**Frequency of electrode migration after cochlear implantation in the early postoperative period. What are associated risk factors?**

**Abstract** (240 words)

Objectives:

To estimate the prevalence of, and risk factors associated with electrode migration in cochlear implant (CI) recipients.

Design:

Retrospective cohort study of all CIs performed between 1 January 2018-1 August 2021 in a single tertiary adult and paediatric CI centre in the UK.

Main outcome measures:

The primary aim is to determine the prevalence of electrode migration, comparing intraoperative surgeon report and examination of a routine plain radiograph performed two weeks after surgery. Electrode migration is defined as the detection of movement of two or more electrodes out of the cochlea from the time of surgery. Multivariate analysis was performed to investigate preoperative and intraoperative risk factors that might predispose to migration.

Results:

465 patients, having 516 distinct surgeries, with 628 implants were analysed. Electrode migration occurred following 11.5% of implant operations. Pre-existing cochlear abnormality was an independent associated risk factor for electrode migration (OR:3.40<1.20-9.62> p=0.021). Demographics, surgical technique, usage of a precurved electrode, CSF leak, surgeon seniority and intraoperative telemetry did not influence risk of migration. There were five implants (0.8%) which migrated later than two weeks, with a median date of imaging diagnosis (X-ray or CT scan) of 263 days <IQR:198>, for which head injury was a common precipitating factor. There were differences in the risk of migration between different lateral wall electrodes.

Conclusion:

Electrode migration in the early postoperative period is a common occurrence and is more likely in implant recipients with obstructed or malformed cochleae.

**Keywords :** Cochlear implants, Electrode migration, Risk factors

**Key points:**

1. Electrode migration in the early postoperative period occurs in approximately 1 in 10 CIs.
2. Cochlear abnormalities ( cochlear obstruction / malformations ) portends a higher risk of electrode migration in the early postoperative period.
3. Variations in surgical technique (e.g. round window packing or package fixation) did not affect the risk of migration.
4. Precurved electrodes were not associated with reduced risk of migration in our cohort, possibly due to selection bias.
5. Delayed electrode migration occurring in the late post-operative phase was associated with head injury.

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Introduction

One modifiable factor that can affect cochlear implant(CI) performance is the presence of extracochlear electrodes, particularly if they are undetected and hence assigned frequencies in the CI programming map that are not delivered to the cochlea.1–3 The reported incidence of electrode migration(EM) ranges from 2-29%.4–8 Clinical manifestations of extracochlear electrodes are nonspecific, and therefore often underdiagnosed. CI hearing performance is variable in the early post-operative period, and poorer outcomes may simply be ascribed to this variability, perhaps due to poor neural health or intracochlear fibrosis.6 Inactivation of extracochlear electrodes may improve hearing function if identified early.9

CI electrode migration has a magnified impact in patients with malformed cochleas or cochlear ossification, in who full electrode insertion cannot be achieved, as every electrode extruded represents a greater proportion of the total. Continued migration of CI electrodes in these patients may render the implant unusable, necessitating revision surgery. Electrode migration is the second most common indication for revision surgery, after implant failure.10

Objectives:

Our aim was to measure the incidence of early extracochlear EM in our CI recipients, and to look for associated predisposing factors that indicate higher risk. Given our high CI volume and protocol of performing the postoperative radiographs at 2 weeks postoperatively, this study, to our knowledge, is the largest and first to systemically examine EM occurring in the early postoperative period.

Methods

We performed a retrospective observational study of CI recipients at a tertiary CI centre from 1/1/2018-29/7/2021. This study was approved by our institutional review board as a clinical audit(ID4059). Use of the automated Health Research Authority Decision Tool confirmed the project did not require ethical approval. CI surgeries were performed by or under direct supervision of four consultants. Depth of insertion was determined by direct inspection at surgery. Intraoperative telemetry, if performed, was completed during periosteum/skin closure. Abnormalities in telemetry triggered re-opening of the incision to visually check electrode position. Intraoperative telemetry(impendences/electric field imaging(EFI) or transimpendence matrix(TIM) and/or neural response measurements were performed in 89% of implants in paediatric patients(<=18 year olds) versus 31% of adults.

The number of extracochlear electrodes was determined using plain skull radiographs(Caldwell/Towne view) performed at approximately 2 weeks post-surgery. Electrode migration(EM) was defined as extracochlear electrodes found on imaging additional to those on intraoperative documentation. Determination of extracochlear electrodes on radiographs was based on finding electrodes lateral to a line drawn down from the radiological mid-position of the superior semicircular canal - the approximation of the round window position(Figure 1) as described by Xu et al.11 To account for measurement bias associated with assessment on plain radiographs, we defined *a priori* a threshold of migration to be movement of 2 or more electrode compared to intraoperative assessment. Implanted ears were divided into two groups, implanted ears with EM(lateral migration of 2 or more electrodes) and implanted ears with no migration(lateral migration of 1 or less electrodes). Patient demographics, pre-operative workup, intra-operative notes, and post-operative follow-up were recorded. Ears exhibiting EM were compared with ears without migration to determine predisposing factors for EM. Records were also checked for documentation of further migration on follow-up, and any information regarding inactivated electrodes. For this study, all radiographs were reviewed by a single experienced CI surgeon(“blinded for review”). Implant brands are coded ‘A’ to ‘D’, and suffix of ‘s’ or ‘c’ is added to indicate if the implant electrode is straight or precurved respectively. Implant ‘C’ has 2 variations of its straight electrodes used in our cohort.

Statistical analysis was performed using Stata/SE 15.1(StataCorp, Texas, USA). Univariate and multivariate analyses of the patient characteristics, implant and electrode used, intraoperative findings and variations in surgical techniques was performed to find factors associated with EM. Logistic regression, Wilcoxon rank sum tests, Chi square or Fisher’s exact test were used for univariate analysis. Multinomial logistic regression was performed for multivariate analysis. P value of <0.05 was considered statistically significant. The STROBE reporting guidelines were adhered to.

Results

We examined 516 CI surgeries in 465 patients in whom 628 implants were implanted. Forty-five percent(211/465) of patients were male. The median age at surgery was 40.5 years(IQR=62years). The median age of the adult(>=18 year old) and paediatric population were 65 years(IQR=26 years) and 5 years(IQR=10 years) respectively.

Table 1 summarizes descriptive statistics. A significant proportion(18.3%) were revision surgeries. The majority(86%) of implanted electrodes were straight, and the most common electrode used was electrode ‘As’. Full electrode insertion was achieved in 97.1%. Intraoperative telemetry was performed for 54.6% of the implantations. Round window packing with soft tissue was explicitly documented in 60.1% of implantations, although we believe this to be higher in reality, as this practice is considered routine among our surgeons.

Post-operative radiographs were performed at a median of 14 days after surgery(IQR=6.8 days). The prevalence of EM(2 or more electrodes), between intraoperative assessment and post-operative radiograph was 11.5%. Table 2 also shows the prevalence of EM, stratified by the number of electrode that migrated.

Univariate analysis suggested that cochlear fibrosis and intraoperative partial insertion were associated with increased odds of EM. Interestingly, methods to secure the receiver-stimulator package intraoperatively were associated with an increased risk of migration, though this ceased to be statistically significant after multivariate analysis. Securing of the package is not routinely performed in our practice, and most of the packages secured in our cohort were implants with ‘screw-down’ flanges on the package(13/16:81.3%). Two implant packages were secured due to package malposition intraoperatively and the remaining package was secured as an extra measure during revision surgery for EM.

Multivariate analysis adjusting for interactions and confounding factors suggest cochlear abnormalities to be an independent risk factor for EM(OR: 3.40 <1.20-9.62> p=0.021). The ‘Bs’ electrode was also less likely to migrate in our sample, when compared to the ‘As’ electrode(OR: 0.46 <0.23-0.93> p=0.034). Table 3 shows the unadjusted and adjusted odds ratios(OR) of each risk factor analysed.

Delayed Migration:

There were five cases of delayed migration, that is electrodes migrating after the post-operative radiograph(0.8%). These were detected by imaging at a median of 263 days(IQR:198days) after the post-operative radiograph. Three cases(60%) had a history of trauma to the implant site. Three cases(60%) had partial insertions on early radiographs and had further EM. None of these patients had cochlear abnormalities. The median duration of follow-up for these patients was 928 days(IQR: 379days). Table 4 summarises the details of implants with delayed migration.

Discussion

This study demonstrates that the prevalence of EM in our institution is 11.5%, based on a radiograph 2 weeks after surgery. This is within the range of rates previously reported(2-29%).4–8 It is likely that this variability in reported prevalence is affected by case selection, imaging method used and criteria used to determine migration. A recent systematic review reported a pooled migration rate of 6%.5 Studies that report migrations where imaging was triggered by impedance or performance changes 4,6,12tended to have a lower incidence of migration compared to studies defining migration based on imaging performed at pre-defined intervals for all implant recipients7,8,13(2.8-9% vs 13.4-29%). This difference is suggests under-diagnosis in the former group, as some cases of migration might not manifest as overt performance or electrophysiological abnormalities.

Our study has information bias due to lack of standardised data recording, a weakness of retrospective data collection. Cone beam computed tomography(CT) scan is often considered gold standard for determining EM, however this modality is not routinely available,14 and not at our center during this period. A conventional CT may be more precise than plain radiographs, but multiple studies have shown that plain radiographs perform equally well in determining implant insertion depth and extracochlear electrodes, avoiding exposure to high doses ionizing radiation.15–17 In our study, we endeavored to address the inherent imprecision of plain radiographs by taking a higher threshold of 2 or more electrodes lateral to the approximate position of the round window to define extracochlear electrodes. With this definition, the prevalence of migration in our study cohort concurs with a previous report using CT to define EM.7

We opted to study movement of discrete electrodes out of the cochlea as it was considered the most clinically relevant measure. It was also not possible to *directly* measure angular or linear movement of the electrode out of the cochlea due to the absence of routine baseline intraoperative imaging.

*Estimation of linear movement of migrated electrodes*

A variety of CI electrodes were used in our cohort, each with a different electrode spacing. Hence, movement of a single electrode out of the cochlea translates to varying degrees of linear/angular movement of the electrode array. Given the significant difference in migration risk between ‘As’ and ‘Bs’ lateral wall electrodes, we attempted to also compare the linear movement distance for these electrodes.

In our centre, full electrode insertion entails insertion to the full-insertion marker for the ‘As’ electrode and the second of two insertion markers for the ‘Bs’ electrode(Figure 2). Derivation of outward migration in millimetres was calculated for each of the migrated electrodes based on measurements from the full insertion markers.(i.e. x number of migrated electrodes for a fully inserted array would be 3mm+<x\*1.3mm> for an ‘As’ electrode, and 5mm+<x\*0.87mm> for a ‘Bs’ electrode)

Of the implants that migrated, analysing only fully inserted electrodes, ‘As’ electrodes had a median migration of 5.6mm(IQR:1.3), while ‘Bs’ electrode had a median migration of 7.6mm(IQR:0.9). A Wilcoxon rank-sum test found that this difference is statistically significant(z=3.319, p<0.001). This suggests that the variation in migration of discrete electrodes between electrodes makes could be a function of how deep the basal electrode was inserted in the first place. It is however important to acknowledge a selection bias and thereby possible overestimation, as implants with no extracochlear electrodes were counted.

Our data is an important window on the movement of electrodes occurring in the interval between completion of implant surgery and 2 weeks post-surgery, for a large cohort of implant recipients, adult and children, primary and revision cases, with a variety of implants, in a large implant centre. The results show that EM occurs in at least 1 in 10 implant recipients during these 2 weeks, and is more likely in the presence of cochlear abnormalities(fibrosis/ossification/malformation). There is a threefold increased risk of EM with intraoperative partial insertion when compared to full insertion(29.4%vs11.0%).(Table 3) Although the increased risk of EM in partial insertions is not unexpected, it presents a challenge to surgeons to try to reduce further migration in partially inserted implants, as further migration might render them unusable.

Extracochlear electrodes have been shown to impact CI performance; Hilly *et al.* found that speech-in-noise outcomes at 1 year were worse in patients who had more than 3 of 16 electrodes extracochlear, while Coombs reported similar findings at 6 months.2,3 Migration and undetected extracochlear electrodes can lead to poor performance by mechanisms described by De Rijk et al.18 Although many studies have shown that precurved electrodes tend to be more resistant to migration4,8,12, this was not seen in our cohort(Table 3). One possible explanation is sampling bias, as most of our implants are straight lateral wall electrodes. In our practice, precurved electrodes(especially the ‘Bc’ electrodes) are used most frequently in patients with cochlear ossification and fibrosis, with the stylet in these electrodes used to aid insertion.

Our study also suggests that the ‘Bs’ electrodes had a lower risk of discrete EM when compared to the ‘As’ electrode, but not perhaps in distance extruded, for reasons that warrant further study. There are obvious differences between these electrodes(Figure 2); ‘Bs’ electrode has a cylindrical cross-sectional profile compared to the flatter profile of the ‘As’ electrode.14,19 However, based on our analysis of migration distance, a more likely reason for this disparity could be the depth of insertion, with the ‘As’ electrode having approximately 3mm of electrode length between the full-insertion indicator mark and the first basal electrode, compared to the ‘Bs” electrode which has more than 5mm between the second insertion indicator marking and the basal electrode. A fully inserted ‘Bs’ electrode would have a larger buffer for outward migration of the array, before the first basal electrode is extracochlear. These factors, together with factors like the stiffness of the electrode and its recoil forces after insertion deserve to be studied as factors that influence migration, guiding continued improvement in electrode design.

In our study, there was a distinct cohort of 5 delayed implant electrode migrations(0.8%). The detection of migration in this cohort of patients was usually made on imaging performed for trauma or deteriorating performance. Most of the implants in our delayed migration cohort had head trauma, occurring several months after surgery, resulting in reduction in performance. Interestingly, 3 out of the 5 patients who had delayed migration had less than full insertion or migration on the first post-operative radiograph, suggesting that delayed EM may occur more often in partial insertions.

The underlying mechanisms of EM are poorly understood. The electrodes may be pushed out by scarring or recoil forces in a small cochlea, perhaps the explaining the higher rate in cochlear abnormalities, or pulled out by forces stored in the leads to the processor, or scarring. At present, we do not have enough data to discriminate between these possibilities.

Many techniques have been devised to try to prevent migration, including techniques focused at the round window20, facial recess21–23, mastoid bowl6 or around the receiver-stimulator package.24 Apart from round window packing, we do not routinely practice these techniques. Given the risk of EM in ears whereby these techniques were employed(high-risk ears) were not significantly higher than the general cohort, it could be conjectured that these did ameliorate EM. Previous retrospective cohort studies have reported that these techniques reduce migration.21,22 Further prospective controlled studies may determine if, and which of these techniques make a sustained difference, especially in patients at risk of early migration, such as those with cochlear abnormalities.

*Inactivated electrodes*

There is evidence that having a large number of inactivated basal electrodes is associated with poorer outcomes.2 We found that 30%(187/624) of implants had one or more basal electrodes inactivated. After an intraoperative full insertion, 11% of implants experience 2 or more electrodes moving outside the cochlea at 2 weeks, and this migration was associated with an approximately 28 times higher odds of having more than 3 basal electrodes inactivated(29.7%vs1.5% OR: 27.8 <11.5-67.1> p<0.001), compared to implants that have not migrated.

Conclusion

This study is, to our knowledge, the largest study that investigates EM, and the first that specifically investigates migration in the early post-operative period(within first 14 days from surgery). The results suggest that 1/10 implant electrodes migrate out of the cochlea in this timeframe. Patients with cochlear abnormalities are at increased risk. Different makes of lateral wall electrodes have varying extrusion rates. This variation may be related to how deep the basal electrode is inserted. Delayed migration(>2 weeks after surgery) occurs in at least 0.8%.

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