

Residual hearing preservation for cochlear implantation surgery

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ABSTRACT

Cochlear implantation (CI) has developed for more than four decades. Initially, CI was used for profound bilateral hearing impairment. However, the indications for CI have expanded in recent years to include children with symptomatic partial deafness. Therefore, CI strategies to preserve residual hearing are important for both patients and otologists. The loss of residual low-frequency hearing is thought to be the result of many factors. All surgical methods have the same goal: protect the delicate intracochlear structures and preserve residual low-frequency hearing to improve speech perception abilities. Fully opening the round window membrane, a straight electrode array, slower insertion speed, and the use of corticosteroids result in a higher rate of hearing preservation. Several factors, like the way of surgical approaches, length of arrays and timing of activation, may not affect the residual hearing preservation. Therefore, the classic atraumatic technique, including the very slow and delicate insertion and administration of intraoperative corticosteroids, can improve hearing outcomes.

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INTRODUCTION

ochlear implantation (CI) is an electronic device that can - help restore hearing to people. Initially, the criteria for surgical implantation procedures were moderate-to-profound hearing loss. Besides this, it also includes patients with bilateral hearing loss who have used appropriate binaural hearing aids over 3 months, which showed limited benefits. For younger children, limited benefits are defined as a lack of progress in the development of simple auditory skills and measured by the Meaningful Auditory Integration Scale or the Early Speech Perception test. For older children, limited benefits are defined as 0%-12% correct answers on the openset Phonetically Balanced Word Test in a quiet environment or $\leq 30\%$ correct answers on the open-set Phonetically Balanced Word Test in a noisy environment [1]. For adults, limited benefits are defined as the test scores of open-set Phonetically Balanced Word Test being 30% correct orf less on the ear to be implanted (60% or less in the best-aided listening condition) on tape-recorded tests of open-set sentence recognition. Later, it was extended to include patients with mild-to-moderate hearing loss in low frequencies and severe-to-profound hearing loss in high frequencies. This kind of hearing loss pattern, called partial deafness, included a significant population of patients who could receive limited benefits from hearing aids [2,3]. Thus, residual hearing preservation was important during CI for these patients to regain hearing ability. There are several

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advantages to preserving low-frequency hearing in cochlear implant users, which help the users to understand speech and melodies, even in noisy environments.

Although the implantation devices continue to improve, there are still some users who underfgo reimplantation due to sudden or progressive failure of their system, especially in the pediatric group. Therefore, CI aims to preserve hearing by focusing on reducing trauma during surgery. This can lower the chance of postoperative fibrosis and scarring, and increase the success rate of re-implantation surgery without complication.

Early in the 1990s, preservation of residual hearing became well recognized and documefnted [4,5]. In the late 1990s, the new concept, termed electric-acoustic stimulation, was used in cases with severe-to-profound high-frequency hearing loss while preserving the hearing in low frequencies [6]. Over time, CI electrode array design and modified surgical technique improved immensely to minimize insertion trauma, even with long electrode arrays.

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The loss of residual low-frequency hearing is thought to be caused by trauma to neuronal cells during surgery [5]. Different opinions with regard to residual hearing preservation were given with regard to minimally invasive surgery, use of atraumatic electrode (depth of insertion, length, diameter, and stiffness), suitable route for insertion (cochleostomy vs. round window approach), gentle insertion technique, and control of the inflammatory response to electrode insertion (the pharmacological therapy). This review will examine the data behind each issue [Table 1].

THE FACTORS AFFECTING RESIDUAL HEARING PRESERVATION IN COCHLEAR IMPLANTATION Surgical technique

Lehnhardt first proposed the soft-surgery CI technique in 1993 [33]. There are several potential hazards resulted from cochlear implantation surgery, like incidental drill to the ossicles, perilymphatic fistula and intracochlear soft tissue injuries [34].

Two types of approaches (cochleostomy and round window) were accepted methods for electrode array insertion, and round window insertion was initially used. It had the advantage of a safe morphological landmark of the scala tympani [35]. However, it became less popular due to insertion damage by rigid and large diameter electrodes. As time went by, more flexible devices were invented, and the damage was reduced. In the last 11 years, 1500 patients with partial deafness were implanted [36], and the round window technique seems to have a better hearing preservation rate than that of cochleostomy. Conflicting with this view, in a more recent nonrandomized prospective study, forty patients underwent CI surgery by either cochleostomy or round window approaches, using

devices from MED-EL Co. (Innsbruck, Austria), between November 2013 and July 2014. Data from this study showed no statistically significant difference in the preservation of residual hearing between the two groups [7].

Several disadvantages of a cochleostomy, such as the presence of bone dust, the possibility of acoustic trauma during drilling, and the higher risk of electrode insertion into the scala vestibule, have been discussed. One temporal bone study showed no evidence of significant histological intracochlear damage by either insertion technique [8]. Nonetheless, a recent systematic review [9] shows that surgical insertion of the electrode via the cochleostomy and round window approaches are associated with trauma rates of 30% and 20.2%, respectively, by radiological and histological evidence. Therefore, soft surgery may be more important than the choice of different surgical approaches for residual hearing preservation.

Furthermore, when we use the round window techniques, slit or puncture opening of the round window leads to significantly higher intracochlear pressure gradients during electrode insertion than a half-open or wide-open round window did in a laboratory model [10]. Higher pressure gradients may result in more intracochlear trauma, reducing the residual hearing preservation rate. In a recent clinical study to compare the hearing preservation following different size opening of the round window, the rate of complete hearing preservation in the open group (71.4%) was significantly better than that of the slit group (45.7%) [11]. Thereafter, the widely opened round window may be a better choice for surgeons to improve hearing preservation outcomes.

The impact of the insertion speed was evaluated in 2011. The period of time from the insertion of the electrode tip until the second mark was reached and was equivalent to a length

	Factors	Treatment choice	Consensus
Surgical technique	Surgical approach	Cochleostomy	No significant difference [7-9]
		Round window approaches	
	Round window opening	Slit	Wide open is better than slit [10,11]
	size	Wide open	
	Insertion speed	Slow	Slower is better, but the ideal insertion speed
		Fast	remains unclear. [12,13]
Electrode selection	Electrode type	Perimodiolar	Straight array is significantly better than that with
		Straight	perimodiolar array [14-16]
	Electrode stiffness		Flexibility is better [15]
	Electrode length	Short	Shorter electrodes may have better hearing
		Medium	preservation, but longer straight electrode have
		Full insertion	significantly better speech outcome [17-21]
Pharmacological	Hyaluronic acid (Healon)		No significant difference [3]
therapy	Corticosteroid	Route	Regardless of the route or timing, extended- or
		Timing	single-dose regimen, corticosteroids have a
		Extended- or single-dose regimen	positive effect on hearing preservation [13,22,23]
	Antibiotics	Perioperative use	No conclusion [24-26]
		Prophylactic use	
Activation after	Time of switch-on	4-6 weeks after surgery	No significant difference [27-29]
surgery		Within 24 h after surgery	
Other factors	Age	Young	No conclusion [11,21,30-32]
		Adult	

of 18-25 mm. A slow and steady insertion speed of the electrode array reduces the fluid forces within the cochlea [12]. This subsequently reduces the intracochlear volume displacement with less mechanical effects on the basilar membrane and the organ of Corti [37]. It has been proven that the basilar membrane is readily damaged with forces of only 0.029-0.039 N. Gotamco et al. [13] found that the insertion speed was significantly different between the complete hearing preservation and partial hearing preservation groups with average speeds of 33.03 ± 16.66 and 43.68 ± 18.27 mm/min, respectively. One experimental research suggests a direct relationship between insertion speed and insertion forces, with speeds ranging between 40 and 200 mm/min [12]. An insertion speed of 40 mm/min causes average insertion forces of 0.13-0.28 N [12], and it had been proved that forces of only 0.029-0.039 N were required to rupture the basilar membrane [12]. Therefore, surgeons should insert the electrode array as slow as possible. There are some other studies which have recorded the insertion speed [38-40] [Table 2]. Unfortunately, the detail and impact of insertion speed was not discussed in these papers. Hence, it was difficult to conduct an analysis due to the small case number and high variability of the studies. This table still reveals a certain number of elements. First, compared to the study by Gotamco et al. (speed: 35.37 ± 17.30 mm/min), de Carvalho et al. [40] seem to use a very slow insertion speed but obtained a lower hearing preservation rate. These authors believe that this is due to less surgical experience and a poor electric acoustic stimulation candidate. Thus, the insertion speed is not the only impact factor related to hearing preservation, and a steady insertion may be also important. Second, the insertion speed of the complete residual hearing preservation group in Gotamco et al.'s study was 33.03 ± 16.66 mm/min [13]. Besides this, Gotamco et al. not only inserted electrode array slowly, but also applied many evidence-based practice for hearing preservation. Maybe, a speed of 33.03 mm/min or a little faster is enough to preserve residual hearing. However, until now, the ideal insertion speed remains unclear, and more research is needed to determine the relationship between implant insertion speed and hearing preservation.

Electrode selection

Several factors influence the electrode behavior in the cochlea, namely, the surface of the electrode, the stiffness and length of the electrode, as well as the electrode type (perimodiolar versus straight). Hearing loss can occur at the time of implantation due to insertion trauma or secondary to a chronic inflammatory response [17,41]. The

first electrodes designed for hearing preservation were the Nucleus CI 24 multichannel implant (Sydney, Australia) [42], and were either 6 or 10 mm in length. In recent years, more hearing preservation electrodes were invented, including the FLEX series by Med-El (Innsbruck, Austria), CI422 with slim straight electrode, CI532 with slim modiolar by Cochlear Limited (Sydney, Australia), and mid-scala electrode by Advanced Bionics (CA, USA).

No conclusion can be made on the optimal insertion depth for hearing preservation surgery. Intracochlear trauma increases with insertion depth, pushing the electrode forward beyond 18–20 mm [17,18]. The distance of 20 mm from the round window corresponds to frequencies near 1000 Hz. One meta-analysis supported this finding and found that the shortest electrode had the best hearing preservation rates [19].

Shorter electrodes may have better rates of early hearing preservation. However, intracochlear neuronal damage may be early or late in onset. Sometimes, late-onset damage may occur due to disease progression or chronic inflammatory reaction in the cochlea [43,44]. Then, complete electrical stimulation of the cochlea might not be possible in this kind of cases. In one study comparing the CI422 with shorter Hybrid-L electrode, significantly better speech understanding was found following residual hearing loss in patients implanted with the CI422 electrode [20]. This proves that while shorter electrodes may have better rates of hearing preservation, patients with longer straight electrode have significantly better speech outcome. Another meta-analysis contradicted this finding and showed no difference in hearing preservation based on either electrode length or design [2]. Nevertheless, due to the heterogeneousness of each study, the author did not support the full insertion of the electrode in this study [2].

The electrode arrays can be divided into two types (perimodiolar and straight). One meta-analysis[14] showed that CI with a straight array has a significantly better hearing preservation rate than that with a perimodiolar array. In these studies, however, most surgeons preferred to combine a straight electrode with a round window insertion, whereas the perimodiolar electrodes are often inserted through a cochleostomy. Thus, the analysis was done with a combination of surgical techniques and electrode array designs, making comparison difficult. However, as mentioned above, there is no significant difference in hearing preservation and speech perception between the two approaches [10,45]. Therefore, it seems that the loss of residual healing may be related to intracochlear

Table 2: Study characteristics for insertion speed of electrode array										
	Mean age in Gend years (range) (mal	Gender	ender Cochleostomy/ nale/ round	Electrode	Insertion length (mm)/	Insertion speed	Follow-up range	Complete hearing		
		(male/								
		female)	window		time period	(mm/min,	(months)	preservation		
					(min) [†]	mean±SD)		(%)		
Gstoettner et al. [38]	46.13 (7.62-71.32)	2/7	2/7	MED-EL FlexEAS	18-22/3	Nil	6-17	44.4		
Kuthubutheen et al. [39]	8 (1-15)	2/3	0/5	MED-EL FlexEAS	18/2	Nil	8-20	100		
de Carvalho et al. [40]	47 (29-63)	5/1	1/5	MED-EL FlexEAS	18-24/3	Nil	14-18	16.7		
Gotamco et al. [13]	18.03±22.07*	18/17	0/35	Nucleus Slim Straight CI422	25/nil	35.37±17.30	6	77.1		

*This author recorded the mean age with standard deviation, [†]The authors of the first three papers only recorded the data of insertion length and time period without calculating for speed. SD: Standard deviation

trauma caused by different arrays. Briggs *et al.* [15] showed that the narrow, flexible, straight arrays are the least traumatic and the stiffer and precurved perimodiolar arrays are associated with perforation of the basilar membrane in the temporal bones. In one experiment that used an artificial model [16], when a perimodiolar electrode array was inserted in an artificial cochlea, it caused higher intracochlear pressure than insertion by a straight array. This higher intracochlear pressure is thought to result in more intracochlear damage.

Studies slim-straight electrodes from both on Med-El (Innsbruck, Austria) and Cochlear Limited (Sydney, Australia) have found acceptable hearing preservation rates and postoperative speech understanding scores in the medium-length range (20-25 mm). MED-EL (Innsbruck, Austria) constructed three thin, flexible electrode arrays (TFEA) with different lengths (20 mm, 24 mm, and 28 mm). Suhling et al.[46] showed that hearing preservation is possible in the majority of individuals who are implanted with a TFEA20, 24, or 28. Less than 15 dB hearing loss was noted in 45.6%, 29.4%, and 15.0% of TFEA20, TFEA24, and 15.0% TFEA28 individuals, respectively. Another study used Cochlear Nucleus CI422 Slim Straight (Sydney, Australia) electrode array for CI via the round window technique [21]. It has straight, medium-length (20-25 mm), thin (0.3-0.6 mm), and flexible characteristics. Forty-seven percent of the patients had functional hearing preservation (low-frequency pure tone average at 0.25 k and 0.5 k dB HL no poorer than 85 dB HL) in 6 months after activation. In these studies, the two electrode arrays from Med El and Cochlear Limited had acceptable postoperative speech understanding scores. Therefore, the medium length of 20 mm may represent a balance between cochlear trauma and cochlear coverage.

There is no definite conclusion about an "ideal" electrode length. It will depend on the individual anatomic features of the cochlea, the level of residual hearing, the etiology of hearing loss, as well as numerous other patient factors.

Pharmacological therapy

Several kinds of pharmacological agents were used to reduce intracochlear trauma during CI surgery. Hyaluronic acid or Healon has been used for a long time. It works as a lubricant during electrode insertion and also functions as a seal to keep the perilymph inside the cochlea. However, one meta-analysis [2] revealed no significant benefit for hearing preservation.

When inserting the electrode array into the cochlear, foreign body reaction is unavoidable, and limiting the inflammatory response during surgery helps preserve residual hearing [47]. Therefore, anti-inflammatory drugs are needed to minimize the trauma and inflammation in the inner ear during CI. Corticosteroid is a well-known anti-inflammatory drug, and steroid usage is common in hearing preservation protocols to decrease any incidental loss of hearing. There had been several discussions, however, about how much steroid should be administered preoperatively, intraoperatively, and postoperatively [22,23,37]. Moreover, the timing of administering steroids is not standard. One retrospective study showed that the use of perioperative steroids, along with

intraoperative topical steroids, seems to have a positive impact on hearing preservation when compared to other steroid regimens or no steroids at all [19].

However, anything is a double-edged sword. Steroid therapy, especially for a prolonged period, can sometimes lead to inhibition of the hypothalamic-pituitary axis, which should especially be avoided in children [48]. In a prospective study, extended and single-dose steroid regimens were compared for hearing preservation outcome [37]. They both had a positive impact on hearing preservation without any significant difference. However, several side effects of steroids have been noted, even with their short-term use. Thus, single-dose steroid regimens were suggested by this study, instead of an extended-use regimen.

While the currently available devices are encased with silastic, titanium, and/or ceramics, like any foreign material within the body, they still have a potential risk of infection after insertion. If the inserted device becomes contaminated with microorganisms, it necessitates medical or even surgical intervention. This is a disaster for the surgeon and the patient! Prophylactic systemic antibiotics administered perioperatively are provided to minimize the risk of bacterial contamination at the time of surgery. When perioperative versus prophylactic antibiotics for CI were compared, there was no sufficient evidence to make definitive conclusions [24-26]. Therefore, each center has its own strategy for prevention of infection in these patients.

Early activation after cochlear implantation

After finishing the implantation, the activation of the external processor is routinely scheduled at 4-6 weeks after surgery. This period accounts for wound healing, possible implant migration, possible damage induced by electrical stimulation, and the array impedance instability. As time goes by, the improvements in surgical techniques and CI devices make early activation possible. However, there is not enough data concerning the best initial activation time. Chen et al. [27] first observed 54 patients who had their devices switched on within 24 h after CI. No major complications were reported. There were also no differences between preoperative and postoperative hearing thresholds. Another study by Marsella et al. [28] also showed no significant difference in impedances, speech perception, and complication rate between the two groups. Nevertheless, the hearing preservation rate was not mentioned in this paper.

In a more recent study, Sun *et al.* [29] prospectively enrolled twenty individuals for early activation by evaluating long-term impedance change and speech perception. In the control group, 12 patients (60%) achieved complete preservation and 8 patients (40%) achieved partial preservation. In the early activation group, 15 patients (75%) achieved complete preservation and 5 patients (25%) achieved partial preservation. No difference in the rate of complete and partial hearing preservation was observed between the two groups. It was the first clinical study to use the hearing preservation formula to compare between the early activation group and the conventional activation group. However, the case number of this study was limited. A further randomized, prospective study with a larger case number is needed to clarify the impact of early activation after CI for hearing preservation.

Other factors

As mentioned above, many factors will affect hearing preservation after CI. Young age seems to have a positive impact on hearing preservation. In a retrospective study by Anagiotos *et al.* [30], a total of 153 implantations with a mean age at implantation of 36 years (from 10 months to 83 years) were included. Residual hearing preservation was noted in almost half of the cases (47%). Moreover, 54% of the implantations reached complete hearing preservation, and the remaining 29% and 17% of implantations showed moderate and marginal hearing preservation rates, respectively. They also found that children and adolescents had a significantly better hearing preservation rate than adults. Other studies also showed that higher hearing preservation rate was significantly noted in younger age at implantation [31,32]. This may be due to differences in the inflammation and apoptosis mechanisms caused by insertion trauma.

However, two studies came to contrary conclusions [10,21] – that age at implantation was not associated with hearing preservation. Therefore, further investigation should be needed to confirm the impact of age on hearing preservation.

CONCLUSION

Development of cochlear implant has significantly progressed over the past decades, including electrode array characteristics, surgical techniques, and pharmacological therapies. All of these improvements aim to avoid the damage of intracochlear structures during implantation in order to preserve residual low-frequency hearing and speech perception. This review discusses some factors that can improve the residual hearing preservation rate, such as the full opening of the round window membrane, a straight electrode array, slower insertion speed, use of corticosteroids, and younger age at that time of implantation. However, some other decisions seem to provide no benefits, including cochleostomy or round window approaches, standard or shorter length arrays, and early or conventional activation schedule after CI.

Many studies use different inclusion criteria for their patients on pre- and post-operative residual hearing. This results in significant heterogeneity within studies. Thereafter, more prospective, comparative studies are warranted to determine which methods ensure a better residual hearing preservation rate.

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Conflicts of interest

There are no conflicts of interest.

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