



Universiteit
Leiden
The Netherlands

Prolonged insertion time reduces translocation rate of a precurved electrode array in cochlear implantation

Jagt, A.M.A. van der; Briaire, J.J.; Boehringer, S.; Verbist, B.M.; Frijns, J.H.M.

Citation

Jagt, A. M. A. van der, Briaire, J. J., Boehringer, S., Verbist, B. M., & Frijns, J. H. M. (2022). Prolonged insertion time reduces translocation rate of a precurved electrode array in cochlear implantation. *Otology And Neurotology*, 43(4), E427-E434. doi:10.1097/MAO.0000000000003499

Version: Publisher's Version

License: [Creative Commons CC BY-NC-ND 4.0 license](https://creativecommons.org/licenses/by-nc-nd/4.0/)

Downloaded from: <https://hdl.handle.net/1887/3567317>

Note: To cite this publication please use the final published version (if applicable).

Prolonged Insertion Time Reduces Translocation Rate of a Precurved Electrode Array in Cochlear Implantation

*Annerie M. A. van der Jagt, *Jeroen J. Briare, †Stefan Boehringer, ‡§Berit M. Verbist, and *||Johan H. M. Frijns

**Department of Otorhinolaryngology; †Department of Biomedical Data Science; ‡Department of Radiology; §Department of Radiology, Radboud University Medical Center Nijmegen, Nijmegen; and ||Leiden Institute for Brain and Cognition, Leiden University Medical Center, Leiden, the Netherlands*

Hypothesis: Insertion speed during cochlear implantation determines the risk of cochlear trauma. By slowing down insertion speed tactile feedback is improved. This is highly conducive to control the course of the electrode array along the cochlear contour and prevent translocation from the scala tympani to the scala vestibuli.

Background: Limiting insertion trauma is a dedicated goal in cochlear implantation to maintain the most favorable situation for electrical stimulation of the remaining stimula- ble neural components of the cochlea. Surgical technique is one of the potential influencers on translocation behavior of the electrode array.

Methods: The intrascalar position of 226 patients, all implanted with a precurved electrode array, aiming a mid- scalar position, was evaluated. One group (n = 113) repre- sented implantation with an insertion time less than 25 sec- onds (fast insertion) and the other group (n = 113) was implanted in 25 or more seconds (slow insertion). A logistic regression analysis studied the effect of insertion speed on

insertion trauma, controlled for surgical approach, cochlear size, and angular insertion depth. Furthermore, the effect of translocation on speech performance was evaluated using a linear mixed model.

Results: The translocation rate within the fast and slow insertion groups were respectively 27 and 10%. A logistic regression analysis showed that the odds of dislocation increases by 2.527 times with a fast insertion, controlled for surgical approach, cochlear size, and angular insertion depth (95% CI = 1.135, 5.625). We failed to find a difference in speech recognition between patients with and without translocated electrode arrays.

Conclusion: Slowing down insertion speed till 25 seconds or longer reduces the incidence of translocation.

Key Words: Cochlear implantation—Insertion speed— Insertion trauma—Speech perception outcome—Surgical approach.

Otol Neurotol 43:e427–e434, 2022

A dedicated goal with cochlear implants (CIs) is to limit intracochlear trauma during surgery. Atraumatic insertions preserve residual hearing, accommodate simultaneous electric and acoustic stimulation, and provide the best conditions for optimal stimulation of audi- tory neurons; thus, they should facilitate best speech perception outcomes (1,2).

Although it remains largely unknown how translocation of a CI electrode array occurs, it is assumed that this is influenced by the surgical technique, cochlear morphology, and the physical qualities of the array (i.e., length, stiffness, and cross-sectional diameter). To reduce insertion trauma,

several advances have been made in implant designs and surgical techniques, referred to as “soft surgery techni- ques” (3). To minimize damage to the basilar membrane, arrays were designed with soft, thinner tips, reduced cross- sectional dimensions, and less vertical stiffness. Despite these improvements, insertion trauma rates remain high with all current devices (up to 32.6%) (4).

In recent years, a CI with a precurved electrode array that was designed to maintain a mid-modiolar position within the scala tympani was introduced (HiFocus Mid-Scala [MS] electrode array; Advanced Bionics, Valencia, CA). Theoretically, this design retains an optimal dis- tance between the electrode contacts and the modiolus, but avoids contact with both the modiolus and lateral wall. Moreover, the small size of the array allows a pure round window (RW) insertion, potentially causing less trauma during insertions. Three studies investigated the electrode position and angular insertion depth of this implant design when inserted into temporal bones of small cohorts. They reported translocation rates of 0 to 12.5% (5–7). In previous clinical studies on several

Address correspondence and reprint requests to Annerie M. A. van der Jagt, M.D., Department of Otorhinolaryngology, Leiden University Medical Center, PO Box 9600, 2300 RC Leiden, The Netherlands; E-mail: M.A.van_der_Jagt@lumc.nl

Disclosure of funding: This research was financially supported by Advanced Bionics.

The authors disclose no conflicts of interest

DOI: 10.1097/MAO.0000000000003499

precurved designs, considerably higher translocation rates were reported (29–54%) (4).

Currently, the favored surgical approach technique is a pure RW insertion; indeed, some have considered it to be the least traumatic approach (8,9). With this approach, the implant is inserted directly into the RW without drilling a cochleostomy or drilling away part of the crista ante fenestram. However, this approach might impair visualization into the scala tympani, and thus, reduce control of the optimal direction of insertion, which could increase the risk of initial trauma at the base (10). Furthermore, slowing down the insertion speed was reported to facilitate hearing preservation (11). It is postulated that slower insertion speeds can maintain the intracochlear fluid pressure, and thus, prevent basilar membrane rupture. A correlation between the insertion speed and intracochlear fluid pressure was previously shown by Todt et al. (12).

This study investigated the rate of translocations with the precurved HiFocus MS electrode array. We evaluated whether different insertion times, and cochlear approaches affected the translocation rate.

MATERIALS AND METHODS

Patients

This study included data of 226 primarily implanted ears from 209 consecutive patients of all ages that received implantations with a HiFocus MS electrode array, between June 2012 and November 2017 at our institution. We excluded patients with characteristics that might influence the electrode array trajectory, such as severe malformations or cochlear ossifications. A subgroup of unilaterally implanted adult patients with postlingual deafness was selected for a speech perception analysis. Baseline characteristics are presented in Table 1.

Electrode Designs and Surgical Approach

The precurved HiFocus MS electrode array was launched in 2013 and was designed to maintain a mid-scalar position. The array has a total active length of 15.0 mm, from the basal contact to the tip and contains 16 electrode contacts, arranged on a 0.9 mm pitch. Two blue markers, with a distance of 13.5 mm in-between, are included to ensure proper insertion, either with an

insertion tool or free-hand, and to indicate full insertion of the active electrode array. The cross-sectional diameter is approximately 0.5 and 0.7 mm at the most apical and basal contact, respectively. In this study, all insertions were performed with the insertion tool provided with the implant. Insertion was performed either with a pure RW (n=43) or an extended RW (n=183) approach, based on the size and orientation of the RW opening. RWs were measured with a 0.8 mm sizer during the surgical procedure. The insertion of the electrode array is performed as one steady, continuous progression.

In the context of evaluation of care, an uncontrolled analysis was performed in January 2015 to evaluate and compare translocation rate between the two surgical approaches. A higher incidence of translocations was found with the pure RW insertions (30% versus 23%). This finding somewhat changed the procedure by making the surgeons more reluctant to use this approach in future implantations. Consequently, most pure RW insertions were performed before 2015 with faster implantations. This confounding factor was taken into account with the later analyses. All implantations were performed by five otorhinolaryngologists with different levels of experience in cochlear implantations (i.e., 1–20 yr). The majority of the implantations (183/226) was performed by the two most experienced surgeons.

Radiological Evaluation of Electrode Contact Positions

All 226 patients were scanned with a multislice computed tomography scanner (Aquilion; Toshiba Medical Systems, Otawara, Japan), both before and 1 day after implantation, according to the standard work-up for CI candidates in our institution. Multiplanar reconstructions were created from these scans. A 3D coordinate system was applied, which is generally used for universal evaluation of the CI position (13). The angular and radial positions of each individual electrode contact within the coordinate system were calculated with an in-house post-processing program, written in Matlab (Mathworks, Novi, MI). This program generated spatially synchronized midmodiolar cross-sectional images, which allowed a side-by-side presentation of the pre- and postoperative CT scans acquired at the same angular distance from the RW. This method was validated in an earlier study (14).

Intracochlear CI electrode array positions were evaluated with a five-point scale. Evaluations were based on the superior–inferior position of the electrode contact within the cochlear lumen and the level of certainty, as follows: scores of 1 and 2 indicated a certain and probable scala tympani position, respectively; a score of 3 indicated an intermediate position; and scores of 4 and 5 indicated a probable and certain scala vestibuli position, respectively. When two or more electrode contacts were within the scala vestibuli (i.e., a score 4 or 5), the electrode array was considered translocated.

Evaluation of Insertion Time and Insertion Characteristics

To gain more insight into the effect of the insertion speed on the trauma incidence, the exact duration of the tool insertion was recorded, starting in January 2015. This insertion time was defined as the time between insertion of the apical and basal blue marker of the electrode array through the (extended) RW. From January 2015, surgeons were asked to pursue an insertion time of 25 seconds or more, corresponding with an insertion speed of 32 mm/min. This cut off of 25 seconds was chosen, in part, based on the results of Todt et al. (12), who reported an

TABLE 1. Characteristics of the study population

Patients	N = 226
Insertion speed* (fast: slow)	113: 113
Age at implantation, years (mean ± SD)	43 (±29)
Male: female	93:133
Side (AD: AS)	114:112
Cochlear size (mean, ±SD)	60 (±5)
Audiological characteristics	
Preoperative phoneme scores (mean ± SD)	50 (±23)
Preoperative word scores (mean ± SD)	28 (±20)

*Fast insertions: electrode arrays inserted in 25 seconds or less, or implanted before January 2015. Slow insertions: electrode arrays inserted in 25 seconds or more.

AD indicates right ear; AS, left ear; RW, round window; SD, standard deviation.

increase in intracochlear fluid pressure with rapid insertions. In contrast, insertions performed before 2015 were performed well within 25 seconds, probably even within 10 seconds; therefore, an objective comparison was feasible.

Group 1 included all patients that received implants before the change in January 2015 ($n=108$) and all patients that received implants after this change with insertion times of 25 seconds or less ($n=5$). Group 2 included all patients that received implants with insertion times longer than 25 seconds ($n=113$).

We also extracted data from the surgical and radiological reports to assess the angular insertion depth, resistance, electrode array rotations, and incomplete insertions.

Factors That Influence Translocation

Potential factors that might influence the translocation behavior of a CI electrode array were analyzed with a multivariate logistic regression analysis. The following variables were included; a fast or slow insertion, the surgical approach, the angular insertion depth, and the surgeon. Because data regarding the absolute insertion time was only available of the patients implanted since January 2015, a sub-analysis studying absolute insertion time on translocation rate was performed with an estimated time of insertion of 10 seconds in the fast inserted population.

Evaluation of Speech Performance

Speech performance was evaluated in a group of 133 adults with postlingual deafness; of these, 59 and 74 were in the fast and slow insertion groups, respectively. Speech perception was assessed with the standard Dutch speech test of the Dutch Society of Audiology (15). Briefly, four lists of 11 monosyllabic words were administered, and we recorded the number of phonemes and words correctly recognized. These assessments were conducted at 1 week, 2 weeks, and at 1, 3, 6, and 12 months after hook-up of the implant.

Statistical Analysis

Statistical analyses were performed with SPSS (version 20, IBM, Armonk, NY). A multivariate logistic regression analysis was performed to study the effects of the surgical approach, the insertion time, the surgical approach, the cochlear size, and the angular insertion depth on the incidence of traumatic insertions. A linear mixed model analysis was performed to study the effect of translocation on speech performance. In the mixed models, a random intercept per patient and a random effect for time was used. These random effects measure the fluctuation of patient slopes and intercepts for speech performance around the overall regression line. Covariance structure was chosen as unstructured. All tests were 2-tailed. p -values <0.05 were considered statistically significant.

RESULTS

Translocations and Insertion Characteristics

In all 226 cases, a complete insertion was achieved. Translocations occurred in 41 cases (18%). Thirty translocations occurred following a fast insertion (27%), versus 11 after a slow insertion (10%). All translocations occurred in a relatively restricted area. The mean angular depth of the most basal translocated electrode contact was 167 degrees (SD 20 degrees). In all cases, the electrode array remained within the scala vestibuli after translocation.

Table 2 provides an overview of the surgical characteristics, specified for the fast and slow insertions.

In seven out of 226 implantations, the electrode array had to be reinserted due to twisting of the electrode array ($n=2$) in one of these cases also resistance was felt. Other reasons for reinsertion were; incomplete insertion ($n=2$), an unstable position of the lead ($n=2$), and in one case the opening of the extended window turned out to be too narrow.

After beginning to pursue slower insertion times (25 s or more), the insertion times were recorded in 113 cases. Among these, five cases failed to achieve the 25-second limit, because either the final array insertion was reached earlier than expected, or the slow insertion resulted in instability of the surgeon's hand. Among the remaining 108 cases, the mean insertion time was 45 seconds (range, 25–95 s).

With a multivariate logistic regression analysis we studied the effect of the variables fast/slow insertion, angular insertion depth, surgical approach, cochlear size, and surgeon on the occurrence of translocation. To rule out an interaction between angular insertion depth and cochlear size, between angular insertion depth and fast/slow insertion, and between surgical approach and fast/slow insertion, the possibilities of these interactions were included in the work-up of the model. No interaction was found between angular insertion depth and cochlear size ($p=0.441$), angular insertion depth and fast/slow insertion ($p=0.683$), and surgical approach and fast/slow insertion ($p=0.722$). For the final analysis we tried to follow the “number of events/10 rule” to analyze a reliable model. This means a maximum of four variables were included, i.e., fast/slow insertion, angular insertion depth, surgical approach, and cochlear size. The outcomes of the multivariate logistic regression analysis are shown in Table 3. With a fast insertion the odds for a translocation of the electrode array increases by 2.527 times (95% CI = 1.135–5.625), controlled for surgical approach, angular insertion depth, and size of the implanted cochlea. The Hosmer Lemeshow test shows a good fit of the model (χ^2 5.773, eight degrees of freedom, $p=0.673$). Likely, there is also an association between angular insertion depth and translocation, although with a p -value of 0.050 this cannot be asserted

TABLE 2. Surgical characteristics of the study population

Surgical Characteristics	Fast Insertion ($n=113$)	Slow Insertion ($n=113$)
Translocation (N, %)	30, 23%	11, 10%
Angular insertion depth, degrees (mean \pm SD)	420 (± 29)	409 (± 40)
Duration of insertion, s (mean \pm SD)	N/A	44 (± 16)
Surgical approach		
Extended: pure RW insertion	77:36	106:7

Fast insertions: electrode arrays inserted in 25 seconds or less, or implanted before January 2015. Slow insertions: electrode arrays inserted in 25 seconds or more.

RW indicates round window; SD, standard deviation.

TABLE 3. Output logistic regression analysis; effect parameters on translocation outcomes

Parameter	Odds Ratio Estimate	p-Value	Lower Bound 95% CI Interval	Upper Bound 95% CI Interval
Fast insertion speed	2.527	0.023	1.135	5.625
Pure round window insertion	1.817	0.154	0.799	4.132
Angular insertion depth	1.011	0.050	1.000	1.023
Size of the implanted cochlea	0.964	0.270	0.904	1.029

with certainty. The sub-analysis studying insertion time as a continuous variable, with the estimated insertion time of 10 seconds for all the fast implanted patients, did not show a significant association of the absolute insertion time with translocation ($p = 0.354$).

Speech Performance

Among the 172 patients that received unilateral implants, 133 had postlingual deafness and were included in the sub-analysis for evaluating speech perception.

Translocations were detected in 21 patients. Figure 1A and B shows the results of phoneme and word tests conducted after implantation. At all six time points, the groups showed no significant differences in speech perception. Table 4 shows the number of patients per number of follow-up measurements. Overall, 97/798 (12.2%) and 110/798 (13.4) of the phoneme and word scores, respectively, were missing. These percentages were deemed to be acceptable, especially because of the linear mixed model (missing at random). We

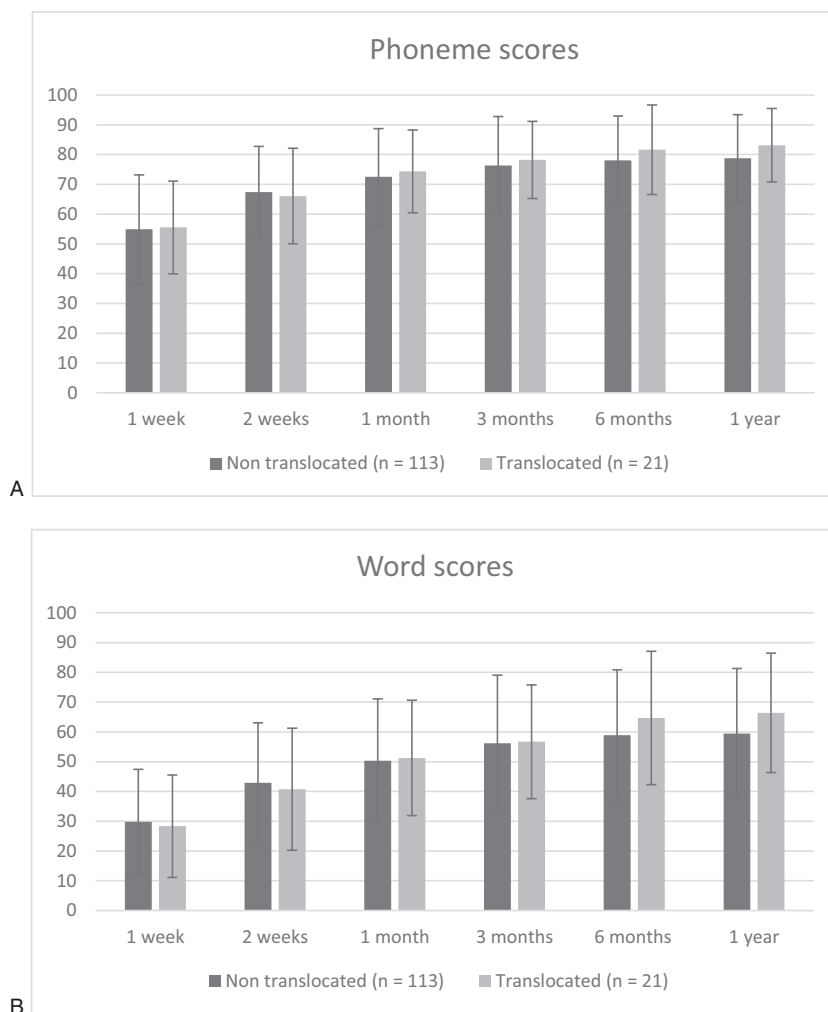


FIG. 1. Mean phoneme (A) and word (B) recognition scores and standard deviations at six follow-up intervals of non-translocated (dark grey) and translocated (light grey) and HiFocus MS electrode arrays.

TABLE 4. Number of patients per number of follow-up measurements

Number of Follow-up Measurements	Phonemes	Words
6 (complete follow-up)	62	58
5	53	54
4	12	12
3	5	6
2	0	0
1	1	0
0 ^a	0	3
Total	133	133

^aThese patients were not included in the linear mixed model analysis.

constructed a linear mixed model, for the phonemes and word scores separately, while taking into account other possible influencing factors; the preoperative speech perception scores and the angular insertion depth. These two variables were analyzed as fixed effects. A random intercept and random time model was fit for the six time intervals. The analyses show an effect of preoperative speech perception scores on postoperative speech perception scores; for each added preoperative phoneme score, the postoperative phoneme outcome increases with 0.264 ($p < 0.001$) and for each added preoperative word score, the postoperative word outcome increases with 0.385 ($p < 0.001$). We failed to find a difference in speech recognition between patients with and without translocated electrode arrays. The random effects show

large variances as compared with residual variance, indicating heterogeneity between patients. The details of the linear mixed model analyses are presented in Tables 5 and 6.

DISCUSSION

We demonstrated that using a fast, versus a slow, insertion of the precurved MS electrode array, increases the odds of translocation by 2.527 times. The translocations of the CI array were found to occur in a relatively narrow region around 167 degrees (SD 20 degrees) from the RW, approximately halfway the basal turn of the cochlea, where its vertical trajectory usually shows a steep increase (16,17). Yet, speech recognition till 1 year after implantation was similar in patients with and without translocations. These findings should be considered in the future development and evaluation of CI electrode arrays and surgical techniques.

Implant Designs

The ideal electrode array should combine trauma prevention features with an intracochlear position that provides optimal stimulation of the spiral ganglion cells; i.e., closely corresponds to the natural cochlear tonotopy, has a broad dynamic range, and provides high spatial discrimination. However, improvements in one domain often lead to compromises in other domains. Earlier studies that investigated insertion trauma rates with different electrode arrays have shown divergent out-

TABLE 5. Output linear mixed model analyses; effect parameters on speech perception outcomes (phonemes)

Parameter	Estimate	<i>p</i> -Value	95% Confidence Interval	
			Lower Bound	Upper Bound
Estimates of fixed effects				
Intercept	44,757	0.005	14,051	75,463
Dislocation = yes	−3,010	0.342	−9,261	3,242
Angular insertion depth	0.025	0.460	−0.042	0.931
Preoperative phoneme score	0.252	<0.001	0.140	0.363
Estimates of random effects				
Time interval ^a	0.371	<0.001	0.315	0.427

^aIn weeks after first hook-up.

TABLE 6. Output linear mixed model analyses; effect parameters on speech perception outcomes (words)

Parameter	Estimate	<i>p</i> -Value	95% Confidence Interval	
			Lower Bound	Upper Bound
Estimates of fixed effects				
Intercept	10,778	0.613	−31,272	52,829
Dislocation = yes	−1,766	0.685	−10,377	6,845
Angular insertion depth	0.051	0.285	−0.043	0.145
Preoperative word score	0.393	<0.001	0.231	0.555
Estimates of random effects				
Time interval ^a	0.514	<0.001	0.443	0.585

^aIn weeks after first hook-up.

comes. A recent systematic review of 653 implantations from 21 studies, including *in vivo*, *ex vivo*, radiological, and histological studies, reported that 115 cases (17.6%) showed evidence of trauma. The traumas varied from an elevated basilar membrane to scalar translocations (18). Focusing on the studies comparable to ours, which included only the *in vivo* radiological studies that applied conventional, cone-beam, or flat-plane computed-tomography (CT) images to evaluate trauma (five studies), they found an average trauma incidence of 26% (range, 13–57%). This rate was substantially higher than our 10% incidence achieved with prolonged insertion times, but it was comparable to the 27% observed in our fast insertion group. Similarly, in the 12 histological examinations, the trauma incidence was 28%. However, it should be emphasized that, in those studies, in addition to translocations from the scala tympani to scala vestibuli, they included any evidence of basilar membrane elevations or ruptures, which can only be investigated histologically. The latter types of trauma might also lead to impairments in residual hearing and fibrosis formation; thus, they could potentially negatively influence postoperative speech intelligibility. Consequently, an *in vivo* evaluation might underestimate the actual extent of trauma.

During insertion, precurved arrays are thought to behave differently from lateral-wall electrode arrays, due to differences in stiffness in the horizontal and vertical planes. Rebscher (19) reported that the size and shape of the array directly affected the trauma incidence. For example, arrays that are stiffer in the plane perpendicular to the cochlear spiral plane are less likely to cause severe trauma than arrays with similar stiffness in the vertical and horizontal planes. Less stiffness made it difficult to steer arrays and provided less tactile feedback during insertion. On the other hand, more stiffness could cause more damage when it contacted the basilar membrane or floor of the scala tympani, therefore precurved arrays carry a greater risk of translocation (20). Moreover, the variability in cochlear morphology, in particular the vertical trajectory (16), presumably plays a role in the occurrence of translocation of the CI electrode array. This suggests a difference in compatibility with individual coiling geometries between electrode array designs. Further research is necessary to clarify this.

Because the HiFocus MS electrode array is a relatively new design on the CI market, few reports have focused on insertion traumas with this particular design. In three cadaveric studies, the HiFocus MS electrode array was inserted into 8, 16, and 20 temporal bones; they reported translocation rates of 12.5, 0, and 5.3%, respectively (5–7). Two clinical studies reported divergent translocation rates of 57.1% (8/14) and 6.7% (2/30). Both included relatively small patient populations and none of them reported on insertion speed.

Surgical Approach

Over time, new insights have led to changes in the definition of the ideal or least traumatic surgical approach. Early electrode arrays were introduced through

a cochleostomy, simply because the arrays were relatively large. However, several later studies demonstrated that electrode arrays inserted through a cochleostomy carried a higher risk of basal trauma (48%) compared with insertions through the RW membrane (21,22). With the introduction of smaller CIs, a pure RW window approach was feasible; this approach avoided drilling-induced trauma and allowed preservation of the intracochlear architecture. However, it should be noted that the trajectory of the electrode array is highly influenced by the anatomical features of the RW. In addition, a slit RW insertion limits the view into the scala tympani, which risks damage to the modiolus or insertion into the vestibulum. With the extended RW approach, a good balance was found between avoiding the harm caused by drilling and increasing the visualization into the scala tympani by enlarging the RW opening, which facilitated determinations of the ideal insertion vector. Although we initially found a higher incidence of traumatic insertions in the pure RW insertions in the uncontrolled interim analysis, this was not found in the final evaluation, using more comprehensive statistical tests, in a larger population. Because the outcomes of the uncontrolled interim analysis led to an alteration of procedure, *i.e.*, being more reluctant with pure RW insertion, while at the same time insertion was prolonged, the question raised whether the lack of a significant effect of surgical approach on translocation was potentially biased by the almost predominantly use of an extended RW approach in the slow inserted population. However, the multivariate logistic regression analyses rejected this.

Insertion Speed

Little is known about the relationship between insertion speed and trauma incidence. However, the role of insertion speed in preserving residual hearing was previously discussed (11,12,23). Those studies investigated the effects of insertion speed on intracochlear fluid pressure (12), insertion forces (23), and inner ear function (11), which are all presumably related to intracochlear trauma. Todt et al. (12) showed that rapid insertion speeds were associated with high intracochlear fluid pressures. Increased pressure can damage the neuroepithelium of the cochlea and the vestibular system (24). Kontorinis et al. (23) demonstrated that higher insertion speeds significantly increased insertion forces, which increased the risk of damaging intracochlear structures. Speeds of 10 to 200 mm/min led to average insertion forces of 0.09 to 0.185 N and maximum forces of 0.18 to 0.42 N. In human cochlear implantations, the average insertion speed was 96.5 mm/min, which corresponded to average forces of 0.138 to 0.155 N (23). Another study showed that forces of 0.029 to 0.039 N could rupture the basilar membrane (25). Rajan et al. (11) compared implantations at the standard speed (60 mm/min) and implantations at a slower speed (15 mm/min). The slow insertions significantly reduced hearing loss (10.5 dB versus 16 dB) and the incidence of impaired balance (0% versus 22%). Consistent with our results,

these outcomes advocated a prolonged insertion time to preserve intracochlear structures and residual hearing. The mean insertion speed in the slow insertion groups corresponds to 18 mm/min (45 s), comparable with the speed in the slow insertions described by Rajan et al. (11). We also analyzed insertion times as a continuous variable. However, this analysis did not show a significant effect. However, when we analyzed the insertion time as a dichotomous variable with a cut-off of 25 seconds, corresponding to a speed of 32 mm/min, the results favored the slowly inserted array. This result suggested that our cut-off value was correctly chosen within a realistic clinical framework.

Translocation and Hearing Outcomes

Interest in soft surgery has arisen from the general belief that atraumatic insertions are beneficial for electrical stimulus transmissions and the preservation of residual hearing, and therefore, they should lead to optimized speech recognition. However, convincing studies are sparse, partly due to the limited number of in vivo determinations of the cochlear implant position. Nevertheless, Holden et al. (1) showed that monosyllabic word test scores were higher in patients with larger numbers of electrode contacts situated in the scala tympani. More recently, O'Connell et al. (21) studied a group of 137 patients at 12 to 16 months after implantation, and found that purely scala tympani insertions showed superior audiological results compared with translocated insertions. Those results contrasted with our findings. This discrepancy might be explained by: 1) different method for evaluation of translocation, 2) different types of electrode arrays; they tested nine different electrode arrays and we only tested the HiFocus Mid-Scala electrode array; or 3) different methods for measuring post-operative audiometric performance; or 4) heterogeneity of the patient populations. They studied 14 HiFocus Mid-Scala electrode arrays and found eight translocations (57%). Interestingly, they found that the mean angular electrode array insertion depths were shallower in the non-translocated group (385 degrees) compared with the translocation group (438 degrees). Additionally, they found that the electrode array angular insertion depth was an independent predictor of better speech perception; that is, deep insertions showed better outcomes than shallow insertions. Again, that finding was not consistent with our findings, and the discrepancy might be explained by methodological differences between the two studies.

CONCLUSION AND FUTURE REMARKS

This study showed that an extended insertion time could limit insertion trauma. These results can support future developments in atraumatic surgical procedures and electrode arrays. In the present study the surgeon received the feedback from imaging postoperatively. However, ideally, surgeons should receive real-time feedback during surgery to adjust the insertion of an

electrode array if desired. Such feedback can be provided with intracochlear electrocochleography. However, preliminary results with this method are still ambiguous (26,27).

REFERENCES

1. Holden LK, Finley CC, Firszt JB, et al. Factors affecting open-set word recognition in adults with cochlear implants. *Ear Hear* 2013;34:342–60.
2. Kamakura T, Nadol JB. Correlation between word recognition score and intracochlear new bone and fibrous tissue after cochlear implantation in the human. *Hear Res* 2016;339:132–41.
3. Friedland DR, Runge-Samuelson C. Soft cochlear implantation: rationale for the surgical approach. *Trends Amplif* 2009;13:124–38.
4. Hoskison E, Mitchell S, Coulson C. Systematic review: radiological and histological evidence of cochlear implant insertion trauma in adult patients. *Cochlear Implants Int* 2017;18:192–7.
5. Hassepass F, Bulla S, Maier W, et al. The New Mid-Scala electrode array: a radiologic and histologic study in human temporal bones. *Otol Neurotol* 2014;35:1415–20.
6. Frisch CD, Carlson ML, Lane JI, Driscoll CL. Evaluation of a new mid-scala cochlear implant electrode using microcomputed tomography. *Laryngoscope* 2015;125:2778–83.
7. Dietz A, Gazibegovic D, Tervaniemi J, Vartiainen VM, Löppönen H. Insertion characteristics and placement of the Mid-Scala electrode array in human temporal bones using detailed cone beam computed tomography. *Eur Arch Otorhinolaryngol* 2016;273:4135–43.
8. Briggs RJS, Tykocinski M, Xu J, et al. Comparison of round window and cochleostomy approaches with a prototype hearing preservation electrode. *Audiol Neurotol* 2006;11 (suppl): 42–8.
9. Roland PS, Wright CG, Isaacson B. Cochlear implant electrode insertion: the round window revisited. *Laryngoscope* 2007; 117:1397–402.
10. Richard C, Fayad JN, Doherty J, Linthicum FH Jr. Round window versus cochleostomy technique in cochlear implantation: histological findings. *Otology* 2013;33:1181–7.
11. Rajan GP, Kontorinis G, Kuthubutheen J. The effects of insertion speed on inner ear function during cochlear implantation: a comparison study. *Audiol Neurotol* 2012;18:17–22.
12. Todt I, Mittmann P, Ernst A. Intracochlear fluid pressure changes related to the insertional speed of a CI electrode. *Biomed Res Int* 2014;2014:507241.
13. Verbist BM, Finley CC, Roland PS, Thomas J. Consensus panel on a cochlear coordinate system applicable in histological, physiological and radiological studies of the human cochlea. *Otol Neurotol* 2010;31:722–30.
14. van der Jagt AMA, Briare JJ, Boehringer S, Verbist BM, Frijns JHM. Improved cochlear implant position detection with spatially synchronized pre- and post-operative midmodiolar cross-section CT and MR images, submitted.
15. Bosman A, Smoorenburg G. Intelligibility of Dutch CVC syllables and sentences for listeners with normal hearing and with three types of hearing impairment. *Audiology* 1995;34:260–84.
16. van der Jagt AMA, Kalkman RK, Briare JJ, Verbist BM, Frijns JHM. Variations in cochlear duct shape revealed on clinical CT images with an automatic tracing method. *Sci Rep* 2017; 7:17566.
17. Verbist BM, Ferrarini L, Briare JJ, et al. Anatomic considerations of cochlear morphology and its implications for insertion trauma in cochlear implant surgery. *Otol Neurotol* 2009;30:471–7.
18. Hoskison E, Mitchell S, Coulson C, Hoskison E, Mitchell S, Coulson C. Systematic review: radiological and histological evidence of cochlear implant insertion trauma in adult patients. *Cochlear Implants Int* 2017;18:192–7.
19. Rebscher SJ. Considerations for design of future cochlear implant electrode arrays: electrode array stiffness, size. *J Rehabil Res Dev* 2008;45:731–48.

20. Wana GB, Noble JH, Carlson ML, et al. Impact of electrode design and surgical approach on scalar location and cochlear implant outcomes. *Laryngoscope* 2014;124:1–7.
21. O'Connell BP, Cakir A, Hunter JB, et al. Electrode location and angular insertion depth are predictors of audiologic outcomes in cochlear implantation. *Otol Neurotol* 2016;37:1016–23.
22. Adunka OF, Dillon MT, Adunka MC, King ER, Pillsbury HC, Buchman CA. Cochleostomy versus round window insertions: influence on functional outcomes in electric-acoustic stimulation of the auditory system. *Otol Neurotol* 2014;35:613–8.
23. Kontorinis G, Lenarz T, Stöver T, Paasche G. Impact of the insertion speed of cochlear implant electrodes on the insertion forces. *Otol Neurotol* 2011;32:565–70.
24. Roland JT. A model for cochlear implant electrode insertion and force evaluation: results with a new electrode design and insertion technique. *Laryngoscope* 2005;115:1325–39.
25. Ishii T, Takayama M, Takahashi Y. Mechanical properties of human round window, basilar and Reissner's membranes. *Acta Otolaryngol Suppl* 1995;519:78–82.
26. Riggs WJ, Dwyer RT, Holder JT, et al. Intracochlear electrocochleography: influence of scalar position of the cochlear implant electrode on postinsertion results. *Otol Neurotol* 2019;40:e503–10.
27. Koka K, Riggs WJ, Dwyer R, et al. Intra-cochlear electrocochleography during cochlear implant electrode insertion is predictive of final scalar location. *Otol Neurotol* 2018;39:e654–9.