapes. The presence of an intact malleus manibrium and intact stapes suprastructure is required is necessary for application of this prosthesis which replaces the incus defects. Patients were selected among 180 patients suffering from chronic otitis media between July 2008 and June 2010. In all selected 20 cases incus was completely eroded. Canal-wall-down tympanoplasty (CWDT) was performed in 6 cases, and intact-canal-wall tympanoplasty (ICWT) was applied in 14. The study was carried out with the informed consent of each patient and approved by ethics committee of İzmir Atatürk Training and Research Hospital.

To avoid unnecessary loss of time during the operation, wire prostheses were prepared in various sizes appropriate for left and right ears prior to surgery. A 0.2-mm biocompatibility-tested golden wire was used. The distance between the ossicles was measured (Fig. 1, wire prosthesis preparation devices). Wire hook–spiral prostheses prepared with a Katilmis wire prosthesis preparation device (Fig. 1A; Omur Surgical Instruments) were designed specifically for this procedure (Fig. 2). They were placed between the malleus and stapes in patients with an eroded long arm of the incus (Fig. 3). We determined the sizes of the hooks and spirals fixed to the malleus and the stapes in this wire prosthesis method based on the ossicle measurements that we had performed on 15 temporal bone cadavers. Manubrium mallei thickness and the head of the stapes were calculated as an average of 1 mm. To minimize the risk of protrusion, the prosthesis was fixed to the malleus and stapes. We used a specially designed Katilmis forceps to fix the hook to the handle of the malleus (Fig. 1C and D; EM-2534; Omur Surgical Instruments). The prosthesis is fixed to the stapes by placing the spiral on the stapedial capitulum. Employing a space of approximately 1 × 1 mm on the medial side of the stapedial tendon, we extended the lower edge of the spiral for 1 mm, with an angle to the left for the left ear and to the right for the right ear, so that it passed under the stapedial tendon to fix it to the stapes (Fig 4). The possibility of trauma to the facial nerve by the free tip of the prosthesis was thereby prevented. In CWDT, we cut the malleus head from the collum to prevent fixation of the malleus to the epitimpanium and to disarticulate the incudomalleolar joint. We aimed to provide direct conduction of sound energy from the malleus to the stapes. Patients were followed with audiogram at regular intervals. Pure tone average thresholds were calculated for 500, 1000, 2000, and 3000 Hz. Preoperative and postoperative ABG and AC were compared. An ABG ≤20 dB and AC ≥20 dB were accepted as successful hearing gains.

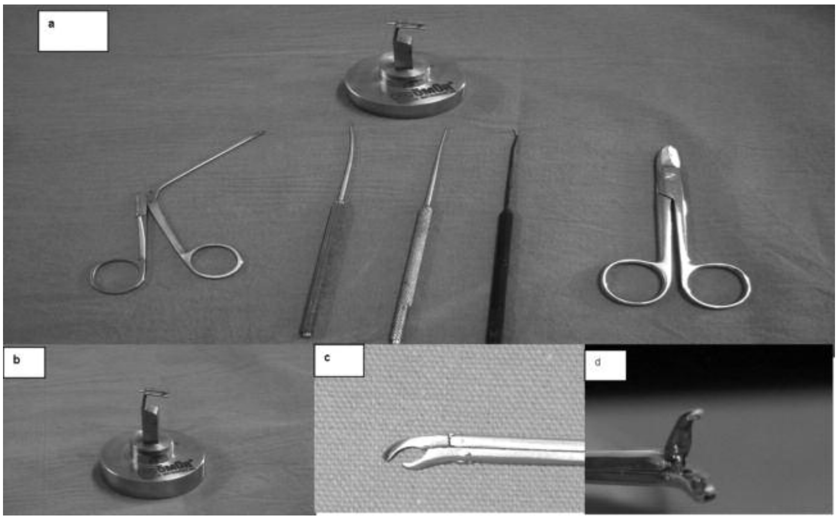

Figure 1. A: Wire prosthesis preparation tool; **B:** Katilmis wire prosthesis preparation tool; **C and D:** Katilmis forceps (the mouthpiece had a 0.2-mm thick groove on the interior surface and was designed to close with a 1-mm gap).

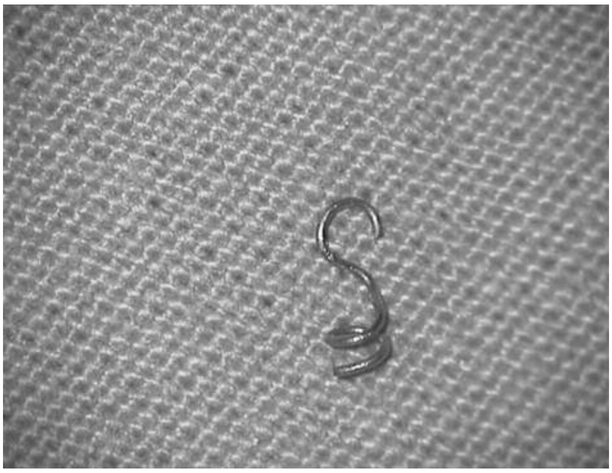

Figure 2. Wire prosthesis between the malleus and stapes.

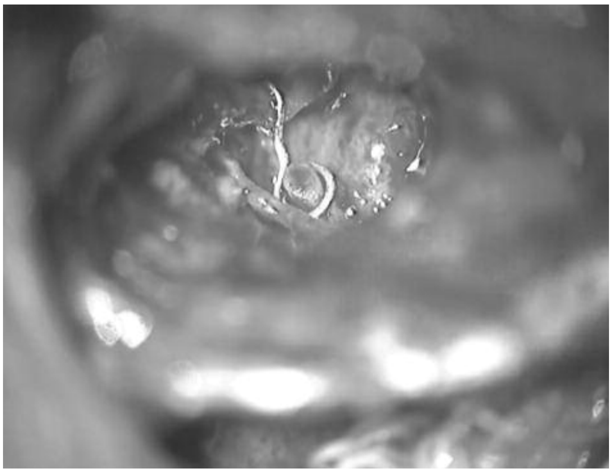

Figure 3. Wire prosthesis placed between the malleus head and the stapes and stapedial tendon (the end of the prosthesis extended under the tendon).

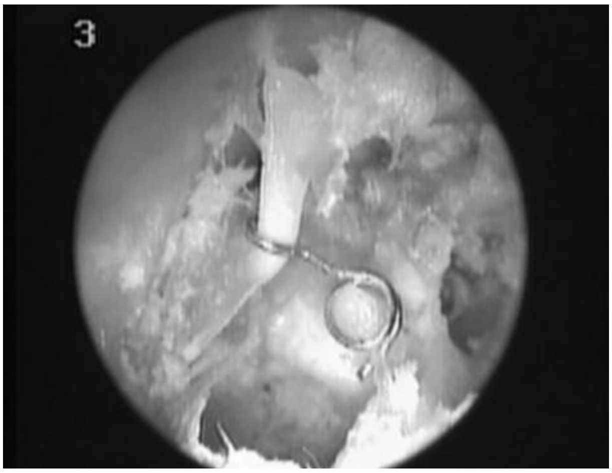

Figure 4. Cadaveric photograph of the prosthesis placed between the malleus head and the stapes and stapedial tendon

Analysis of all data was performed using SPSS version 16.0 software. The Mann–Whitney U-test and Fisher's exact test were used. $P < 0.05$ was deemed statistically significant.

Results

Thirteen (65%) of the patients were female, and seven (35%) were male. The average age was 33.65 years. The average follow-up period was 11.9 (3–24) months. Tympanosclerosis was found in seven patients, cholesteatoma in six, and granulation tissue with chronic otitis media in seven.

Patients were assessed with audiologic follow-up in the postoperative period. The preoperative average ABG was 38.25 ± 11.98 dB, and the postoperative average ABG was 17.25 ± 9.92 dB. The preoperative average AC was 53.90 ± 14.99 dB, and the postoperative average AC was 34.05 ± 18.50 dB (Table 1). Both results were statistically significant ($P = 0.001$).

Six of these patients underwent CWDT because of cholesteatoma, and 14 were treated with ICWT. We reached the goal of an ABG of <20 dB in 9 (64.3%) of 14 patients who underwent the canal-wall-up tympanoplasty (CWUT), but in only 2 (33.3%) of 6 who underwent CWDT (Table 2). These differences were statistically significant ($P = 0.033$).

No foreign-body reaction occurred in any of the patients. The tympanic membranes were intact at postoperative observation.

Table 1. Preoperative and postoperative mean air–bone gap (ABG) and air-conduction gain (AC) values.

	Preoperative	**Postoperative**	
	Mean ± SD	Mean ± SD	p
ABG	38,25 ± 11,98	17,25 ± 9,92	0.000*
AC	53,90 ± 14,99	34,05 ± 18,50	0.000*

**p < 0.05, Mann–Whitney U-test*

Table 2. Preoperative and postoperative mean ABG values in canal-wall-up tympanoplasty (CWUT) and canal-wall-down tympanoplasty (CWDT) patients

	CWUT (n = 14)	**CWDT (n = 6)**	
	n (%)	n (%)	p
ABG			0.033*
>20 dB	5 (35,7)		4 (66,7)
≤20dB	9 (64,3)		2 (33,3)

**p < 0.05, Fisher's exact test*

Discussion

An evaluation of pre-op and post-op hearing revealed that highly significant pre-op negative prognostic factors included the presence of cholesteatoma, the presence of perforation of the tympanic membrane, ossicular status, and previous surgery,[5] Incus is the most vulnerable ossicle, both to trauma and infection, because of its anatomical position and the course of its blood supply. Mawson and Glasscock [6] reported the presence damaged incus as a surgical finding among 75% of ossicular reconstructions.

The primary disadvantages of autografts are; prolonged surgery while remodelling the bone graft sorption, high risk of displacement. Besides those stated by Steinbach and Hildmann [7], the risk of resorptive osteitis should be considered, and the use of autologous ossicles in cholesteatoma cases should be avoided to prevent recurrence of the disease. The wire prostheses that we use do not prolong surgery because they are prepared in various sizes appropriate for the left and right ears prior to surgery.

Homograft ossicles e carry the risk of contamination with HIV and Creutzfeldt–Jacob viruses. Studies have therefore been launched to examine the use of synthetic implants [8]. The protrusion risk of hydroxyapatite prostheses was reported as 2–16%, and they have low antigenity . However, intraoperative modification of these prostheses is difficult because they can be broken when sharp instruments are used. For this reason, hybrid prostheses have been developed, and plastipore material was in building the body of the prosthesis. The protrusion risk of plastypore is high in cases in which there is contact with the tympanic membrane [10].

Gold is a biocompatible material that is easy to shape and stabilize, and it is well tolerated. Schneider et al. found similar results with their application of gold and titanium prostheses, and determined that the ratio of extrusion is less in titanium than in gold prostheses [11]. Gjuric et al. observed no implant rejection in their golden-wire-prosthesis patients and concluded that gold is highly biocompatible [12].

A surgically ideal middle-ear implant should be easily applied, stable, and biocompatible and should be available for total or partial implant procedures[13]. In terms of functionality, it should weigh between 10 and 40 mg, provide adequate tension between the stapes and tympanic membrane, and make an angle <30° to adapt to the malleus [14]. Most of these features are applicable in the prosthesis that we use: 15 mm of our golden wire prosthesis weighs 15 mg and has a diameter of 0.2 mm. The antigenicity and protrusion risk of the wire prostheses are low. In this preliminary study, no protrusion or reaction against the prosthesis was seen in any of our patients. The radiologic view of the prosthesis obtained 6 months later is shown. (Fig. 5). Its rigidity and suitable flexibility, easy applicability and malleability, fixation facilities to ossicular structures, and availability are the advantages of this prosthesis. Another important issue that should be considered is its price which costs only 1 Euro.

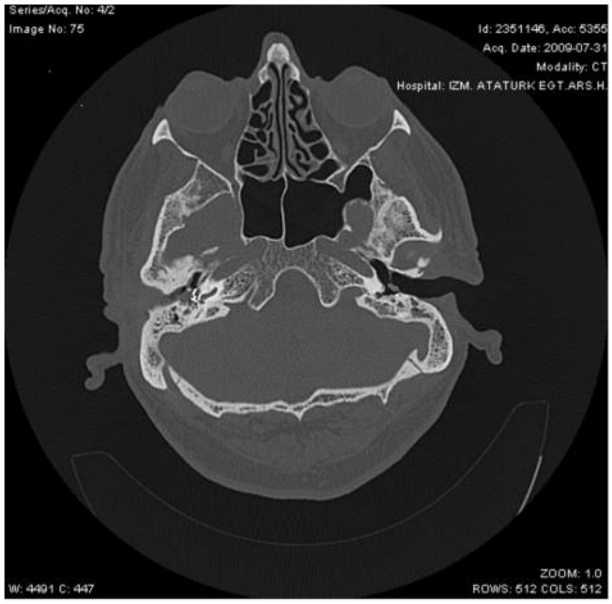

Figure 5. Control CT showing the wire prosthesis between the malleus and stapes.

Previously, Plester et al. used similar ossicular reconstruction techniques, but our prostheses are different with respect to the fixation of the prosthesis to the malleus and stapes and the stability of the fixation [15–17]. Titanium prostheses are costly and are difficult to find and stabilize. O'Reilly et al. reported that sculpted autologous or homologous incus interposition results in successful hearing, comparable to that reported in current allograft-prosthesis studies, has a very low extrusion rate, and remains stable over time [6]. Woods et al. suggested that incus interposition is as effective as titanium prostheses [18]. A study by Neudert et al. compared incus interposition with two different prostheses and reported that the results with titanium angular clip prostheses and titanium clip prostheses were better than those with incus interposition. The mean preoperative air bone gap of all patients included in this study was 25,5 dB. Postoperative air bone gap was 15,9dB with titanium angle prosthesis patients, 16,9dB with titanium clip prosthesis patients and 19,1dB with autologous incus interposition patients [19]. Gjuric et al. determined air bone gap was reduced to≤20dB in 62% of the cases in which PORPs were used. Total ossicular replacement prosthesis showed a residual air bone gap ≤20dB in 42% of the cases [12]. In our study; preoperative average ABG was 38.25 ± 11.98 dB, and the postoperative average ABG was 17.25 ± 9.92 dB. The preoperative average AC was 53.90 ± 14.99 dB, and the postoperative average AC was 34.05 ± 18.50 dB (Table 1). Both results were statistically significant (P = 0.001).

To achieve good long-term results, the connection between the implant and ossicle remnants should be firm and tight to enable good sound transmission. The connection must also be stable with changes in ambient air pressure, as even minor dislocations can lead to a significant reduction in the transfer of acoustic energy. However, although these circumstances are well known, dislocations of the prosthesis continue to be a common complication after middle-ear operations and are a major reason for long-term unsatisfactory postoperative hearing [4].

The best functional results with middle-ear implants are obtained with synthetic implants [9]. The most important factor affecting functional results is the grade of disease in the middle ear [20]. Success of ossiculoplasty during chronic otitis media surgery is decreased by pathology such as mucosal adherence, tympanosclerosis, eustachian tube dysfunction, otorrhea, and cholesteatoma [5]. The tympanoplasty technique is also important. It is known that hearing gains in ICWT patients are better than in CWDT cases. However, recent studies have emphasized that similar hearing gains could be obtained with CWDT [21,22]. In nine of 14 CWUT patients in whom we used our prosthesis, the postoperative ABG was <20 dB, but such a gap was only found in two of six CWDT patients. Our good results with the ICWT technique are similar to those reported in the literature.

Our prosthesis provides good conduction for the physiology of stapes movement. At speech frequencies, movement of the stapes is known to be predominantly similar to a piston (mediolateral). Above speech frequencies, the movement becomes a more complex rocking-like (anteroposterior and inferosuperior) movement that develops around the long and short axes of the stapedial footplate [3]. The new prosthesis provides these movements. Primarily, due to the lateral position of the malleus and medial position of the stapes, the new prosthesis transmits sound energy at nearly a right angle, which results in the piston movement of the stapes. Additionally, because the long axis of our prosthesis is in the same plane as the long axis of the stapes, the anteroposterior movement of the stapes can also be accomplished with our prosthesis. Moreover, the fixation of the tip of the prosthesis to the stapedial tendon improves the hearing results.

The safety of ossiculoplasty materials during MRI is controversial. According to the latest study by Syms [22], stainless steel (40.9%) has frequently been used for prostheses. That study noted that 87.6% of surgeons allow MRI after stapedectomy. In the same study, an in vivo evaluation was done using ferromagnetic stainless steel for stapes prosthesis in guinea pigs, and no displacement in the prostheses and no damage or reactive cells were seen around the oval window or vestibule after MRI. According to that study, MRI with <4.7 Tesla is safe in patients with stapes prosthesis.

Conclusion

Ossiculoplasty using malleus and stapes golden wire prosthesis gives successful results. The advantages of golden wire prostheses include low cost, biocompatibility, high stability, malleability, and shortened operation time. Our study shows that golden wire prostheses are biocompatible with ossiculoplasty, are easily applied, and are accepted by the tissue. This was a preliminary study; as we increase the number of cases using golden wire prosthesis, and with the development and perfection of the technique, we believe that the functional results will improve.

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