

# Development and Evaluation of an Improved Cochlear Implant Electrode Design for Electric Acoustic Stimulation

Oliver Adunka, MD; Jan Kiefer, MD, PhD; Marc H. Unkelbach; Thomas Lehnert, MD;  
Wolfgang Gstottner, MD, PhD

**Objective:** The objective of this study was to assess the intracochlear position and the extent of trauma to cochlear structures using a new prototype electrode carrier (Flex EAS). Special emphasis was placed on the practicality for combined electric and acoustic stimulation of the auditory system. **Study Design:** Human temporal bones were evaluated histologically after insertion of the electrodes, and insertion forces were measured in an acrylic model of the scala tympani. **Methods:** 1) Insertion forces with the regular C40+ array and the new electrode prototype were measured in an acrylic model of the scala tympani. 2) Ten human temporal bones were implanted using the same surgical procedure as in vivo. All bones underwent fixation methacrylate embedding to allow cutting of the undecalcified bone with the electrode in situ. In addition, radiography of the implanted devices was performed and correlated to histologic results. Electrode positions and trauma to cochlear structures were then evaluated histologically. **Results:** All insertions of the new electrode array were performed in the scala tympani of the cochlea. All insertions were atraumatic and covered one cochlear turn. The only effect on cochlear structures that could be observed was a slight lifting of the basilar membrane in the middle turn limited to the tip of the electrode. In three bones, basal trauma, which resulted from the cochleostomy itself, could be observed as well. All neural structures remained intact. **Conclusions:** The new electrode prototype provides very good mechanical properties for safe and atraumatic implantation. All criteria for the use in hearing-preservation cochlear implantation for electric and acoustic stimulation were fulfilled. Surgical measures to prevent basal trauma appear to be very

important. **Key Words:** Cochlear implant, intracochlear trauma, electric acoustic stimulation.

*Laryngoscope*, 114:1237–1241, 2004

## INTRODUCTION

Throughout the last decade, cochlear implants have become standard in the treatment of bilateral sensory deafness, and with improved implant designs and better speech-coding strategies, the successful implantation of patients with severe to profound hearing loss (HL) became possible. In 1999, a new treatment modality for patients with preserved low-frequency hearing and complete HL for high frequencies was developed at our department<sup>1</sup>: combined electric and acoustic stimulation (EAS). With this method, intact deep-frequency hearing of the cochlea is stimulated by way of a conventional hearing aid, whereas high-frequency hearing is provided by means of a cochlear implant. In a previous report, we were able to show that combined EAS of the auditory system is possible in humans. In addition, a synergistic effect, which resulted in highly significant improved speech discrimination scores, especially in noise conditions, were observed.<sup>2</sup> We also reported on at least partial hearing preservation in six of eight subjects,<sup>1</sup> with complete hearing preservation in four patients undergoing cochlear implantation for combined stimulation. Recently, we were able to show that hearing preservation could be accomplished in 12 of 14 patients.<sup>3</sup> These patients received either a standard Combi 40+ implant or a modified version with reduced spacing of electrode contacts, both manufactured by Med-El, Innsbruck, Austria. For EAS implantations, a 360° insertion was chosen to stimulate the majority of nerve fibers. Deeper insertions, which were shown to be possible with the C40+ array,<sup>4</sup> would increase the risk of damage to apical cochlear structures and impair the acoustic enhancement of deep frequency residual hearing by way of a conventional hearing aid.

To ensure hearing preservation during implantation, an atraumatic electrode insertion is fundamental. This will also prevent neuronal cell death subsequent to loss of residual hair cells or to trauma to the spiral osseous ligament and modiolar wall<sup>5</sup> and formation of fibrous tissue or new bone in the cochlea.<sup>6</sup> In contrast with other stud-

From the ENT Department (O.A., J.K., M.H.U., W.G.) and the Department of Radiology (T.L.), J.W. Goethe University Frankfurt am Main, Frankfurt am Main, Germany.

Editor's Note: This Manuscript was accepted for publication January 23, 2004.

Send Correspondence to Dr. Oliver Adunka, ENT Department, University Clinic Frankfurt am Main, Theodor Stern Kai 7, D-60590 Frankfurt am Main, Germany. Email: adunka@em.uni-frankfurt.de

ies,<sup>7-12</sup> we were able to evaluate the intracochlear position of cochlear implant electrodes using a special technique, which allowed us to section human temporal bones with the electrodes still in situ.<sup>12,13</sup> Detailed information on the extent of trauma to inner ear structures and electrode positions was gathered. In further human temporal bone studies,<sup>14-17</sup> it was shown that perimodiolar electrode prototypes and forceful insertion maneuvers when using regular arrays produced greater trauma to cochlear structures than atraumatically inserted standard electrodes. Currently, patients with profound binaural HL are candidates for deep, traumatic insertions,<sup>4</sup> whereas subjects with remaining cochlear function should be implanted carefully to provide hearing preservation. Several surgical factors, such as avoiding bone drilling after incision of the cochlear endosteum and the application of intrasclerular glucocorticosteroids, are currently under discussion.

The purpose of this investigation was to evaluate and compare the intracochlear positions and insertion properties of a new prototype electrode carrier, which has been designed to minimize the forces generated during insertion. Special emphasis was placed on the resulting trauma to cochlear structures using atraumatic surgical techniques.

## MATERIALS AND METHODS

A prototype electrode carrier, called the Flex EAS, was developed in collaboration with the manufacturer Med-El, Innsbruck, Austria and used in this study. The aim was to develop an electrode for shorter insertion depths, which requires less force for insertion into the human cochlea. The body of this electrode is made of two-component silicon (medical grade). All contacts are platinum and measure  $800 \times 500 \mu\text{m}$ . Wires are made of a platinum-iridium alloy (90/10) and measure  $25 \mu\text{m}$  in diameter. In the regular C40+ electrode, contact spacing is 2.4 mm, whereas contacts in the new prototype device are placed 1.9 mm apart. The regular C40+ electrode has paired electrode contacts, which are placed on opposite sides within the electrode body.

The entire electrode body of the standard C40+ electrode



Fig. 1. The electrode array. The five most apical electrode contacts are single, whereas the basal seven contacts are paired.

measures 133.7 mm, and the intracochlear part has a length of 31.5 mm. Electrode contacts are distributed over a range of 26.4 mm, with the most apical contact being placed 1.2 mm from the tip of the body. The intracochlear part of the C40+ electrode is slightly oval, with diameters of  $0.80 \times 0.78 \text{ mm}$  at the basal end and  $0.50 \times 0.48 \text{ mm}$  at the tip. Because of reduced contact spacing of 1.9 mm, the overall distance of electrode distribution is 20.9 mm, and the distance from the tip to the marker ring (maximal intended insertion depth) is 24.9. Basal electrode configuration and diameters are the same as for the standard C40+ array. To increase flexibility of the new electrode, the five most apical contacts are not paired, through which the diameter at the tip is oval and reduced to 70% of the standard C40+ electrode to provide better apical flexibility (Fig. 1).

Ten fresh human cadaver temporal bones were harvested within 24 hours of death and relayed to processing (Table I). The size of all temporal bones was reduced to structures necessary for inserting the electrodes only. In every temporal bone, inner ear structures were left intact. All insertions were performed by the same surgeons (J.K. and O.A.) under standardized conditions. A posterior tympanotomy (by way of the facial recess) and cochleostomy approach, such as that used for regular cochlear implantation, was performed. Full 22 mm insertions (i.e., all active contacts inside the cochlea) were intended in all bones. To prevent cochlear damage, insertions were performed only until the point of first resistance was reached. Forceful insertion maneuvers were prevented. After insertion, electrodes were fixed with histoacryl adhesive.

After all surgical procedures were finished, temporal bones with the fixed electrode carrier were relayed to fixation, dehydration, and embedding. Fixation was accomplished by perilymphatic perfusion of buffered formalin solution through the oval window, followed by dehydration with an ascending series of

TABLE I.  
Data on Temporal Bones, Insertions, and Cochlear Damage.

| Case | Electrode |           | Insertion Depth           |                    |                           | Index Percent Trauma Grade > 0 | Trauma Locations (degrees around the modiolus) |         |         |         |         |
|------|-----------|-----------|---------------------------|--------------------|---------------------------|--------------------------------|--|---------|---------|---------|---------|
|      | Type      | Side      | Histologic Data (degrees) | Surgical Data (mm) | Radiologic Data (degrees) |                                | Grade 0  | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| 1    | Flex EAS  | Right     | 360                       | 22                 | 360                       | 0.0                            | 0-360  |         |         |         |         |
| 2    | Flex EAS  | Right     | 630                       | 22                 | 600                       | 4.8                            | 0-600  | 600-630 |         |         |         |
| 3    | Flex EAS  | Right     | 360                       | 22                 | 360                       | 0.0                            | 0-360  |         |         |         |         |
| 4    | Flex EAS  | Left      | 360                       | 22                 | 360                       | 8.3                            | 30-360   |         | 0-30    |         |         |
| 5    | Flex EAS  | Right     | 360                       | 22                 | 420                       | 16.7                           | 60-360   | 30-60   |         | 0-30    |         |
| 6    | Flex EAS  | Left      | 360                       | 22                 | 360                       | 0.0                            | 0-360  |         |         |         |         |
| 7    | Flex EAS  | Right     | 270                       | 22                 | 240                       | 0.0                            | 0-270  |         |         |         |         |
| 8    | Flex EAS  | Right     | 360                       | 20                 | 360                       | 8.3                            | 30-360   |         |         | 0-30    |         |
| 9    | Flex EAS  | Left      | 360                       | 22                 | 330                       | 0.0                            | 0-360  |         |         |         |         |
| 10   | Flex EAS  | Right     | 300                       | 22                 | 290                       | 15.0                           | 45-300   |         |         | 0-45    |         |
| Min  |           | 7 × right | 270.0                     | 20.0               | 240.0                     | 0.0                            | 255.0  | 30.0    | 30.0    | 0.0     | 30.0    |
| Max  |           | 3 × left  | 630.0                     | 22.0               | 600.0                     | 16.7                           | 600.0  | 30.0    | 30.0    | 0.0     | 45.0    |
| Mean |           |           | 372.0                     | 21.8               | 368.0                     | 5.3                            | 352.5  | 30.0    | 30.0    |         | 35.0    |

In the right columns, location of cochlear trauma is specified.

TABLE II.  
Classification of Cochlear Trauma.<sup>19</sup>

| Grade   | Histopathologic Changes                            |
|---------|--|
| Grade 0 | No trauma  |
| Grade 1 | Elevation of basilar membrane                      |
| Grade 2 | Rupture of basilar membrane or spiral ligament     |
| Grade 3 | Dislocation into scala vestibuli                   |
| Grade 4 | Fracture of osseous spiral lamina or modiolar wall |

alcohols (70–100% ethanol). Then, all specimens were embedded in polymethylmethacrylate at 20°C. This special fixation routine allows sectioning of undecalcified bone with the implanted electrode. After embedding, each temporal bone was examined under radiography to determine the depth of insertion in terms of degrees (turns around the modiolus). For correct sectioning, the cochlear axis and position within the block were marked, and serial sections of 100  $\mu\text{m}$  were made of all specimens. A special grinding–polishing technique that allows sectioning of the temporal bones with the electrodes in situ was used. For a detailed description of the procedure, please refer to Plenk et al.<sup>18</sup>

Histologic slides were then examined by two of the authors (O.A. and J.K.) independently, whereas parameters such as electrode position in different parts of the cochlea, cochlear damage, histologic insertion depth, and perforation of the basilar membrane were evaluated according to the guidelines recently published by Eshraghi et al.<sup>19</sup> (Table II). Only concordant findings were included in the analysis. Representative slides were documented photographically. Also, electrode diameters of the embedded arrays were measured to exclude swelling of the carrier caused by histologic processing.

Insertion forces were measured during electrode insertion in a scala tympani model. The insertion forces were compared between the prototype (Flex EAS) and standard electrode (C40+). The scala tympani model is made of acrylic and replicates the human organ. The model is based on radiographic microscopy images of a human scala tympani<sup>20</sup> and was built using stereolithographic methods.

The insertion force measurement system consists of a testing

machine (Lloyd Instrument Ltd., Fareham, UK) and a high precision scale (Precisa Instrument AG, Zurich, Switzerland). The electrode under test is fixed to the load cell and is slowly driven into the scala tympani model at precise intervals and speed. As the electrode penetrates the model, the force generated is recorded by the scale. The model was filled with a medical grade silicone oil to reduce the friction between the outer wall and the array. During the electrode insertion into the scala tympani, the force measurements at each insertion step were recorded from the scale.

## RESULTS

Force measurement data for the C40+ standard and the prototype array are shown in Figure 1. As can be seen, the force of insertion was reduced significantly by more than 40% with the Flex-EAS electrode (Fig. 2).

Using the sawing, grinding, and polishing technique, inner ear and adjacent middle ear structures could be clearly identified. Neighboring structures of the bony labyrinth showed no fractures or dislocation of membranes. Insertion depths could be clearly measured as described by Czerny et al.<sup>21</sup> and Marsh et al.<sup>22</sup> Surgical insertion depths ranged from 20 to 22 mm, with a mean of 21.8 mm (Table I). In none of the implanted electrodes did swelling exceed 20% of the normal diameter.

In all specimens, the electrode carrier could be found in the scala tympani of the cochlea. The basal parts were located near the outer wall of the scala, and the apical electrode components were found in the middle turn of the cochlea. In terms of degrees around the modiolus measured radiologically, the insertion depths ranged from 240 to 600 degrees, with an average of 368.0 degrees. As a control for our histologic evaluation of position-related trauma, we correlated radiologically and histologically evaluated insertion depths, which correlated well (Table I) (no statistically significant difference).

According to the criteria for the evaluation of cochlear damage mentioned previously<sup>19</sup> (Table II), 5 of 10 electrodes produced no cochlear trauma (grade 0) over the

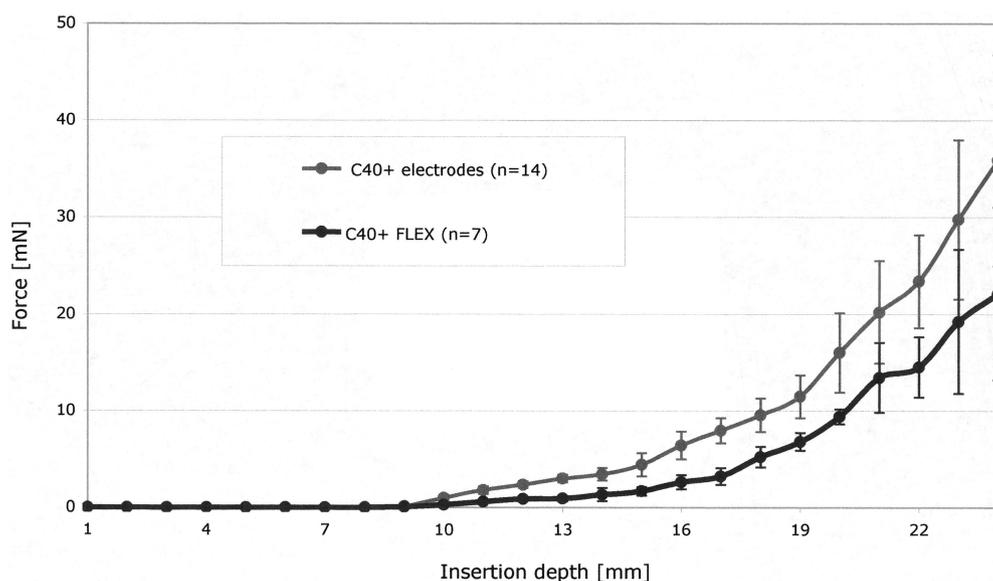


Fig. 2. Force measurement data. As can be seen, the force of insertion was reduced significantly by more than 40% with the Flex-EAS electrode.

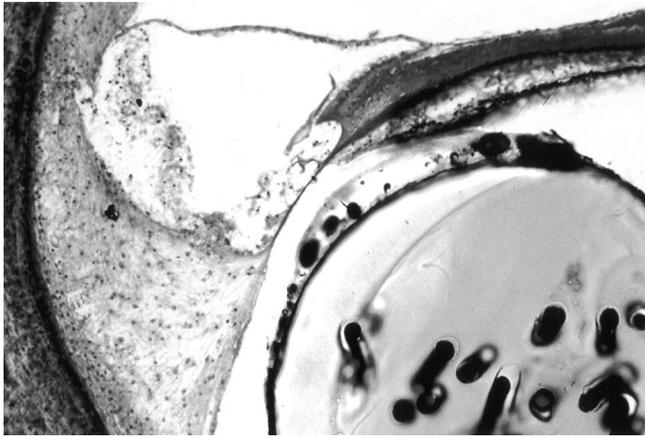


Fig. 3. Temporal bone 2: basal turn, no cochlear trauma.

entire length of the array. A slight lifting of the basilar membrane in the apical regions of the array was seen in two bones. Grade 2 to 4 trauma could only be observed in the region of the cochleostomy in four bones. This trauma is not related to the electrode carrier but to the location and the angle of the cochleostomy. During the histologic processing, fixation of bone 7 loosened, and the electrode had to be reimplanted with a limited insertion depth (240°). Detailed data on the extent of trauma are given in Table I. Exemplary histologic pictures of the implanted bones are given in Figures 3 to 7.

## DISCUSSION

Ideally, cochlear implantation should not compromise residual hearing, especially with the prospect of combined EAS and its benefits for the patient. New prototype electrode arrays are therefore currently under development to ensure hearing preservation. This report deals with a new electrode prototype specifically designed for combined EAS stimulation. Our results demonstrate that this electrode array, which is highly flexible especially in the tip region, produce no substantial trauma to cochlear structures if inserted using an appropriate atraumatic

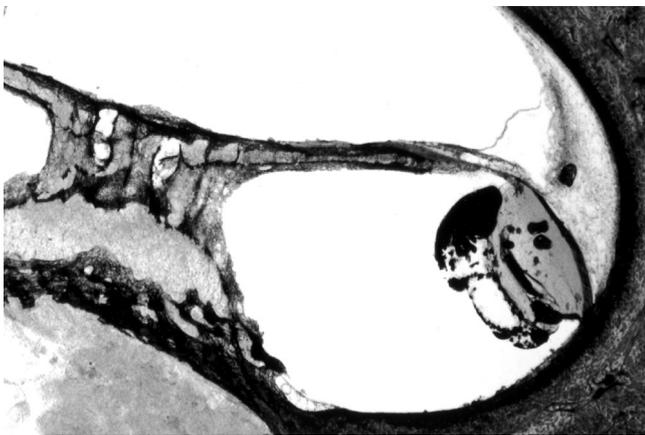


Fig. 4. Temporal bone 4: apical regions of the array with structures of the modiolus, middle cochlear turn. Contacts are facing the modiolus, oval shaped electrode.

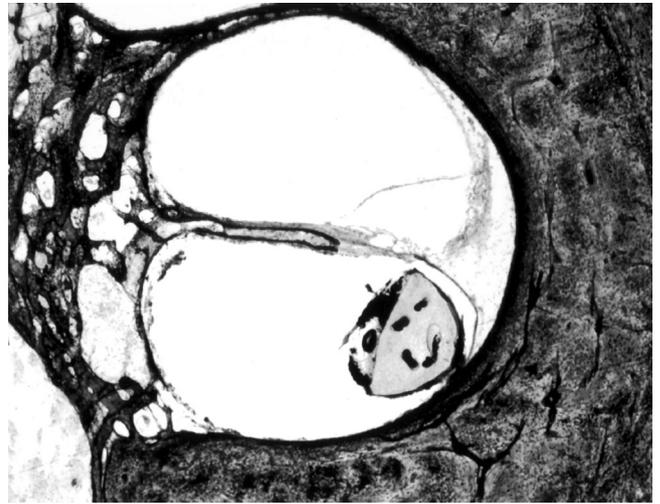


Fig. 5. Temporal bone 5: 360° insertion, middle cochlear turn, no trauma.

surgical technique. Absence of anatomic trauma to cochlear structures is necessary for preservation of residual low-frequency hearing. This in turn is the basis for combined stimulation of the auditory system.<sup>1,2</sup>

As shown previously,<sup>12,13</sup> the tissue-processing procedure used in this study proved to be very effective because all criteria for evaluation of implanted temporal bones could be clearly specified in all specimens. Details of the basilar membrane, the organ of Corti, the spiral osseous lamina, and the spiral ligament could be visualized. Several authors used different techniques to evaluate the intracochlear extent of insertion trauma and electrode position. In a recent article, Eshranghi et al.<sup>19</sup> used a cryosectioning technique and a videofluoroscopy technique to evaluate insertion properties of perimodiolar electrode devices. This method could not identify details of the cochlear structures, and only substantial trauma and dislocations of the array could be observed. Other authors<sup>9,10,23</sup> used regular decalcification techniques to section human temporal bones, but explantation of the array

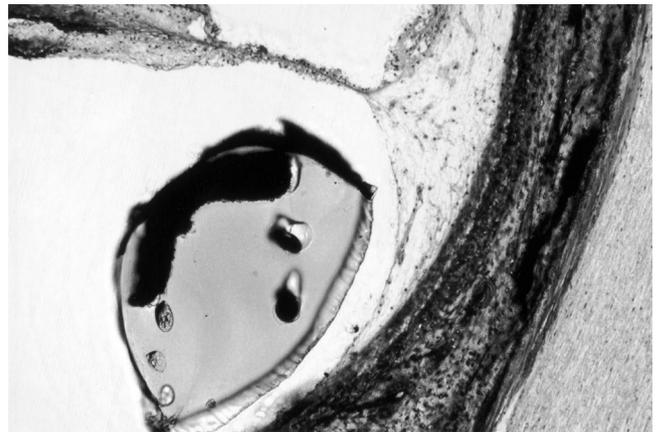


Fig. 6. Temporal bone 8: apical region of the electrode, middle turn. Contacts are facing the modiolus, no trauma.

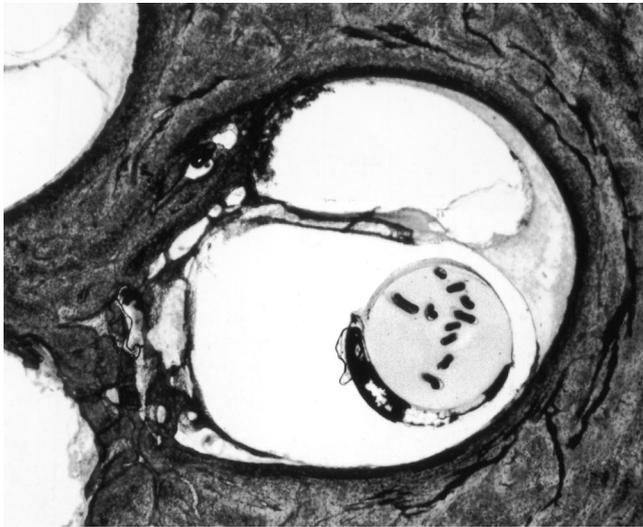


Fig. 7. Temporal bone 10: basal turn, no trauma to cochlear structures.

before tissue processing was necessary. Thus, only limited information of the insertion trauma and practically no information on the position of the devices were available.

Several articles also processed undecalcified human cadaver temporal bones with the electrodes in situ similarly to those discussed in this report. In our opinion, this is the most effective method to study insertion properties of intracochlear cochlear implants because the location of the implanted device can be clearly evaluated. In a previous report,<sup>17</sup> our group evaluated and compared the insertion properties of perimodiolar cochlear implant arrays. Some of these electrode carriers produced substantial trauma to neural structures when compared with the results of this study. Although survival of neural structures was possible when using other arrays,<sup>9,12,13</sup> the extent of the reported trauma exceeds the limit for complete hearing preservation, in our opinion.

In their report using a Nucleus 22 array (Cochlear Corp., Lane Cove, Australia), Burton et al.<sup>11</sup> found substantial preservation of neural structures and hair cell loss, which was confined to the region of the electrode array 3 years after implantation in five macaque monkeys. Although there was evidence of hair cell preservation adjacent to the array, normal hair cell populations were found toward the apex. With the enhanced flexibility of this new prototype array, atraumatic insertions were possible, and hearing preservation should be possible in vivo even in cochlear regions of the electrode carrier.

## CONCLUSION

Smooth cadaver implantations with the new prototype electrode carriers resulted in deep and atraumatic insertions necessary for combined EAS of the auditory system. Further functional results should be gathered to verify the importance of atraumatic electrode placing into the human cochlea.

## Acknowledgments

The authors thank Mrs. Anne Schubert for excellent technical assistance.

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