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A year of intraoperative experience with Cochlear™ Nucleus® SmartNav System

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Introduction

Cochlear implant intraoperative testing provides reassurance to the surgical team regarding device function and optimal electrode placement. SmartNav has been used in a Controlled Market Release trial on 69 CI surgeries over a year at University Hospitals of Birmingham (version used is not commercially available). A survey was answered by four surgeons of the West Midlands Adult Cochlear Implant program. Cases where SmartNav influenced intra-operative decision making were reviewed.

Cochlear Nucleus SmartNav System

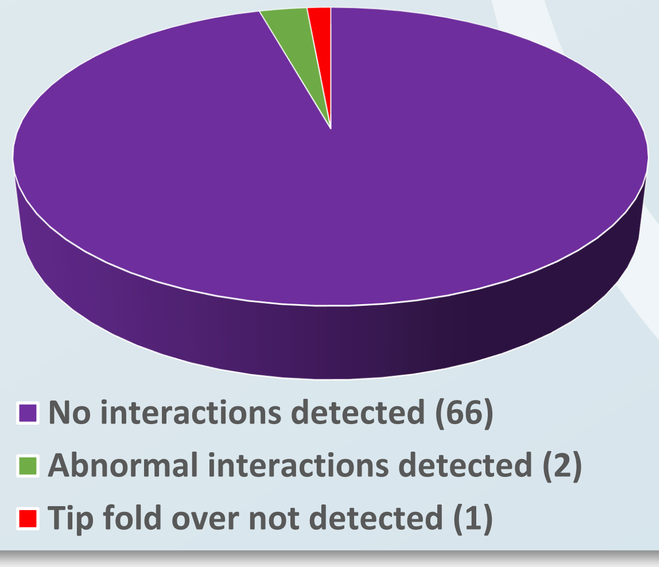
- The system is composed of a compatible iPad wirelessly paired to a CP1150S surgical processor, which is magnetically paired to the implant before inserting the electrode.
- During insertion, the system measures and gives feedback on real-time angular insertion depth and consistency of speed of insertion.
- Following insertion, a placement check **can help identify a fold over** by detecting abnormal interaction of 2 or more electrodes. Impedance and NRT are also measured.

Survey results

- ¾ surgeons used SmartNav for all their Cochlear surgeries.
- Surgeon's favourite feature was **unanimously post-insertion diagnostics** including Placement Check, Impedance and Auto-NRT.
- 2/4 thought the technology helped them reduce speed of electrode insertion.
- **Magnet pairing of the processor** to the implant was initially challenging to all respondents.
- A change in draping technique was implemented, using a **thin adhesive drape** over the site of the implant. Pairing also became easier with the second release of SmartNav.

Other challenges encountered on occasion by respondents were :
- iPad pairing to processor (3/4 surgeons)
- Inaccurate real-time depth of insertion (1/4 surgeon)
- Loss of data (1/4 surgeon)

Electrode interactions detection by SmartNav



Case 1

In a patient with incomplete partition type 2, the initial placement check identified interactions. The electrode was withdrawn slightly and placement check was repeated confirming correct placement. Auto-NRT elicited NRT thresholds on 2 electrodes. Repeating NRT with Nucleus® CR220 intraoperative remote assistant elicited responses on 9 electrodes.

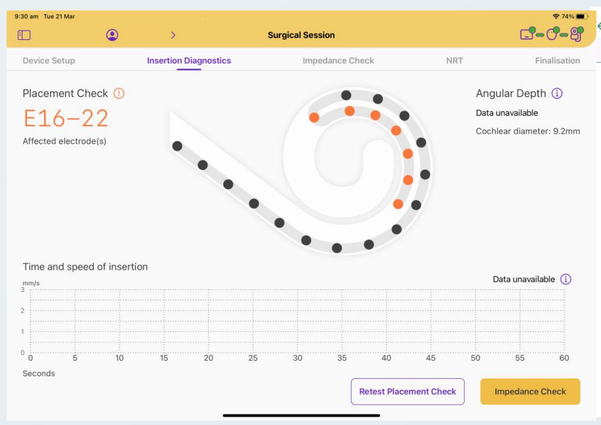


Fig 3. Detection of a compression kink on placement check

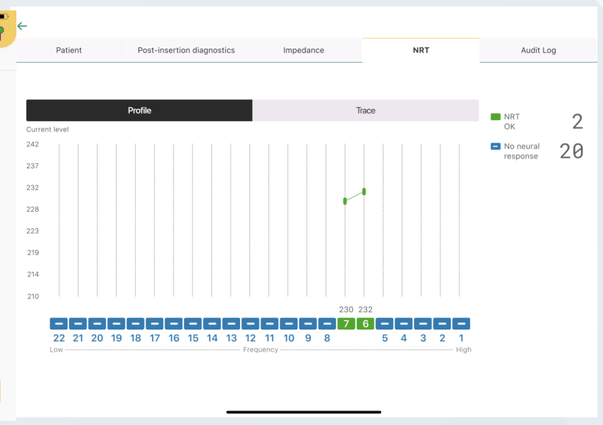
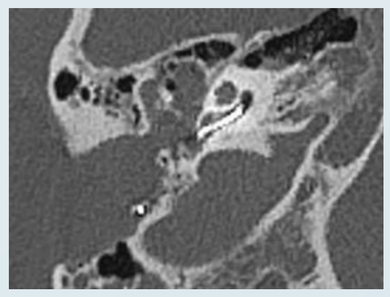


Fig 4. Neural response testing (NRT) display

Case 2

In a patient with a small cochlea, we encountered a profuse gusher on needle opening of the round window membrane. After slow insertion of CI622, SmartNav detected interactions and electrode was reinserted. Round window was packed with fascia. Second placement check with SmartNav confirmed correct placement of the electrode, also confirmed by post-operative CT-Scan.



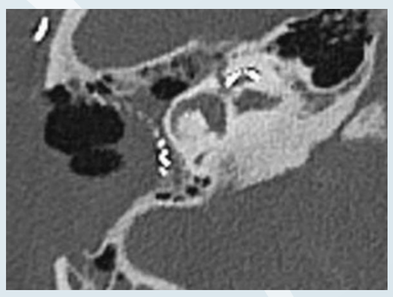


Fig 5. Pre-operative MRI

Fig 6-7. Correct electrode placement on post-operative CT

Case 3

In a patient with normal anatomy, SmartNav indicated correct placement of CI622 while routine post-operative X-Ray detected a tip foldover. Patient had revision surgery the next day and, on reinsertion, SmartNav detected a interactions. A new implant CI622 was used, and correct placement was confirmed by SmartNav and intra-operative X-Ray.

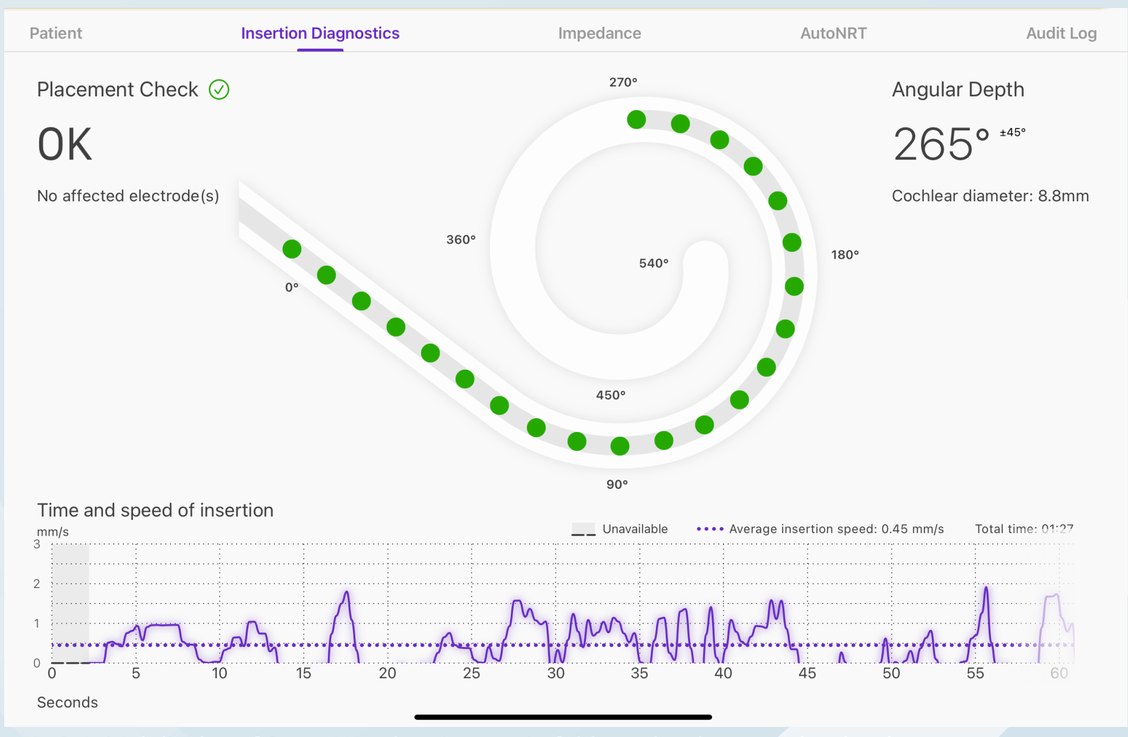


Fig 8 Initial display of SmartNav showing no tip foldover but low angular depth

Conclusion

Cochlear™ Nucleus® SmartNav System was appreciated by our surgical team and further versions will tackle the challenges encountered. Although detection rate of interactions is not 100%, intraoperative detection of electrode misplacement led to immediate reposition in 2 cases, potentially avoiding reoperation.