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## Multicenter US Clinical Trial With an Electric-Acoustic Stimulation (EAS) System in Adults: Final Outcomes

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**Objective:** To demonstrate the safety and effectiveness of the MED-EL Electric-Acoustic Stimulation (EAS) System, for adults with residual low-frequency hearing and severe-to-profound hearing loss in the mid to high frequencies.

**Study Design:** Prospective, repeated measures.

**Setting:** Multicenter, hospital.

**Patients:** Seventy-three subjects implanted with PULSAR or SONATA cochlear implants with FLEX<sup>24</sup> electrode arrays.

**Intervention:** Subjects were fit postoperatively with an audio processor, combining electric stimulation and acoustic amplification.

**Main Outcome Measures:** Unaided thresholds were measured preoperatively and at 3, 6, and 12 months postactivation.

Speech perception was assessed at these intervals using City University of New York sentences in noise and consonant–nucleus–consonant words in quiet. Subjective benefit was assessed at these intervals via the Abbreviated Profile of Hearing Aid Benefit and Hearing Device Satisfaction Scale questionnaires.

**Results:** Sixty-seven of 73 subjects (92%) completed outcome measures for all study intervals. Of those 67 subjects, 79% experienced less than a 30 dB HL low-frequency pure-tone average (250–1000 Hz) shift, and 97% were able to use the acoustic unit at 12 months postactivation. In the EAS condition, 94% of subjects performed similarly to or better than their preoperative performance on City University of New York sentences in noise at 12 months postactivation, with 85% demonstrating improvement. Ninety-seven percent of subjects performed similarly or better on consonant–nucleus–consonant words in quiet, with 84% demonstrating improvement.

**Conclusion:** The MED-EL EAS System is a safe and effective treatment option for adults with normal hearing to moderate sensorineural hearing loss in the low frequencies and severe-to-profound sensorineural hearing loss in the high frequencies who do not benefit from traditional amplification. **Key Words:** Cochlear implant—Electric-acoustic stimulation—Hearing preservation—Hybrid cochlear implant. *Otol Neurotol* 39:299–305, 2018.

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Cochlear implantation has long been an accepted treatment option for individuals with severe to profound sensorineural hearing loss across the frequency range. Individuals falling outside this range have traditionally been considered hearing aid candidates. Hearing aids, however, do not provide sufficient amplification for some individuals with normal hearing to moderate hearing loss in the low frequencies and severe to profound hearing loss in the high frequencies, a configuration sometimes known as “ski-slope” hearing loss (1). Such individuals frequently have difficulty understanding speech, particularly in noisy or reverberant environments, even with appropriately fit hearing aids. Providing a combination of electric and acoustic stimulation (EAS) ipsilaterally to individuals with this “ski slope” hearing loss can significantly improve their hearing and speech recognition outcomes (2–4).

In 1999, Von Ilberg et al. (5) demonstrated successful implantation of the MED-EL COMBI 40+ cochlear implant (CI) with a 24 mm electrode array in an individual with ski-slope hearing loss. Postoperatively, this individual had a threshold shift of 15 to 20 dB HL in the low frequencies, with enough low-frequency residual hearing to amplify via a hearing aid. Further work with the same device indicated that it was possible to maintain residual hearing postoperatively in 29 of 31 subjects (6,7).

MED-EL developed and introduced the FLEX<sup>24</sup> electrode array (formerly known as the FLEX<sup>EAS</sup>) in an effort to minimize cochlear trauma. It is 24 mm long and has a flexible tip, with five single-sided electrode contacts on the apical end (8). Additionally, an audio processor with combined EAS in one device, the DUET, was made available. A European multicenter clinical trial with the FLEX<sup>24</sup> electrode array and DUET Audio Processor found that 18 of 18 subjects had some degree of postoperative residual hearing and 17 of 18 subjects had enough residual hearing to use EAS via the DUET Audio Processor (9). Significant improvements in postoperative speech understanding when using EAS, compared with the preoperative aided condition, were reported.

The aim of the present study was to determine the safety and effectiveness of the MED-EL EAS System through a multicenter US clinical trial.

## METHODS

The US clinical trial was conducted at 14 clinical trial sites across the United States. The protocol was approved by the US Food and Drug Administration (FDA) and the individual site institutional review boards. The first subject was enrolled in 2006. All subjects provided written consent.

### Subjects

To be included in the study, potential subjects had to be between 18 and 70 years of age with residual low-frequency hearing (pure-tone air-conduction thresholds  $\leq$  65 dB HL at 250 and 500 Hz) and severe to profound high-frequency sensorineural hearing loss (pure-tone air-conduction thresholds  $\geq$  70 dB HL at 2000, 4000, and 8000 Hz), bilaterally. Subjects also

needed to demonstrate monosyllabic word scores (consonant–nucleus–consonant [CNC]) of 60% or less in the best-aided condition when tested with recorded speech at 70 dB SPL in quiet and unaided intra-aural threshold differences of not more than 20 dB HL at 250, 500, and 1000 Hz. Subjects were excluded if there was evidence of 1) conductive or retrocochlear hearing loss or 2) a fluctuation of 15 dB HL or greater at two or more frequencies within the last 18 months.

### Procedures

Subjects were implanted unilaterally with either a MED-EL PULSAR or MED-EL SONATA cochlear implant with a FLEX<sup>24</sup> electrode array (MED-EL GmbH, Innsbruck, Austria). A soft surgical procedure was used, similar to that described by Kiefer et al., Roland et al., Skarzynski et al., and Friedland and Runge-Samuelson (10–13). In addition to surgical techniques used in standard cochlear implantation, the surgical guideline included steps intended to further minimize cochlear trauma and maximize the preservation of residual low-frequency hearing. Soft surgical procedures included administering intravenous antibiotics and corticosteroids intraoperatively, eliminating blood and bone dust, applying corticosteroid solution and lubricant at the site of the cochleostomy or round window insertion, changing or washing gloves before handling the electrode, and inserting the electrode slowly and gently. Electrodes were inserted to approximately 20 mm via either a cochleostomy or round window approach, at the surgeon’s discretion.

Subjects were fit with the DUET Audio Processor, combining an Acoustic Unit (earhook with acoustic receiver attached to a custom earmold and acoustic battery pack) and the TEMPO+ Speech Processor. Two to 4 weeks postoperatively, subjects were programmed with electric stimulation only. The acoustic unit was added (EAS activation) 1 month later.

### Residual Hearing

Residual hearing was assessed via unaided air-conduction thresholds at four intervals: preoperatively and at 3, 6, and 12 months postactivation. The low-frequency pure-tone average (LF-PTA) was calculated as the average of thresholds at 250, 500, 750, and 1000 Hz. Subjects with any low-frequency threshold (250–1000 Hz) at 80 dB HL or better were fit with appropriate acoustic amplification through the DUET Audio Processor.

### Speech Perception

Speech perception was evaluated via the City University of New York (CUNY) Sentence Test and the CNC Word Recognition Test. Testing was conducted preoperatively (best-aided) and at 3, 6, and 12 months postactivation. For the postactivation testing, subjects were tested in both the EAS condition and the CI-alone (electric stimulation only) condition. A full-frequency (250–8500 Hz) map was used for testing in the CI-alone condition.

Open-set sentence testing was conducted using the CUNY Sentence Test. Subjects were evaluated using recorded stimuli in steady-state noise at 70 dB SPL in the soundfield with varying signal-to-noise ratios (0, +5, or +10 dB) that were held constant for each individual subject throughout the duration of the study. One practice list and four test lists were completed for each condition. The final score is the mean percentage of correctly identified words per sentence.

The CNC Word test is an open-set, monosyllabic word recognition test. Recorded materials were presented in quiet

**TABLE 1.** Subject demographics at the time of implantation

n = 73	Mean ± SD (Min, Max)
Age in years	53.7 ± 13.7 (17–76)
Duration of noticeable hearing loss in years	
Left	25.7 ± 12.23 (2–60)
Right	25.7 ± 12.24 (2–60)
Duration of hearing aid use in years	
Left	17.4 ± 10.63 (1–48)
Right <sup>a</sup>	17.4 ± 10.30 (1–47)
Sex % (n/total)	
Male	42.5 (31/73)
Female	57.5 (42/73)

<sup>a</sup>One subject did not report duration of hearing aid use for the right ear. Mean calculated for 72 subjects.  
SD indicates standard deviation.

at 70 dB SPL in the soundfield. One list was administered for each condition. The final score is the percentage of correctly identified words.

### Quality of Life

Subjective benefit was measured using the Abbreviated Profile of Hearing Aid Benefit (APHAB) and Hearing Device Satisfaction Scale (HDSS) preoperatively and at 12 months postactivation. The APHAB is a validated 24-item self-assessment questionnaire used to measure disability related to hearing loss in the areas of ease of communication, reverberation, background noise, and aversiveness (14). The HDSS was used to evaluate satisfaction with the EAS system, compared with preoperative hearing aids.

### Statistical Analysis

The primary effectiveness endpoint was defined by improvement in the CUNY sentence test in noise score at 12 months postactivation in the EAS condition, compared with the preoperative aided condition. Secondary analyses included comparison of the EAS condition at 12 months to the preoperative aided condition on CNC words in quiet, comparison of the CI-alone condition at 12 months to the preoperative aided condition on CNC words in quiet, as well as the comparison of EAS to the CI-alone at 12 months on CUNY sentences in noise. The total sample size of 73 implanted subjects surpassed the minimum requirement for 80% statistical power based on an assumed mean improvement on CUNY sentences from baseline and an alpha level of 0.05.

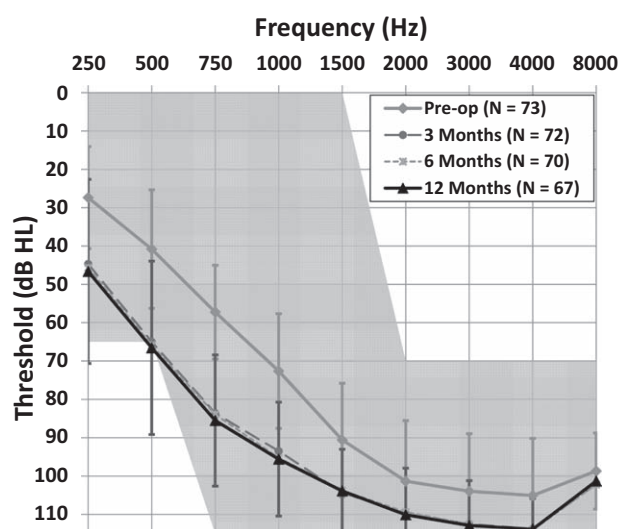
Primary and secondary endpoints were analyzed using paired *t* tests and Wilcoxon signed-rank tests, with least squares means used to estimate change from the preoperative interval. Confidence intervals for mean differences were calculated using two-sided 95% confidence bounds. Missing data were imputed using both last value carried forward analysis and worst case scenario analysis to evaluate the robustness of the results. An ANOVA was used to obtain tests of homogeneity for the covariates of duration of hearing impairment (yr), etiology of hearing loss, and sex (male/female). These factors were summarized descriptively for each site, and a cross-site test for homogeneity of results was performed. Although residual hearing was not included in the original statistical analysis plan, group audiometric data were analyzed post-hoc and are reported below.

## RESULTS

### Subjects

Seventy-three subjects (42 female, 31 male) were included in the study. Their mean age was 53.7 years (range 17–76 yr). Two subjects outside of the age range criteria (17 and 76 yr) were implanted under compassionate clearance from FDA. The mean duration of noticeable hearing loss was 25.7 years, with a mean duration of hearing aid use of 17.4 years (see Table 1). There were no statistically significant associations of demographic or preoperative characteristics with outcomes. Regression analyses were performed on CUNY and CNC scores for all subjects as a function of sex, age, duration of hearing impairment, preoperative low-frequency hearing loss, and baseline speech score. Multivariate analyses were also completed for the same factors as categorical and continuous variables where applicable. Both the sets of analyses showed general improvements for all subgroups and yielded no statistically significant differences in outcome. Access to the cochlea was achieved via the round window in 55 of 73 patients (75.3%), a cochleostomy in 17 patients (23.3%), and was unspecified in one patient (1.4%).

In total, 67 of the 73 subjects (91.8%) completed the audiometric testing and effectiveness outcome measures for all the study intervals. Of the six subjects who did not complete all intervals, three voluntarily withdrew from the study, two subjects were lost to follow-up, and one was still undergoing follow-up at the time of data analysis. Data from these subjects were included in demographics and adverse event results but were excluded from additional analyses.



**FIG. 1.** Average pure-tone unaided thresholds. Lines show mean audiograms obtained preoperatively (gray, solid line, diamonds), at 3 months (gray, long-dash line, circles), at 6 months (gray, short-dash line, stars) and at 12 months postactivation (black line, triangles). Error bars indicating standard deviation from the mean are shown for the preop and 12 month intervals.

**TABLE 2.** Summary of primary and secondary effectiveness endpoints

	Acoustic Hearing Preop (Baseline) Mean $\pm$ SD	EAS 12 Mo Postactivation Mean $\pm$ SD	Electric Only 12 Mo Postactivation Mean $\pm$ SD
	n = 67	n = 66 <sup>a</sup>	n = 67
		Percentage point change from baseline <sup>b</sup>	Percentage point change from baseline
CUNY sentences in noise	30.9 $\pm$ 27.2	73.4 $\pm$ 23.9	+42.2 $\pm$ 29.8
CNC words	30.4 $\pm$ 13.4	66.9 $\pm$ 18.5	+36.5 $\pm$ 23.5
			48.4 $\pm$ 19.0
			+18.0 $\pm$ 23.0

<sup>a</sup>66 of 67 subjects were tested in an EAS condition.

<sup>b</sup>Percentage point change from baseline calculated using the baseline mean of subjects tested in the EAS condition.

CNC indicates consonant–nucleus–consonant; CUNY, City University of New York; EAS, electric-acoustic stimulation; SD, standard deviation.

### Hearing Sensitivity

An initial decrease in unaided thresholds was shown by 3 months postactivation, and thresholds remained stable (within 2 dB HL) through the 12-month interval (see Fig. 1). Mean LF-PTA increased by 24.1 dB for the 67 subjects who were tested at both the preoperative and the 12-month postactivation intervals. Of these 67, 53 subjects (79.1%) experienced a LF-PTA shift of less than 30 dB HL. Eight subjects (11.9%) had profound or total hearing loss, as determined by a LF-PTA of > 90 dB HL. Of those subjects, six were able to use both electric and acoustic portions of the DUET Audio Processor at 12 months postactivation based on having at least one low-frequency threshold better than 80 dB HL. A total of 65 out of 67 subjects (97.0%) were able to use EAS through the DUET Audio Processor at 12 months postactivation. Two subjects were unable to be fit with the Acoustic Unit due to insufficient residual hearing in the implanted ear.

### Speech Perception Outcomes

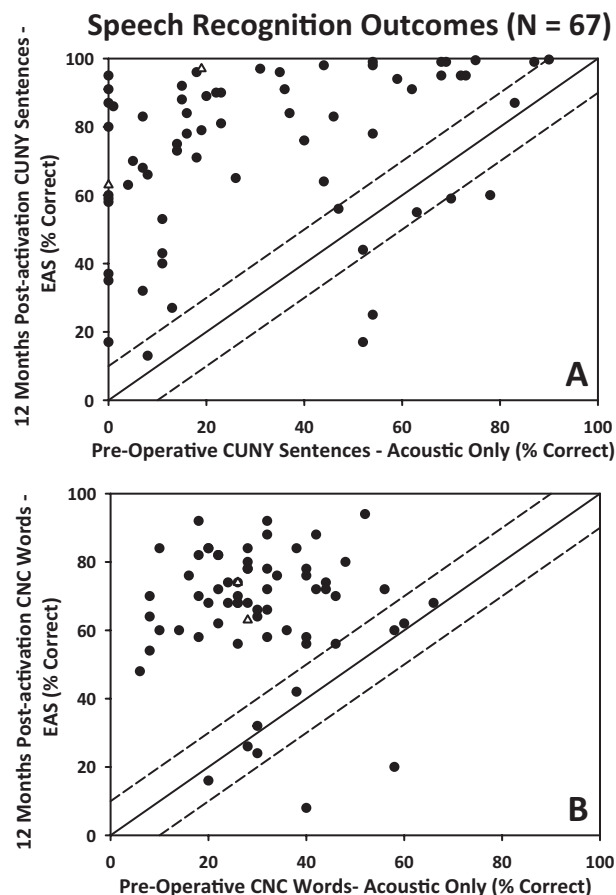
Data supporting the primary and secondary endpoints are presented below. Speech perception outcomes on CUNY sentences in noise and CNC words in quiet are provided in Table 2. Sixty-six of 67 subjects completed testing in the EAS condition. Of the two who were not using the Acoustic Unit, one subject was tested bimodally with a hearing aid on the contralateral ear for the EAS condition, per the protocol at that time. The second subject was not tested with ipsilateral EAS and was only tested in the CI-alone condition, reflecting a change in the protocol. All 67 subjects followed to 12 months postactivation completed testing in the CI-alone condition.

For the primary outcome measure of CUNY sentences in noise, an improvement of 42.2 percentage points ( $p < 0.001$ ; SD = 29.8) occurred from the baseline preoperative hearing aid condition to the 12-month postactivation EAS condition. A comparison of CNC words in the same conditions showed an improvement of 36.5 percentage points ( $p < 0.001$ ; SD = 23.5).

In the CI-alone condition, an improvement of 18.0 percentage points ( $p < 0.001$ ; SD = 23.0) was demonstrated for CNC words in quiet at 12 months postactivation, compared with the preoperative aided condition. For CUNY sentences in noise in the same conditions, an improvement of 24.6 percentage points (SD = 31.5) was found. Additionally, when comparing the EAS condition

to the CI-alone condition at 12 months postactivation, an improvement of 18.4 percentage points ( $p = 0.003$ ; SD = 22.0) was demonstrated on CUNY sentences in noise in the EAS condition.

Individual speech perception data are displayed in Figure 2 for all 67 subjects reaching the 12-month endpoint,



**FIG. 2.** Speech recognition scores for all subjects followed through the 12-month postactivation interval. Scores for CUNY sentences in noise (A) and CNC words in quiet (B) are represented by filled circles for subjects using EAS and open triangles for subjects tested in the CI-alone condition. A solid reference line is shown on both figures, indicating no change in score from the preoperative to the 12 month postactivation interval. Dashed lines are shown at  $\pm 10\%$  of the solid reference line to indicate scores that may fall within test-retest variability. CI indicates cochlear implant; CNC, consonant-nucleus-consonant; CUNY, City University of New York; EAS, electric-acoustic stimulation.

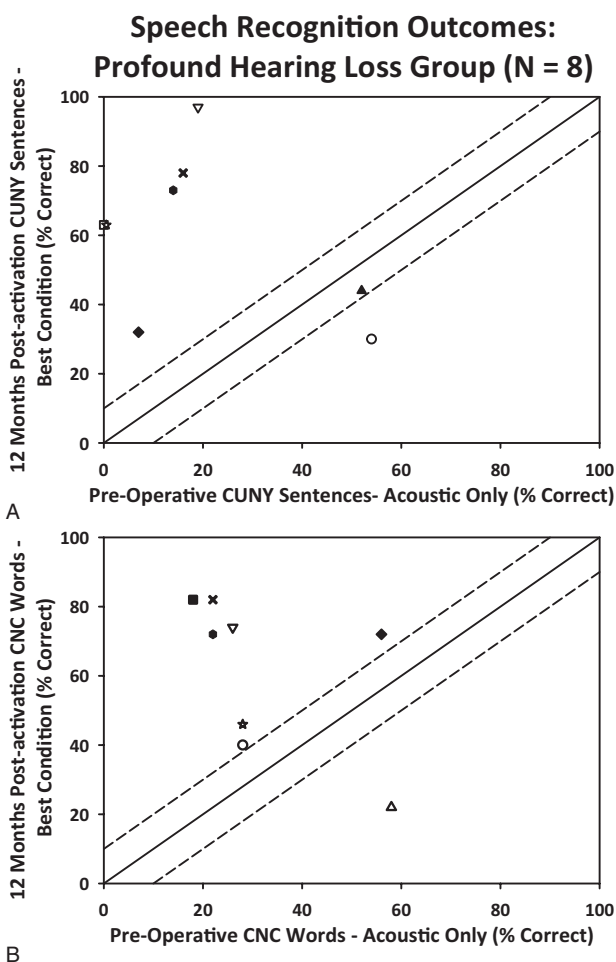


with percent correct at the 12-month postactivation interval shown as a function of preoperative score. EAS results are shown for all subjects able to use the Acoustic Unit, with CI-alone results shown for the two subjects not using DUET EAS. Subjects with speech perception scores greater than 10% above the reference line were classified as performing better. Scores within ( $\pm$ ) 10% of the reference were classified as performing similar, and those with scores more than 10% below the reference were classified as performing worse for a given condition.

On CUNY sentences in noise, 57 of 67 subjects (85.1%) performed better at 12 months in the EAS condition (or CI-alone, as applicable), compared with the preoperative aided condition, when tested in the implanted ear. On CNC words in quiet, 56 of 67 subjects (83.6%) performed better in the EAS condition (or CI-alone, as applicable) at 12 months than in the preoperative aided condition, when tested in the implanted ear. Five subjects (7.5%) performed worse in the EAS condition for at least one test (CNC or CUNY), with only one subject performing worse for both tests.

In the CI-alone condition, 59 of 67 subjects (88.1%) performed similarly or better at 12 months with electric stimulation only, compared with the preoperative aided condition on CUNY sentences in noise. On CNC words in quiet, 59 of 67 (88.1%) performed similarly or better at 12 months in the CI-alone condition compared with the preoperative aided condition. Four of 67 subjects (6.0%) performed worse on both the tests (CNC and CUNY) at 12 months with electric stimulation only. It should be noted that when tested in the CI-alone condition, subjects used a full-frequency electric map with which they had no previous listening experience. In comparing the CI-alone condition to the EAS condition, one subject performed better with electric stimulation alone on CUNY sentences in noise, while four subjects performed better with electric stimulation alone on CNC words in quiet.

For the eight subjects with a profound/total LF-PTA of greater than 90 dB HL postoperatively, individual speech perception data are also displayed in Figure 3. Percent correct at the 12-month postactivation interval for the subject's better listening condition (either EAS or CI-alone) is shown as a function of preoperative aided score for CUNY sentences in noise (Fig. 3A) and CNC words in quiet (Fig. 3B). Out of the profound/total hearing loss group, six subjects performed better on CUNY sentences in noise (three using EAS and three using CI-alone), with one subject performing similarly (EAS) and one subject performing worse (CI-alone) at 12 months compared with the preoperative aided condition. On CNC words in quiet, seven subjects performed better at 12 months postactivation than at the preoperative interval (four using EAS and three using CI-alone), while one subject performed worse (CI-alone). No subject in the profound/total hearing loss group performed poorer at 12 months postactivation than at the preoperative interval on both the CUNY sentence in noise and CNC words in quiet tests.



**FIG. 3.** Speech recognition scores for the profound hearing loss group. Individual subject scores for CUNY sentences in noise (A) and CNC words in quiet (B) are represented by the same symbol in both the figures. Filled symbols indicate subjects with best performance using EAS and open symbols indicate subjects with best performance using CI-alone. A solid reference line is shown on both the figures, indicating no change in score from the preoperative to the 12 month postactivation interval. Dashed lines are shown at  $\pm$  10% of the solid reference line to indicate scores that may fall within test-retest variability. CI indicates cochlear implant; CNC, consonant-nucleus-consonant; CUNY, City University of New York; EAS, electric-acoustic stimulation.

### Quality of Life

Sixty subjects completed the APHAB and 59 subjects completed the HDSS self-assessments preoperatively and at 12-months postactivation. The mean score on the APHAB Global Scale decreased (i.e., improved) by 30.2%, indicating a significant reduction in perceived disability ( $p < 0.001$ ). For the APHAB subscales, 54 of 60 subjects (90.0%) reported a benefit of using EAS for the Ease of Communication and Reverberation subscales and 55 of 60 subjects (91.7%) reported benefit for the Background Noise scale. Fifty-one of 59 subjects (86.4%) reported a higher device satisfaction on the HDSS at 12 months postactivation (with EAS) than they had preoperatively (with hearing aids).

**TABLE 3.** Number and percentage of adverse events observed for EAS subjects

Event	Number of Events	Percentage of Events	Number of Subjects	Percentage of Subjects
Profound/total loss of residual hearing	8	22.9%	8	11.0%
Type B or type C tympanogram	8	22.9%	6	8.2%
Conductive hearing loss	5	14.3%	5	6.8%
Pain at site	3	8.6%	3	4.1%
Other (singular occurrences)	11	31.4%	11	15.1%

EAS indicates electric-acoustic stimulation.

### Adverse Events

Thirty-five device- or procedure-related adverse events were reported for 29 of 73 subjects (39.7%). All the events were consistent with known risks associated with cochlear implantation. The most frequently observed adverse events were profound/total loss of residual hearing, which occurred in 8 of 73 subjects (11.0%) and type B or C tympanograms, which occurred in 6 of 73 subjects (8.2%). Table 3 lists all events reported for multiple subjects. Other adverse events showed only singular occurrences, accounting for 11 of the 35 adverse events. The aforementioned events were reported in 15.0% of the clinical trial subjects (11/73).

### DISCUSSION

Data obtained in the clinical trial demonstrate that the MED-EL EAS System is safe and effective for CI users with residual hearing in the low frequencies. For the 67 subjects with baseline and 12-month data, the LF-PTA increased by an average of 24.1 dB HL, with 53 of 67 subjects (79.1%) experiencing a LF-PTA shift of less than 30 dB HL. Speech perception testing in the EAS condition at 12 months postactivation showed significant mean improvements of 42.2 percentage points on CUNY sentences in noise and 36.5 percentage points on CNC words, compared with the preoperative interval. Sixty-two of 67 subjects (92.5%) performed similarly or better on both speech perception outcome measures with EAS alone, compared with their preoperative performance with hearing aids, and 66 subjects (98.5%) performed better on at least one test. In the CI-Alone condition at 12 months, 63 of 67 subjects (94.0%) performed similarly or better on at least one test compared with the preoperative aided condition. Ninety-two percent of subjects reported a subjective improvement in their ability to understand speech in background noise on the quality of life measures.

To date, no subjects from the clinical trial have been revised to a longer electrode for deeper insertion due to poor performance. Of the eight subjects (11.9%) with a LF-PTA greater than 90 dB HL, six were still able to be fit with the Acoustic Unit postoperatively (at least one low-frequency threshold better than 80 dB). Five of the six performed better in the EAS condition than they had preoperatively on at least one of the two speech tests. Both subjects who were unable to use the Acoustic Unit demonstrated an improvement in speech understanding

scores using electric stimulation (CI) only, with individual improvements of 63 and 78 percentage points on CUNY sentences in noise and 18 and 48 percentage points on CNC words in quiet from the preoperative interval to the 12-month interval.

Results of this clinical trial are consistent with those found in the MED-EL European multicenter clinical study, published by Helbig et al. (9) where measurable low-frequency residual hearing was maintained in all 18 subjects implanted with the PULSAR Cochlear Implant and FLEX<sup>24</sup> electrode array. In that study, 17 of 18 subjects (94.4%) used EAS through 12 months postactivation. Mean improvements of 44.2 percentage points on open-set monosyllabic words and 38.1 percentage points on open-set sentence testing in quiet were demonstrated in the EAS condition, compared with the preoperative hearing aid condition. Speech performance improvements reported in both the present and European clinical trials of EAS are comparable to those found in clinical trials of similar devices (15,16).

Additional results from the published literature are consistent with the present clinical trial. Lorens et al. (17) reported on 11 subjects fit with the DUET Audio Processor for combined electric and acoustic stimulation. Subjects demonstrated significant improvement when tested in quiet and noise with EAS, compared with CI-alone. A comparison of the same subject population to a group of 22 traditional CI users showed that the EAS group had higher speech perception scores. Usami et al. (18) published results on 27 subjects (29 ears) implanted with the MED-EL FLEX<sup>24</sup> electrode array, including 24 subjects from the Japanese clinical trial. This group reported that 27 of 29 ears (93.1%) maintained enough residual hearing to be fit with the Acoustic Unit of the EAS System. Speech perception on monosyllabic words in quiet and sentences in noise showed significant improvements of 43.3 and 36.9 percentage points, respectively, with EAS at 12 months post-EAS fitting (electric and acoustic stimulation fit simultaneously at 4 weeks postoperatively), compared with preoperatively with hearing aids.

There is limited data on long-term outcomes. Mertens et al. (19) published long-term data on nine subjects (11 ears) followed for up to 10 years postoperatively. Some degree of residual hearing was maintained for nine ears (81.8%) at the most recent follow-up visit reported. Speech perception data showed significant improvement on words in quiet and sentences in noise up to 10 years

postoperatively. Recently, Moteki et al. (20) published data demonstrating benefit with EAS up to 5 years postoperatively in 17 subjects implanted with the FLEX<sup>24</sup> electrode, with 17 of 19 ears (89.5%) retaining measurable hearing thresholds allowing continued use of EAS. Long-term follow-up data from subjects implanted in the US clinical trial will be obtained, including speech perception and residual hearing data through at least 5 years postoperatively.

Limitations of the clinical trial data presented here include the test material used for sentences in noise. CUNY sentence materials were widely used at the time of study initiation. Since that time, it has been established that ceiling effects can impact data obtained using CUNY sentences (21). However, in addition to significantly improved CUNY sentence scores, subjects in the present study also had significantly improved CNC word scores in quiet, a test that is not subject to the same degree of ceiling effects.

The MED-EL EAS System is an integrated electric and acoustic solution that provides a new treatment option for an existing population that has historically had few rehabilitative alternatives. The FDA clinical trial data presented here illustrate the successful application of combined electric and acoustic stimulation in adult CI recipients with low-frequency residual hearing. Subjects experienced additional performance and subjective benefits from EAS, beyond those of electric stimulation alone, confirming the advantages of EAS, particularly for difficult listening environments and quality of life. The FDA approval of implantation with a thin, flexible long electrode and combined EAS provides an effective treatment option for individuals with low-frequency acoustic hearing who do not meet traditional CI candidacy.

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