

# Evaluating cochlear implant trauma to the scala vestibuli

Adunka, O.,\* Kiefer, J.,<sup>†</sup> Unkelbach, M.H.,\* Radeloff, A.<sup>†</sup> & Gstoettner, W.\*

\*Clinic of Otolaryngology, Head and Neck Surgery, Johann Wolfgang Goethe University, Frankfurt am Main, and

<sup>†</sup>Clinic of Otolaryngology, Head and Neck Surgery, Clinic "Rechts der Isar", Technical University, Munich, Germany

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**Objectives:** Placement of cochlear implant electrodes into the scala vestibuli may be intentional, e.g. in case of blocked scala tympani or unintentional as a result of trauma to the basilar membrane or erroneous location of the cochleostomy. The aim of this study was to evaluate the morphological consequences and cochlear trauma after implantation of different cochlear implant electrode arrays in the scala vestibuli.

**Design:** Human temporal bone study with histological and radiological evaluation.

**Setting:** Twelve human cadaver temporal bones were implanted with different cochlear implant electrodes. Implanted bones were processed using a special method to section undecalcified bone.

**Main outcome measures:** Cochlear trauma and intra-cochlear positions.

**Results:** All implanted electrodes were implanted into the scala vestibuli using a special approach that allows direct scala vestibuli insertions. Fractures of the osseous spiral lamina were evaluated in some bones in the basal cochlear regions. In most electrodes, delicate structures of the organ of Corti were left intact, however, Reissner's membrane was destroyed in all specimens and the electrode lay upon the tectorial membrane. In some bones the organ of Corti was destroyed.

**Conclusions:** Scala vestibuli insertions did not cause severe trauma to osseous or neural structures, thus preserving the basis for electrostimulation of the cochlea. However, destruction of Reissner's membrane and impact on the Organ of Corti can be assumed to destroy residual hearing.

Since the introduction of intracochlear electrode arrays for cochlear implantation, in general, the scala tympani has been chosen to accommodate the electrode. However, placement of the electrode in the scala vestibuli is possible and has been described either as a result of unintentional dislocation or of intentional placement.<sup>1–4</sup> Unintentional placement into scala vestibuli can occur if the cochleostomy is performed cranially to the round window or if the electrode array disrupts the basilar membrane or osseous spiral lamina and crosses these structures. Unintentional placement into scala vestibuli has been discussed in implanted specimens of human temporal bones in histological studies with a frequency of up to 30% for some types of electrode arrays (A. Aschendorff, pers. comm., and results from our own temporal bone laboratory) and could also be demonstrated in implanted patients using rotational tomography.<sup>5</sup> Intentional placement has been described as a surgical alternative in cases of absent, malformed or obliterated scala tympani<sup>1–4</sup> because of cochlear malformations, meningitis, severe otosclerosis or

fractures of the cochlea. Here, modified surgical approaches to enter the scala vestibuli without destroying delicate structures of the scala media are reported. Although speech understanding and other functional results of scala vestibuli insertion seem to be comparable with scala tympani insertion,<sup>1–3</sup> to our knowledge, there is no report on the resulting trauma to cochlear structures after primary insertion of cochlear implant electrodes into the scala vestibuli. In the light of extending indications for cochlear implantations to patients with remaining low frequency hearing, the morphological impact of scala vestibuli insertions on cochlear structures is of interest.<sup>6–8</sup> Therefore, the aim of this study was to evaluate cochlear trauma when intentionally inserting the array into the scala vestibuli. Special emphasis was laid on the evaluation of electrode position in the scala vestibuli in relation to delicate structures of the organ of Corti.

## Materials and methods

### Electrode types

Three different prototype cochlear implant electrodes, manufactured by MED-EL (Innsbruck, Austria), have

Correspondence: Dr Oliver Adunka, MD, ENT University Clinic, J.W. Goethe University, Theodor Stern Kai 7, 60590 Frankfurt am Main, Germany, E-mail: adunka@em.uni-frankfurt.de

**Table 1.** Description of all electrodes used in this study compared with the C40+ standard array

Array	Diameter (mm)			No. of contacts	Spacing	Length (mm)		
	Basal	Tip, vertical plane	Tip, horizontal plane			Distribution of contacts	Length of intracochlear part	Distance first contact from tip
C40+	0.8	0.50	0.48	12	2.4	26.4	31.5	1.2
C40+ Medium	0.8	0.50	0.48	12	1.9	20.9	26.0	1.2
Flex EAS	0.8	0.50	0.35	12	1.9	20.9	26.0	1.2
FLEX <sup>soft</sup>	0.8	0.50	0.35	12	2.4	26.4	31.5	1.2

been used in this study (Table 1). The Flex EAS prototype ( $n = 4$ ) and the C40+ Medium ( $n = 6$ ) electrode have been developed for combined electric acoustic stimulation of the auditory system with insertion depths of 20–22 mm to reach the 1.000 Hz region. Both electrodes have therefore a reduced length from the tip of the electrode to the last contact of 22.1 mm. The first contact is placed 1 mm from the tip and contact spacing for both carriers is 1.9 mm (compared with 2.4 mm in the regular C40+ electrode). All contacts are made of a platinum–iridium alloy (90/10) and measure 25  $\mu\text{m}$  in diameter. Contacts are usually paired on opposite sides of the array, like in the standard C40+ array. In the Flex EAS array, the five most apical contacts are single. This allows a reduction of the apical electrode diameter to 70% of the regular electrodes. As shown in a recent report,<sup>7</sup> a 40% reduction of insertion force could be achieved with this design. In all arrays used in this study, the diameter at the basal end measures 0.80 mm  $\times$  0.78 mm. For the C40+ Medium, the diameter at the tip measures 0.50 mm  $\times$  0.48 mm. Both Flex prototypes feature single contacts at the tip and therefore a reduction of the apical diameter of 30%.

The FLEX<sup>soft</sup> prototype ( $n = 2$ ) is intended for deep atraumatic insertions (unpublished observations). Contact spacing is 2.4 mm like in the regular C40+ array. Like in the Flex EAS array, the FLEX<sup>soft</sup> electrode features five single contacts at the tip. Analogue to the Flex EAS design, a reduction of the electrode diameter at the tip and less insertion forces during implantation are achieved. The body of all electrodes used is made of two-component silicone (medical grade). A description on all electrodes in comparison with the C40+ standard array is given in Table 1.

### Surgical procedure

Twelve human temporal bones (six right, six left ears) were harvested 6–18 h postmortem and implanted with electrodes. All structures not necessary for implantation

were removed from the bones but inner ear structures were left intact. Then, a regular mastoidectomy, posterior tympanotomy approach was used to access the middle ear. All implantations were performed by the same surgeons, both experienced in regular and experimental cochlear implantations (OA and JK). To approach the scala vestibuli, a superior drilling procedure was chosen. As described in a previous report,<sup>1</sup> this requires the removal of the incus and the suprastructure of the stapes. The footplate of the stapes is left in place. The cochleostomy itself is then drilled in the anterior niche of the oval window. In order to fit the electrode carriers into the scala vestibuli, the cochleostomy is enlarged to a maximum diameter of  $\approx 1$  mm. Insertions of the electrode arrays were performed smoothly. Forceful insertion procedures were strictly avoided and all insertions were stopped at the point of first resistance. Surgical insertion depths were evaluated during insertions. All arrays were fixed with non-resorbable sutures.

### Histological processing

For the processing of the temporal bones, a special polishing, grinding technique established by Plenk<sup>9</sup> was used. After all surgical steps were completed, specimens were relayed to fixation, dehydration and embedding. Perilymphatic perfusion of buffered formalin solution through the oval window was used for fixation. Then, dehydration with an ascending series of alcohol (70–100% ethanol) was performed followed by embedding in polymethylmethacrylate at room temperature. This processing procedure allows sectioning of undecalcified bone. The electrode carrier can be left *in situ*. The position, orientation and insertion depth in terms of degrees around the modiolus of the implant were evaluated using X-ray.<sup>10,11</sup> Serial sections with a slide thickness of 100–150  $\mu\text{m}$  were made and each slide was marked to determine the exact position of the electrode within the cochlea. A special grinding, polishing procedure to enhance the quality of the histological slides

**Table 2.** Surgical, histological and radiological data on all 12 specimens. On the right columns, the location and extent of trauma is described. Additionally, the percentage of cochlear trauma in relation to the entire intracochlear length of the array is calculated. Mean values of each array are described at the bottom

Number	Electrode Type	Bone Side	Insertion depths			Location and extent of trauma (°) [see Table 3]					
			Surgical (mm)	Histological (°)	Radiological (°)	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	% trauma >grade 3
1	C40+ Medium	Right	20	540	480		60–360, 420–540	30–60, 360–420		0–30	22.2
2	C40+ Medium	Left	22	450	420		45–450			0–45	10.0
3	C40+ Medium	Right	24	400	450		60–400			0–60	15.0
4	C40+ Medium	Right	22	450	420		45–450			0–45	10.0
5	C40+ Medium	Left	22	540	540		30–540			0–30	5.6
6	C40+ Medium	right	19	300	300		30–300			0–30	10.0
7	FLEX <sup>soft</sup>	Left	30	720	720		90–720			0–90	12.5
8	FLEX <sup>soft</sup>	Left	30	720	720		60–720			0–60	8.3
9	Flex EAS	Left	22	450	540	0–30	30–450				0.0
10	Flex EAS	Right	22	600	540		45–600			0–45	7.5
11	Flex EAS	Right	22	540	540		30–540			0–30	5.6
12	Flex EAS	Left	22	400	400	30–70	0–30, 70–400				0.0
Min*		6 × right	19	300	300	30	270	90	0	30	0
Max*		6 × left	30	720	720	40	660	90	0	90	22
Mean (all electrodes)*			<b>23.1</b>	<b>509.2</b>	<b>505.8</b>	35.0	457.1	90.0	0.0	46.5	<b>9.7</b>
Mean C40 +Medium			21.5	446.7	435.0						12.1
Mean FLEX <sup>soft</sup>			30.0	720.0	720.0						10.4
Mean Flex EAS			22.0	497.5	505.0						3.3

\*Data represents minimal, maximal and mean values for the specific grades if seen in temporal bones. Values in bold represent the mean.

was then used. Staining was accomplished with a Giemsa stain. See Table 2 for detailed surgical, radiological and histological data.

#### Evaluation of cochlear trauma

All specimens were histologically examined by two of the authors (OA and JK) independently. Location and extent of trauma in different parts of the cochlea was evaluated. In addition, the site of the cochleostomy was examined to evaluate trauma in that region. Trauma was evaluated using a new grading system described in Table 3. This is a modification of a grading scheme for scala tympani insertions described in a recent paper.<sup>12</sup> Also, insertion depths in terms of degrees around the

modiolus were evaluated and correlated to radiological data. To exclude artefacts caused by electrode swelling caused by the embedding procedure, all slides were measured with a special microscopic measuring system (Zeiss, Göttingen, Germany).

#### Results

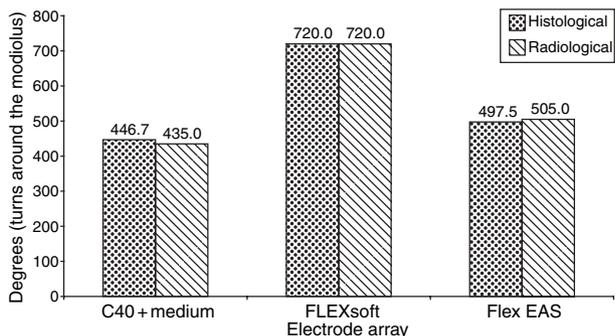
Surgically, all insertions were performed according to the protocol described above. Six right and six left bones were implanted. Surgical insertion depths ranged from 19 to 30 mm (mean 23.1 mm) for all electrode carriers used. Average insertion depths were 21.5 mm for the C40+Medium, 30 mm for the FLEX<sup>soft</sup> carrier and 22.0 mm for the Flex EAS array.

**Table 3.** Grading scheme for scala vestibuli insertions. A scheme for regular scala tympani insertions established by Eshraghi *et al.*<sup>12</sup> was modified to contribute to important structures within the scala vestibuli

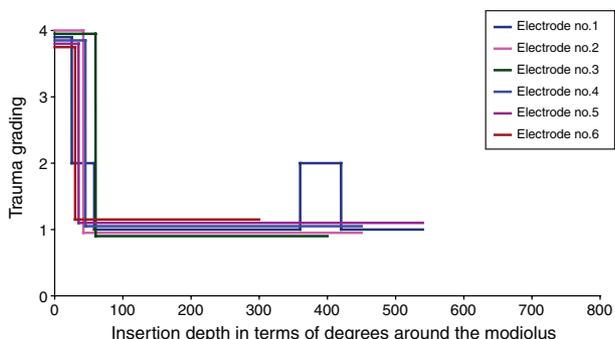
Grade	Histopathological changes
0	No trauma to cochlear structures, Reissner’s membrane and bony structures left intact
1	Rupture of Reissner’s membrane, all other cochlear structures left intact, electrode might lie on top of the Tectorial membrane and might lead to a slight dislocation of the basilar membrane
2	Destruction of the stria vascularis and or severe dislocation but not rupture of the basilar membrane with impingement of organ of Corti
3	Dislocation of the electrode into the scala tympani via rupture of the basilar membrane without fracture of the osseous spiral lamina
4	Fracture of the osseous spiral lamina and/or the bony modiolar wall

With the X-ray of the embedded specimens, orientation, radiological insertion depths and position of the electrode could be clearly evaluated. Correct planes for sectioning allowed an evaluation of cochlear trauma with respect to location within the cochlea. Histological and radiological

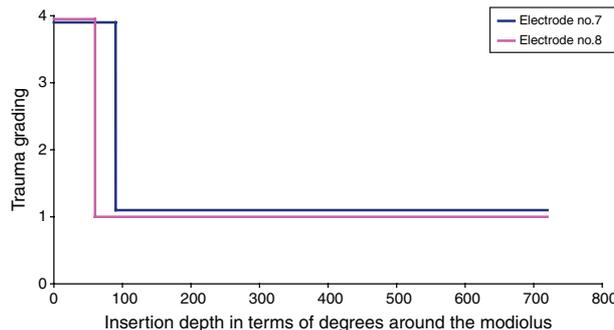
gathered insertion depths correlated well. Histological insertion depths ranged from 300 to 720° for all electrodes (mean 509.2°). Radiological data also ranged from 300 to 720° (mean 505.8°, Pearson’s correlation between radiological and histological data: 0.944). Mean histological



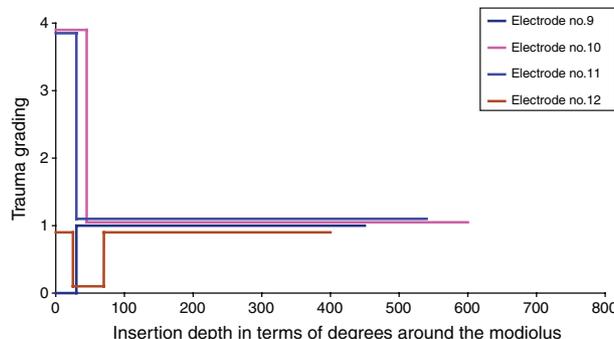
**Fig. 1.** Histological and radiological insertion depths of all three arrays used in this study. Note the correlation between histological and radiological data.



**Fig. 2.** Insertion graph for six C40+ Medium electrodes. This electrode was designed for use in EAS surgeries. Contact spacing of 1.9 mm. Note that basal trauma is the result of cochleostomy location and angle and is not related to the array itself. Only grade 1 trauma (rupture of Reissner’s membrane, but other structures of the organ of Corti left intact) in the apical parts of the electrode.



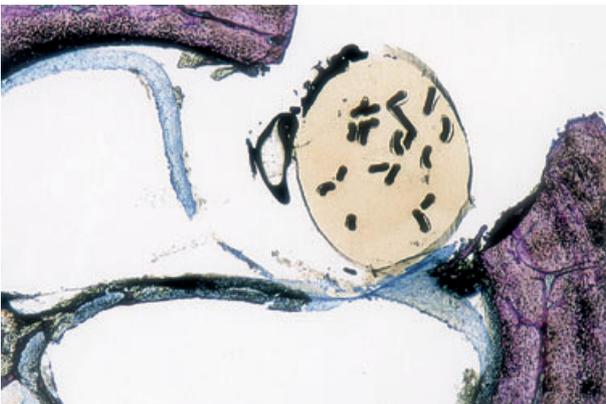
**Fig. 3.** Insertion graph for two FLEX<sup>soft</sup> electrodes basal trauma is strictly related to the surgical procedure as in the other electrode types. Grade 1 trauma throughout the rest of the basal and middle cochlear turn.



**Fig. 4.** Insertion graph for four Flex EAS electrodes. In two specimens, cochlear structures of the scala vestibuli were left intact in the basal parts. Other two arrays show grade 4 trauma which is related to site and angle of the cochleostomy. No trauma greater than grade 1 in all four electrodes beyond 45° insertion depth.

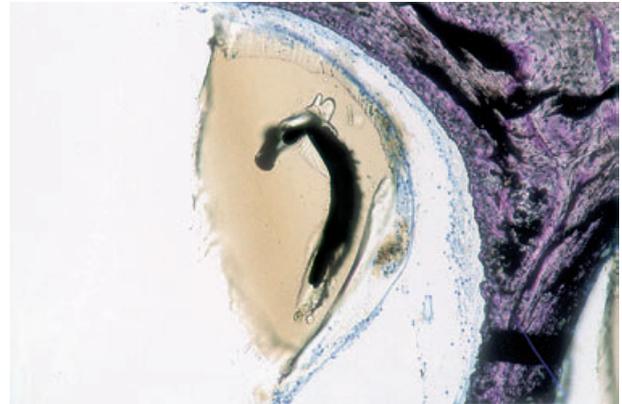


**Fig. 5.** Electrode 6, C40+ Medium electrode,  $1 \times 600$ , Giemsa stain, middle cochlear turn, right temporal bone, 19 mm surgical insertion depth,  $300^\circ$  histological insertion depth.



**Fig. 6.** Electrode 12, Flex EAS array,  $1 \times 400$ , Giemsa stain, site of the cochleostomy, no fracture of the osseous spiral lamina.

values for each electrode were  $446.7^\circ$  for the C40+ Medium,  $720.0^\circ$  for the FLEX<sup>soft</sup> and  $497.5^\circ$  for the Flex EAS array. Detailed data are given in Table 2 and Fig. 1.



**Fig. 7.** Electrode 12, Flex EAS electrode,  $1 \times 630$ , apical parts of the electrode, middle cochlear turn, left ear,  $400^\circ$  histological insertion depth, 22 mm surgical insertion depth. Trauma grade 1 (destruction of Reissner's membrane, organ of Corti intact).

Cochlear trauma was evaluated for each electrode. All insertions were primarily performed into the scala vestibuli. No fractures of the modiolar wall were seen in any bone. Insertion graphs are shown in Figs 2–4. Each of the six C40+ Medium electrodes produced a grade 4 trauma (fractures of the osseous spiral lamina) in the region of the cochleostomy. This trauma is strictly related to the surgical procedure (drilling of the cochleostomy) as can be seen in histological slides with the cochleostomy. Five of the six C40+ Medium specimens show a grade 1 trauma throughout the rest of the intracochlear extent of the array. In one bone, grade 2 trauma was present in the middle cochlear turn (Figs 2 and 5). As seen in all C40+ Medium arrays, both FLEX<sup>soft</sup> electrodes show basal grade 4 (fracture of the osseous spiral lamina) trauma because of the surgical approach. Apically, both arrays show grade 1 trauma with no destructions of the organ of Corti (Fig. 3). In contrast to those two arrays, two of the Flex EAS electrodes produce no trauma (grade 0) in the vicinity of the cochleostomy. In the other two specimens implanted with the Flex EAS carrier, grade 4 trauma was present. Beyond the very basal parts of the cochlea, grade 1 trauma like seen in almost all other electrodes was observed (Figs 4, 6, 7).

When calculating the relative extent of trauma greater than grade 1 with respect to the entire length of the intracochlear part of the array, average value of cochlear trauma for all electrode arrays is 9.7%. This means that a mean of 9.7% of the intracochlear extent of all electrode arrays used produce real cochlear trauma to the organ of Corti (grades 0 and 1 represent no trauma to the organ of Corti). Respective mean percentage of trauma for the C40+ Medium electrode is 12.1, 10.4 in the FLEX<sup>soft</sup> carrier and 3.3 in the Flex EAS electrode (Table 2).

## Discussion

In the current report we could evaluate cochlear trauma of three prototype electrode arrays when intentionally inserting them into the scala vestibuli of the cochlea. Results show that relatively atraumatic electrode insertions into the scala vestibuli are possible. Grade 4 trauma was confined to the basal parts of the cochlea only, close to the cochleostomy. We relate that trauma strictly to the surgical procedure, drilling of the cochleostomy itself. The remaining intracochlear parts of the electrodes show a grade 1 trauma mostly. In our proposed grading scheme for scala vestibuli insertions, grade 1 describes a rupture of Reissner's membrane, but no further trauma to the architecture of the organ of Corti. However, destruction of residual function of hair cells may be expected if, as seen in our preparations, the electrode is lying directly upon the tectorial membrane. In two of the Flex EAS electrodes, Reissner's membrane stayed intact for a short extent of the array. Although a rupture of Reissner's membrane is graded as minimal anatomical trauma only, one would anticipate severe functional impairments of remaining hearing. Despite that, studies in animal models have suggested that localized rupture of the cochlear membrane alone does not necessarily induce profound sensorineural hearing loss.<sup>13,14</sup> Simmonds<sup>15</sup> proposed the double-membrane break theory, which suggests that acute profound sensorineural hearing loss results from rupture of both Reissner's membrane and the round window membrane. Mixing of the endolymph and perilymph results in an increase in the perilymph concentration of potassium ions, which depolarizes hair cells and causes loss of cochlear function.<sup>16</sup> But potassium intoxication depends on certain conditions. Studies suggest that a radial component may be involved in the dynamic equilibrium of electrolytes in cochlear fluids. Histologically, degeneration of the organ of Corti remains localized even several months following the induction of discrete lesions of Reissner's membrane.<sup>17,18</sup> The results of these studies suggest that the radial pattern predominates in cochlear fluids. Therefore, localized damage to the cochlea would not cause a widespread dispersion of the fluid admixture of perilymph and endolymph. A drop in pressure at one end of the perilymphatic component creates longitudinal flow towards the round window, which causes the fluid admixture to become widespread. Double-membrane ruptures therefore produce acute sensorineural hearing loss in guinea-pigs<sup>19</sup> and such ruptures have also been described in humans.<sup>20</sup> However, in scala tympani insertions, rupture of Reissner's membrane may not be localized but extended. In these cases, hearing loss will be present, if some functional hearing was present

before the operation. As not all details of cochlear fluid flow are known, scala vestibuli implantations should be avoided during surgery for electric acoustic stimulation, where hearing preservation is fundamental.<sup>6–8</sup>

In all other cochlear implant surgeries, scala vestibuli insertions should not affect the outcome as we did not see greater trauma to neural structures compared with scala tympani insertions. Comparing insertion depths, no statistical significant differences could be evaluated when comparing scala vestibuli and scala tympani electrode placements.<sup>9,10</sup>

## Conclusion

Using electrode designs that produce little or no trauma in scala tympani insertions, relatively atraumatic insertions into the scala vestibuli are possible. All neural and osseous structures were left intact beyond the site of cochleostomy. Mostly, trauma was only confined to that very region. Scala vestibuli insertions can be regarded as a safe alternative in cases, in which scala tympani insertions are not possible. However, in patients with remaining cochlear function, scala vestibuli insertions should be avoided because rupture of Reissner's membrane was present in every specimen. Improved surgical techniques to clearly identify scala tympani and scala vestibuli should help to avoid trauma at the site of the cochleostomy.

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