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Navigation as a quality management tool in cochlear implant surgery

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Abstract
This cadaver study assessed the value of navigation in cochlear implant surgery. Cochlear implantation was simulated on a cadaver using a Stryker-Leibinger navigation system and a Nucleus 24 Contour implant. A conventional surgical strategy consisting of mastoidectomy, posterior tympanotomy, and cochleostomy was performed. The navigated surgical procedure was evaluated for accuracy, reliability, reproducibility, and practicability. The technology of computer-assisted surgery is applicable in cochlear implantation and beneficial in as much as the navigation-controlled implantation constitutes a non-invasive instrument of quality management. Nevertheless, in order to keep the point accuracy below one millimeter, a referencing method using concealed bordering anatomical structures may be further needed to perform the cochleostomy reliably under the guidance of a navigation system. More reproducible reference systems are needed if navigated lateral skull base surgery is to be fully relied upon.

Key words: Surgery, Computer-Assisted; Cochlear implants; Reproducibility of Results

Introduction

Computer-assisted surgery (CAS) is now a well-accepted method in skull base surgery as well as in implant surgery. Navigation systems used in CAS are extensively used in reconstructive bone surgery where, for instance, it is intended for the precise and reproducible hip implantation. The advantages reside in the detailed pre-operative planning by simulation, precise controlled drilling, and accurate fixation of the implant. Furthermore, the successful outcome of surgery is less dependent on the surgeon's operative experience.

Cochlear implant (CI) technology has come a long way since its infancy in the early 1960s, and further improvement in auditory ability are likely by improved coding strategies, better implant electronic designs, as well as a closer interface with the neural environment. Whereas most of these are limited by current technological advances, it depends on the surgeon's skill and effort to optimize the insertion and positioning of the electrode array in the cochlea, namely, achieving proximity to the modiolus. The current limiting factor in optimizing the integration of an electronic device into a biological system is surgical experience. In has been shown that the location and orientation of the cochleostomy has a bearing on the subsequent position of the electrode array, with a major impact on post-operative hearing ability, especially in cases of cochlear malformation or obliteration.[1,2] In view of the extended selection criteria for CI, such as residual hearing,[3,4] a most atraumatic surgical procedure[5–7] is necessary to avoid any lesions of the membranous components of the cochlea.

All these requirements of CI surgery demand extensive surgical experience and any method of assistance at the surgeon's pre- and intra-operative disposal may be most beneficial. In this regard, CAS has established itself as an instrument of quality management in surgery. In the particular case of CI, the surgeon could evaluate pre-operatively the optimal location and size of the receiver-stimulator's seat and the cochleostomy, and anticipate the possible anomalous course of the facial nerve. For example, in designing the seat for the receiver-stimulator portion of the internal device of the Nucleus® system, one has to allow for the behind-the-ear (BTE) speech processor, yet the soft tissue at the base of the auricle is retracted anteriorly during surgery, therefore establishing the optimal location of the seat is not straightforward. With navigated computer assistance the continual feedback and self-

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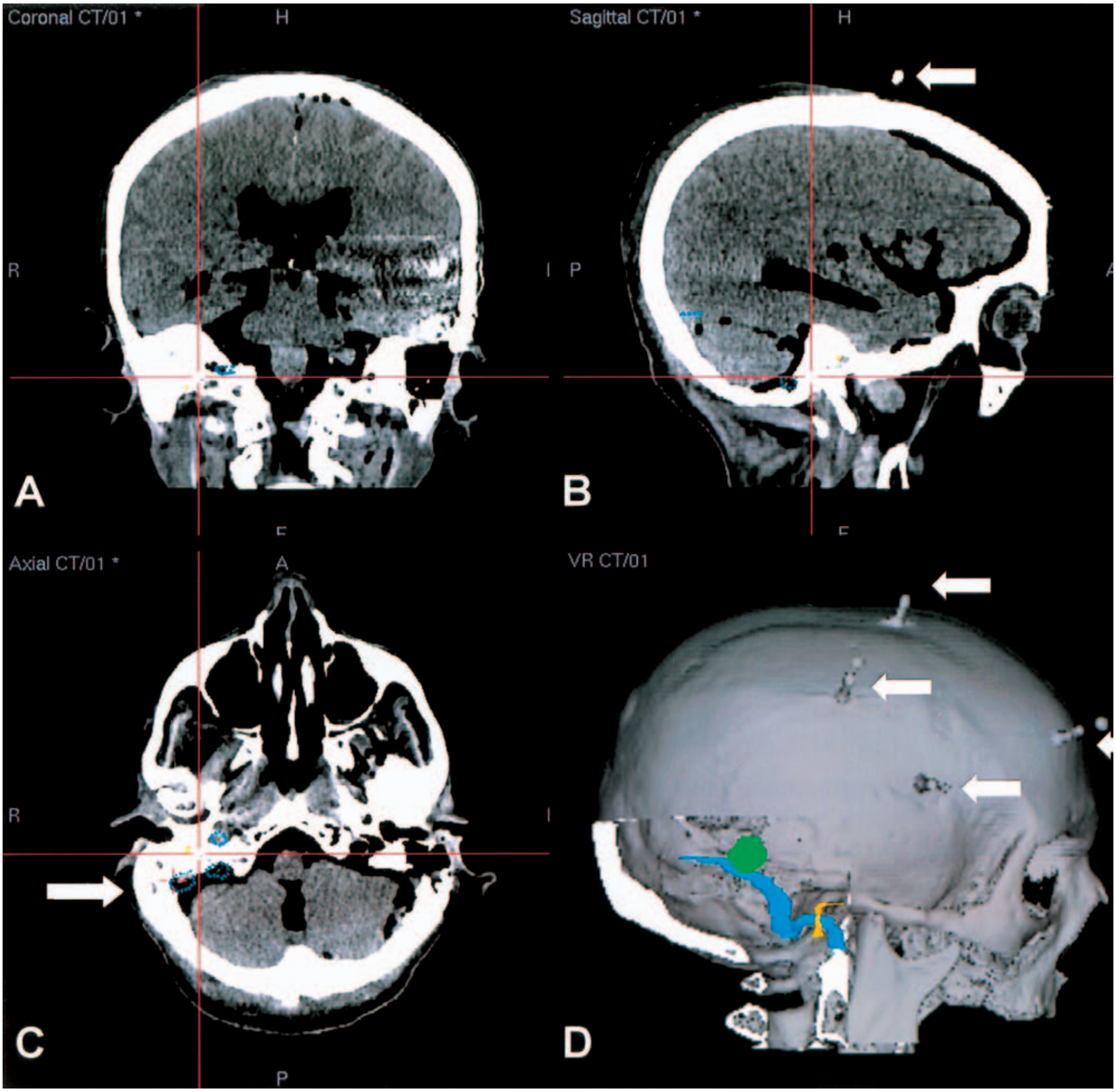

Fig. 1

Coronal (a), sagittal (b), and axial (c) CT image from the triplanar dataset of the scanned cadaver head, in the navigation mode; arrow in (b) shows the tip of a titanium screw. Arrows in (c) show the contoured sigmoid sinus and jugular bulb. (d) Volume model reconstructed from the triplanar dataset of the scanned cadaver head, in the navigation mode.

control in identifying and exploring the correct target may be facilitated during surgery.

A cadaver model study was carried out with the purpose of analyzing the possibility of employing CAS in CI surgery, with particular emphasis on questions of accuracy, reproducibility, and practicability of CAS in this particular kind of operation.

Method

The numeric three-plane dataset of high-resolution computerized tomography (i.e., slice thickness of 1 mm) (Figure 1a-d) of a formalin-fixed adult human cadaver head, including the nose, pinna, and neck down to the C-2 vertebral level, were transferred into the navigation system (Stryker-Leibinger®, Freiburg, Germany).

Four titanium screw markers (Leibinger®, Freiburg, Germany) were used for referencing, as they still constitute the best referencing procedure (Figure 1d).[8] The screw markers were positioned close to the surgical field of interest to generate a high accuracy at the surface and in the depth of the petrous bone.

With the navigation system, the surgeon outlines the contours of typical surgical landmarks, e.g., the sigmoid sinus, jugular bulb in its intratemporal course, facial nerve in all its segments from the internal auditory meatus down to the stylomastoid

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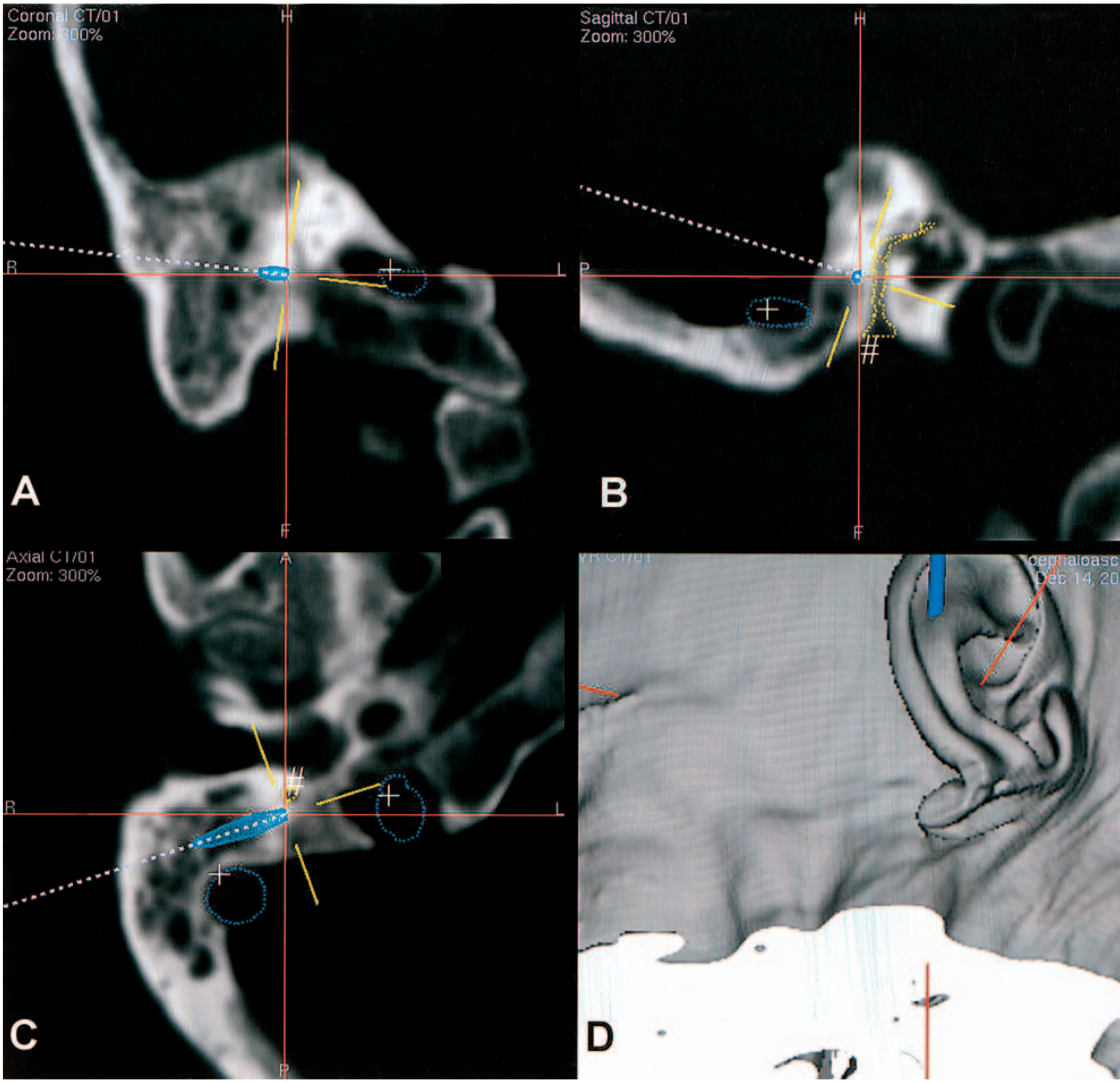

FIG. 2

Navigation-controlled mastoidectomy. Coronal (a), sagittal (b), and axial (c) CT image from the triplanar dataset of the scanned cadaver head, in the navigation mode; the crosshairs show the microscope's focus on the right-sided mastoid; the blue dotted line shows the direction of view through the microscope; + marks the outlined sigmoid sinus; # marks the outlined facial nerve. (d) Reconstructed 3-D model of the skull in simulation mode.

foramen, the optimal position and contour of the planned well for the imbedded implant, and the optimal point of cochleostomy (Figure 2). The latter was planned at the basal turn of the cochlea, antero-inferior to the round window niche. The optimal location of the imbedded implant pocket was designed posterior to the occipito-mastoid suture to enable the later use of the BTE speech processor of the Nucleus® cochlear implant. The contours of important surgical landmarks and intended drillings were marked in all three planes of the CT dataset (coronal, sagittal, and axial) by using a special software tool implemented within the navigation system. A Nucleus®24 Contour™ (Basel, Switzerland) implant was used and it permitted a simpler contouring procedure owing to its round receiver-stimulator that required drilling a disk-shaped well 16 mm in diameter and 3 mm in depth, as opposed to the rectangular-shaped implant seat of other systems. The contoured targets were visualized through the oculars and on the heads-up display of the Zeiss® NC4 neurosurgical microscope (Oberkochem, Germany). The position of the laser-controlled optical focus of the microscope was being visualized through the navigation system, i.e., navigated on-screen on the triplanar CT images (Figure 2). By focusing the microscope's crosshairs onto the point of interest, the real-time visualization through the oculars of the outlined contours of neighbouring targets was made possible. The image

TABLE I

COMPARISON BETWEEN REFERENCING SYSTEMS: TITANIUM SCREW MARKERS AND ANATOMICAL LANDMARKS

Characteristics	Titanium screw markers	Anatomical landmarks
Mean duration of referencing	3.3 minutes	8.2 minutes
Virtual mean accuracy, indicated by the navigation system (referencing mode)	0.8 mm	1 mm
Real mean accuracy, calculated as the deviation from target point in millimetres (referencing mode)	1.2 mm	1.5 mm
Reproducibility	93%	87%
Practicability	High	High
Patient comfort	Low	High
Invasiveness	Yes	No
Duration of pre-CT/MRI reference points setup	> 15 minutes	Needless

thus visualized was recorded on videotape.

For the surgical procedure the cadaver head was secured in a Mayfield clamp. Following the head fixation, the referencing process proceeded by identifying the titanium screw markers in the navigated pointing mode (Figure 1b, d), and an additional referencing technique was employed by using seven anatomical landmarks (e.g., tip of the nose, nasion, subnasale, external canthus, and the bilateral tips of tragus and antitragus) and matched them up to the results of referencing with titanium screw markers. Both referencing procedures were verified for reproducibility by performing them with 10 repetitions. The accuracy was calculated by the navigation system in millimetres of deviation of the navigated point of aim from the anatomical point of touch on the cadaver model. The referencing process was completed with a virtual accuracy (a parameter calculated and displayed by the computer) equal to or less than 1 mm. Some of the reference points had to be evaluated several times because of too high a deviation indicated by the navigation system, a fact that increased the duration of referencing.

A conventional cochlear implantation via mastoidectomy and posterior tympanotomy (as opposed to alternative procedures such as the suprameatal approach[9]) was performed. The surgical strategy was simulated by means of the navigation system preoperatively. The extent of mastoidectomy and posterior tympanotomy was determined.

Results

The goals of CAS in CI surgery were the positioning and optimal sizing of the implant seat, the early identification of both the bone-covered course of the sigmoid sinus (Figure 2) and fallopian canal for performing the posterior tympanotomy, and identification and determination of the optimal spot and size of the cochleostomy.

The surgical procedure of CI was successfully performed under CAS control. Every step of the operation, i.e., mastoidectomy (Figure 2), siting and shaping of the implant seat, posterior tympanotomy and cochleostomy, were amenable to control by navigation. The use of the heads-up display of the microscope simplified the early identification and sizing of the facial nerve, identification of sigmoid sinus, and sizing of both the implant seat and cochleostomy. Thus, important bordering anatomical structures of the surgical corridor could be already visualized although they were still covered by bone. On the other hand, the two-dimensional imaging of the contoured structures in the heads-up display may distort the three dimensional view through the ocular of the microscope. Some contoured structures will appear larger on the heads-up display than they are in reality, e.g., the point of cochleostomy. A reason for this phenomenon lies in the fact that the outlined contours in different CT slices were overlaid and merged by the computer. For example, the optimal point of cochleostomy was marked with a circle in two consecutive CT slices of the three-plane dataset (in each of the coronal, sagittal, and axial views), but for the two-dimensional visualization in the heads-up display the contoured circles from these successive layers are overlaid in the algorithms of the navigation system, resulting in an enlarged contour.

The value of a navigation system in CI surgery is limited by the system's accuracy. Accuracy of the navigation system reflects in this case the measure of reliability compared to that of an experienced surgeon in identifying concealed anatomical structures and verifying their potential proximity along the surgical corridor. Referencing by means of implanted skull screws yielded a virtual accuracy (a parameter indicated by the navigation system) of 0.8 mm, and a real accuracy (the one measured intra-operatively as the deviation between the actual and indicated point) of 1.2 mm (Table I). When referencing by way of pointing to anatomical landmarks, a virtual accuracy of 1.0 mm and a real accuracy of 1.5 mm were obtained (Table I). Nonetheless, accuracy is neither constant in time, nor uniform in space: in the working mode the real accuracy increased from 1.0 mm to 1.6 mm along the duration of surgery, and also varied depending on surgical penetration depth (Figure 3). Thus, by the step when the highest possible accuracy was needed, i.e., during the later stage of placing and sizing the cochleostomy, there was a real deviation of 1.6 mm, *versus* 1.2 mm at the beginning of surgery. Taking into account the 0.4 mm diameter of the used electrode array (Figure 4) and the distance between scala vestibuli and tympani of about 1 mm,[10–12] the 1.6 mm deviation was too high for a precise

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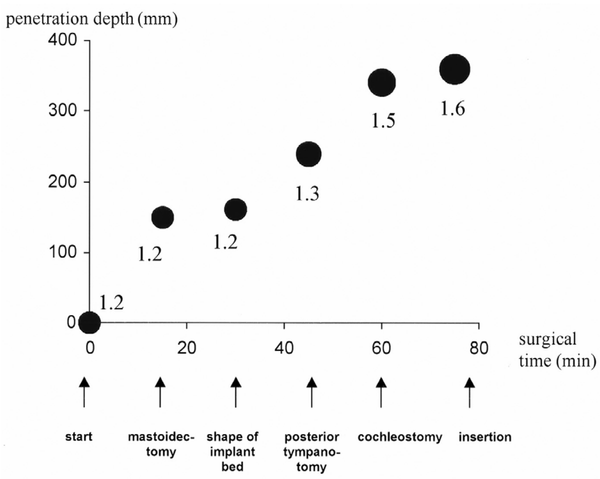

FIG. 3

The real point accuracy as a function of penetration depth along the surgical corridor and surgery time. The diameter of the circle on the graph is proportional to real deviation from the target point, indicated in mm next to each circle.

cochleostomy drilling.

The reproducibility of titanium screw markers was 93 per cent (tested 10 times), whereas that of the anatomical landmarks used as reference markers was 87 per cent (tested 10 times).

The practicability of both referencing methods for the lateral skull base is high, but titanium screw markers are invasive tools and therefore less comfortable for the patient compared to referencing with anatomical landmarks. The preparation of the titanium screw markers for the CT scan in our cadaver model required a duration of 15 minutes, whereas the use of anatomical landmarks as reference points makes the pre-imaging setup of referencing unnecessary (Table I).

Discussion

Since the first electrical stimulation of the auditory nerve in 1957 by Djourno and Eyries[13] and the pioneering CI research conducted in California in the early 1960s by House,[14] Michelson,[15] and Simmons,[16] CI has improved considerably in terms of biocompatibility and reliability of implants, while its clinical results have improved as reflected in enhanced speech perception and speech production skills. As patient selection criteria have been expanded, so far more than 50 000 cochlear implantations have been performed worldwide.[17] Further developments in CI are currently anticipated in electrode design, smart telemetry and computer development, and total implantability. One of the aspects of electrode design and insertion deals with its placement near the modiolus in a reasonably reproducible manner in order to reduce power consumption and increase stimulation selectivity.[18]

Working in the simulation mode of the navigation system compels the surgeon to a thorough pre-operative analysis of the CT scan with the identification of anatomical variations or anomalies,

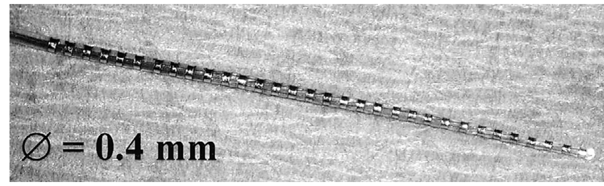

FIG. 4

Overview of certain aspects of accuracy in navigated cochlear implant surgery in comparison with the electrode array diameter.

noticing any occasional obliteration of the cochleovestibular organ, designing the surgical corridor, defining the posterior tympanotomy, and setting the optimal site of cochleostomy. By means of CAS, one could pre-operatively determine the optimal location of the well for the imbedded receiver-stimulator, with a particular benefit in children and young patients with a thin cranial cortex[19] for whom a BTE device is provided, in which case the presurgical simulation can reduce the risk of implant displacement caused by insufficient space. CAS may also prove of great assistance in temporal bone surgery in cases of anomalous or variable anatomy. Thus, the precise demarcation of the posterior tympanotomy corridor allows a safer exploration in anatomical variants characterized by an atypical course of the facial nerve. Furthermore, CAS may provide a better orientation in the alternative CI approaches, such as the suprameatal and subtemporal approach.[9,20] Likewise, a narrow angle between the facial nerve and chorda tympani may reduce the view of the promontory when the chorda tympani is to be preserved, i.e., in bilateral CI. In all these cases, navigation could help the surgeon in finding precisely the optimal point of cochleostomy. Preserving the membranous structures of the cochlea may become a necessity in the future[4] in order to maintain the viability of inner ear structures required for potential future technological and pharmacological developments. In this sense, the navigation-controlled precise cochleostomy may allow the dismantling of the cochlear bone without damaging the contiguous soft tissue structures such as the spiral ligament and the endosteal layer. CI CAS may become an important surgical tool in achieving optimal modiolar proximity with the future electrode arrays.

New concerns have been raised recently of the risk of post-implantation infection possibly spreading along the electrode array through the cochleostomy and causing meningitis.[21–23] Attention to the manner in which the perilymphatic space is sealed after surgical implantation of prostheses in scala tympani was probably first given more substantially two decades ago.[24] Ever since, measures of infection containment at the middle/inner ear interface have been routinely used by means of soft tissue cochleostomy sealing around the inserted electrode.[23,25,26] In this regard, a smaller but optimally created cochleostomy by means of CAS would, at least theoretically, increase the effectiveness of the cochleostomy window seal in protecting the inner ear from spread of middle ear infection. Oversizing the cochleostomy (with the dual risk of an inadequately positioned mobile electrode array and a port of entry for pathogen) may be avoided, at least theoretically, by navigated location of the optimal point of cochleostomy and confidently opening the basal cochlear turn for electrode insertion into the scala tympani. CAS should in theory reduce the length of surgery – an important factor to be considered when one-step bilateral CI strategies are implemented in the future.

- **This is a study, performed in cadaveric preparations, of the use of a navigation system in placing cochlear implants**
- **Titanium screw markers were utilized as well as anatomical landmarks**
- **The authors conclude that the accuracy of anatomical referencing is at present unreliable using both methods**
- **The conclusion of the paper is that such technology may be of help in the future with the development of newer and more sophisticated referencing systems**

Today, diagnostic CT scans are commonly scrutinized and studied on workstations provided with image-processing software. Based on the CT raw data such software readily executes multiplanar reconstructions destined for navigation, and this process has also become common practice in recent years. Thus, the need for the special three-plane CT scans involving excessive X-ray exposure has been avoided, especially when implanting hearing-impaired children.

The present cadaver study showed that the possible beneficial aspect offered by the technological advance of navigation-controlled surgery can be taken advantage of in CI. Computer assistance may in this sense supplement the experience of the implanting surgeon as a result of constant navigation-controlled orientation. By way of its potential to set a standard of surgical practice independent of surgical experience, CAS may establish itself in the future as an instrument of quality management in CI surgery just as it has in reconstructive procedures. Nevertheless, the analyzed aspects of reliability, reproducibility, and practicability of CAS indicated that all the above-mentioned potential advantages may be seriously offset as long as the lack of sufficient accuracy is not improved by future technological developments. Our analysis shows that the accuracy decreased as a function of surgery time and penetration depth along the surgical corridor (Figure 3). The crucial step in CI requiring a high accuracy and reproducibility is the cochleostomy, yet this is performed at the deepest point of the surgical corridor and latest in the course of the operation. The deviation measured at this surgical step was 1.6 mm (Figure 4), which corresponds to a calculated arithmetic deviation of about 2.0 mm (Figure 3). The latter is a composite value of inaccuracy brought about by the possible digression of the referencing screw markers (the tip of the reference pointer can be off the exact centre of the screw), technical deviation of the single-slice CT scan (position of the patient table), and deviation of the navigation system (calibration of cameras, accuracy of software algorithms). By contrast, the diameter of the inserted electrode array was 0.4 mm, i.e., generating a failure rate of one to four. For the correction of this inaccuracy and potential failure rate, a re-referencing procedure was deemed mandatory before proceeding with drilling the cochleostomy. This prompted an investigation into the outcome of a special re-referencing procedure meant to improve the local accuracy in the middle and inner ear. The goal of such a local re-referencing procedure would be to achieve easily and quickly a local accuracy of about 0.5 mm with a high reproducibility, and independent of the surgeon's experience. Such correcting procedures are not uncommon. As an analogy, the navigation of an aircraft is performed via linked satellites with a deviation of several metres, which is excessive for safe landing. Consequently, the navigation system of the airplane is updated during landing by instant re-referencing via a set of local reference points on the airport, and thus the deviation is reduced to less than one metre. The re-referencing procedure in our case by means of anatomical landmarks will prolong the duration of CI surgery only by 8.2 minutes on the average (Table I), without further time-consuming procedures. Future local re-referencing procedures based on proven anatomical landmarks (especially laser-controlled referencing systems that are currently under development) may ultimately attain a sufficient degree of accuracy at the lateral skull base in CI surgery.

Conclusion

Precision and reproducibility in current CAS applied in CI remains too high to be fully reliable. Nevertheless, while in anticipation of future technological improvements, it may be used as a tool of quality management by assisting the surgeon in optimizing the insertion of the electrode array (or any other upcoming technical device) into the biological system of the human cochlea.

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