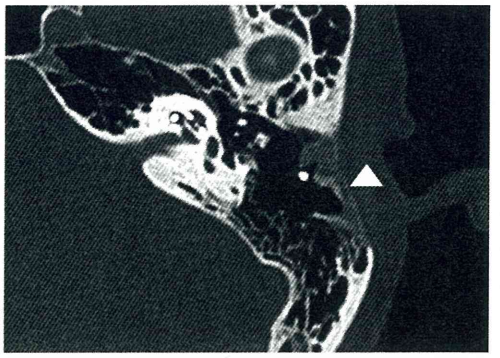

図 4　術後 5 か月後の側頭骨 CT 所見
骨パテにより閉鎖部は骨化し，良好な含気が得られている（矢頭：骨化部位）。

後 1 か月では気導聴力の改善を認め術前と比較し低音部は平均 17 dB の聴力悪化にとどまり，良好な聴力温存が可能であった。

術後 5 か月後の側頭骨 CT では，骨パテによる閉鎖部は骨化し，中耳，乳突蜂巣の含気は良好であった（**図 4**）。

IV．考察

従来の人工内耳埋込み術は両側高度難聴に対して適応とされているため，中耳伝音系に大きな注意を払う必要性がほとんどなかった。しかし，両側高音急墜型感音難聴症例に対する EAS 埋め込みは残存聴力をいかに保存できるかが重要となる。特に術後早期は中耳内の血腫形成や炎症などにより気導聴力が安定せず，これが遷延することは人工内耳のマッピングに支障をきたす可能性がある。したがって，EAS 症例に対して骨導聴力をいかに保存できるかが重要であることは第一条件であるが，中耳内をいかに早く物理的，生理的に元の状態に戻すか，または中耳内の変化を最小限にとどめるかが術後早期の QOL に影響するため，対策が必要である。

乳突蜂巣の機能はいまだ不明な点が多いが，特にヒトにおいては含気を促し，中耳腔陰圧化を防ぐ役割や乳突蜂巣がガス交換能を有していると考えられている。また，広い含気腔では中耳腔容積が大きいため，不要な圧変化が吸収，分離されて伝音の効率を上げ，良好な伝音系の働きを促すことが考えられている[3]。

柳原ら[4,5]は，乳突削開後の中耳含気性を回復することは伝音機能の回復を確実にするためには不可欠であり，骨パテによる乳突皮質形成術は中耳含気性の改善に好影響を与えると報告しており，チタンメッシュやセプラフイルム®による乳突皮質形成の報告でも中耳，乳突蜂巣の良好な含気化が得られるとの報告もみられる[6〜8]。

今回われわれは，より早期の中耳伝音系の回復を目的として乳突皮質形成を EAS 症例に対して行った。今回の結果では，乳突皮質形成により術後の気骨導差の増大の軽減および早期の気骨導差の改善をきたす可能性が示唆された。従来の乳突皮質形成を行わなかった症例では，人工内耳埋め込み術の際に側頭筋を広く剝離するため，術後側頭筋からの血液が乳突皮質削開部より中耳腔内へ流入し術後鼓室内血腫を認めていたと考えられる。一方，乳突皮質形成症例では術後早期より漿液性滲出液の貯留を認め，およそ 1 週間後に貯留液が最も著明となった。これに伴い気骨導差も 1 週間後に最大となり，鼓室内の貯留液の消失とともに気骨導差の改善を認めた。漿液性滲出液の原因としては，骨パテからの滲出および削開した乳突蜂巣粘膜や中耳粘膜からの直接的な滲出と考えられ，これが術後徐々に鼓室内に貯留し約 1 か月後には消失したものと考えられる。今回の乳突皮質形成の目的は中耳腔の早期含気化だけではなく早期の聴力変化のモニタリングを可能にすることにもある。中耳含気腔が正常な症例では乳突皮質形成の有無にかかわらず最終的には中耳腔は含気化する。しかしながら，EAS では特に術直後の聴力のモニタリングが重要であり，人工内耳電極挿入により聴力が悪化した場合にはそれに迅速に対応する必要がある。今回の症例では聴力悪化例は認められなかったが，術直後では中耳に貯留液があるために聴力変化がどの因子によるかの判断がむずかしい。今回の結果からそれらの因子をより有効に除外することが明らかになった。

また，術後 CT でも乳突削開部および鼓室内は肉芽形成なども認めず良好な含気が得られており，より術前に近い生理的，物理的な機能を保存できると考えられる。鼓室内の血腫の貯留は中耳内の感染源になる可能性や器質化に伴い中耳内への貯留が遷延する可能性，Web 形成による中耳内

にブロックをきたしコレステリン肉芽腫の誘因になることも予想される。今回はすべての症例で乳突蜂巣の発育が良好な症例に対して行ったため，大きく中耳の含気に影響しなかったが，中耳換気能および耳管機能が未発達の小児に対しては特に注意が必要と考えられ，将来的にEASが小児へ適応拡大となった場合，聴力温存の観点からも早期の中耳所見の改善は重要になると考えられる。

したがって，小児や乳突蜂巣の発育不良例，耳管機能低下例に対して骨パテによる乳突皮質形成は鼓室内血腫の予防および早期の中耳腔内の安定により有利に働くと考えられる。

今後さらに症例を重ね聴力温存に向けた検討を続けていきたいと考える。

V. まとめ

EAS症例に対するより良好な聴力温存のための工夫として，乳突削開部に対して骨パテ板を用いた乳突皮質形成を施行した。術後，鼓室内は漿液性滲出液の貯留を認め，術後1か月後には良好な鼓室内の含気化が得られた。

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□ Abstract

Post-operative hearing effects of mastoid cortex-plasty in EAS patients

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EAS (electric acoustic stimulation) accompanied with residual hearing preservation is a new trend for patients with residual hearing at lower frequencies. The good environment of middle ears also have to be paid attention to preserve residual hearing. Especially, reduction of air-bone gap at the early stage after cochlear implantation may increase the quality of life for hearing preservation. Therefore, we attempted to use mastoid cortex-plasty using bone pate to provide better middle ear environment. The middle ears had serous effusions after implantations and the middle ear effusions and air-bone gap were improved early.

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高音急墜型難聴の語音弁別能の検討

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【はじめに】

近年、低音域に残存聴力を有するが、高音域の聴力が高度に低下している高音急墜型の聴力像を呈する難聴患者に対する新しい治療法として、残存聴力活用型人工内耳（EAS：electric acoustic stimulation）（以下 EAS）が開発され、欧米を中心に実用化されている。欧米での EAS の適応基準は聴力と語音弁別能で定義されており、125 から 750Hz の純音聴力閾値が 65dB 以内であり、2000Hz では 80dB 以上、4000、8000Hz では 80dB 以上の高音急墜型難聴であること、静寂下における 65dBSPL 呈示の単音節聴取能が 60% 未満であることとされている。今回、日本語話者における EAS の有用性を検討することを目的に、欧米と同様の適応聴力を満たす症例、低周波数である 500Hz が適応に満たない症例、高周波数である 2000Hz あるいは 4000Hz の純音聴力検査結果が適応基準に満たない症例の語音弁別検査の成績に関して検討を行ったので報告する。

【対象と方法】

2001 年 7 月から 2011 年 9 月までに当科において純音聴力検査、語音弁別検査（呈示音圧 80dB、70dB、60dB、50dB）を実施した症例のうち、全周波数が EAS の適応基準（125 から 500Hz が 65dB 以内、2000Hz が 80dB 以上、4000、8000Hz が 80dB 以上）を満たしている 50 例（そのうち、1000Hz が 65dB 以内である 25 例、1000Hz が 70dB 以上である 25 例）、500Hz のみ適応外である 23 例、2000Hz のみ適応外である 25 例、4000Hz が適応外である 81 例を対象（図 1 に平均聴力レベルを示す）とし、語音弁別検査（67－S）の成績を比較検討した。

【結果】

図 2 に各群の語音弁別検査の結果を示した。呈示音圧 80dB 時には、全周波数適応基準を満たす群では 84.9% に対して、500Hz のみ適応外である群では 40.6%、2000Hz のみ適応外である群では 76.7%、4000Hz のみ適応外である群では 90.7% であり、全周波数とも適応基準を満たす群と、500Hz のみ適応外である群の間に有意差が認められた（$p<0.001$）。

また、全周波数とも適応基準を満たす群を、1000Hz の聴力が 70dB 以上である群と、65dB 以内である群に分けて比較を行うと、呈示音圧 80dB 時には、1000Hz の聴力が 70dB 以上の群では 74.6%、全周波数適応基準を満たす群では 84.9%、1000Hz の聴力が 65dB 以内の群では 92.0% となり、1000Hz の聴力が 70dB 以上の群と 65dB 以内の群の間にも有意差が認められた（$p<0.01$）。

また、日常会話レベルである呈示音圧 60dB 時では、500Hz のみ適応外では 13.0%、1000 Hz の聴力 70dB 以上では 29.4%、全周波数適応聴力では 38.0%、1000Hz の聴力 65dB 以内で

は 43.9%、2000Hz のみ適応外では 39.4%、4000Hz のみ適応外では 45.3% であった。呈示音圧 80dB 時と同様に、1000Hz の聴力が 70dB 以上の群と 65dB 以内の群の間にも有意傾向が認められた（$p<0.1$）。

【考察】

今回の検討により、呈示音圧 80dB 時には、全周波数適応基準を満たす群と 500Hz のみ適応外である群の間に有意差が認められた（$p<0.001$）。また、1000Hz の聴力が 70dB 以上の群と 65dB 以内の群の間では、呈示音圧 60dB では有意傾向が認められ（$p<0.1$）、呈示音圧 80dB では有意差が認められた（$p<0.01$）。日本語は全体のおよそ 60% が母音であることが報告されており、また母音の周波数は 1000Hz 以下であることより、日本語の聴取には 1000 Hz 以下の低音域の聴力が重要であることが改めて確認された。

また、高音急墜型の難聴の場合、高音域の周波数を用いる子音を弁別することが難しいことが推測される。今回の検討においても、60dB 時の語音弁別能は 50% 以下であり、日常会話でも半分程度しか聴きとることができないことが考えられ、高音部を補聴することの必要性が改めて示された。また、今回は純音聴力検査と単音節のみの検討だが、実際の日本語の聴取においては、単語や文章の流れなどからの類推していることが考えられることより、今後は単語、文章においての検討を行うことが必要である。また、生活環境に近い雑音下での弁別能の検討も必要であると考えられる。

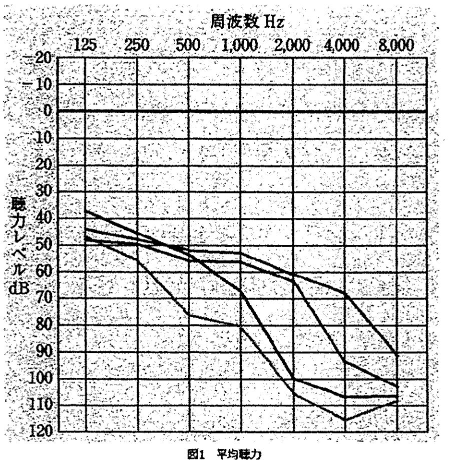

図1 平均聴力

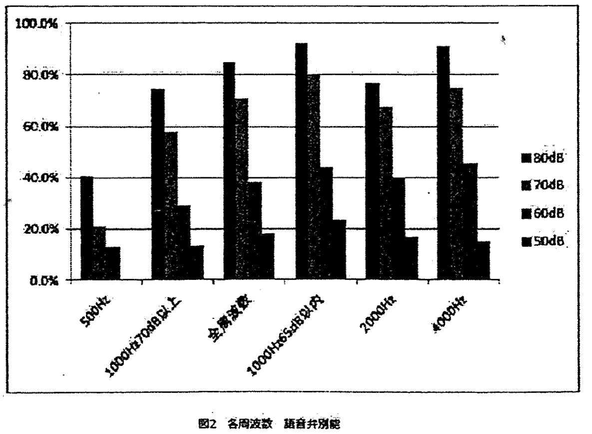

図2 各周波数 語音弁別能

Acta Oto-Laryngologica. 2014; Early Online, 1–11

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ORIGINAL ARTICLE

Hearing preservation and clinical outcome of 32 consecutive electric acoustic stimulation (EAS) surgeries

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Abstract

Conclusions: Our results indicated that electric acoustic stimulation (EAS) is beneficial for Japanese-speaking patients, including those with less residual hearing at lower frequencies. Comparable outcomes for the patients with less residual hearing indicated that current audiological criteria for EAS could be expanded. Successful hearing preservation results, together with the progressive nature of loss of residual hearing in these patients, mean that minimally invasive full insertion of medium/long electrodes in cochlear implantation (CI) surgery is a desirable solution. The minimally invasive concepts that have been obtained through EAS surgery are, in fact, crucial for all CI patients. *Objectives:* This study was conducted to evaluate hearing preservation results and speech discrimination outcomes of hearing preservation surgeries using medium/long electrodes. *Methods:* A total of 32 consecutive minimally invasive hearing preservation CIs (using a round window approach with deep insertion of a flexible electrode) were performed in 30 Japanese patients (two were bilateral cases), including patients with less residual hearing. Hearing preservation rates as well as speech discrimination/perception scores were investigated on a multicenter basis. *Results:* Postoperative evaluation after full insertion of the flexible electrodes (24 mm, 31.5 mm) showed that residual hearing was well preserved in all 32 ears. In all patients, speech discrimination and perception scores were improved postoperatively.

Keywords: *Deep insertion, residual hearing, high-frequency hearing loss*

Introduction

Hearing preservation with electric acoustic stimulation (EAS) is a new trend for patients with residual hearing at the lower frequencies. Recent techniques, including round window insertion [1], use of minimally invasive electrodes [2,3], and postoperative steroid administration [4], enable hearing preservation rates of around 90–100% [5–11]. We demonstrated in our previous report that hearing preservation can be achieved even in the presence of a long electrode covering the residual hearing region [12]. This is an extremely important observation not only for EAS, but also because of the advantage of the electrode being in place to cover future hearing deterioration, which is very likely to happen as hearing loss in almost all the candidates is more or less progressive. A recent series of studies in different centers further confirmed that hearing

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(Received 23 January 2014; accepted 7 February 2014)

ISSN 0001-6489 print/ISSN 1651-2251 online © 2014 Informa Healthcare
DOI: 10.3109/00016489.2014.894254

preservation could be possible with full insertion of a longer electrode [4,6,8,9,12–15].

When performing the hearing preservation surgery, together with the natural course of progressive hearing loss, the surgeon should keep in mind that hearing threshold shift is unavoidable in the majority of cases after insertion of an electrode. To choose the optimal electrode for each individual, detailed data of hearing threshold shifts on a multicenter basis are crucial.

We have previously published a report on short-term hearing preservation results of five cases included in the current paper [12]. The present study expanded the duration of observation, the number of patients, and the number of the centers.

In this study, based on the minimally invasive concepts and using a round window insertion, we evaluated (1) hearing preservation results in 32 consecutive surgeries in 30 patients (including 2 bilateral cases), (2) the postoperative threshold shift of air conduction and bone conduction, (3) whether or not EAS is beneficial for Japanese-speaking patients, and (4) whether or not EAS is beneficial even for patients who do not meet the current audiological EAS criteria.

Material and methods

We performed 32 consecutive hearing preservation surgeries in 30 patients with residual hearing (Table I) who all had late or post-lingual onset, high-frequency involved sensorineural hearing loss. The subjects were divided into two groups according to the length of the electrode used. Group 1 consisted of 29 ears in 27 patients who received MEDEL PULSAR® with a 24 mm FLEX24® device. Among them were 24 patients (case nos. 1–24) who participated in a multicenter clinical trial in Japan and fulfilled the audiological criteria for EAS, slightly modified from that of a multicenter trial in the EU. (The criteria were: pure-tone hearing levels bilaterally at 65 dBHL for 125 Hz, 250 Hz, and 500 Hz; 80 dBHL at 2000 Hz; and 85 dBHL at 4000 and 8000 Hz; as well as minimal benefit from conventional hearing aids, i.e. monosyllable scores in quiet under 60% in the best aided condition.) The remaining three patients (case nos. 25–27; two of which were bilateral cases) had hearing levels only partially fulfilling the above EAS criteria, therefore were not included in the clinical trial. Group 2 comprised three ears in three patients who had less residual hearing and received longer (31.5 mm length) electrodes. One patient (no. 28) received a MEDEL COMBI40+® with a 31.5 mm Standard electrode. Two patients (nos. 29 and 30) received MEDEL PULSAR® with a 31.5 mm FLEXSOFT® electrode. A round window approach was used and full insertion of the electrode was achieved in all 32 surgeries.

The ages of the patients at time of surgery ranged from 21 to 71 years and all had late or post-lingual onset hearing loss at higher frequencies that was slowly progressive, starting at age 3–52 years (Table I).

The round window approach was applied to reduce the insertion damage of the cochlea. The surgeries were performed by four surgeons (Table I). Intraoperative and postoperative systemic dexamethasone treatment was given according to our protocol [12], i.e. intraoperative infusion of dexamethasone sodium phosphate (8 mg) applied before drilling of the bony edge of the round window niche and postoperative dexamethasone treatment administered for 6 days (8 mg, 8 mg, 4 mg, 4 mg, 2 mg, and 2 mg, respectively). The insertion depth of the electrode and the corresponding frequencies were estimated using postoperative X-ray (X-ray digital linear tomosynthesis).

EAS fitting

The frequency at which the audiogram surpassed 65 dBHL hearing loss was determined and the CI low frequency crossover point was set at that frequency point for fitting the EAS.

Audiometric evaluation

Audiometric evaluation from 125 to 8000 Hz was performed preoperatively and at 1, 3, 6, and 12 months after the initial EAS stimulation. Pure-tone hearing was evaluated at 4 weeks postoperatively; at the time of CI and EAS fittings; as well as at 3, 6, and 12 months postoperatively. Proper masking was applied to the contralateral ear and bone-conduction thresholds were used.

To evaluate speech perception outcomes, speech discrimination scores (using the 67S Japanese monosyllable test) and speech perception scores (using the Japanese CI2004 word and sentence test) were used. Subjects sat 1 meter away from the sound source facing 0° azimuth and recorded monosyllable words in quiet were presented in the sound field at 65 dB SPL. Three listening conditions were used: hearing aid alone, CI alone, and combined EAS. Each subject also underwent hearing in noise-testing using a monosyllable, word, and sentences protocol. A 10 dB signal-to-noise ratio (SNR) was used for subsequent testing determined at 1, 3, 6, and 12 months after the initial EAS stimulation.

This study was approved by the Ethics Committee of Shinshu University School of Medicine as well as

Table I. Clinical features of cases undergoing electric acoustic stimulation (EAS).

Case no.	Gender	Age at time of surgery (years)	Operative side	Inheritance mode	Onset age (years)	Responsible gene	Implant	Insertion depth (mm)	Surgeon
1	F	59	R	Sporadic	43	–	PULSAR FLEX24	24	S.U.
2	F	71	R	AD	30	–	PULSAR FLEX24	24	S.U.
3	F	45	R	Sporadic	25	–	PULSAR FLEX24	24	S.U.
4	F	38	L	Sporadic	28	–	PULSAR FLEX24	24	S.U.
5	F	46	R	AD	30	–	PULSAR FLEX24	24	S.U.
6	M	29	R	AD	7	–	PULSAR FLEX24	24	S.U.
7	M	39	L	AD	11	*ACTG1*	PULSAR FLEX24	24	S.U.
8	F	35	L	Sporadic	25	–	PULSAR FLEX24	24	S.U.
9	M	52	R	Mit	3	Mt.1555A>G	PULSAR FLEX24	24	S.U.
10	F	52	L	Sporadic	48	–	PULSAR FLEX24	24	S.U.
11	F	59	L	Sporadic	38	–	PULSAR FLEX24	24	S.U.
12	F	38	R	AD	13	–	PULSAR FLEX24	24	S.U.
13	F	52	L	Sporadic	37	–	PULSAR FLEX24	24	S.U.
14	M	45	L	Sporadic	35	–	PULSAR FLEX24	24	S.U.
15	M	54	R	Sporadic	52	–	PULSAR FLEX24	24	S.U.
16	M	21	R	AD	7	–	PULSAR FLEX24	24	T.T.
17	F	54	L	Sporadic	32	–	PULSAR FLEX24	24	T.T.
18	M	34	R	Sporadic	7	–	PULSAR FLEX24	24	T.T.
19	F	51	R	Sporadic	3	–	PULSAR FLEX24	24	T.T.
20	F	38	L	Sporadic	18	–	PULSAR FLEX24	24	Y.N.
21	F	58	L	Sporadic	35	–	PULSAR FLEX24	24	Y.N.
22	F	43	R	AR	30	–	PULSAR FLEX24	24	Y.N.
23	M	35	L	AD	10	–	PULSAR FLEX24	24	Y.N.
24	F	69	L	Sporadic	20	–	PULSAR FLEX24	24	H.T./Y.K.
25	M	39	R	Sporadic	30	–	PULSAR FLEX24	24	S.U.
26-1	F	45	L	Sporadic	25	–	PULSAR FLEX24	24	S.U.
26-2	F	48	R	Sporadic	25	–	PULSAR FLEX24	24	S.U.
27-1	F	38	L	AR	10	*TMPRSS3*	PULSAR FLEX24	24	S.U.
27-2	F	40	R	AR	10	*TMPRSS3*	PULSAR FLEX24	24	S.U.
28	F	60	R	Sporadic	40	–	Combi 40+ Standard	31.5	S.U.
29	M	68	R	Sporadic	52	–	PULSAR FLEX SOFT	31.5	S.U.
30	F	64	L	Sporadic	42	–	PULSAR FLEX SOFT	31.5	S.U.

AD, autosomal dominant; AR, autosomal recessive; F, female; L, left; M, male; Mit, mitochondrial mutation; R, right.

the respective ethical committees of the other participating institutions and prior written consent was obtained from each patient after a full explanation of the study.

Results

The current study included five cases (nos. 25, 26, 27, 28, and 29) from our previous report [12] on short-term hearing preservation results, and expanded the duration of observation, the number of patients, and the number of centers involved.

Hearing preservation

Achievement of full insertion was confirmed by combined postoperative imaging with the referential tonotopic map and the corresponding frequencies and the depth of the electrode were evaluated (see Usami et al. [12] for examples).

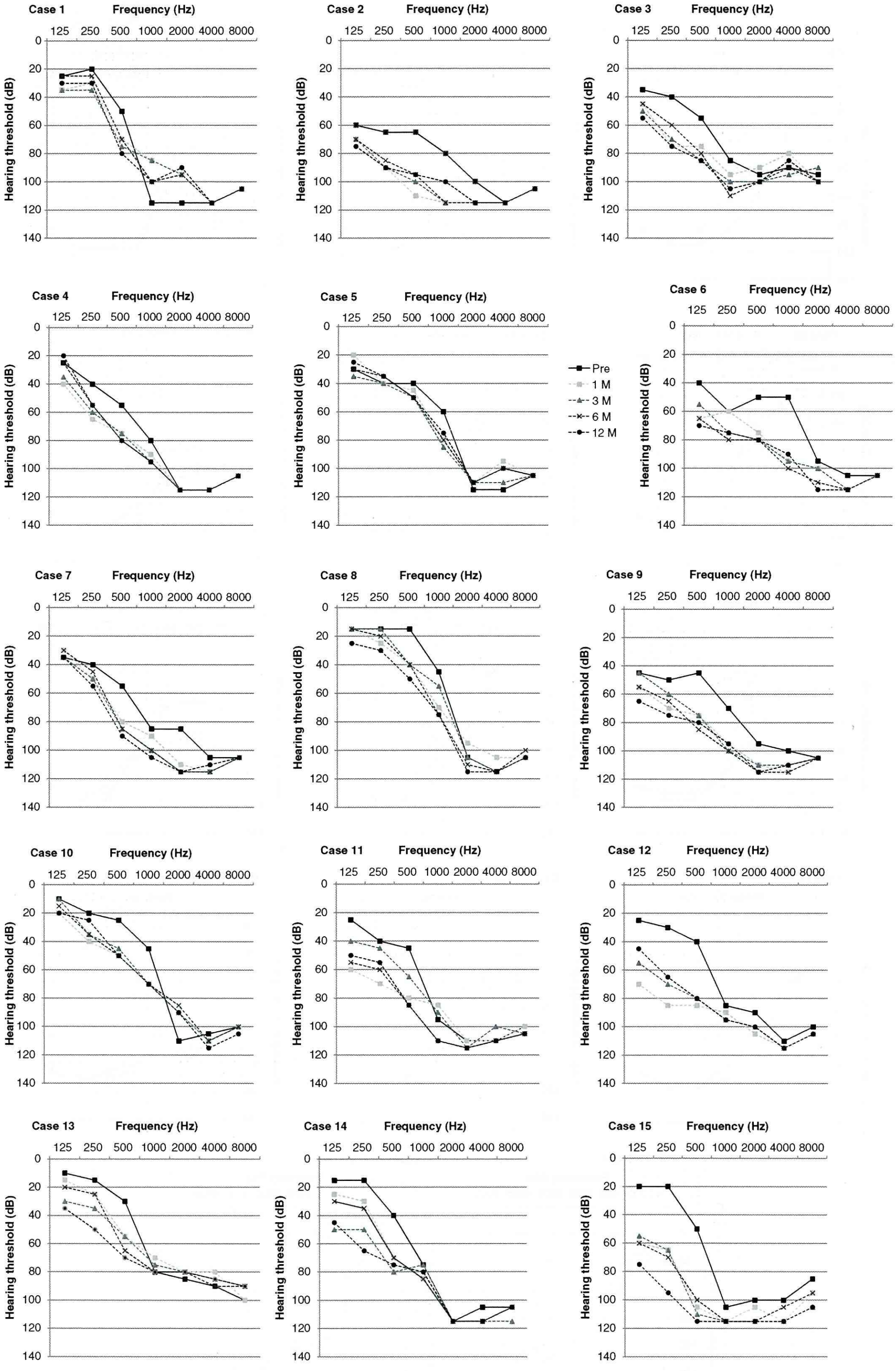

Figure 1. Hearing preservation results of group 1 with FLEX24 electrode. The lines indicate preoperative, and 1, 3, 6, and 12 months postoperative audiograms. Shadow indicates the audiological criteria for electric acoustic stimulation (EAS) clinical trial (patient nos. 1–24 fulfilling the audiological criteria for EAS, nos. 25–27 not fulfilling the criteria for the clinical trial for EAS).

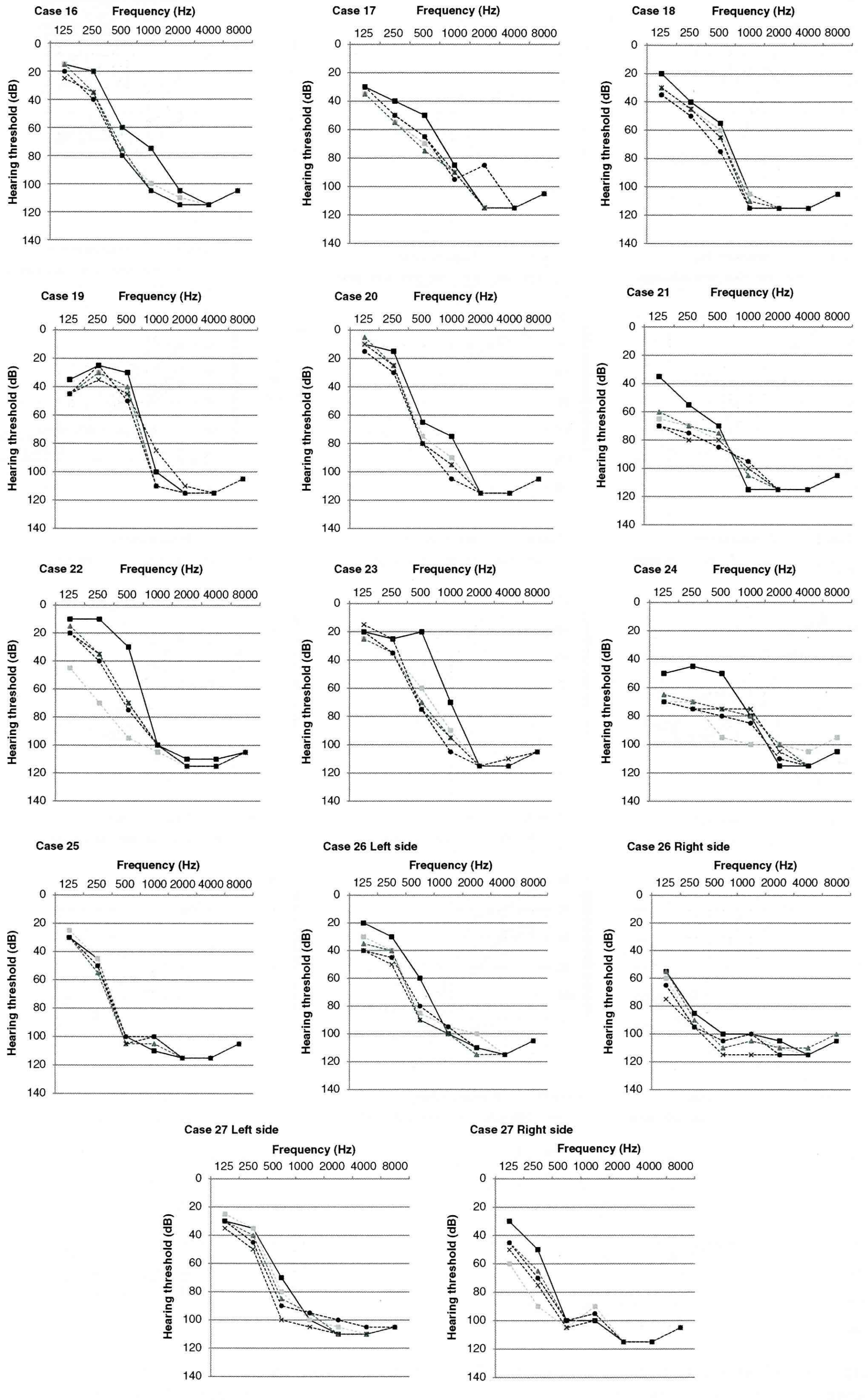

Figure 1. (*Continued*).

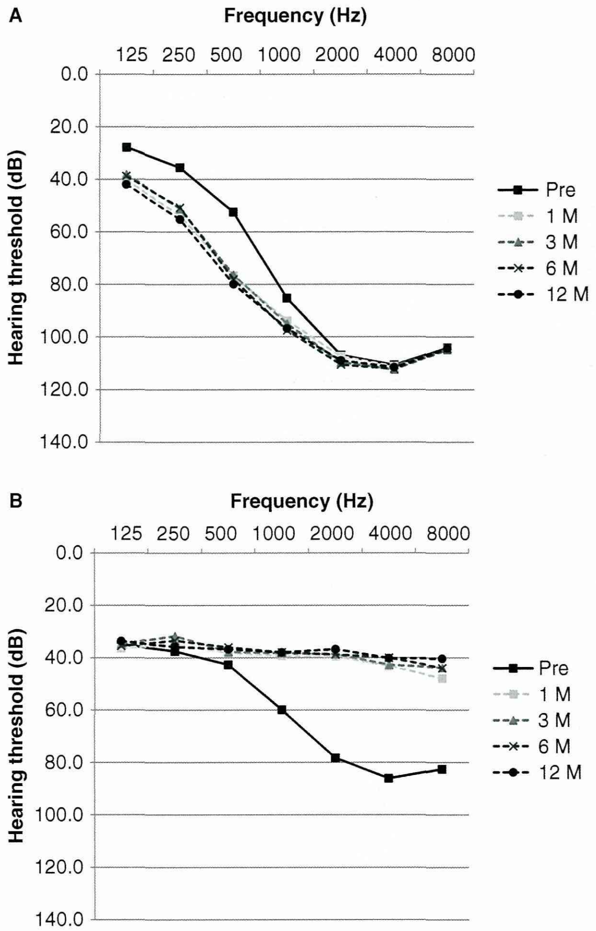

Figure 2. (A) Average audiogram of group 1. The lines indicate preoperative, 1, 3, 6, and 12 months postoperative audiograms. Note that good hearing preservation could be achieved. (B) Hearing level of group 1 with electric acoustic stimulation (EAS).

Overall, postoperative evaluation after deep insertion (24 or 31.5 mm) of the electrodes showed that residual hearing was well preserved in all 32 ears.

Individual preoperative and postoperative audiograms for group 1 are shown in Figure 1. Up to the 12-month follow-up, postoperative evaluation after full insertion of the electrodes showed that hearing in the low frequencies was well preserved in all 24 ears, but 1 patient (case no. 2) lost hearing at more than 6 months following surgery without any episode. The average audiograms for group 1 are shown in Figure 2A. Details of hearing threshold shift are indicated in Table II. Change in air conduction was 14.1 dB in 125 Hz, 19.7 dB in 250 Hz, 27.4 dB in 500 Hz, and 11.6 dB in 1000 Hz. Change in bone conduction was 8.3 dB in 250 Hz, 16.7 dB in 500 Hz, and 5.0 dB in 1000 Hz, respectively.

Low-frequency (250–1000 Hz) pure-tone thresholds dropped at the initial cochlear implant activation at 1 month postoperatively. In particular, hearing deterioration at 500 Hz was evident compared with 250 Hz or 1000 Hz. After initial deterioration, pure-tone thresholds were maintained until the 12-month evaluation.

In group 2, in which there was less residual hearing, it was also well preserved. Individual preoperative and postoperative audiograms are shown in Figure 3 and the average audiogram is shown in Figure 4A. Change in air conduction was 20.0 dB in 125 Hz, 25.0 dB in 500 Hz, and 8.3 dB in 500 Hz. Bone conduction was 10.8 dB in 250 Hz. Details of hearing threshold shift for group 2 are indicated in Table III.

EAS fitting

In two subjects (case nos. 2 and 15), residual hearing was not sufficient to utilize acoustic stimulation. Cochlear implant fitting using a full-frequency map and subsequent bimodal mode of stimulation with a contralateral hearing aid was used. Their cochlear implant alone monosyllable perception scores were 50% and 40% after 1 year, and 75% and 70% in the bimodal setting, respectively. We excluded these two cases from the evaluation of the speech perception outcome. For all other patients, an EAS speech processor (DUET II®) was applied. Postoperative hearing levels of groups 1 and 2 with EAS are shown in Figures 2B and 4B, respectively.

Table II. Average hearing thresholds of electric acoustic stimulation (EAS) patients in group 1.

	Air conductive hearing level (dB)							Bone conductive hearing level (dB)				
Timing	125 Hz	250 Hz	500 Hz	1000 Hz	2000 Hz	4000 Hz	8000 Hz	250 Hz	500 Hz	1000 Hz	2000 Hz	4000 Hz
Preoperative	27.8	35.5	52.4	85.2	106.9	110.7	104.1	29.3	42.6	67.9	73.6	64.5
1 month	40.3	53.8	76.7	93.8	107.4	111.2	104.5	35.2	54.8	72.7	73.8	63.9
3 months	38.1	51.2	76.4	95.0	109.7	112.4	104.8	35.9	55.0	73.3	73.6	63.6
6 months	38.8	50.7	78.0	97.5	110.5	112.1	104.5	33.7	56.4	73.6	74.3	63.9
12 months	41.9	55.2	79.8	96.7	109.0	111.6	104.3	37.6	59.3	73.0	73.9	63.9

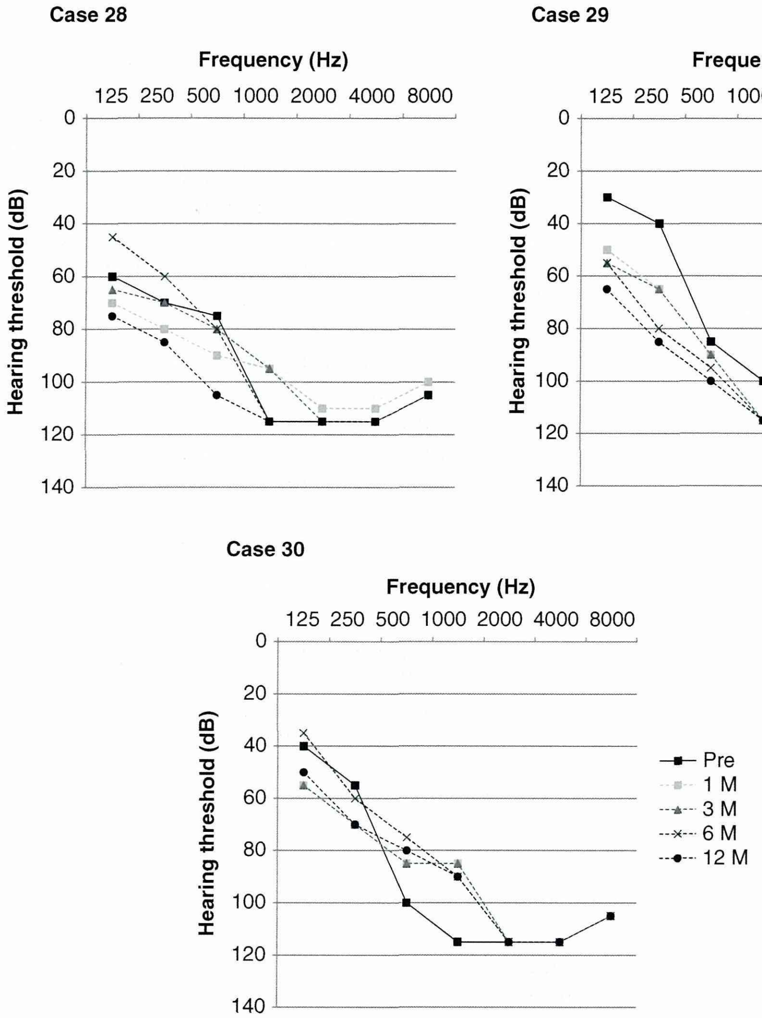

Figure 3. Hearing preservation results of group 2 (cases with less residual hearing and receiving longer electrodes (no. 28 with standard electrode, nos. 29 and 30 with FLEXSOFT electrode). The lines indicate preoperative, and 1, 3, 6, and 12 months postoperative audiograms. Note that good hearing preservation could be achieved.

Speech perception outcome

Improvement of speech discrimination and perception scores was seen in both groups (Figures 5 and 6). In group 1, the average monosyllable discrimination score in quiet (67S 65 dBSPL) was improved from 24.1% preoperatively with hearing aid to 67.4% with EAS 12 months after the first fitting. This postoperative improvement occurred gradually from 48.4% at 1 month to 67.4% at 12 months (Figure 5) and was mainly based on the adaptation of electrical stimulation, because in a comparison of monosyllable discrimination scores in three conditions (acoustic stimulation only (AS only), electric stimulation only (ES only) and EAS), acoustic stimulation scores changed only slightly from 13.8% to 18.1% at 12 months after the first fitting, but electrical stimulation improved from 35.0% to 55.4%. Also, the EAS condition showing the best performance for monosyllable discrimination revealed that acoustic stimulation combined with electrical stimulation increases perception ability (EAS results were significantly better than ES only; $p < 0.001$, paired *t* test). Similar results were observed in monosyllable, word, and sentence perception tests in noise. The results for monosyllable perception in noise were improved from 21.0% preoperatively with hearing aid to 60.2% with EAS 12 months after the first fitting. This postoperative improvement occurred gradually from 36.9% at 1 month to 60.2% at 12 months. Also, EAS results (60.2% correct) were significantly better than AS only (13.9% correct) and ES only (46.0% correct) results ($p < 0.001$ and $p = 0.009$, paired *t* test). The average word and sentence perception test score in noise improved from 35.8%, and 51.3% to 77.0%, and 88.2%, respectively. In both word and sentence

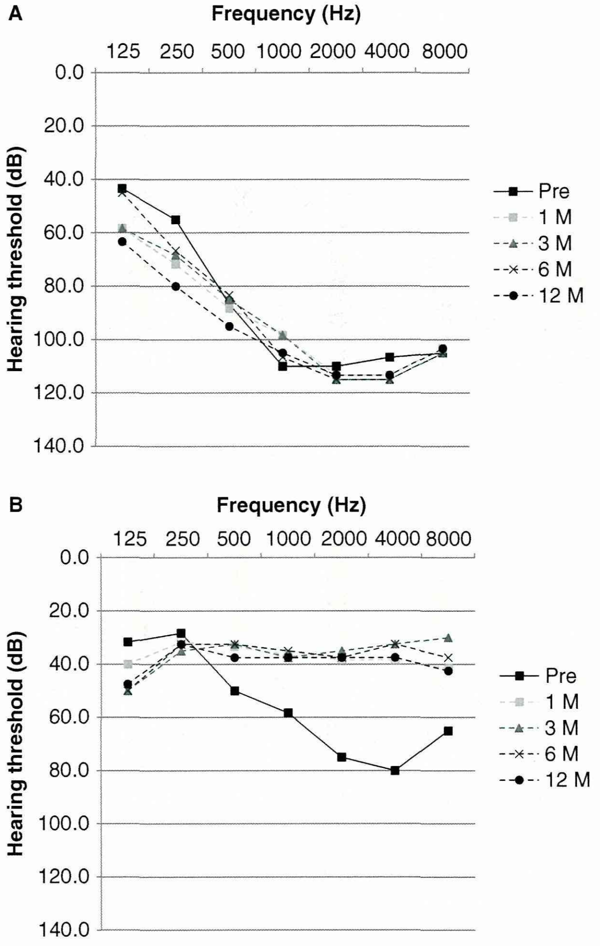

Figure 4. (A) Average audiogram of group 2. The lines indicate preoperative, and 1, 3, 6, and 12 months postoperative audiograms. Note that good hearing preservation could be achieved. (B) Hearing level of group 2 with electric acoustic stimulation (EAS).

perception tests, EAS showed the best results (Figure 5). EAS results were significantly better than the ES only results (p = 0.002 for word and p = 0.01 for sentence, paired t test).

Similar results were obtained for the patients in group 2, who had less residual hearing and received longer (31.5 mm length) electrodes. Good performance after EAS was observed. The average monosyllable discrimination score in quiet (67S 65 dBSPL) was improved from 28% preoperatively with hearing aid to 66.7% with EAS 12 months after the first fitting (Figure 6). The results for monosyllable, word, and sentence perception in noise were improved from 25%, 12%, and 25%, preoperatively with hearing aid to 66.7%, 82%, and 89% with EAS 12 months after the first fitting. In all of the conditions, EAS showed the best results (Figure 6).

Discussion

We first consider hearing preservation. We combined postoperative imaging with the referential tonotopic map and clearly showed that even with the use of a long electrode covering the residual hearing region it is possible to achieve hearing preservation with EAS.

Overall, hearing preservation as well as speech perception data obtained in this study correlate well with recent reports [5–11]. As to hearing preservation, residual hearing was well preserved even after deep insertion (full insertion of 24 mm or 31.5 mm length electrodes). As in other reports, hearing thresholds dropped at the initial cochlear implant activation 1 month postoperatively. In particular, hearing deterioration at 500 Hz was evident compared with 250 Hz or 1000 Hz. After initial deterioration, pure-tone thresholds were stable until 12 months. In particular, air-conduction hearing was elevated compared with bone-conduction hearing, suggesting that this initial deterioration may be most likely due to changes in cochlear micromechanics rather than acute acoustic trauma. This phenomenon could be explained by the slight lifting of the basilar membrane in the middle turn that was seen in a temporal bone study [16].

In contrast, a slight hearing improvement could also be observed in some cases (group 1, case no. 1, 1000 and 2000 Hz; group 1, case no. 10, 2000 Hz; group 1, case no. 21, 1000 Hz; group 1, case no. 24,

Table III. Average hearing thresholds of electric acoustic stimulation (EAS) patients in group 2.

	Air conductive hearing level (dB)							Bone conductive hearing level (dB)				
Timing	125 Hz	250 Hz	500 Hz	1000 Hz	2000 Hz	4000 Hz	8000 Hz	250 Hz	500 Hz	1000 Hz	2000 Hz	4000 Hz
Preoperative	43.3	55.0	86.7	110.0	110.0	106.7	105.0	36.7	63.3	75.0	75.0	65.0
1 month	58.3	71.7	88.3	98.3	113.3	113.3	103.3	48.3	58.3	73.3	75.0	65.0
3 months	58.3	68.3	85.0	98.3	115.0	115.0	105.0	53.3	63.3	73.3	75.0	65.0
6 months	45.0	66.7	83.3	106.7	115.0	115.0	105.0	48.3	61.7	75.0	75.0	65.0
12 months	63.3	80.0	95.0	105.0	113.3	113.3	103.3	47.5	62.5	75.0	75.0	65.0

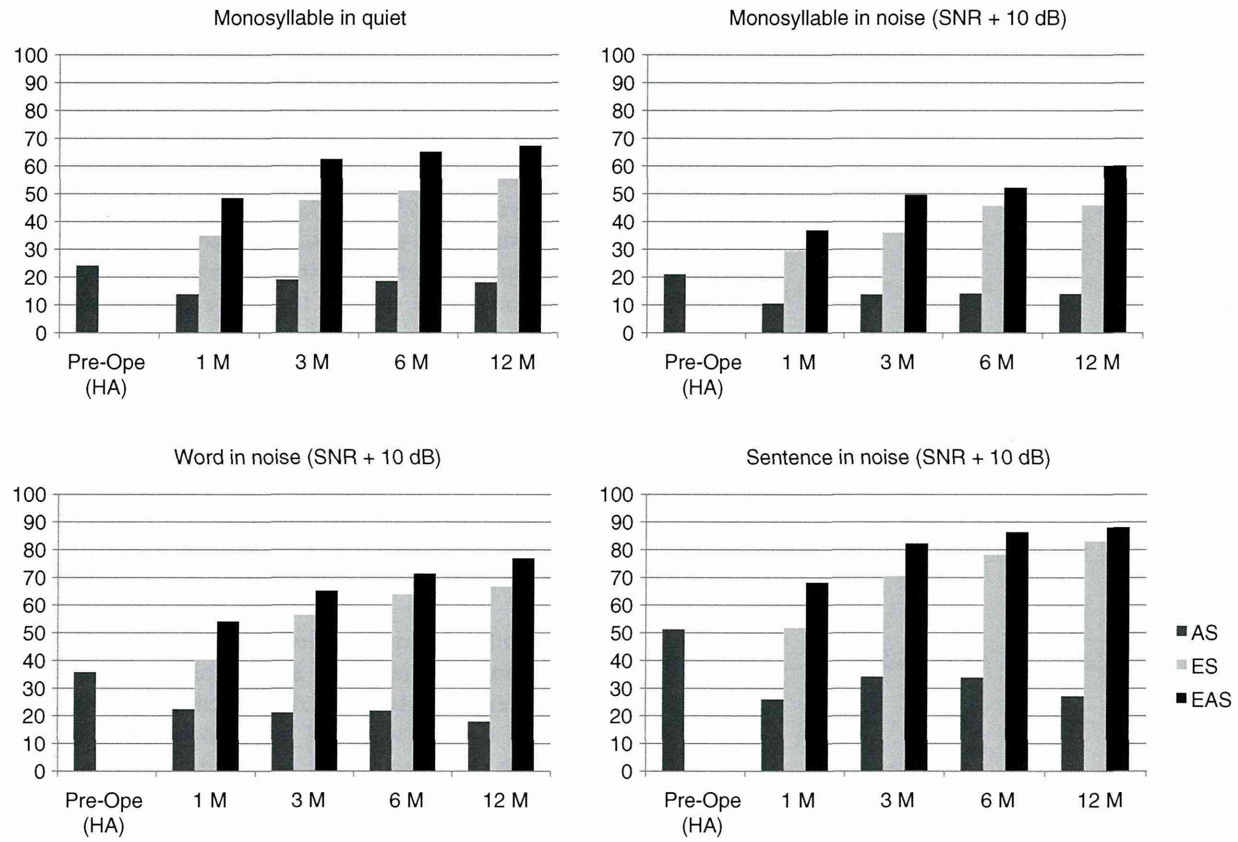

Figure 5. Speech discrimination and perception scores of group 1 (with FLEX24 electrode). Speech discrimination and perception scores were improved postoperatively with electric acoustic stimulation (EAS). SNR, signal-to-noise ratio.

2000 Hz; group 2, case no. 28, 1000 Hz; group 2, case no. 30, 500 and 1000 Hz), as seen in the preliminary data we have previously reported [12]. This phenomenon was constant until the 12-month evaluation, suggesting that this was not a measuring error but true improvement. This is probably due to alterations of the basilar membrane behavior occurring after electrode insertion.

We turn now to speech perception outcome. Hearing preservation could be achieved in a high number of patients, and combined EAS provided good speech perception in both quiet and noise. Speech discrimination and perception scores were improved postoperatively with EAS in both of our groups, indicating that (1) EAS is beneficial for Japanese-speaking patients within particular audiogram indications, and (2) EAS is also beneficial for patients with less residual hearing at lower frequencies. In the present study, patients with less residual hearing (case nos. 25–30) showed good results equal to those fulfilling the audiological criteria (case nos. 1–24), indicating that these patients are also good candidates for EAS. The current results indicated that the audiological criteria for EAS should not be limited to the conventional range of audiogram, but also expanded to the patients with less residual hearing.

Hearing loss in the majority of patients with residual hearing at lower frequencies is more or less progressive and therefore they may have fulfilled the audiological criteria for EAS at an earlier date. Actually an audiogram from the past showed that our case no. 27 in group 1 had previously fulfilled the audiological criteria (data not shown) and it is possible that this was also true for case nos. 25, 26, and 28–30. Throughout the selection process for EAS candidates, we have paid attention to the progressive nature of their hearing loss. We need to consider that patients who fulfill the criteria at a certain point possibly may not fit the criteria in the future. In contrast, most of the patients who did not totally meet the audiological criteria for EAS may have fulfilled the criteria several years before. Considering such progressive nature of hearing loss, audiological criteria should not be tightly limited to the conventional criteria for EAS. The present results support the proposition that the criteria could be expanded to include the cases with less residual hearing. Since shallow insertion of short electrodes cannot recruit neurons in the apical region,

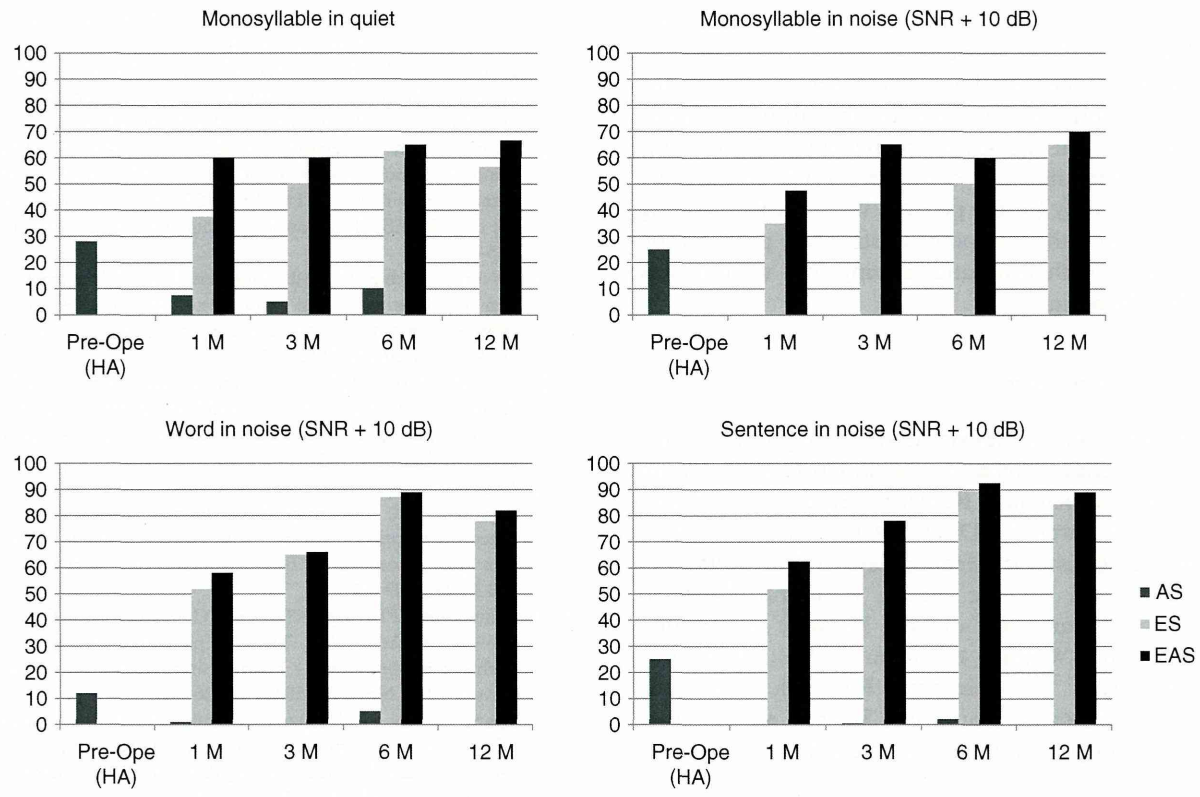

Figure 6. Speech discrimination and perception scores of group 2 (standard electrode or FLEXSOFT electrode with less residual hearing). Speech discrimination and perception scores were improved postoperatively with electric acoustic stimulation (EAS). SNR, signal-to-noise ratio.

deeper insertion would be the best solution to compensate for future hearing deterioration at the lower frequencies. However, full insertion with a long/medium electrode for the patients with residual hearing at the low frequencies is still a controversial field because of possible loss of their residual hearing due to mechanical trauma of the corresponding area.

In this study, 24 mm or 31.5 mm electrodes were chosen for all patients. FLEX24 was used for the patients with residual hearing that was more evident, while FLEXSOFT was used for the patients with less residual hearing.

The speed of progression, i.e. rapid or rather stable, may be dependent on the individual etiology. An unresolved issue is the prediction of progressiveness based on the etiology of individual hearing loss, but we have recently reported at least five genes that are responsible for the candidates for EAS, and therefore there is not a single etiology but rather a great genetic heterogeneity involved in this particular type of hearing loss [17–19].

In the present study, the responsible gene (*m.1555A>G, TMPRRS3, ACTG1*) was identified in 3 of 30 patients (Table I) [18,19], and will contribute to such decision-making in the near future.

The benefits of minimally invasive concepts in CI surgery are needed not only for the patients with residual hearing but also for the patients with profound hearing loss without any residual hearing, because structure preservation is critical for (1) future therapeutic interventions including gene therapy and/ or regeneration therapy, and (2) vestibular function. If acoustic stimulation is not applicable due to less residual hearing, vestibular function could be a good marker for structure preservation. Our recent study on vestibular function of the patients with EAS clearly demonstrated that the patients have comparatively good vestibular function and it is important to preserve not only residual hearing function but also the vestibular function of the implanted ears, using minimally invasive surgical techniques [20]. The round window approach and soft electrode should be preferred to decrease the risk of damage to vestibular function [12].

Conclusions

EAS is beneficial for Japanese-speaking patients including those with less residual hearing at lower frequencies, indicating that current audiological criteria for EAS can be expanded. Since hearing loss of EAS candidates is more or less progressive, full insertion of medium/long electrodes would be the best solution to compensate for future hearing deterioration at the lower frequencies. The benefits of minimally invasive concepts in CI surgery are crucial not only for the patients with residual hearing but also from the viewpoint of structure preservation in patients with profound hearing loss without any residual hearing.

Acknowledgments

We thank A.C. Apple-Mathews for help in preparing the manuscript. This study was supported by a Health and Labour Sciences Research Grant for Comprehensive Research on Disability Health and Welfare from the Ministry of Health, Labour and Welfare of Japan (S.U.), by the Acute Profound Deafness Research Committee of the Ministry of Health, Labour and Welfare of Japan (S.U.), and by a Grant-in-Aid for Scientific Research from the (then) Ministry of Education, Science and Culture of Japan (http://www.mext.go.jp/english/) (S.U.).

Declaration of interest: The Ministry of Health, Labour and Welfare approved our clinical research for Advanced Medical Technology using electric acoustic stimulation (EAS). Because the EAS devices had not yet been approved for clinical use in Japan, they were supplied by MEDEL. The Shinshu University Conflict of Interest Committee also approved the study. The authors alone are responsible for the content and writing of the paper.

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Acta Oto-Laryngologica. 2013; 133: 1128–1132

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ORIGINAL ARTICLE

Effects of EAS cochlear implantation surgery on vestibular function

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Abstract

Conclusions: The patients who received electric acoustic stimulation (EAS) cochlear implantation had relatively good vestibular function compared with the patients who did not have residual hearing. The vestibular function was well preserved after atraumatic EAS surgery. The round window approach and soft electrode are preferred to decrease the risk of impairing vestibular function. *Objectives:* The aim of this study was to examine the characteristic features of vestibular functions before and after implantations in patients undergoing EAS. *Methods:* Vestibular functions in patients who underwent EAS implantation were examined by caloric testing and vestibular evoked myogenic potential (VEMP) in 11 patients before and in 13 patients after implantation. *Results:* Preoperative evaluation showed that of the 11 patients, most (73%) had good vestibular function. One of 11 patients (9%) had decreased response in postoperative VEMP but all of the patients had unchanged results in postoperative caloric testing.

Keywords: *Cochlear implant, VEMP, caloric test, preservation*

Introduction

Recently, a series of reports have shown the efficiency of electric acoustic stimulation (EAS) in patients with residual acoustic hearing in the lower frequencies [1]. The development of techniques such as soft surgery when performing cochleostomy [2], round window insertion [3], use of atraumatic electrodes [4,5], and postoperative steroid administration has enabled preservation of residual hearing after cochlear implantation (CI) surgery.

Current techniques of CI also facilitate remarkable improvement in hearing ability. However, consideration must still be given to the complications that can accompany a CI.

One possible such complication is impairment of vestibular function with resulting vertigo symptoms. The incidence of this complication as reported in the literature varies widely from 0.33% to 75% [6].

Although numerous studies have reported the effects of CI on the vestibular function in deaf patients, there have been no reports examining the vestibular function in patients who had residual hearing at lower frequencies, or of the postoperative effects on vestibular function of new atraumatic concepts of electrode and surgical techniques.

We recently published a preliminary report that the round window approach (RWA) is preferable from the viewpoint of vestibular function [7].

The aim of the present study was to further examine the changes in vestibular functions after implantation in patients who underwent EAS CI.

Material and methods

Patients

Thirteen patients (four males and nine females) who underwent EAS CI in our center were included in this

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(Received 11 May 2013; accepted 30 June 2013)

ISSN 0001-6489 print/ISSN 1651-2251 online © 2013 Informa Healthcare
DOI: 10.3109/00016489.2013.824110

study after obtaining informed written consent. The study was carried out with the approval of the Shinshu University Ethical Committee.

The age at implantation ranged from 30 to 60 years, and the mean age was 45.2 years. All patients fulfilled the following inclusion criteria: post-lingually acquired, bilateral sensorineural hearing loss (HL) with pure tone thresholds of <65 dB HL at the low frequencies (125, 250, and 500 Hz), of ≥80 dB HL at frequency 2 kHz, and of ≥85 dB HL at frequencies >4 kHz, and monosyllabic word recognition scores in quiet of ≤60% at 65 dB sound pressure level (SPL) in both ears in best-aided condition. Subjects were still included in this study if one of these frequencies was out of the mentioned decibel levels by only 10 dB or less.

Cochlear implantations

We performed CI with full insertion of the MEDEL FLEX$^{EAS®}$ electrode (MED-EL, Innsbruck, Austria) in all patients.

All surgeries were performed by a single surgeon and the RWA was applied for electrode insertion. Systemic antibiotics and dexamethasone were administered peri- and postoperatively. Residual hearing was successfully preserved in all patients (data not shown).

Vestibular testing

The patients were examined by caloric testing and vestibular evoked myogenic potential (VEMP) before or after implantation, or both, to obtain data on semicircular canal function and otolithic function, respectively.

In VEMP testing, electromyography (EMG) was carried out using a pair of surface electrodes mounted on the upper half and the sterna head of the sternocleidomastoid (SCM) muscle. The electrographic signal was recorded using a Neuropack evoked potential recorder (Nihon Kohden Co. Ltd, Tokyo, Japan). Clicks lasting for 0.1 ms at 105 dBnHL were presented through a headphone. The stimulation rate was 5 Hz, the bandpass filter intensity was 20–2000 Hz, and analysis time was 50 ms. The responses to 200 stimuli were averaged twice. Because the amplitude of the VEMP based on the unrectified EMG is correlated with the activity of the SCM muscle during the test [8], we measured the activity of the SCM muscle using the background integrated EMG response, the area under the averaged rectified EMG curve, from –20 ms to 0 ms before the sound stimulation. The correction of the amplitude was calculated as follows [9]:

Corrected amplitude (ms^{-1}) = amplitude of the averaged unrectified EMG (micro V)/background integrated EMG (micro V ms)

In caloric testing, maximum slow phase velocity (SPV) was measured by cold water irrigation (20°C, 5 ml, 20 s). We defined below 10°/s of SPV as areflexia and between 10 and 20°/s as hyporeflexia.

Statistical analysis

SPSS for Windows software (Chicago, IL, USA) was used for all analyses, and paired t test was applied when comparing differences in preoperative and postoperative vestibular functions. Statistical significance was set at $p < 0.05$.

Results

The results are summarized in Table I.

Semicircular canal function

Preoperative evaluation was performed bilaterally. Three of 11 patients (27%, nos 3, 4, and 5) showed areflexia or hyporeflexia in caloric testing. Patient no. 4 had bilateral areflexia, no. 5 had implanted ear areflexia and non-implanted ear hyporeflexia, and no. 3, had hypoflexia only in the non-implanted ear.

Postoperative caloric testing was obtained after 1 month or more. All 13 patients underwent postoperative caloric testing and 11 of them were also examined before the EAS implantations. Two (nos 4 and 5) of 13 patients (15%) had abnormal postoperative caloric test results in the implanted ear, although both of them also had abnormal results before implantations. Figure 1 shows the caloric response before and after EAS implantations for the implanted ear. Compared with before implantations, the results after implantations were unchanged in all of the 11 patients who underwent both preoperative and postoperative testing. One patient (no. 4) had areflexia both before and after implantation. The mean SPV was 28.06°/s preoperatively (SD = 17.61) and 28.68°/s postoperatively (SD = 15.53). There were no significant differences between results before and after implantations in caloric testing ($p = 0.67$).

Otolithic function

When preoperative evaluation was performed, no patients showed absent response in VEMP.

Postoperative VEMP was obtained after 1 month or more. All 13 patients underwent postoperative VEMP and 11 of them were also examined before EAS implantations. No patient had absent VEMP response

Table I. Summary of patients' details.

Patient no.	Age (years)/sex	Implanted side	Caloric test (°/s)				VEMP (ms^{-1})			
			Implanted ear		Non-implanted ear		Implanted ear		Non-implanted ear	
			Preop	Postop	Preop	Postop	Preop	Postop	Preop	Postop
1	41/M	R	NA	22.28	NA	20.74	NA	0.060	NA	0.068
2	47/F	L	NA	24.41	NA	9.09†	NA	0.029	NA	0.022
3	40/F	L	22.67	24.65	17.61*	17.76*	0.055	0.053	0.041	0.061
4	60/F	R	0†	0†	6.05†	0†	0.017	0.012	0.029	0.022
5	46/F	R	4.46†	8.31†	15.14*	19.94*	0.012	0.015	0.024	0.025
6	39/F	L	52.84	50	46.26	38.76	0.027	0.023	0.028	0.047
7	47/F	R	26.64	28.2	22.18	27.31	0.020	0.018	0.024	0.022
8	30/M	R	29.62	39.65	31.1	14.69	0.062	0.032	0.045	0.028
9	40/M	L	24.94	29.39	38.11	23.4	0.026	0.019	0.046	0.025
10	35/F	L	23.18	22.91	22.24	21.96	0.025	0.026	0.030	0.040
11	52/M	R	22.57	22.02	22.44	22.98	0.018	0.020	0.023	0.017
12	51/F	L	52.57	45.97	50.26	54.95	0.036	0.033	0.041	0.026
13	59/F	L	49.18	43.44	54.3	43.44	0.010	0.008	0.038	0.024

NA, not available.
*Hyporeflexia.
†Areflexia.

in the implanted ear. Figure 2 shows corrected VEMP amplitudes before and after EAS implantations for the implanted ear. Although one (no. 8) of the 11 patients (9%) had a decreased response in corrected VEMP amplitude, corrected VEMP amplitudes after implantations were unchanged in all but one of the patients, when compared with preoperative results. The mean corrected amplitude was 0.028 preoperatively (SD = 0.017) and 0.023 postoperatively (SD = 0.013). There were no significant differences between results before and after implantation in VEMP testing ($p = 0.095$).

Discussion

Previous reports showed that the frequencies of 'preoperative' vestibular disorders in profound hearing loss patients were about 30–73% in caloric testing [10–14] and about 11–65% in VEMP [10–15].

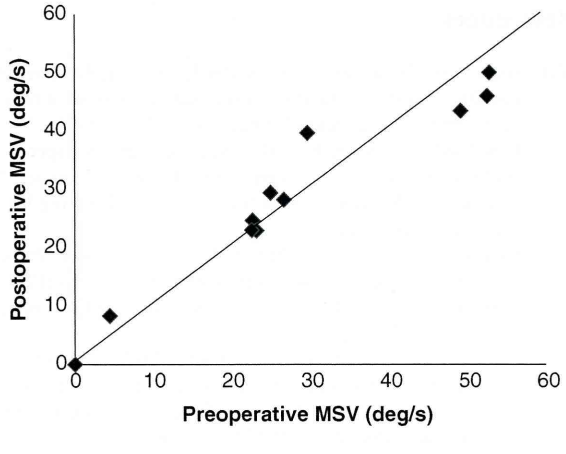

Figure 1. Results of caloric testing before and after EAS implantations in the implanted ear. There were no significant differences between preoperative and postoperative results ($p = 0.67$). MSV, maximum slow eye velocity.

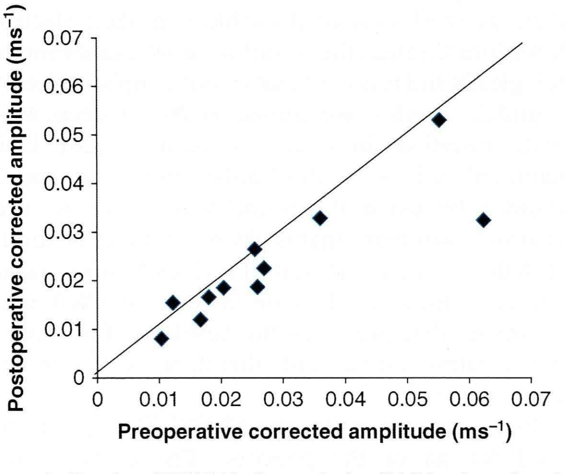

Figure 2. Results of VEMP before and after EAS implantations in the implanted ear. There were no significant differences between preoperative and postoperative results of VEMP testing in EAS implanted ears ($p = 0.095$). Corrected amplitude was used to compare the results.

In this study, we found that the 'preoperative' frequencies of vestibular disorders in hearing loss patients with residual hearing who received EAS were 27% and 0% in caloric testing and VEMP, respectively.

This finding suggested that vestibular function of the patients who underwent EAS was relatively good compared with the patients with profound hearing loss who underwent conventional CI.

In this study, to preserve such good vestibular function, atraumatic CI surgery (RWA with flexible thin electrode) was performed. Although one patient showed a decreased VEMP result, there was no hypofunction in postoperative caloric testing when compared with preoperative results in the implanted ear.

According to previous reports, various frequencies of postoperative deterioration in vestibular function were demonstrated. Postoperative hypofunction was found in 6–58% in the caloric testing [10–14,16–18], and 13–86% in VEMP [10–15]. One of the reasons for such variation is probably the surgical technique applied.

Todt et al. reported that hypofunction of postoperative VEMP was seen in 50% of patients who underwent cochleostomy and 13% of those with RWA Also, abnormal postoperative caloric testing results were seen in 42.9% of the patients who underwent cochleostomy and 9.4% of those who had the RWA [10].

Temporal bone studies have shown that an electrode insertion into the scala vestibuli involves damage of the osseous spiral lamina, basilar membrane, and vestibular receptors. The saccule was the most frequently damaged vestibular receptor, followed by the utricle and the semicircular canals [19].

However, when the electrode was inserted into the scala tympani, no vestibular damage was found [19]. Adunka et al. evaluated cochlear implant electrode insertions through the round window membrane histologically and reported that smooth implantations via round the window membrane resulted in deep, atraumatic insertions into the scala tympani [20]. Unintentional lesions to the basilar membrane can be avoided by using the round window as an exact anatomic landmark that is always in direct continuity with the scala tympani [20]. Previous histological and clinical studies clearly showed that the RWA is the technique that preserves the vestibular functions to the greatest extent and therefore is better than cochleostomy.

In the present study, the $FLEX^{EAS}$ electrode was used for all of the patients. The cross-sectional diameter of the electrode is smaller than a conventional electrode, varying from 0.33 by 0.49 mm at the apex and to 0.8 mm at the basal, and a major feature of the device is its superior flexibility. Histology and dissection of human temporal bones performed by Adunka et al. confirmed the atraumatic character of this device [20]. Insertion forces with the conventional array and FLEX array were measured in an acrylic model of the scala tympani, demonstrating that insertion force could be reduced significantly by more than 40% with the $FLEX^{EAS}$ electrode [4]. As in our previous study [7], such a smaller diameter and more flexible electrode might enable less damage to not only the cochlear tissue, but also the vestibular organs.

In conclusion, patients undergoing EAS implantation have good vestibular function compared with the vestibular function of the patients with profound hearing loss. It is important to preserve not only residual hearing but also the vestibular function of the implanted ears, using atraumatic surgical techniques. The RWA with soft electrode is preferable to decrease the risk of damage to vestibular function.

Acknowledgments

We thank A.C. Apple-Mathews for help in preparing the manuscript. This study was supported by a Health and Labour Sciences Research Grant for Comprehensive Research on Disability Health and Welfare from the Ministry of Health, Labour and Welfare of Japan (S.U.) and by a Grant-in-Aid for Scientific Research from the Ministry of Education, Science and Culture of Japan (S.U.).

Declaration of interest: The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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