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Round Window versus Cochleostomy Technique in Cochlear Implantation: Histological Findings

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Abstract

Hypothesis—Cochleostomy or round window enlargement techniques for cochlear implant electrode insertion result in more abnormal tissue formation in the basal cochlea and are more apt to produce endolymphatic hydrops than round window electrode insertion.

Methods—Twelve temporal bones from implanted patients were examined under light microscopy and reconstructed with 3D reconstruction software to determine cochlear damage and volume of neo-ossification and fibrosis following electrode insertion. Amount of new tissue was compared between three groups of bones: insertion through the round window (RW), after enlarging the round window (RWE) and cochleostomy (Cochl). The probable role of the electrode was evaluated in each case with hydrops.

Results—More initial damage occurred in the Cochl and RWE groups than in the RW group, and the difference was significant between RWE and RW in cochlear segment I ($p < 0.026$). The volume of new bone in segment I differed significantly between groups ($p < .012$) and was greater in the RWE group than in either the Cochl or RW groups (post hoc p 's $< .035$ and $.019$). Hydrops was seen in 5 cases, all in the Cochl and RWE groups. Blockage of the duct was due to new tissue formation in 4 of the 5 hydrops cases.

Conclusion—With the electrodes in this serie, implantation through the round window minimized initial intracochlear trauma and subsequent new tissue formation, while the round window extension technique used at the time of these implantations produced the greatest damage. Future studies may clarify whether today's techniques and electrodes will produce these same patterns of damage.

Keywords

Round window; cochleostomy; cochlear implant; fibrosis tissue; new bone

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Introduction

Since the introduction of cochlear implants, and the first FDA approval for clinical use in 1984, efforts continue to try to improve their benefits. Intracochlear lesions and new tissue formation (new bone and fibrous tissue) induced by electrode insertion should be minimized by surgical technique and electrode design. The first published evaluation of cochlear implant electrode insertion trauma was in 1985 (1), and since then researchers have continued to examine intracochlear changes resulting from implantation (2-7). This has led to growing interest in performing “soft” surgery to maintain residual hearing (8).

Cochlear implant (CI) electrode placement into the scala tympani was first described using the round window technique (9). Since then, different approaches have been proposed to improve visualization, ease of electrode insertion and, more recently, for emphasis on preservation of residual hearing. When performing cochlear implantation, the surgeon has the options to insert the electrode into the scala tympani through the round window (RW), with or without drilling its edges, or via a cochleostomy adjacent to the round window, based on anatomy and/or surgeon preference.

When round window anatomy is favorable, insertion directly through the RW is assumed to be the least traumatic approach. When the anatomy is less favorable and the patient has no residual hearing, the RW and the area of the hook can be enlarged, allowing good visualization of the scala tympani. Finally, when anatomy requires and residual hearing is present or by surgeon preference, a cochleostomy may be the method of choice as it involves less drilling and may also be advantageous with particular electrode designs.

Some authors have used the term “cochleostomy” to also designate a round window enlargement, referring to this annular bone removal as a “round window margin” cochleostomy (10). Others group such a technique with round window insertion rather than cochleostomy (11).

Intracochlear trauma due to a cochlear implant includes two kinds of lesions: immediate or initial lesions, which are represented by the trauma caused by the path of the electrode on the intracochlear structures, and delayed lesions, defined as new fibrous tissue or bone formed secondary to this initial trauma (7). Previous studies have shown great variations in the amount of fibrosis and new bone formation (2, 7, 12), but none have focused on the proximal cochlear lesions as a function of the surgical method of insertion.

The purpose of the present study was to compare the impact of cochleostomy (Cochl), round window enlargement (RWE) and round window (RW) approaches to electrode insertion on initial and delayed intracochlear changes, including cochlear hydrops, using histopathologic findings and three-dimensional reconstruction.

Material and Methods

Subjects

Twelve temporal bones from nine patients who had undergone cochlear implantation—three bilateral—were included in this study. Cases with etiologies inducing neo-ossification, such as meningitis, were excluded. To avoid any inconsistency with the denomination “cochleostomy”, all case slides were studied under microscopy and each time a drilling path was seen, the presence or absence of bone between it and the round window was evaluated to determine whether a cochleostomy or a round window enlargement was performed. Thus, by cochleostomy, we meant all the cases in which the electrode was inserted through a hole drilled into the scala tympani, separate from the round window. In addition, the round

window cases (RW) were grouped separately from the round window enlarged cases (RWE) as well as from the cochleostomy cases (Cochl).

Five temporal bones were obtained from patients who presented a cochlear insertion through a cochleostomy, four through an enlarged round window, and three through the round window. The cases were obtained from the Temporal Bone Collection at the House Research Institute and all clinical data were ascertained from the clinical chart of each patient.

Patient characteristics are shown in Table 1. Seven ears were implanted with a House single-electrode implant, either the earlier longer-electrode House/Urban device or the short-electrode 3M/House device. The remaining five ears all had Nucleus 22 devices. Some of the patients had multiple surgeries, with a revision from one device to another or replacement by the same type of device. Age of patients at death ranged from 61.2 to 87.4 years, with a mean of 75 years and 8 months; duration of implantation ranged from 10 months to 24 years 6 months, with a mean of 8 years and 8 months.

Histological study

After removal, the bones were processed as follows: They were first fixed in 10% buffered formalin for 1 month, and then decalcified in ethylenediaminetetracetic acid (EDTA) for several months. X-ray was performed to verify complete decalcification prior to proceeding to the next step in processing. All specimens were dehydrated in graded alcohols (80%, 95%, 100%) before being placed into increasing concentrations of celloidin (2%, 4%, 6% and 12%). To avoid any damage to the inner ear structures during removal, the implant electrodes were taken out after 2 weeks of immersion in celloidin 12%. The celloidin blocks were cleared with cedar wood oil, then cut into 20 micron sections in the horizontal plane, stained with hematoxylin and eosin, and finally, mounted on 1"×3" glass slides.

Microscopic evaluation was performed for each case, noting initial trauma, new tissue formation and the presence or not of hydrops. To evaluate the extent of initial intracochlear trauma, a scale of 0 to 4, previously described by Eshraghi et al (13), was used. In this grading scheme, 0 represents no observable trauma; 1, elevation of the basilar membrane; 2, rupture of basilar membrane; 3, electrode in scala vestibuli; and 4, severe trauma such as fracture of the osseous spiral lamina or modiolus or tear of stria vascularis. Delayed changes evaluated included the presence or absence of cochlear hydrops and the presence, location and amount of fibrous tissue and new bone along the cochlear duct. In cases with hydrops, the relationship of the electrode array to the saccule and ductus reuniens was studied.

Cochlear Reconstruction

A three-dimensional reconstruction was performed for each case. The process, previously described (6, 14), uses Amira 4.1 (Mercury Computer Systems/TGS, San Diego, California), software that enables a three-dimensional reconstruction of digital images of each mounted slide, with identification of the different tissues involved in the cochlear remodeling process: blue was used to label healthy cochlear space, usually filled with peri- and endolymph, white for neo-osteogenesis, red for fibrosis, and green for the electrode array pathway (14). The cochlea was divided into four segments for convenience in 3D imaging (Fig. 1), (14).

Data analysis

All data were entered into Excel files and then coded in a statistical data file for analysis using SPSS (version 12.0.1). Duration of implantation was compared to the amount of fibrous tissue and new bone using the Pearson's product-moment correlation and to initial trauma rating using the nonparametric Spearman Rho correlation. Amounts of bone and

fibrous tissue were compared between segments, for the different methods, using paired t-tests. As the small number of cases for each technique and large differences in inter-subject variability do not allow parametric tests, the nonparametric Kruskal-Wallis test was used when comparing all three groups and pair-wise comparisons between the three methods were performed using the Mann-Whitney U for independent groups. Histologic changes were evaluated as a 5-point scale, and the distribution across all methods was tested using the Mann-Whitney test. Criterion for statistical significance was set at $p = 0.05$.

Results

First, we evaluated the relationship between tissue formation and duration of implantation. We found no significant correlations to total new tissue in either Segment I or II, even when excluding the 3M/House short-electrode RW cases.

Table 2 presents the histological findings for each individual patient for segments I and II. Little new tissue was found in segments III or IV so no further analyses were performed for these segments. Across all groups taken together, initial histologic changes were slightly greater in the second segment than the first, with median damage ratings of 2.5 and 1.5, respectively, though this difference was not statistically significant. Light microscopic examination of H&E-stained sections revealed a greater amount of cochlear damage for the CochI and RWE groups compared to the RW group in both segments I and II, and this difference was statistically significant between the RWE and the RW groups in segment I ($p < 0.026$) (Fig. 2 a & b). The fracture of the osseous spiral lamina in 3 of 4 RWE cases was due to drilling the superior edge of the RW. The cochlear implant was found in the scala vestibuli in these 3 cases. Hydrops was seen in five bones; three in the RWE group and two in the CochI group. The electrode was directly implicated as a cause of the hydrops in 4 of the 5 cases. In fact, hydrops occurred in all cases in which the surgical drilling defect included the scala vestibuli (Fig. 3).

Most of the RW group presented a type of fibrosis called “areolar fibrosis”, meaning a quite translucent fibrous tissue (Fig. 4a), while new tissue in all of the RWE and CochI cases was dense fibrosis or new bone (Fig. 4b).

The amounts of fibrous tissue and new bone in cubic microns were obtained by volumetric measurement on the 3D reconstructions (Table 2). Results varied among temporal bones, ranging from $0.29 \mu\text{m}^3$ to $10.65 \mu\text{m}^3$ of fibrous tissue in segment I for the CochI group and from $2.13 \mu\text{m}^3$ to $10.59 \mu\text{m}^3$ in the RWE group, with very little fibrous tissue observed in the RW group (Table 3). There was a significant difference between groups in volume of new bone ($p < 0.012$), with the RWE method yielding greater content of new bone than either the CochI or the RW method in segment I ($p < 0.035$ and $p < 0.019$, respectively) (Figs. 5 a & b). For segment II, the amount of new tissue in the RWE group tended to be greater than in the other groups, but there was large variability and the differences were not significant.

The number of subjects with any particular combination of implant device type and insertion method was small, limiting statistical analyses. However, Table 4 shows the mean total new tissue for segment I by insertion method and electrode type. Single electrodes include the House/3M and the House/Urban. We have limited the data to segment I so that electrode length is reduced as a factor. The two ears of subject 9 which both had revisions from a single- to a multielectrode device are excluded. For both device types, we still see the tendency for the RWE method to produce more new tissue than the other insertion methods in Segment I.

Discussion

In the early days of cochlear implantation, candidates had hearing thresholds of 100 dB or greater. Recently, the candidacy criteria were re-evaluated and broadened to patients with residual hearing, making hearing preservation an important issue. It has been suggested that even very limited preserved residual hearing below 500Hz could be sufficient to significantly improve speech perception outcomes (15). However, minimizing the impact of cochlear implantation on residual hearing remains challenging, as damage to the cochlea can worsen or destroy this residual hearing in the majority of patients (16). In response to the desire to preserve residual hearing, special focus has been placed on the surgical technique (“soft surgery”) (8).

Intracochlear changes from electrode insertion damage may be either initial or delayed (2, 7). Initial intracochlear trauma includes fracture or dislocation of the osseous spiral lamina, damage to the organ of Corti, and disruption of the spiral ligament and stria vascularis (2). In cases with multiple surgeries, initial trauma was most likely due to the first implantation, as we have not seen evidence of damage from removal of an electrode. There is some conflicting evidence regarding the status of the sheath that surrounds an implant electrode after removal and reimplantation (17, 18). In this study, attention was paid in each multiple surgery case to determine whether a new electrode track was present. The sheath that surrounds the electrode appears to remain intact, without any additional electrode track noted. In any case, for all revisions in this series, the same insertion technique was used as in the original procedure.

Examination of the data in the tables shows that of the four cases with revisions, one had a relatively low amount of total new tissue compared to other patients, two were in the middle, and one was at the high end. Patient #7 in particular is of interest as both ears were implanted but only one ear underwent a revision procedure. Total tissue in Segment I was similar in both ears.

Most of the initial trauma following round window insertion was of a lower grade than with the cochleostomy or round window enlargement techniques (Fig. 2 a & b), suggesting that grade 4 trauma could be avoided by using the RW technique, as previously shown in insertion studies (19). Li, Somdas, Eddington, et al. (7), reported similar findings regarding damage to the lateral wall and the formation of new tissue and proposed two hypotheses regarding this neo-ossification. First, the exposure of the underlying endosteum of the lateral cochlear wall might contribute to local inflammation, thus leading to new bone formation. A second possibility is based on a murine model with a disruption of protein regulation. Peri modiolar trauma is also of important concern and should be taken into account by manufacturers as they develop new electrodes designed to get closer to the modiolus or to even be modiolar hugging.

The amount of fibrous tissue and new bone observed in the present study corroborates previous data which suggest that the greatest amounts of new tissue are localized in the basal turn, with a decrease as one progresses apically and little beyond the tip of the electrode (14, 20). Choi and Oghalai studied the formation of scar tissue around the electrode and the impact of such changes to the biophysical properties of the cochlea and therefore to the preservation of residual acoustical hearing. The model they created predicts a decrease in residual hearing as scar tissue appears (5). The fact that very little new tissue formation was found beyond the tip of the short electrode in the RW cases is encouraging when considering hearing preservation.

Several explanations can be proposed to account for finding more new tissue following the round window enlargement technique than with the cochleostomy technique. First, initial

change (insertion trauma) was greater for the RWE compared to the other techniques. This is due to extensive drilling of the hook area and to the path of the electrode which follows the lateral wall of the cochlea, violating the endosteum and generating new bone formation. In the cochleostomy cases, the path of the electrode bypasses somewhat the lateral wall, still creating initial trauma but less delayed trauma (Fig. 6). Similar findings have been reported by others (21). The current technique for extending the round window is “softer” than that used in these early cases, without the same degree of drilling through the labyrinthine bone and endosteum. However, until human temporal bones become available for histopathological study, it is only an assumption that this produces less damage.

The impact of new bone and fibrosis in the implanted cochlea can include an alteration of the psychophysical percepts (22, 23) as well as the modification of the electrode-tissue impedance (24), leading to increased electrical stimulus threshold. This has implications for energy requirements, with present devices and as we develop new totally implanted devices. Another effect of new tissue formation is the alteration of the capacity to perform explantation and reimplantation of electrodes. This is a potential concern for implantation of children, as they will most likely need cochlear implant replacement over their lifetimes, either due to component failure or to benefit from technological progress, although this has generally not been problematic. It is encouraging that this study found no correlation between duration of implantation and amount of new tissue. However, degeneration of the spiral ganglion cannot be predicted either as a consequence of cochlear reaction to the electrode nor to prolonged electrical stimulation (4). Further analysis is currently underway to assess the possible relationship between these two parameters and patient performance. The influence of the approach to the scala tympani on vestibular function still remains unclear (11).

A deleterious effect of new bone and fibrous tissue formation rarely noted in previous reports is the obliteration of the scala vestibuli with disruption of the cochlear fluids, leading to a cochlear hydrops. This hydrops may be crucial when considering residual hearing preservation, especially since this involves low-frequency thresholds.

While some data suggest potential efficacy of pharmacologic methods in reducing the inflammatory response within the inner ear (25), or even helping to prevent the development of labyrinthitis ossificans secondary to bacterial labyrinthitis (26), these methods remain experimental. Focus should continue on optimal insertion techniques, which eventually may be combined with pharmacologic use.

The small number of cases lowers the statistical power and the generalizability of this study. Even so, a number of findings were consistent enough to achieve statistical significance. Another limitation is the inclusion of single-electrode implants in the round window insertion group which are no longer in use. However, the findings from the short electrodes are of relevance, particularly as electrode length is being reconsidered as new ‘hybrid’ or hearing preservation models are designed. Finally, because of the small number of cases with any one combination of electrode type and insertion technique, this study could not completely eliminate the potential confounding factor of electrode type. Long-term changes due to cochlear implantation cannot be studied on normal cadaveric human specimens and histopathology findings in implanted patients are always going to lag current technology and techniques, which are continually evolving.

Conclusions

The histologic examination and three-dimensional reconstructions with volume rendering of 12 temporal bones provides new anatomical clues to understand the relationship between

electrode insertion technique and intracochlear damage. In this series, electrode implantation through the round window minimized initial intracochlear trauma and subsequent new tissue formation, while the round window extension technique used at the time of these implantations produced the greatest damage. Prevention of intracochlear trauma is important as more patients with residual hearing are being implanted. Only future studies can clarify whether today's techniques and electrodes will produce these same patterns of damage.

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Figure 1.
Cochlear rendering showing the four segments (14).

Figure 2.

a & b. Initial histological changes in Segment I (a) and Segment II (b). Larger circles represent multiple cases. Initial histological changes: 0 = no observable trauma; 1 = elevation of the basilar membrane; 2 = rupture of basilar membrane; 3 = electrode in scala

vestibuli; and 4 = severe trauma such as fracture of the osseous spiral lamina or modiolus or tear of stria vascularis (13).

Figure 3. Cochlear hydrops. Reissner's membrane is distended by the hydrops (black arrows); no hydrops was seen into the saccule. Only a small portion of the stria vascularis was evident in the anterior middle turn (black star: cochlear implant). (Hematoxylin & Eosin $\times 20$)

Figure 4.

a & b. (a) Case 1R. The electrode was inserted through the round window (grayed-out path), into the basal turn. The only new tissue seen is an areolar fibrosis (black arrow) surrounding the electrode path. (Skeletonized preparation, [H&E] $\times 200$). (b) Case 5. The cochleostomy path is filled with dense fibrosis (black star), which extends into the cochlea (black triangles). A great amount of new bone is present in the scala tympani of the basal turn (black arrow). (H&E $\times 10$).

Figure 5.
a & b. (a) Case 6. A three-dimensional reconstruction (Amira 4.1) of the first segment of a left cochlea was performed on a case with the electrode inserted through the round window. Normal tissues are represented in blue, with the cochlear implant path, fibrosis and new bone delineated in green, red, and white, respectively. (b) Case 7R. A three-dimensional reconstruction (Amira 4.1) of the first segment of a right cochlea was performed on a case

with the electrode inserted through a round window enlargement. Normal tissues are represented in blue, with the cochlear implant path, fibrosis and new bone delineated in green, red, and white, respectively.

Figure 6.
Graphic depiction of likely electrode path with the different insertion techniques.

Table 1

Patient characteristics.

ID #	Ear	Sex	Year implantation	Implant * device	Insertion **	Revision	Revision insertion	Deaf duration (y)	Age CI (y)	Years CI (y)
1L	L	F	1985	Nucleus 22	Cochl.	-	-	18	60.28	0.87
1R	R	F	1982	House/3M	RW	-	-	18	55.26	5.89
2	L	M	1983	House/3M	Cochl.	1985, House/3M	Same	62	66.21	4.53
3	L	M	1985	House/3M	RW	-	-	48	72.64	7.93
4	R	F	1994	Nucleus 22	Cochl.	-	-	7.42	67.14	4.18
5	R	M	1996	Nucleus 22	Cochl.	-	-	48	84.02	3.36
6	L	M	1997	House/3M	RW	-	-	50	73.99	1.44
7L	L	F	1981	House/Urban	RWE	1985, House/3M	Same	46	67.71	19.48
7R	R	F	1990	Nucleus 22	RWE	-	-	36	77.51	9.68
8	L	F	1994	Nucleus 22	RWE	-	-	10	66.91	6.53
9L	L	F	1984	House/3M	Cochl.	1999, Nucleus 24	Same	46.50	59.18	17.38
9R	R	F	1977	House/Urban	RWE	1991, Nucleus 22	Same	31	52.03	24.52

* Nucleus 24 and 22 intra-cochlear length = 19mm; House/Urban intra-cochlear length=16-18mm; House/3M electrode length = 6mm

** Cochl=cochleostomy, RW=Round Window, RWE= Round Window Enlarged

Table 2

Histopathological changes and amount of new tissue (percentage of total cochlear tissue measured in cubic microns).

ID #	Insertion *	Segment I					Segment II				
		Initial Damage #	Hydrops	Fibrous Tissue	New Bone	Total New Tissue	Initial Damage #	Hydrops	Fibrous Tissue	New Bone	Total New Tissue
1L	Cochl	4	No	10.65	0.67	11.32	4	No	9.70	0.01	9.71
1R	RW	1	No	0.01	0.01	0.02	2	No	0.01	0.01	0.02
2	Cochl	0	No	0.64	0.06	0.70	0	No	0.01	0.01	0.02
3	RW	0	No	0.20	0.03	0.23	0	No	0.11	0.01	0.12
4	Cochl	3	Yes	0.29	0.07	0.36	4	Yes	0.04	0.01	0.05
5	Cochl	1	Yes	9.29	8.36	17.65	2	Yes	8.36	1.18	9.54
6	RW	0	No	2.13	0.94	3.08	0	No	0.30	0.08	0.38
7L	RWE	4	Yes	2.13	6.64	8.77	1	Yes	0.12	0.11	0.23
7R	RWE	4	Yes	3.46	5.93	9.39	4	Yes	0.69	0.15	0.84
8	RWE	2	No	10.59	8.33	18.92	3	No	10.08	1.20	11.28
9L	Cochl	0	No	8.08	1.35	9.43	4	No	2.40	0.15	2.55
9R	RWE	4	Yes	7.41	13.34	20.75	4	Yes	10.60	15.55	26.15

* Cochl=cochleostomy, RW=Round Window, RWE= Round Window Enlarged

0 = no observable trauma; 1 = elevation of the basilar membrane; 2 = rupture of basilar membrane; 3 = electrode in scala vestibuli; and 4 = severe trauma such as fracture of the osseous spiral lamina or modiolus or tear of stria vascularis (13). Segment I: RW < RWE, p<.026.

Table 3

Amount of new tissue (percentage of total cochlear tissue measured in cubic microns) by electrode insertion technique and cochlear segment.

	Cochl.			RW			RWE			Stat. Signif.
	Mean	SD		Mean	SD		Mean	SD		
<i>Seg I</i>	Fibrous tissue	5.79	4.95	0.78	1.96		5.90	4.81		NS
	New bone	2.10	3.54	0.33	0.89		8.56	4.18		p<0.012 [#]
	Total new tissue	7.89	7.38	1.11	2.85		14.46	7.82		NS (p<0.055)
<i>Seg II</i>	Fibrous tissue	4.10	4.63	0.14	0.24		5.37	7.18		NS
	New bone	0.27	0.51	0.03	0.07		4.25	9.44		NS
	Total new tissue	4.37	4.90	0.17	0.31		9.63	15.16		NS

[#] RWE>Cochl and RW (post hoc p's <.035 and .019, respectively)

Table 4

Mean total new tissue for segment I by insertion method and electrode type.*

Electrode Type	Cochl.			RWE			RW		
	n	Mean	SD	n	Mean	SD	n	Mean	SD
Single electrode **	1	0.7	--	1	8.8	--	3	1.1	1.7
Nucleus 22	3	9.8	8.7	2	14.2	6.7	--	--	--

* Excludes subject 9, both ears of whom were revised from single electrode type devices to multielectrode devices.

** Includes House/3M and House/Urban.