Hearing preservation rates after cochlear implantation using soft surgery techniques: a 10 year retrospective review at an academic medical center

A Thesis
SUBMITTED TO THE FACULTY OF THE
UNIVERSITY OF MINNESOTA
BY

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IN PARTIAL FULFILLMENT OF THE REQUIREMENTS
FOR THE DEGREE OF
MASTER OF SCIENCE

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December 2021

Abstract

Objective: To determine whether the hearing preservation rate after cochlear implantation has varied over a time at an academic medical center with the evolution of soft surgery techniques.

Methods: Adult cochlear implant patient data was identified over 10 years with a total of 316 implanted ears. The hearing preservation rate trend over time was analyzed. The association between the hearing preservation rate and sex, age, perioperative steroid dose and type of electrode was also analyzed.

Results: There was no statistical difference with sex, age or type of electrode. There was a statistically significant improvement with a higher dose of perioperative steroid. There was a small but significant correlation between improved rate and later year of implantation.

Conclusions: There was a small but significant correlation between the hearing preservation rate over time with the use of soft surgery techniques including a significant difference with the use of a higher steroid dose. These findings bolster the benefit of soft surgery technique.

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Introduction

The first published report of electrical stimulation of the acoustic system was by Volta in 1790. This produced an unpleasant sensation and was not repeated. However, this did not dissuade others to attempt electrical stimulation but it was not until 1937 when Stevens was able to produce sound of different frequencies using alternating electrical current. The first implanted electrode was reported in 1957. The patient was able to distinguish different frequencies and intensity of sound but no speech and the electrode broke several times. In the 1960s, multiple researchers around the United States experimented with electrode implantation with one patient able to carry on simple telephone conversations. The 1970s was the start of commercial cochlear implantation with the formation of Cochlear Corporation, currently based in Australia, and Med El Corporation, based in Austria. Advanced Bionics, based in the United States, became the third major manufacturer in the 1980s.

Cochlear implant technology has advanced from the first implanted single channel electrodes to the present day multi channel electrodes. And, far from being an experimental device with the possibility of speech understanding, the average speech understanding score for an implanted patient is now in the 70 percent range with many people, particularly young implanted children, scoring in the high 90s. This improvement in performance has also led to a widening of the criteria for those qualifying for a cochlear implant.

Initially, only patients with severe to profound bilateral hearing loss were accepted for cochlear implantation due to the complete loss of residual hearing.

Hodges et al in 1997 reported on 40 patients who had undergone cochlear implantation with 21 of those having recordable hearing in one frequency between 500Hz and 2000Hz.[1] Prior to this, the expectation was that all patients lost residual hearing. Once it became apparent that hearing preservation was possible, research accelerated in this field.

A large percentage of people who seek implantation are older adults with a down sloping pattern of hearing loss with a moderate to severe loss in the low frequencies that drops to a severe to profound loss in the high frequencies. Given the tonotopic orientation of the cochlea with the apical turn coding the lower frequencies and the basal turn coding the highest frequencies, the possibility of preserving lower frequency hearing became more established as the electrode is inserted into the basal turn and, at most, enters the middle turn with the apical turn potentially unaffected. This led to Gantz and Turner partnering with Cochlear Corporation to test a hybrid electrode that was extremely thin and shorter than the standard electrodes with the goal of preserving low frequency hearing.[2] The 6 subjects in the trial all had preservation of low frequency hearing and improvement in speech understanding when wearing both the cochlear implant and hearing aid plus a hearing aid in the non-implanted ear. Additionally, they showed that, with residual hearing, use of both a hearing aid and a cochlear implant, termed electro-acoustic stimulation (EAS), in the same ear were feasible.

The goal of hearing preservation has led to changes in both the implant electrode as well as surgical technique. Versions of the hybrid electrode continue

to be thinnest electrodes on the market but performance with the hybrid electrodes can be problematic due to their short length. In patients who do lose further hearing, performance can decline as the electrode does not cover the same amount of cochlea as traditional long electrodes. Therefore, the cochlear implant manufacturers have produced thinner long electrodes that continue to cover a longer distance within the cochlea but with a small diameter in order to cause less trauma within the cochlea. The electrodes are also more flexible and can more easily bend and twist to accommodate the shape of the spiral cochlea. An animal study showed that insertion with a stiff electrode produced more hearing loss than with a soft electrode and that an opening into the cochlea itself did not produce long term worsening in hearing.[4]

A temporal bone study showed that variations in surgical technique can also result in less trauma to the hair cells within the cochlea. This was termed “soft surgery” technique and has become standard insertion technique.[3] A review of electrode design and surgical technique evolution for EAS stressed that mechanical damage, waves within the perilymph of the cochlea, acoustic trauma from drilling into the cochlea, loss of perilymph, fibrous tissue formation and possibly infection were factors in loss of residual hearing.[5] This has led to a change in the way the cochlea is entered with longer insertion times to minimize fluid waves and avoidance of suctioning perilymph out of the cochlea.

The entry point into the cochlea has changed from a cochleostomy opening where the otic capsule of the cochlea was drilled open slightly anterior and inferior to the round window to entry through the round window itself. This

change has been a reversal of prior technique as surgeons had gone from initial round window insertion to a cochleostomy approach due to previous temporal bone studies showing that the electrode caused more damage when inserted through the round window and that a straighter angle of insertion through a cochleostomy was less traumatic. However, this was prior to changes in electrode design when the electrodes were both thicker and stiffer. With the newer thin flexible electrodes, insertion is again through the round window to minimize the acoustic trauma of drilling into the cochlea as well as to facilitate placement through a known landmark. A guinea pig study reported that a round window approach resulted in less fibrosis than a cochleostomy.[10] There is conflicting data regarding whether this is a factor in hearing preservation in humans. Several studies have shown no difference in hearing change.[6,7,8,9] Multiple other studies have shown round window insertion to be superior to cochleostomy insertion for hearing preservation.[11,12,13,14,15,16]

Other factors during surgery have been studied. A slow rate of insertion has also been shown to improve retention of hearing as this may decrease the trauma from the fluid wave that occurs within the cochlea during insertion. The studies have used different rates of insertion but overall it appears that the slower the insertion, the better the hearing outcomes.[18,22,23] Additionally, the choice of packing material for the cochlear opening has been shown to influence hearing results with the use of bone cement or fibrin glue leading to worse outcomes compared to a tissue only or no seal.[10,20]

After implantation, fibrosis within the cochlea occurs. Quesnel et al showed in a human temporal bone study in a patient that had initial hearing preservation but lost hearing over time that there was intracochlear fibrosis and osteogenesis within the cochlea but no change in the number of spiral ganglion neurons between the implanted and non-implanted ear.[15] This led to an animal study looking at the effect of steroids which found that both systemic and topical steroids improved hearing preservation although the systemic steroid dose given would be very high when translated into a human dose.[17] Human studies have shown that steroids, both systemic and systemic plus topical, does improve hearing preservation.[11,18,19,20]

The type of electrode has also been shown to influence hearing preservation results. While all the electrodes have become thinner and more flexible over time, over the ten year time span of this study, the type of electrode offered by the manufacturers has changed although they group within two types: straight or perimodiolar. Early electrodes were all straight arrays but starting in 2000, Cochlear began manufacturing a perimodiolar electrode and shortly thereafter, Advanced Bionics also began manufacturing a periomodiolar electrode. MED-EL has consistently offered multiple lengths of lateral wall electrodes which are classified as straight arrays for the purposes of the study. The impetus for a periomodiolar design was to place the individual electrode placodes as close as possible to the modiolus where the spiral ganglion cells reside. This gave the advantage of less current being needed to stimulate the spiral ganglion cells leading to decreased current spread with a potential greater

fidelity of sound as well as increased battery life secondary to the decreased amount of current needed. The type of electrode selected is typically surgeon driven and based on multiple factors including ease of use, speech understanding results and hearing preservation. As with the other factors, there is conflicting data on the benefits of one type of electrode versus the other. There are some studies showing no difference while others show a benefit with a straight array.[24,25,26,11,27,28]

There are differing ways of reporting the degree of hearing preservation. In 2013, a large multi-national group, known as the HEARRING group, proposed a way to classify hearing preservation after cochlear implantation which takes into account the preoperative hearing levels as many people receiving a cochlear implant have no testable hearing prior to implantation.[29] This alleviates the result of a patient appearing to have excellent hearing preservation because the postoperative and preoperative hearing thresholds are unchanged simply because the thresholds are already as high as possible. While many of the studies on hearing preservation do use the HEARRING method, many do not making comparison of results across studies difficult. A comparison of a range of studies from 2013 through 2021 showed a majority of studies reporting total plus partial hearing preservation rates near 50% with a few reporting rates above 80%.[22,24,25,26,28,30]

This study aims to evaluate the hearing preservation (HP) rates at an academic center over a 10 year period to assess if a trend towards better rates occurred over time with the advent of soft surgery technique. The influence of

other factors such as steroid administration and electrode type was also examined.

Materials and Methods

This study was approved by the University of Minnesota institutional review board. A retrospective chart review was performed of all patients older than 18 years of age who had agreed to participate in research who underwent cochlear implantation between January 1, 2010 and December 31, 2020 using CPT code 69930. Patients with audiometric data from outside institutions were included. Exclusion criteria included: revision surgery, lack of preoperative audiometric data and lack of postoperative audiometric data.

AUDIOMETRIC DATA

Audiometric threshold testing of either unmasked or masked air conduction was used for the preoperative and postoperative threshold evaluation. Thresholds at 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000 and 8000Herz (Hz) were recorded. Pure tone average (PTA) was calculated using as many frequencies as tested for both the preoperative (PTApre) and postoperative (PTApost) audiograms.

SURGICAL TECHNIQUE

The implants were performed by three surgeons with one retiring mid 2019. All implants were placed through a posterior tympanotomy approach. Initial cochlear entry was via a cochleostomy with phasing in of round window insertion between 2012 through 2013 with almost all approaches through the round

window by 2014 unless there was anatomic difficulty in accessing the round window. The speed of insertion, though not specifically measured, increased from less than 30 seconds to more than one minute from 2017 through 2020. Administration of a single preoperative dose of dexamethasone began in 2013. The cochlear opening was packed with fascia with no tissue glue or bone cement used.

IMPLANTS

Cochlear, Advanced Bionics and MED-EL cochlear implants were used throughout the study period. The electrode types were classified as either straight arrays, including lateral wall, or perimodiolar arrays. Choice of manufacturer was made by the patient. The surgeons did not influence the choice of manufacturer unless there were anatomic considerations. However, the electrode type was based on surgeon preference if there was a choice within a manufacturer between a perimodiolar or straight array.

STATISTICAL METHODS

Statistical analyses were performed using SAS V9.4 (SAS Institute Inc., Cary, NC).

The Wilcoxon rank sum test was used to compare hearing preservation for sex, electrode type and steroid dose. Spearman's rank order correlation was used for comparison of hearing preservation over time and age. p value < 0.05 was considered to be statistically significant.

Results

DEMOGRAPHICS

A query based on CPT code 69930 returned 562 procedures from 477 patients with 85 patients receiving bilateral, either simultaneous or concurrent, implants. Of the 477 patients, 264 were identified as meeting criteria. Of the 213 excluded patients, all were due to lack of audiometric data. The 264 patients had a total of 316 implanted ears. The group consisted of 124 males (47%) with a mean age at the time of the first implant of 57.7. The mean time between surgery and the first postoperative audiogram was 27 days. The results are summarized in Table 1.

Table 1: Demographic data

Number of patients		264
Number of implanted ears		316
Sex (%)	Male	124 (47)
	Female	140 (53)
Age (mean, range)		57.7 (18-92)
Days to postoperative audiogram (median, interquartile range)		27 (22-195)
Electrode (n 312) (%)	Straight	234 (75)
	Perimodiolar	78 (25)
Dexamethasone (n 304) (%)	< 8mg	109 (35.9)
	8-10mg	195 (64.1)

TOTAL GROUP HEARING PRESERVATION

Hearing preservation score was calculated using the HEARRING group formula and classified according to the group's classification system.[48] The

formula aims to eliminate the effect of preoperative hearing on preservation results, takes into account maximum detectable thresholds and gives a value that is the relative change of percentage of hearing loss.

$$S = [\ 1 - ((PTApost - PTApre)/(PTAmax - PTApre)) * 100]\ [100\%]$$

Table 2 lists the maximum PTA (PTAmax) for each frequency.

Table 2: Maximum detectable hearing (mdh) measurable for each frequency

Hz	125	250	500	750	1000	1500	2000	3000	4000	6000	8000
mdh	90	105	110	120	120	120	120	120	115	100	95

The HP values are also classified into complete HP, partial HP, minimal HP and loss of hearing/no hearing (Table 3). Higher values indicate better hearing preservation. The HP for all ears was 28.3 with a 95% confidence interval (CI) (19.4,37.3) and standard deviation (SD) 80.9.

Table 3: Scale for HP classification

Percent of residual hearing	Classification
>75%	Complete HP
>25-75%	Partial HP
0-25%	Minimal HP
No measurable hearing	Loss of hearing/No hearing

When this was broken down into categories, 20 (6.33%) had complete HP, 101 (31.96%) had partial HP and 195 (61.7%) had minimal HP (Table 4). Of the minimal HP group, 110 (56.41%) had no measurable hearing which was 34.81%

of the total ears. When looking at PTApre, 12 (3.8%) ears had no measurable hearing.

Table 4: Hearing preservation classification for all ears

Minimal (%)	195 (61.7)
Partial (%)	101 (32)
Complete (%)	20 (6.3)

Due to the number of patients with poor preoperative hearing thresholds, separate analyses were done for ears with PTApre < 100 (n = 226). The mean HP in this group was 25.6 with 95% CI (22.0,29.1) and SD 27. This was not significantly different.

DEMOGRAPHIC

There was no significant difference in HP between sexes in either the entire data set or in those with PTApre < 100. Female mean HP was 24.1 versus 33.9 with a p value 0.4485 and in the PTApre < 100, female mean HP was 24.5 versus 27.2 with a p value 0.5930 (Table 5).

Table 5: Mean hearing preservation for sex, electrode type and dexamethasone dose

		All ears	PTApre < 100dB
Sex (SD) [median]	Male	33.9 (113.10) [13.2]	27.2 (29) [16.1]
	Female	24.1 (33.5) [14.6]	24.5 (25.3) [20.5]
Electrode	Straight	32.8 (92.6) [16]	26.5 (27.2) [20.8]
	Perimodiolar	19.4 (25.6) [10.8]	22.5 (25) [15.5]
Dexamethasone dose*	< 8mg	15 (21.8) [1.4]	18.1 (23.3) [10.5]
	8-10mg	36.4 (100.7) [21.4]	29.6 (27.9) [24.5]

* Wilcoxon rank sum test p-value = 0.0001 (Statistically significant at 0.05 level)

There was also no correlation with increasing age with Spearman correlation coefficient r = -0.08 in the total group and r = 0.05 in the PTApre < 100 group. These r values are not statistically different than 0.

ELECTRODE TYPE

Comparison between straight and perimodiolar electrodes also did not produce a significant difference in either group. The mean perimodiolar HP in the total group was 19.4 versus 32.8 with a p value 0.16 and in the PTApre < 100 group, the mean perimodiolar HP was 22.5 versus 26.5 with a p value 0.52 (Table 5).

DEXAMETHASONE ADMINISTRATION

In 2013, a single dose of preoperative dexamethasone began to be used. The dose was variable and was sometimes not administered and typically varied between 4 – 10mg in amounts of either 4mg, 6mg, 8mg or 10mg. By 2014, a more consistent dose of 10mg was being administered and by 2019 the vast majority of patients were receiving 10mg dexamethasone. To evaluate the effect of a higher dose of dexamethasone, a cut point of 8mg was chosen with one group receiving 0 – 6mg and the other group receiving 8 or 10mg. In both the total group and the PTApre < 100 group, ears which received the greater dose of dexamethasone had significantly better HP. In the total group, mean HP for the < 8 group was 15 while the 8+ group mean was 36.4 with a p value 0.0001. In the

PTApre < 100 group, mean HP for the < 8 group was 18.1 while the 8+ group mean was 29.6 with a p value 0.0044 (Table 5).

TIME (YEAR OF PROCEDURE)

A significant correlation between HP and the year of implantation was identified although the correlation was small. A higher correlation coefficient (closer to 1.0) indicates stronger correlation. The total group had a Spearman correlation coefficient, $r = 0.25$ ($p<0.0001$) and the PTApre < 100 group also had $r = 0.25$ ($p=0.0002$).

Discussion

This study examined the hearing preservation rate after cochlear implantation over 10 years from 2010 through 2020. During this time, soft surgery techniques had been developed to minimize intracochlear damage and improve hearing preservation. Entry into the cochlea via the round window, avoidance of suctioning the perilymph within the cochlea, slow insertion of the electrode, packing with autologous tissue without the use of non autologous sealants and the administration of perioperative steroids are now common techniques.

Since these steps were phased in over time over the 10 year period, there may be an expectation that hearing preservation would improve over time and we did find a small but significant improvement in hearing preservation over time. This was true both in patients with preoperative PTA > 100dB as well as in those with less severe preoperative PTA of < 100dB. The use of a higher dose of preoperative intravenous dexamethasone was also found to be significantly associated with better hearing preservation.

With enough hearing preservation, patients can then utilize both a cochlear implant and a hearing aid. Electroacoustic stimulation patients have better speech understanding than those using a cochlear implant alone. In our patient population, very few patients have elected to use both devices. Several studies have also noted that the use of EAS is less than 50% and declines over time.41,49 However, Dalbert et al has shown that those with residual hearing have better speech understanding with a cochlear implant than those with no

hearing preservation.33 Therefore, hearing preservation should continue to be a priority even if the expectation for usage of EAS is low.

LIMITATIONS

One limitation of this study is that it is a retrospective review. Our institution did not begin systemically testing postoperative residual hearing until three years ago so the postoperative audiometric data collection was not standardized prior to that time which led to some patients having a postoperative audiogram which tested hearing thresholds without the implant within weeks after implantation and some not having an audiogram for more than a year after implantation. Most patients did have an audiogram with the implant in place done within a month after surgery but did not always have residual hearing tested. The majority of the patients also do not have more than one postoperative test so there was insufficient data to look at the stability of HP over time.

Another limitation is that we did not have a systematic approach to standardizing the surgical steps of cochlear implantation. While the three surgeons' operative techniques were similar, the transition for entry to the cochlea from cochleostomy to round window did not occur simultaneously nor did the transition from varied doses of intraoperative steroids to a set dose of dexamethasone occur simultaneously. Additionally, we had neurotology fellows perform implantation surgery during this time period which may have impacted the results.

Now our technique is more standardized with a slow insertion speed and a fixed perioperative steroid dose. Additionally, all recipients who have their cochlear implant programmed at our institution have at least one postoperative audiogram testing non-implanted hearing thresholds within three months of implantation. These changes have resulted in a more uniform approach to cochlear implantation surgery and audiometric testing which should result in data with less variability moving forward.

Conclusions

Cochlear implantation is the only procedure that can restore hearing but, in the past, also took all remaining hearing. Once it became apparent that residual hearing could be preserved, the surgical techniques and design of the cochlear implant changed to facilitate the ability to preserve hearing as patients with residual hearing can have improved functional results after implantation. Our ability to preserve hearing has improved over time with the advent of newer surgical techniques, thinner more flexible electrodes and the use of a higher dose of perioperative dexamethasone.

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