

An Analysis of Methods of Middle Ear Reconstruction and Their Effect on the Auditory Gain and Causes of Graft Failure in CSOM**Dhavala Dakshinamurthy¹, Mannam Ramesh², Ravindra Babu³**¹Associate Professor of ENT, Department of ENT, Government Medical College, Ongole, Andhra Pradesh^{2,3}Assistant Professor of ENT, Department of ENT, Government Medical College, Ongole, Andhra Pradesh

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Conflict of interest: Nil

Abstract:**Background:** Chronic suppurative Otitis media (CSOM) is a suppurative inflammatory disease of the middle ear cleft affecting its mucoperiosteal lining, clinically characterized by discharge from the ear and conductive deafness. A large number of surgical methods are adopted using various graft materials to reconstruct the tympanic membrane and the Ossicles to improve the hearing.**Aim of the study:** To analyze the role of surgical methods, graft material used in the restoration of anatomy and function of the middle ear mechanism; to study the causes of their failure.**Materials:** 78 Patients aged between 18 years and 67 years were studied for the effects of different Tympanoplasty procedures on the auditory gain and causes for graft failures over a period of two years. The patients were analysed after history taking, ENT clinical examination, radiological and auditory investigations and operative procedures. Cortical Mastoidectomy or modified radical Mastoidectomy with ossiculoplasty and tympanic membrane reconstruction were undertaken using autologous, heterologous and synthetic materials (TORP, PORP) for graft. Type I, II and III Tympanoplasty procedures were adopted. Postoperative hearing assessment after 6 months was done to conclude.**Results:** Among the 78 patients there were 21/78 (26.92%) 18 to 27 years, 27/78 (34.61%) in the age group of 28 to 37 years and 18/78 (23.07%) in the age group of 38 to 47 years. The mean age was 36.76± 5.34 years. There were 51/78 (65.38%) males and 27/78 (34.61%) females. Out of 78 patients, 44/78 (56.41%) were tubotympanic CSOM and 34/78 (43.58%) with Atticoantral CSOM. In Tubotympanic CSOM patients, PTA was 45 to 50 dB in 08.97% patients, 35 to 45 dB in 12.82% patients. Air bone gap of 35 to 30 dB was 15.38% patients, 30 to 25 dB in 08.97% patients. There was no statistical significant correlation between the various incidences of CSOM patients in the study (p value was more than 0.05).**Conclusions:** The final outcome of different Tympanoplasty procedures and Ossiculoplasty procedures using various graft materials was not based on the factors such as Gender, site, size of tympanic membrane perforations, grading of pneumatization but the principle of total eradication of the disease in the middle ear cleft and suitable reconstructive methods adopted based on the remnant ossicles and tympanic membrane.**Keywords:** CSOM, Middle ear, Reconstruction, Ossicles, graft, auditory gain and failure of graft.This is an Open Access article that uses a funding model which does not charge readers or their institutions for access and distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>) and the Budapest Open Access Initiative (<http://www.budapestopenaccessinitiative.org/read>), which permit unrestricted use, distribution, and reproduction in any medium, provided original work is properly credited.**Introduction**

Chronic suppurative Otitis media (CSOM) is a suppurative inflammatory disease of the middle ear cleft affecting its mucoperiosteal lining, clinically characterized by discharge from the ear and conductive deafness. [1] A large number of surgical methods are adopted using various graft materials to reconstruct the tympanic membrane and the Ossicles to improve the hearing. [2] In India CSOM is a common ENT disease for which patients attend the Outpatient department and is concerned as a major concern to both the family and the surgeon. [3] The prevalence of CSOM in India according to 2011 population reports is 06%.

[4] Which was found to higher than the prevalence in European countries; 01.8 to 02%. [5] Lack of awareness among the common people about CSOM and correlation between CSOM and diminished hearing was found to be main reason. [6] Hence patients attend the ENT surgeons at an advanced stage of the diseases which itself was a risk factor in achieving near total restoration of hearing. [7] The chances of restoring the normal anatomy and function of the middle ear mechanism increase by four fold if the patients and counseled to undergo surgery at an early stage. [8] The methods commonly adopted in India are cortical

mastoidectomy, Modified radical Mastoidectomy with Tympanoplasty type I or Type II or Type III and Type IV. [9] Reconstruction was primarily with Temporalis fascia, tragal perichondrium with or without cartilage, septal cartilage with or without perichondrium. [10] Ossicular reconstruction was done by harvesting the remnant Ossicles or preserved human Ossicles, malleolar rotation, Partial Ossicular replacement prosthesis (PORP) or Total Ossicular replacement prosthesis (TORP). [11] Synthetic materials used are Gold, Platinum and Teflon material based ossicles. [12] The success rate was assessed by Oto-endoscope or examination under microscope to observe the graft healing ossicular mobility and absence of discharge. [12] The functional outcomes were measured using pure tone audiometry, impedance audiometry and noting the, Pure tone average gained and closure of Air Bone gap in pure tone audiometry. [13] The complications noted are facial weakness, Labyrinthitis and recurrence of discharge from the ear. [14] The present study was conducted to assess the final outcome of these surgeries in terms of functional restoration and good quality of life index.

Type of Study: A prospective analytical study

Period of Study: February 2021 to January 2023

Institute of study: Government Medical College, Ongole, Andhra Pradesh.

Materials: A Prospective study was conducted in the Government Medical College, Ongole, Andhra Pradesh between February 2021 and January 2023. 78 patients attending the ENT OPD with the diagnosis of CSOM were included in the study. An Ethics Committee clearance was obtained from the Institute. An Ethics committee approved proforma was used to collect the data.

Inclusion Criteria: Patients aged between 18 and 67 years were included. Patients of both the genders were included. Patients with CSOM of tubotympanic and Active squamosal disease in quiescent stage were included. Patients with only conductive deafness were included. Patients willing to participate in the study were included.

Exclusive Criteria: Patients aged below 18 years and above 67 years were excluded. Patients with sensory-neural deafness and intracranial complications were excluded. Patients with immunodeficiency diseases were excluded. Patients with Diabetes Mellitus were excluded. All the patients were subjected to thorough history taking, ENT clinical examination including examination under the microscope. Radiological investigations like x-ray and CT scan temporal bones were undertaken in all the patients. Audiological evaluation with Pure tone audiometry pre-operatively. All the patients were subjected to

either cortical Mastoidectomy or modified radical Mastoidectomy before undertaking reconstructive procedures for the tympanic membrane and Ossicles. Type I, II and III Tympanoplasty procedures were adopted in the as per the standard indications in the study. Temporalis fascias, tragal cartilage with perichondrium, septal cartilage with perichondrium were used to reconstruct the tympanic membrane. For ossicular reconstruction autologous ossicles, septal cartilage was used. PORP and TORP Teflon prostheses were used where the natural ossicles were unavailable. All the patients were assessed for hearing 6 weeks after the surgical procedure during the post-operative follow up. All the data was analysed using standard statistical methods.

Statistical Analysis: Statistical parameters used were mean, standard deviation, percentages and levels of significance were tested using student T test. The level of correlation was tested using Chi square test. P value less than 0.05 was taken as significant.

Results

Among the 78 patients with CSOM included in the study there were 21/78 (26.92%) patients in the age group of 18 to 27 years. There were 27/78 (34.61%) patients in the age group of 28 to 37 years. There were 18/78 (23.07%) patients in the age group of 38 to 47 years. There were 08/78 (10.25%) patients in the age group of 48 to 57 years. There were 04/78 (05.12%) patients in the age group of 58 to 67 years. (Table 1) The mean age was 36.76 ± 5.34 years. There were 51/78 (65.38%) male patients and 27/78 (34.61%) female patients with a male to female ratio of 1.88:1. There were 44/78 (56.41%) patients with tubotympanic type of CSOM and 34/78 (43.58%) patients with Atticoantral type of CSOM. Small central perforation was noted in 14/78 (17.94%), medium central perforation was noted in 16/78 (20.51%) patients and large central perforation was noted in 17/78 (21.79%) patients. Perforation of pars flaccida was observed in 11/78 (14.10%) patients, Perforation of postero-superior quadrant was observed in 08/78 (10.25%) patients, retraction pocket was observed in 12/78 (15.38%) patients. (Table 1) Radiological investigations showed acellular mastoid in 22/78 (28.20%) patients, poorly cellular mastoid in 24/78 (30.76%) patients, Moderate cellular mastoid in 16/78 (20.51%) patients and well pneumatized mastoid in 16/78 (20.51%) patients. In Tubotympanic CSOM patients, pure tone Average (PTA) was between 45 and 50 dB in 07/78 (08.97%) patients, between 35 and 45 dB in 10/78 (12.82%) patients, between 25 and 35 dB in 14/78 (17.94%) patients, between 15 and 25 dB in 06/78 (20.51%) patients. Air bone gap of 35 to 30 dB was observed in 12/78 (15.38%)

patients, 30 to 25 dB was observed in 07/78 (08.97%) patients, 25 to 20 dB was observed in 19/78 (24.35%) patients, 20 to 15 dB was observed in 06/78 (07.69%) patients, less than 15dB was observed in 03/78 (03.84%) patients. (Table 1) In Atticoantral type of CSOM patients, pure tone Average (PTA) was between 45 and 50 dB in 16/78 (20.51%) patients, between 35 and 45 dB in 11/78 (14.10%) patients, between 25 and 35 dB in 03/78 (03.84%) patients, between 15 and 25 dB in 01/78

(01.28%) patients. Air bone gap of 35 to 30 dB was observed in 15/78 (19.23%) patients, 30 to 25 dB was observed in 06/78 (07.69%) patients, 25 to 20 dB was observed in 05/78 (06.41%) patients, 20 to 15 dB was observed in 04/78 (05.12%) patients, less than 15dB was observed in 01/78 (01.28%) patients. (Table 1) There was no statistical significant correlation between the various incidences of CSOM patients in the study (p value was more than 0.05).

Table 1: Shows the Demographic Data, Clinical Findings and Functional Assessment of the Patients with CSOM in the Study (N-78)

Observation	Number	Percentage	P value
Age in years			
18 to 27	21	26.92	0.214
28 to 37	27	34.61	
38 to 47	18	23.07	
48 to 57	08	10.25	
58 to 67	04	05.12	
Gender			
Male	51	65.38	0.301
Female	27	34.61	
Diagnosis			
Tubotympanic	44	56.41	0.411
Attico-antral	34	43.58	
Type of Perforation			
Central- 47			0.236
Small	14	17.94	
medium	16	20.51	
Large	17	21.79	
Attic- 31			
Pars flaccida	11	14.10	
Postero-superior	08	10.25	
Retraction pocket	12	15.38	
X-ray/ CT scan Mastoids			
Acellular mastoid	22	28.20	0.312
Poorly pneumatised	24	30.76	
Moderately pneumatised	16	20.51	
Well pneumatised	16	20.51	
Audiological Assessment			
Tubotympanic CSOM- 47			0.211
PTA			
45 to 50 dB loss	07	08.97	
35 to 45 dB loss	10	12.82	
25 to 35 dB loss	14	17.94	
15 to 25 dB loss	16	20.51	
a-b gap			
35 to 30 dB	12	15.38	
30 to 25 dB	07	08.97	
25 to 20 dB	19	24.35	
20 to 15 dB	06	07.69	
Less than 15 dB	03	03.84	
Atticoantral CSOM- 31			
PTA			
45 to 50 dB loss	16	20.51	
35 to 45 dB loss	11	14.10	
25 to 35 dB loss	03	03.84	
15 to 25 dB loss	01	01.28	
a-b gap			

35 to 30 dB	15	19.23	
25 to 30 dB	06	07.69	
20 to 25 dB	05	06.41	
15 to 20 dB	04	05.12	
Less than 15 dB	01	01.28	

Type I Tympanoplasty was performed in 25/78 (32.05%) patients, Type II Tympanoplasty was performed in 29/78 (37.17%) Patients, Type III Tympanoplasty was performed in 24/78 (30.76%) patients. Type "a" Ossiculoplasty was done in 36/78 (46.15%) patients, Type "b" Ossiculoplasty was done in 23/78 (29.48%) patients, Type "c" Ossiculoplasty was done in 11/78 (14.10%) patients and Type "d" Ossiculoplasty was done in 08/78 (10.25%) patients. (Table 2) Temporalis fascia was used as a graft in 31/78 (39.74%) patients, Tragal cartilage with perichondrium (single island) was used as a graft in 19/78 (24.35%) patients, Temporalis fascia was used as a graft in 31/78 (39.74%) patients, Tragal cartilage with perichondrium (double island) was used as a graft in 16/78 (20.51%) patients, Septal cartilage with single island was used as a graft in 07/78

(08.97%) patients, Septal cartilage with double island was used as a graft in 05/78 (06.41%) patients. Autologous ossicles were used for ossiculoplasty in 32/78 (41.02%) patients, Heterologous ossicles were used for ossiculoplasty in 13/78 (15.38%) patients, Autologous septal cartilage was used for ossiculoplasty in 07/78 (08.97%) patients, Heterologous septal cartilage was used for ossiculoplasty in 03/78 (38.84%) patients, TORP was used in 08/78 (10.25%) patients, PORP was used in 09/78 (11.53%) patients, Gold prosthesis was used in 02/78 (02.56%) patients and Platinum prosthesis was used in 01/78 (01.28%) patients. (Table 2) There was no significant statistical correlation between the various incidences of CSOM patients and the procedures adopted in the study (p value was more than 0.05).

Table 2: Showing the Type of Surgeries, Reconstructive Methods Adopted and the Graft Materials used in the Study (N-78)

Observation	Number	Percentage	P value
Tympanoplasty			
Type I	25	32.05	0.211
Type II	29	37.17	
Type III	24	30.76	
Ossiculoplasty			
a	36	46.15	0.305
b	23	29.48	
c	11	14.10	
d	08	10.25	
Graft for Tympanic membrane			
Temporalis fascia	31	39.74	0.421
Tragal cartilage with perichondrium			
Single island	19	24.35	
Double island	16	20.51	
Septal cartilage with Perichondrium			
Single island	07	08.97	
Double island	05	06.41	
Graft for Ossicles			
Autologous Ossicle	32	41.02	0.114
Heterologous Ossicle	13	15.38	
Autologous septal cartilage	07	08.97	
Heterologous septal cartilage	03	03.84	
TORP	08	10.25	
PORP	09	11.53	
Gold	02	02.56	
Platinum	01	01.28	

In Type Tympanoplasty graft uptake was 96%. In Type II the graft uptake was 86.20% and in Type III the graft uptake was 95.83%. In type "a" ossiculoplasty the uptake was 94.44%, In type "a" ossiculoplasty the uptake was 94.44%, In type "b"

ossiculoplasty the uptake was 86.95%, In type "c" ossiculoplasty the uptake was 81.81% and type "d" the uptake was 100%. (Table 3) Temporalis fascia graft uptake was in 90.32% patients, Tragal cartilage with perichondrium (single island) uptake

was in 89.47%) patients, Tragal cartilage with perichondrium (double island) uptake was in 81.25% patients, Septal cartilage with single island the uptake was in 85.71% patients, Septal cartilage with double island graft the uptake was in 100% patients. (Table 3) Autologous ossicles uptake was in 93.75% patients, Heterologous ossicles uptake was in 92.30% patients, Autologous septal cartilage uptake was in 100% patients, Heterologous septal

cartilage uptake was in 100% patients, TORP uptake was in 87.5% patients, PORP uptake was in 100%) patients, Gold prosthesis uptake was in 100% patients and Platinum prosthesis uptake was in 100%) patients. (Table 3) There was significant statistical correlation between the types in Tympanoplasty procedures adopted and graft uptake using different materials in CSOM patients in the study (p value was less than 0.05).

Table 3: Showing the Graft Uptake in Different Types of Procedures Adopted (N-78)

Observation	Number	Graft Uptake	%	Significance
Tympanoplasty				
Type I	25	24	96	0.001
Type II	29	25	86.20	
Type III	24	23	95.83	
Ossiculoplasty				
a	36	34	94.44	0.001
b	23	20	86.95	
c	11	09	81.81	
d	08	08	100	
Graft for Tympanic membrane				
Temporalis fascia				0.001
Tragal cartilage with perichondrium	31	28	90.32	
Single island				
Double island	19	17	89.47	
Septal cartilage with Perichondrium	16	13	81.25	
Single island	07	06	85.71	
Double island	05	05	100	
Graft for Ossicles				
Autologous Ossicle	32	30	93.75	
Heterologous Ossicle	13	12	92.30	
Autologous septal cartilage	07	07	100	
Heterologous septal cartilage	03	03	100	
TORP	08	07	87.5	
PORP	09	09	100	
Gold	02	02	100	
Platinum	01	01	100	

Among the Type I Tympanoplasty patients for CSOM improved hearing in terms of gain in PTA was observed more than 35dB in 92% patients, in Type II Tympanoplasty patients the auditory gain in PTA was more than 35dB in 89.65% patients and in Type III Tympanoplasty patients the auditory gain in PTA was more than 35dB in 87.5% patients. Similarly the closure of air bone gap to less than 15 dB was in 96% patients in Type I Tympanoplasty. The closure of air bone gap to less than 15 dB in 96.55% patients in Type II Tympanoplasty patients and the closure of air bone gap to less than 15 dB in 83.33% patients in Type III Tympanoplasty patients. (Table 4) In type “a” ossiculoplasty patients for CSOM improved hearing in terms of gain in PTA was observed more

than 35dB in 88.88% patients, in Type “b” ossiculoplasty patients it was 84.61% patients, in Type “c” ossiculoplasty patients it was 63.63% patients and in type “d” ossiculoplasty patients it was 62.5% patients. (Table 4) Similarly the closure of air bone gap to less than 15 dB was observed in 86.11% among the type “a: ossiculoplasty patients, in type “b” ossiculoplasty the closure was in 88.46% patients, in type “c” ossiculoplasty it was 63.63% patients and in type “d” ossiculoplasty it was 50% patients. (Table 4) There was significant statistical correlation between the types of Tympanoplasty procedures adopted and Auditory gain using different materials in CSOM patients in the study (p value was less than 0.05).

Table 4: Shows the Auditory Gain Observed in Patients Undergoing Tympanoplasty and Ossiculoplasty Procedure (N-78)

Type of surgeries	Improved Hearing in terms of PTA		Improved Hearing in terms of a-b gap		P value
	More than 35 dB	Less than 35 dB	Less than 15 dB	More than 15 dB	
Tympanoplasty					
Type I- 25	23 (92%)	02 (08%)	24 (96%)	01 (04%)	0.001
Type II- 29	26 (89.65%)	03 (10.4%)	28 (96.55%)	01 (03.44%)	
Type III- 24	21 (87.5%)	03 (12.5%)	21 (87.5%)	03 (12.5%)	
Ossiculoplasty					
a- 36	32 (88.88%)	04 (11.22%)	31 (86.11%)	05 (13.99%)	0.001
b- 26	22 (84.61%)	04 (15.39%)	23 (88.46%)	03 (11.53%)	
c- 11	07 (63.63%)	04 (36.36%)	07 (63.63%)	04 (36.36%)	
d- 08	05 (62.5%)	03 (37.5%)	04 (50%)	04 (50%)	

Discussion

Restoration of hearing function to near normal and achieving the dry ear without interfering with normal anatomy of the middle ear cleft was the main goal of surgeon while treating CSOM patients with various surgical procedures. The present analyzed both anatomical and functional results in CSOM patients of both types undergoing canal wall down/up Tympanoplasty with Ossiculoplasty and canal wall down Tympanoplasty with Ossiculoplasty. The demographic factors like age, gender, type of CSOM and clinical symptoms were correlated with the type of CSOM in the study. The causes of graft failure and the type of CSOM treated were correlated with the type of Tympanoplasty undertaken. Among the 78 patients there were 21/78 (26.92%) 18 to 27 years, 27/78 (34.61%) in the age group of 28 to 37 years and 18/78 (23.07%) in the age group of 38 to 47 years. The mean age was 36.76 ± 5.34 years. There were 51/78 (65.38%) males and 27/78 (34.61%) females with a male to female ratio of 1.88:1. This sample was correlated with the study of McGrew et al.- 29.9 years [13], Webb et al. – 33.2 years [14] and Prasad et al.- 31.32 years [10].

Review of literature showed not much about the predictive values of graft uptake based on the anatomical factors in the procedures of Tympanoplasty and Ossiculoplasty. Sheehy JL, Anderson RG et al [11] the success rate of graft uptake is relied upon the goals of total eradication of the disease from the middle ear cleft, achieving an intact tympanic membrane with fully aerated middle ear cleft with restored middle ear mucosa and a good contact between the sound conducting mechanism between mobile tympanic membrane and inner ear. Most of the ENT surgeons follow the Bellucci's classification [15] to assess the role of risk factors in the graft uptake in Tympanoplasty and Ossiculoplasty procedures. In this study also the Bellucci's risk factors [16] were used to predict the success rate; (status of discharge from the ear, size of the perforation, erosion of the stapes arch, mastoidectomy). Most of the articles in the

literature have analysed the risk factors one at a time to the rate of uptake and restoration of functional gain in hearing but in this study multiple factors are taken into consideration to assess the effect of the procedures, graft material, status of the mastoid pneumatization simultaneously and analysed in a multivariate analysis. 17.94% of the patients had small central perforation of the tympanic membrane, 20.51% of the patients had medium size perforations, and 21.79% of the patients had large central perforation of the tympanic membrane in Tubotympanic type of CSOM. 14.10% of the patients had pars flaccida perforation, 10.25% of the patients had postero-superior quadrant perforation, and 15.38% of the patients had retraction pockets in pars flaccida. Review of literature showed that there was varying reports regarding uptake of grafts based on the site and size of the perforations. Adkins [17] stated that larger the perforation poorer the uptake of grafts. Recently reports from Wasson et al. [18] Similarly Corso EDe, Marchese MR, [19] stated that mastoid cellularity had an effect on the graft uptake and observed 36% of failure of graft uptake in acellular mastoids unlike in the present study it was less than 12% (Table 3). Jackler et al. [20] from their series observed that the improvement in graft uptake was proportionate to the size of the mastoid air cell system pneumatization. In the present study irrespective of the size of the mastoid and pneumatization the graft uptake was noted in more than 90% of the patients (Table 3). In the present study patients with Tubotympanic type, 32.05% of patients underwent Type I Tympanoplasty, 37.17% of patients underwent Type II Tympanoplasty, and 30.76% of patients underwent Type III Tympanoplasty. 46.15% of the patients underwent Type "a" Ossiculoplasty, 29.48% of the patients underwent Type "b" Ossiculoplasty, 14.10% of the patients underwent Type "c" Ossiculoplasty, and 10.25% of the patients underwent Type "d" Ossiculoplasty. There was significant statistical correlation between the types in Tympanoplasty procedures adopted and graft uptake using different materials in CSOM patients in the study (p value

was less than 0.05). In their study Khan et al. [21] noted that among their 82 patients who underwent Tympanoplasty only 84% had graft uptake. Whereas Hay A, Blanshard J et al. [22] could get graft uptake in only in 82% of their 48 patients who had undergone Tympanoplasty and Ossiculoplasty procedures.

In the present study the graft uptake was ranging from 81.25% to 96% depending upon the type of Tympanoplasty. On the other hand in the present study the Post-operative hearing evaluation was analysed and found that 92% patients of Type I Tympanoplasty, 89.65% of the Type II Tympanoplasty patients and 87.5% of the type III Tympanoplasty patients had a gain of more than 35dB. The closure of air bone gap to less than 15 dB was in 96% patients in Type I Tympanoplasty, 96.55% patients in Type II Tympanoplasty patients and the 83.33% patients in Type III Tympanoplasty patients. (Table 4) 88.88% of the type “a” ossiculoplasty patients, 84.61% of the Type “b” ossiculoplasty patients, 63.63% of the type “d” ossiculoplasty patients had a closure up to 15dB. (Table 4) Similar studies by Kyrodimos et al. [23] in 52 patients with type III “shield” cartilage Tympanoplasty the auditory gain in terms of PTA-ABG less than 20 dB was in 54%, and less than 25 dB in 79% of the patients.

Whereas Schember S et al. [24] observed from their study on 111 patients with PORP or TORP the auditory gain of post-operative PTA—ABG of PORP less than 20 dB in 77% and TORP less than 20 dB in 52% respectively.

Conclusions: The final outcome of different Tympanoplasty procedures and Ossiculoplasty procedures using various graft materials was not based on the factors such as Gender, site, size of tympanic membrane perforations, grading of pneumatization but the principle of total eradication of the disease in the middle ear cleft and suitable reconstructive methods adopted based on the remnant ossicles and tympanic membrane.

The auditory gain measured in terms of gain in PTA and closure of air bone gap was an ideal method of auditory assessment matching the stereophonic hearing.

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