

## ABSTRACT

**Objective:** To review the predictive accuracy of Cochlear™ Nucleus Smart Nav system in predicting proper electrode position after cochlear implantation

**Study Design:** Retrospective chart review

**Setting:** A large academically affiliated hospital-based practice

**Methods:** 21 patients underwent routine cochlear implant (CI) surgery with a Cochlear™ CI632 cochlear implant. During implantation, the Smart Nav system was used to determine placement of the electrode array as well and measure impedances and cochlear nerve response. Following each testing, an intra-operative anterior-posterior X-ray of the head was performed and used to determine the proper placement of the electrode array within the cochlea. This was compared to the configuration predicted by the Smart Nav.

**Results:** A total of 21 surgical cases were examined to determine the predictive accuracy of Smart Nav in predicting proper placement. Smart Nav was able to accurately detect tip fold-over, which occurred in 27% of insertions and 14% of patients in this study, but not electrode translocation, which occurred in 3.4% of insertions.

**Conclusion:** The Cochlear™ Nucleus Smart Nav system was accurate in predicting tip fold-over. It was not able to predict translocation of the electrode array. This study demonstrates that using Cochlear™ Smart Nav does not reduce the need for intraoperative X-ray to confirm electrode placement.

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## INTRODUCTION

Tip fold-over and translocation (scalar deviation) of the electrode array are two common complications of cochlear implant placement

- Tip fold-over: incidence of 5-6% for peri-modiolar and 0.8% for lateral wall electrodes<sup>1,2</sup>
- Significantly higher risk of tip fold-over with peri-modiolar arrays<sup>3</sup>
- Translocation of scalar deviation of the electrode: incidence of 32-43% for peri-modiolar arrays and approximately 7% with lateral wall arrays
- Both associated with negative audiological performance and worse hearing outcomes<sup>1,3</sup>
- Tip fold-over: pitch confusion, vertigo, tinnitus<sup>1</sup>
- Translocation: word perception in quiet and residual hearing versus no audiological changes<sup>3,4</sup>

Multiple methods developed to identify CI tip fold-overs:

1. Intraoperative/postoperative X-ray
  - Pros: Accurate, quick
  - Cons: Cost, radiation exposure
2. Electrophysiology
  - a) Neural Spread of Excitation (SOE)
    - 2 different electrodes stimulated and the amplitude of the electrical response (eCAP) measured
    - Multiple peaks suggests tip fold-over (should be only one peak)
    - Pros: quick, no radiation
    - Cons: low accuracy, time consuming if all electrode combinations are checked
  - b) Transimpedance Matrix measurement (incorporated into SMART NAV “placement check”)
    - Stimulates one electrode and measures voltage response at all electrodes (can repeat for all electrodes)
    - Pros: quick (minutes), no radiation, provides more detailed profile of current spread throughout cochlea
    - Cons: effectiveness still being studied, some promising results<sup>2,5</sup>

- Smart Navigation was developed by Cochlear™ to provide a variety of intraoperative metrics:
  - Placement check – reduce intraoperative imaging?
  - Angular insertion depth
  - Speed of insertion
  - Impedances
  - Advanced and AutoNRT® measurements
  - Electrical Stapedius Reflex Threshold – confirms nerve response to electrical stimulation

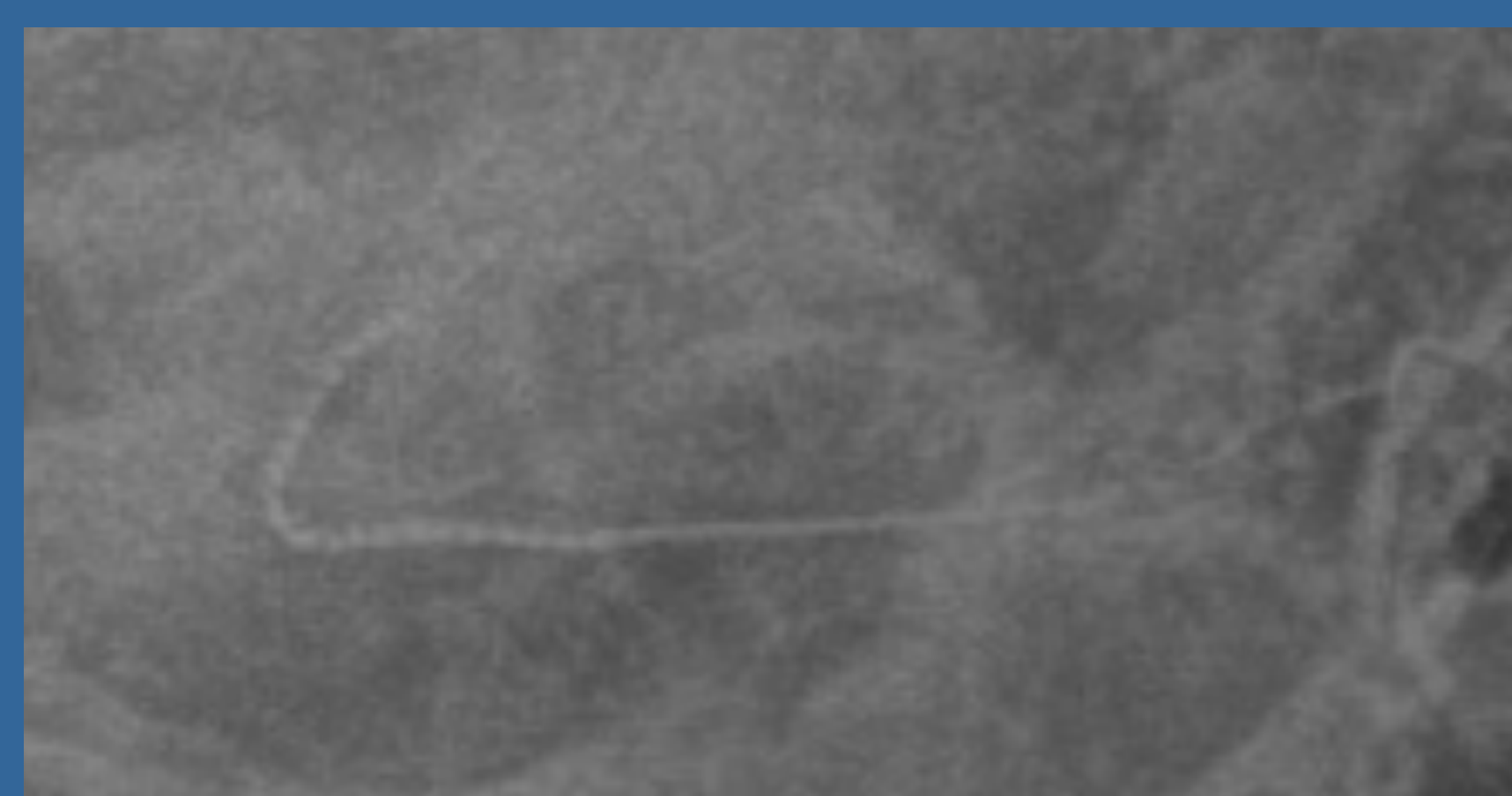


Figure 5: Portable x-ray Translocation of electrode

## METHODS

Patients underwent routine CI surgery with Cochlear™ CI632 or CI 612 cochlear implants. During implantation, the Smart Nav system was used to determine placement of the electrode array as well and measure impedances and cochlear nerve response. Following each testing, an intra-operative anterior-posterior X-ray of the head was performed and used to determine the proper placement of the electrode array within the cochlea, with particular attention to tip fold-over and translocation. This was compared to the configuration predicted by the Smart Nav.

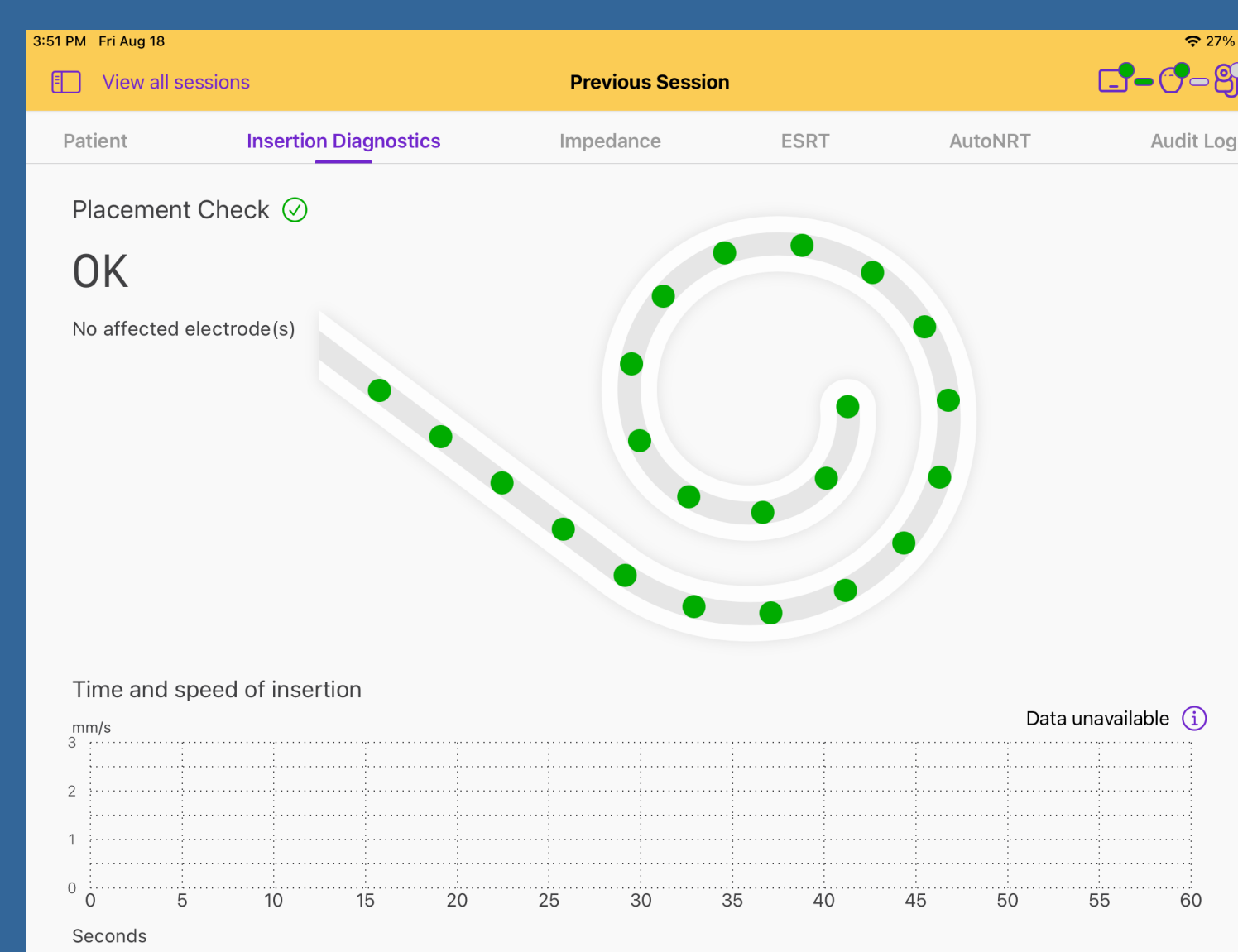


Figure 1. Smart Nav indicating Correct electrode placement

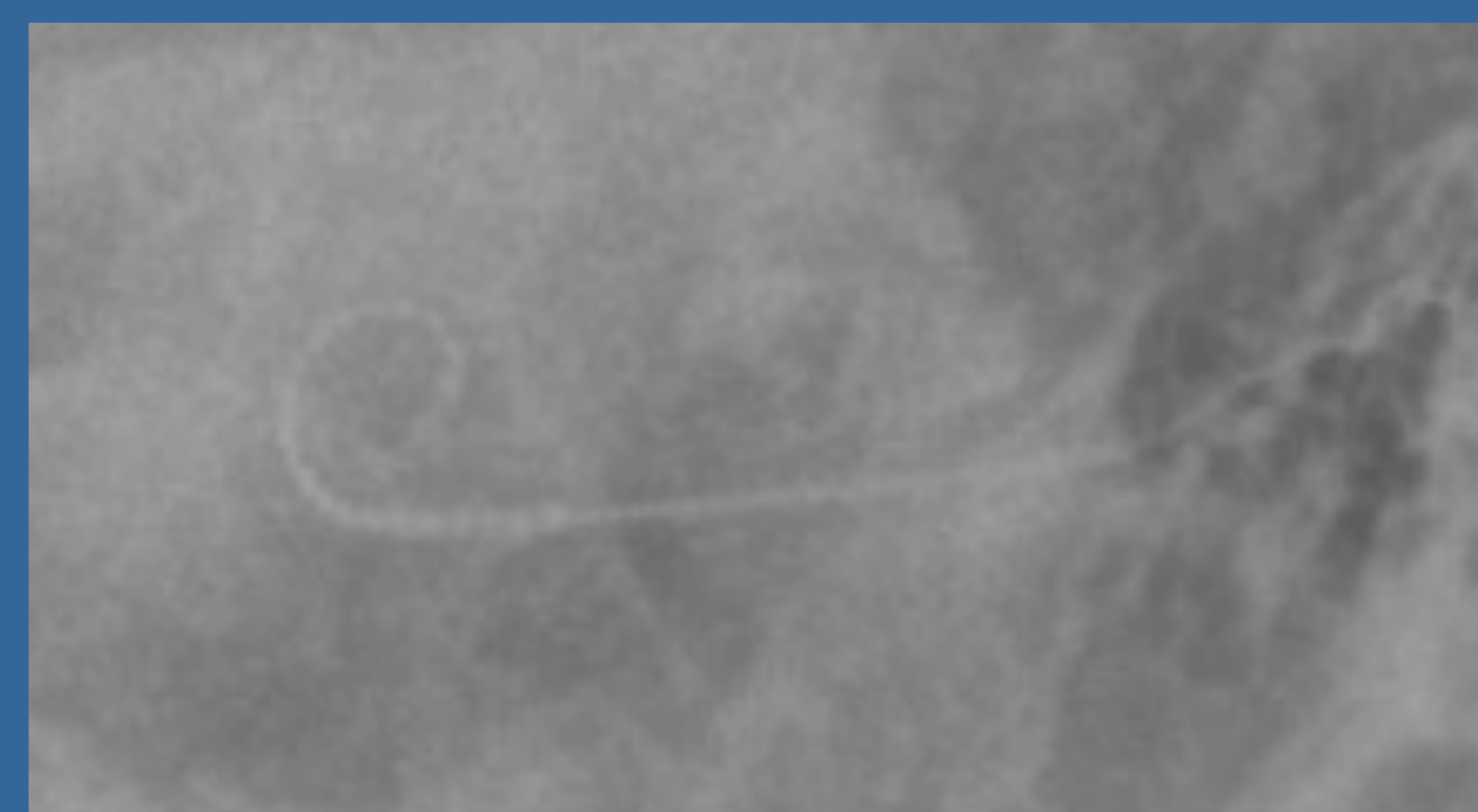


Figure 2: Portable x-ray Accurate electrode placement

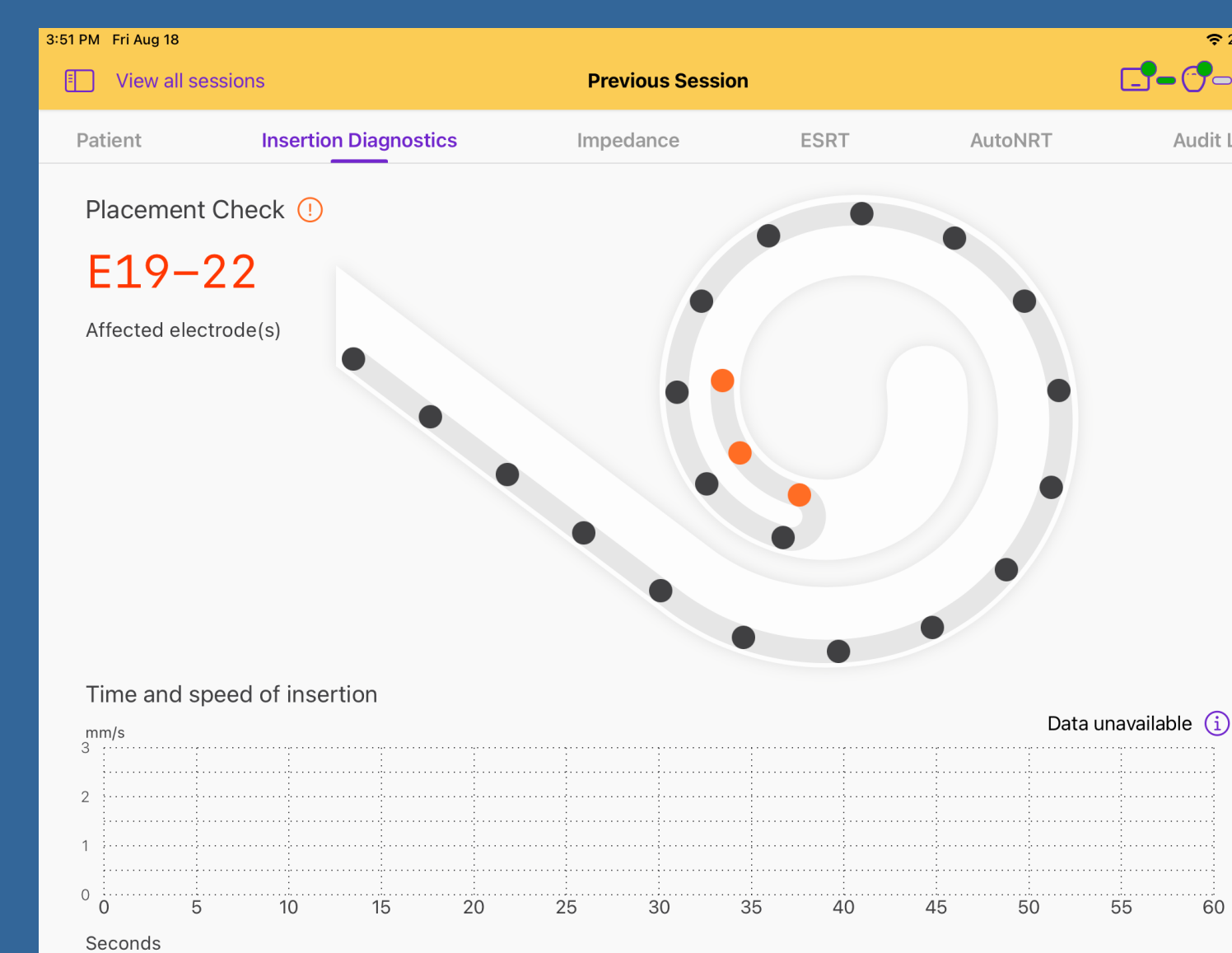


Figure 3. Smart Nav indicating Tip fold-over



Figure 4: Portable x-ray -Tip Fold-over

## RESULTS

This case series reviews 21 patients who underwent cochlear implantation (45% female, 65% right ears) with average age 53.8 years.

- The majority underwent implantation with the Cochlear™ CI 632 electrode, one patient with Cochlear™ CI 612 electrode
- Average duration of non-aidable hearing loss was 60.2 months
- No revision cases
- Average operative time was 112 minutes
- Majority of patients had accurate CI placement as noted on Smart Nav and confirmed by x-ray (Figures 1 and 2)
- **27% of insertions resulted in tip fold-over** (8/29 insertions) identified by Smart Nav and confirmed by x-ray (Figures 3 and 4)
- **14% of patients experienced tip fold-over** (3/21 patients)
- One case of electrode translocation identified with X-ray but not Smart Nav (3.4%) (Figure 5)
- Impedances and NRT results were normal in the case of electrode translocation

## DISCUSSION

- Smart Nav was able to accurately detect tip fold-over, which occurred in 27% of insertions and 14% of patients in this study. (Figure 5) These findings are in accordance with the literature<sup>6-8</sup> that Smart-Nav is able to predict tip fold-over.
- There was a 0% translocation rate noted on Smart Nav and a 3.4% rate of translocation on X-ray. This is consistent with the inability of Smart Nav to identify translocation. X-ray or CT are still needed to identify translocation of CI electrodes.
- Future studies are investigating parameters to identify translocation without the need for intraoperative X-ray, such as access resistance and higher eCAP thresholds<sup>4,9</sup>

## CONCLUSIONS

The Cochlear™ Nucleus Smart Nav system can accurately detect tip fold-over, which occurred in 27% of insertions and 14% of patients in this study. However, the Smart Nav system cannot accurately predict translocation of the electrode array and did not detect it in the one case of translocation in this study. An intraoperative X-ray or high resolution CT scan is still the best way to evaluate for electrode translocation.

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