Radiologic Evidence of Cochlear Implant Bone Bed Formation Following the Subperiosteal Temporal Pocket Technique

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No sponsorships or competing interests have been disclosed for this article.

Abstract

Objective. To compare the thicknesses of bone beneath the internal receiver stimulator (IRS) with the symmetric contralateral unimplanted side in postoperative temporal high-resolution computed tomography (CT) and/or cranial CT of the patients for whom cochlear implants were secured by the subperiosteal temporal pocket technique.

Study Design. Case series with chart review.


Subjects. Cochlear-implanted pediatric patients with postoperative temporal high-resolution CT and/or cranial CT were reviewed. The study group included 10 patients with Clarion devices (Advanced Bionics, Valencia, California).

Methods. Thicknesses of bone were recorded independently by 2 radiologists in the standardized coordinates of proximal, middle, and distal segments of both the IRS bed and the contralateral unimplanted side in each patient. Bone thickness differences in the proximal, middle, and distal segments of IRS were investigated. Any correlation between bone thickness differences and patient age at implantation or duration of implantation was also investigated.

Results. Mean values of bone thicknesses obtained from the IRS side and contralateral unimplanted side were, respectively, as follows: 2.40 ± 0.80 mm and 4.17 ± 1.10 mm in the proximal segment (P = .0001); 1.48 ± 0.33 mm and 3.02 ± 0.85 mm in the middle segment (P = .0001); and 2.13 ± 0.41 mm and 3.40 ± 0.61 mm in the distal segment (P = .006). Significant positive correlation was found between patient age at implantation and decrement values in the distal segments (r = 0.681, P = .03).

Conclusion. The subperiosteally secured IRS eventually creates its own well on the skull vault. This new radiologic evidence shows that device migration risk decreases over time, and it supports the findings of other clinical series showing device stability using the subperiosteal pocket technique.

Keywords
cochlear implant, fixation technique, subperiosteal temporal pocket

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Different methods have been proposed to secure an internal receiver stimulator (IRS) in the search for an ideal fixation technique for cochlear implant (CI) surgery. The ideal technique would minimize the dural exposure and subsequent intracranial complications. It would also maximize the positional stability and thus prevent migration, extrusion, and associated soft tissue complications.

The traditional technique secures the IRS in a socket drilled into the calvarial bone, which prevents migration, but this technique is subject to serious peri- and postoperative intracranial complications due to the exposure of the dura mater.1-5 Modification of this technique with sutures and different alloplastic materials have been attempted to minimize the depth of the well that is drilled to seat the IRS.6 However, these modifications were accompanied by increased costs and operation durations and still did not completely avoid the intracranial complication risks.

The subperiosteal technique, originally described by Balkany et al,7 creates a small-sized subperiosteal pocket on the temporal bone for the IRS, and this pocket is further tightened by periosteal sutures after device placement, without any drilling procedure. This technique lowers the risk of intracranial complications but carries some doubts about the stabilization of the device. The original Balkany et al7 series did not report any case of migration with a minimum 12 months of follow-up. Moreover, recent studies reviewing tight subperiosteal pocket technique with mean follow-up lengths of 18.1 months (Sweeney et al8)

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and 32.6 months (Jethanamset al9) showed no clinical findings of migration.

Pressure-induced bone resorption with different alloplastic onlay implants was reported in animal models.10,11 Thus, with the subperiosteal temporal pocket technique, adaptive bone remodeling may also result in spontaneous bone bed formation beneath the IRS, supporting the clinically reported series of device stability.

In this study, we investigated radiologic evidences of the bony changes beneath the IRS as compared with contralateral unimplanted sides.

Methods

Following approval from the Ethical Committee on Clinical Research of the Istanbul Research and Training Hospital, a retrospective review of 163 consecutive patients who underwent cochlear implantation between August 2008 and August 2011 was performed at our tertiary care cochlear implantation referral center. All operations were performed by the same surgeon using the subperiosteal temporal pocket technique as an IRS fixation method. Food and Drug Administration–approved CI devices were utilized.

Only pediatric patients with postoperative cranial and/or temporal high-resolution computed tomography (CT) were included in the study. Subjects with a history of revision surgery, IRS migration, and flap complications before the imaging were excluded from the study. Age at time of implantation and postoperative CT scan, sex, CI device brand, and model were recorded.

Eighteen patients met the inclusion criteria. Of these 18 subjects, 3 were excluded due to previous revision operations (1 device failure, 1 device extrusion) and flap complications (1 wound infection). The study group, which contains an adequate number of subjects for statistical analysis, included only 10 patients with Clarion devices (Advanced Bionics, Valencia, California). All patients were informed about the study, and informed consents were obtained for their participation.

An Aquilion 64 CT scanner (Toshiba Corp, Tokyo, Japan) with 256 slices (0.5-mm slice thickness) in 1 rotation was used for radiologic evaluation in all patients. Algorithms used for data set modification for display images (also defined as transfer functions) were standardized in our study, as complete user control can lead to wide variability in quantitative measurements. Thus, different window settings and window length (WL) and window width (WW) levels—which provided well-defined contours to separate 2 anatomic areas—were set in our study as follows: for the implanted side, WL: 2000–3000 HU and WW: 6000–7000 HU; for the other side in the same patient, WL: 6000–10000 HU and WW: 6000–6500 HU.

Three-dimensional (3D) medical images of CT data sets were generated with commonly available 3D postprocessing techniques, such as multiplanar reformatting, maximum intensity projection (MIP), shaded-surface display, and volume rendering techniques. Two radiologists independently evaluated the multislice CT display images, which had been created in advance by using all postprocessing techniques except shaded-surface display. The mean values of the measurements were calculated for each patient through multiplanar reformatting of axial 2D/3D, coronal 2D/3D, and sagittal 2D/3D sections, as well as MIP, full-volume MIP, and volume rendering methods.

The primary outcome measurement was bone thicknesses beneath the implanted sides as compared with the symmetrical contralateral unimplanted sides. The boundaries of standard dimensions of the IRS (width: 5 mm, length: 20 mm) were marked, and standard points in the proximal, middle, and distal segments were determined (Figure 1). The distal segment was defined as 8 mm away from the midline of the IRS on the electrode side and the proximal segment as 8 mm away from the midline of the IRS on the receiver gold coil antenna. For each subject, symmetrical contralateral points were determined as a control group on the unimplanted sides. Bone thicknesses were recorded in the standardized coordinates of proximal, middle, and distal segments of the IRS bed and the contralateral control points in each patient, on the predefined display settings of the images (Figure 2). Any correlation between patient age at implantation or duration of implantation and bone remodeling was also investigated. An attempt was made to obtain the same measurements from 3D reconstructed display images.

SPSS 15.0.1 software was used for statistical analysis. Measurements were presented as mean ± SD. A 1-sample Kolmogorov-Smirnov test was performed to determine the distribution of variables. It was observed that variables were normally distributed, and paired-samples t tests were subsequently performed to determine statistical significance. Spearman’s rho test was used for detection of the correlation between variables. Interrater reliability was measured with the 2-way absolute average-measures intraclass correlation coefficient. Differences were considered statistically significant at P < .05.

Results

Finally, a total of 10 patients (9 male, 1 female) with Advanced Bionics devices were included in the study group. The devices were implanted between November 2008 and August 2011, with postoperative radiologic examinations occurring between August 2011 and July 2012. The major reason for imaging was examining the electrode...
position in the cochlea after a recent head trauma (20 minutes to 3 hours). The age of the patients at implantation and at postoperative CT scan ranged from 24 to 69 months (40.2 ± 14.7) and 47 to 89 months (63.1 ± 11.5), respectively. The mean duration of implantation, defined as the period between implantation and imaging, was 22.9 ± 7.3 months.

Bone thicknesses in the proximal, middle, and distal segments of the IRS bed and of the contralateral unimplanted sides were measured independently by 2 radiologists, and mean values were calculated for each patient. Interrater reliability showed near perfect agreement (intraclass correlation coefficient, 0.99). Bone thicknesses of the IRS bed were significantly lower than the contralateral unimplanted sides in the all 3 segments (Table 1). The thickness differences between the bone beneath the IRS and contralateral unimplanted sides were defined as decrement value. There was no significant correlation between duration of implantation and decrement value for all segments. However, a significant positive correlation was observed between the age at implantation and decrement value in the distal segments (r = .681, P = .03). A positive correlation was not statistically significant for the proximal and middle segments.

Our attempts to perform the same measurements in 3D reconstructed images resulted in unreliable values due to the hardware metallic artifacts, as compared with the values obtained with the volume rendering and MIP techniques. Therefore, we were unable to obtain objective and reproducible parametric values from 3D images that would be informative regarding the bone thickness changes due to the device.

Discussion

Different methods have been proposed to secure the IRS in the search for an ideal fixation technique that would minimize dural exposure and subsequent intracranial complications while also maximizing the positional stability to avoid migration, extrusion, and associated soft tissue complications.

The traditional technique involves drilling a socket into the calvarial bone to prevent migration, but this carries potential risks for serious intracranial complications due to exposure of the dura. Fatal cerebral infarction, epidural hematoma, extradural hematoma presenting as contralateral sixth nerve palsy, temporal lobe infarction and lateral sinus thrombosis, subdural hematoma, and cerebrospinal fluid leaks have all been reported as examples of rare but serious complications of this technique. Young children—because of their increased head:body ratios and continuing development of the neuromuscular system—are prone to blunt head traumas; therefore, the thinned temporoparietal skull available for IRS placement potentiates risk of complications. Since the introduction of cochlear implantation surgery in the pediatric population in the 1990s, surgical indications have extended to include patients <1 year old. The decrease in calvarial cortex thicknesses as patients get younger makes these children particularly more vulnerable to intracranial complications with this traditional technique.

Different alloplastic materials (polypropylene mesh, titanium screws, etc) and suturing techniques (periosteal suture, periosteal pocket suture, etc) have been attempted for fixation to reduce the depth of the well that is drilled to seat the IRS, since bony drilling clearly carries a high risk for dural exposure in the pediatric population, whose temporoparietal skull can be as thin as 1 mm. However, the subperiosteal temporal pocket technique, originally described by Balkany et al, takes advantage of dense condensations of the pericranium that bound the tight subperiosteally created pocket anteriorly, anteroinferiorly, and posteroinferiorly, and this pocket is further tightened by periosteal sutures after the device is placed. No drilling is used in this technique for the fixation of the IRS, so no increased intracranial complication risk occurs due to the exposure of the dura mater.

Theoretically, complications that result from an unstable device—such as migration, extrusion, potential seroma and hematoma formation, and device failure—might seem more likely with the subperiosteal securing technique. However, to our knowledge, no randomized prospective study has reported any increased risk of stability-related complications with this technique. Measurement of micro- or macromigrations of the IRS would not be possible without any radiologic evaluation, and so the design of this type of randomized prospective study would be difficult in the pediatric population due to ethical concerns. A previous study compared the subperiosteal temporal pocket and traditional techniques found no intracranial complications or device migration that required surgical repositioning with the subperiosteal technique. In addition, no statistically significant differences were noted in terms of patient satisfaction or for

Figure 2. Right-sided cochlear-implanted patient’s temporal high-resolution computed tomography for demonstration of measurements. The dimensions of the standard internal receiver stimulator markings (1, 2) are shifted down. Parallel lines from proximal, middle, and distal points of the device to the contralateral side are shown for comparison. WL, window length; WW, window width.
the use of device as evaluated by a questionnaire form. The authors did not prefer the subperiosteal technique over the standard skull-drilling technique in CI surgery, as they felt that the standard technique avoided complications such as device migration and subsequent functionality problems of devices bulging from the skin. However, previous studies presented no evidence for increased risk of these types of complications. Therefore, going beyond theoretical hypotheses, neither the authors who support the traditional technique nor the supporters of the subperiosteal technique have presented objective confirmation of micro- or macromigration of the IRS.

A recent case series study reported spontaneous bone bed formation of a subperiosteally secured IRS during revision operations of the CI patients. This is the first study in the literature that demonstrates radiologic evidence of a subperiosteally secured IRS creating its own well in the pediatric population. The retrospective nature of this study did not allow the determination of the depression rate of the IRS on the skull. Periodical CT scans with constant intervals are impossible due to ethical concerns, so the design of a prospective study to determine the rate of depression on the temporoparietal region is difficult. The study results showed that the depression was positively correlated with patient age at implantation in the distal segments. This can be explained by the fact that the thickness of skull increases with age and causes the decrement values to increase as well. A limited number of subjects was considered to be the reason for the insignificance of correlations between the implant duration and decrement values.

Regulatory factors in bone remodeling (eg, genetic, mechanical, vascular, nutritional, hormonal, local) may also play a role in the depression rate of the IRS. Mechanical factors—such as duration of the implant, height of the IRS, and tightness of subperiosteal pocket—will affect the rate of depression by modifying cumulative compressive pressure forces on the bone. A perioperative photo shows IRS bed changes in a male patient whose Advanced Bionics IRS magnet had to be replaced with a magnetic resonance imaging–compatible one in postoperative month 16 (Figure 3). Thus, as time progresses in the postoperative period, we can conclude that the subperiosteal technique becomes safer in terms of specific complications, such as device migration and extrusion in pediatric patients, and that rare but serious intracranial complications can be avoided by not drilling bone adjacent to dura mater.

The major limitations of our study were the limited number of subjects and the male predominance. We had to choose patients with a history of postimplantation radiologic examination and could not perform prospective repeated radiologic examinations for ethical reasons.

<table>
<thead>
<tr>
<th>Case</th>
<th>Sex</th>
<th>Age at Operation, mo</th>
<th>MIP IMP</th>
<th>UNIMP IMP</th>
<th>MIP IMP</th>
<th>UNIMP IMP</th>
<th>MIP IMP</th>
<th>UNIMP IMP</th>
<th>Implant Duration, mo</th>
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<tr>
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<td>1.3</td>
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<td>29</td>
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</table>

Abbreviations: F, female; IMP, implanted; M, male; MIP, maximum intensity projection; UNIMP, unimplanted.

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**Table 1. Demographic Data and the Thicknesses of the Skull on the Internal Receiver Stimulator Side and Contralateral Unimplanted Side.**

<table>
<thead>
<tr>
<th>Case</th>
<th>Sex</th>
<th>Age at Operation, mo</th>
<th>MIP Segment mm</th>
<th>UNIMP Segment mm</th>
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<td></td>
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Abbreviations: F, female; IMP, implanted; M, male; MIP, maximum intensity projection; UNIMP, unimplanted.

*Mean values in the proximal segment: unimplanted side, 4.17 ± 1.10 mm; implanted side, 2.40 ± 0.80 mm (P = .0001).

*Mean values in the middle segment: unimplanted side, 3.02 ± 0.85 mm; implanted side, 1.48 ± 0.33 mm (P = .0001).

*Mean values in the distal segment: unimplanted side, 3.40 ± 0.61 mm; implanted side, 2.13 ± 0.41 mm (P = .0001).
the subperiosteal temporal pocket technique, we also could not compare the results with the standard technique.

Each company’s device has a different size, shape, and thickness. Consequently, selection of coordinates for each brand would not be standardized in the study. Therefore, only the Advanced Bionics group, with more patients, was determined as the study group, and this was another limitation of the study.

In conclusion, following CI surgery with an Advanced Bionics Clarion device, a subperiosteally secured IRS eventually creates its own well on the skull vault. This new radiologic evidence shows that device migration risk of the subperiosteal technique minimizes in time, and it supports the clinically reported series of device stability with the subperiosteal pocket technique. Similar new studies on other device brands are necessary to investigate whether these observations can be generalized for all CI devices.

**Author Contributions**

Artunc Kaan Turanoglu, designed study, collected data, wrote article, data analysis, drafting, final approval, accountability for all aspects of the work; Ozgur Yigit, data analysis, drafting, final approval, accountability for all aspects of the work; Engin Acioglu, designed study, data analysis, drafting, final approval, accountability for all aspects of the work; Ahmet Mufit Okbay, collected data, drafting, final approval, accountability for all aspects of the work.

**Disclosures**

**Competing interests:** None.

**Sponsorships:** None.

**Funding source:** None.

**References**


