

From Theatre to Clinic: Perspectives on the effectiveness of intra-operative measures from the Nucleus® SmartNav

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Background

The Cochlear Nucleus® SmartNav system is an overall theatre and intra-operative measurement package presented in an App on the iPad. The system seeks to replace previous use of the Cochlear Nucleus® CR220 Intraoperative Remote assistant and/or the Custom sound EP software via a laptop in theatre. It is the first system from Cochlear which offers real-time feedback during surgery regarding electrode placement checks, speed of insertion and angular insertion depth. It enables intra-operative measurements which are known to be very valuable to initial audiological programming at switch-on; especially in young children and adults for whom behavioural mapping can be difficult (Di Nardo et al 2023; van Dijk et al 2007). There is only emerging research on the SmartNav (Kelso 2023), leaving room for investigations around the translatability of this intra-operative data from the Smartnav, and its clinical usefulness.

Aims

- To share the learnings and clinical perspectives from our service after use of the SmartNav over a clinical year
- To compare the intra-operative impedance telemetry from the Cochlear Nucleus® SmartNav, with post-operative impedance in clinic.
- To compare the intra-operative Automatic Neural Response Telemetry (NRT) with post-operative measures at Switch on (activation) and consider the translatability of using Auto NRT data during initial audiological programming.

Method

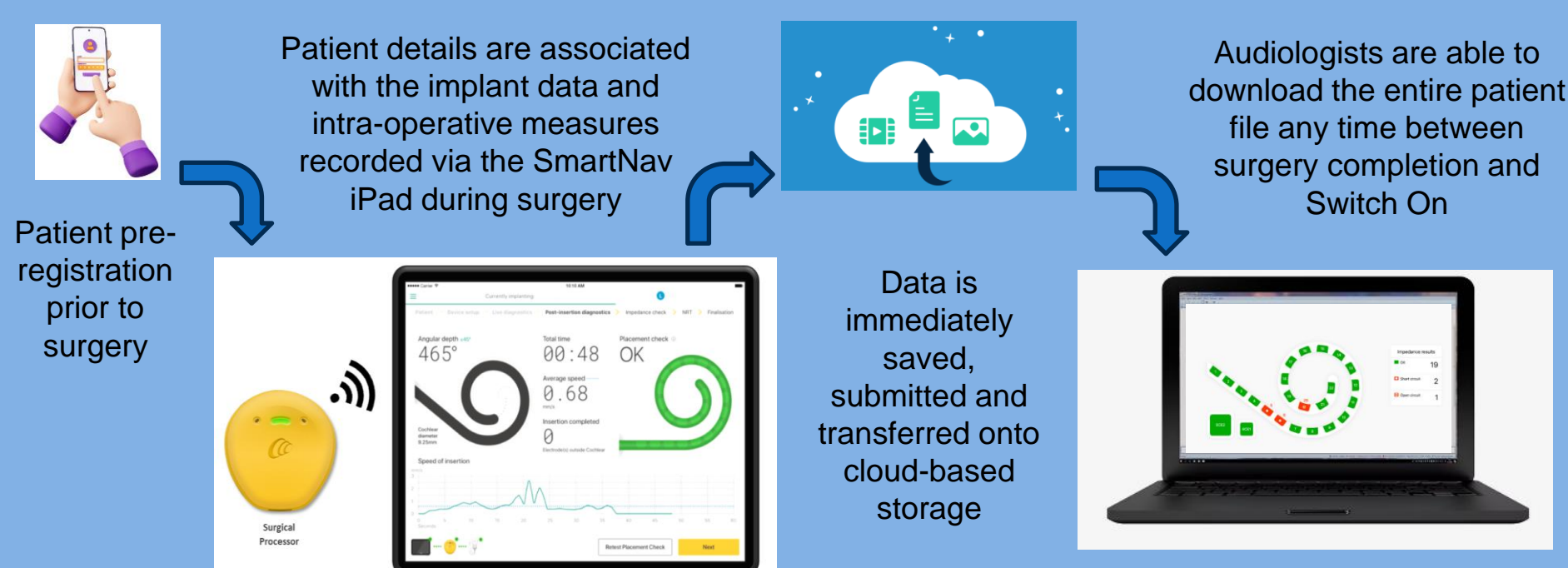
Retrospective analysis was performed on 27 Adults and 12 Paediatric patients (n=51 ears, 12 bilateral and 27 unilateral cases) who underwent surgery with a CI 612 (n=8) or CI 632 (n=43). The intra-operative data from the Nucleus® SmartNav was exported into Custom Sound Pro software and Custom Sound EP was also used for further analysis where any thresholds were questioned. All intra-operative measurements from the SmartNav utilised default Cochlear intra-operative parameters, which are notably different for the asleep patient than post-operative default parameters.

Two objective measures were analysed:

- Impedance telemetry:** impedance responses were obtained from all 22 electrodes during surgery, Switch on (CI activation) and 3 months post-activation. Where the 3 months post-activation appointment was missed, the responses from the next appointment were collected if it was between 3 months and <6 months post-activation. This is the point where we expected their impedances to stabilize with good implant usage. The mean impedance values were compared over the 3 different time points and paired T-test was used for statistical significance where required
- Automatic Neural Response Telemetry (AutoNRT):** AutoNRT was obtained from 9 default recording electrodes (e 1,3,6,8,11,13,16,19 and 22) during surgery and at Switch on. The 9 points were required for better accuracy in correlation with C profile mapping (Maruthurkkara, S., Bennet, C. 2024). The variance between the two time points were assessed using a paired T-test.

Insertional diagnostics data were also collected where possible.

How the SmartNav works in the Remote care pathway:



References:

- Di Nardo W, Ippolito S, Quaranta N, Cadoni G, Galli J. (2023). Correlation between NRT measurement and behavioural levels in patients with the Nucleus 24 cochlear implant. *Acta Otorhinolaryngol Ital.* Oct;23(5):352-5.
- Kelso, D. (2023). Early Clinical Experience with the Cochlear™ Nucleus® SmartNav System: Real-time Surgical Insight. *Cochlear Ltd.*
- Maruthurkkara, S., & Bennett, C. (2024). Development of Custom Sound® Pro software utilising big data and its clinical evaluation. *International journal of audiology*, 63(2), 87–98.
- van Dijk, B., Botros, A., Battmer, R., Begall, K., Dillier, N., Hey, M., Lai, W., Lenarz, T., Laszig, R., Morsnowski, A., Muller-Deile, J., Psarros, C., Shalloo, J., Weber, B., Wesarg, T., Zarowski, A. & Offeciers, E. (2007). Clinical results of AutoNRT: A completely automatic ECAP recording system for cochlear implants. *Ear and Hearing*, 28:4, 558-570

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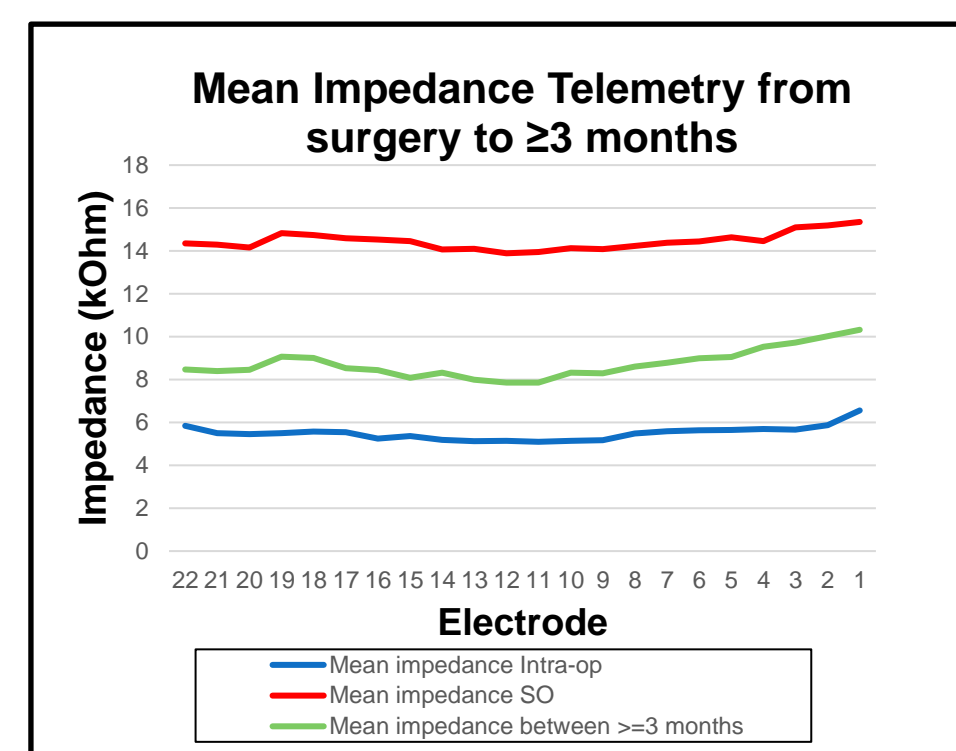
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Results

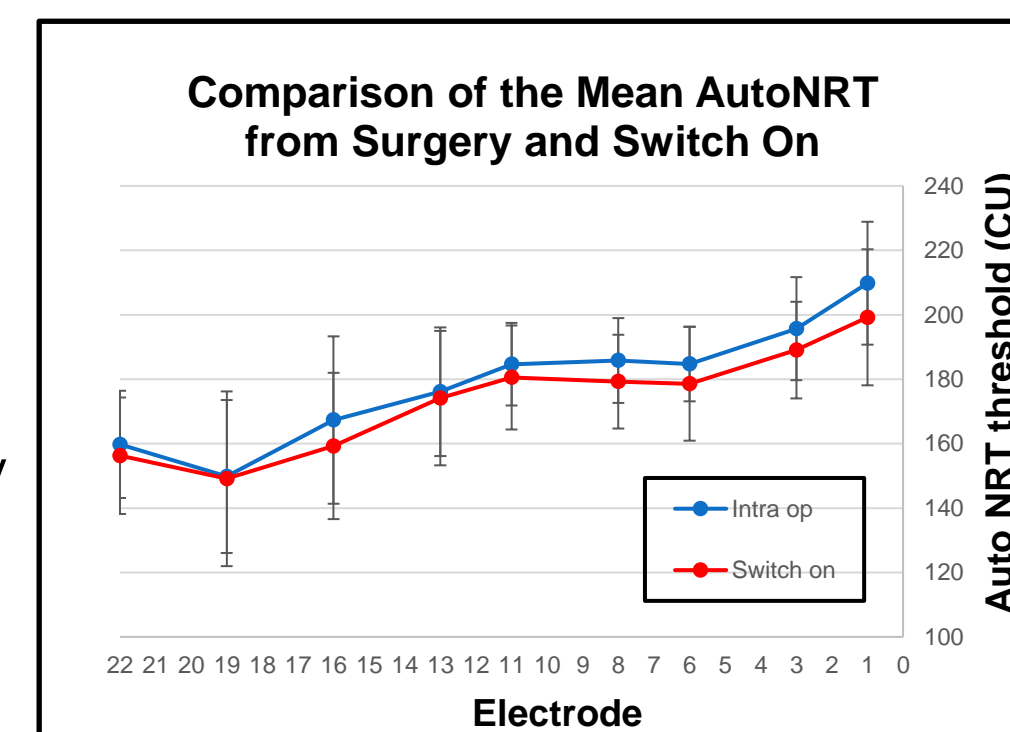
Impedance telemetry:

- Overall trend suggests that the mean impedances were flattish across electrode array
- The intra-operative impedances from the SmartNav were significantly lower ($p < 0.00$) than both the impedances at Switch on and ≥ 3 months post-activation. Switch on impedances were the highest as per expected
- Even after implant stimulation over 3 months, the impedances never returned to as low as those recorded on the SmartNav.



AutoNRT:

- A similar trend and rising profile (from basal to apical) was observed for both intra-operative and switch on mean autoNRT
- The mean autoNRT recorded from the SmartNav during surgery is significantly different ($P < 0.001$) than at Switch on.
- Intra-op mean autoNRTs were always higher than Switch on autoNRTs.



Real-time Insertional diagnostics

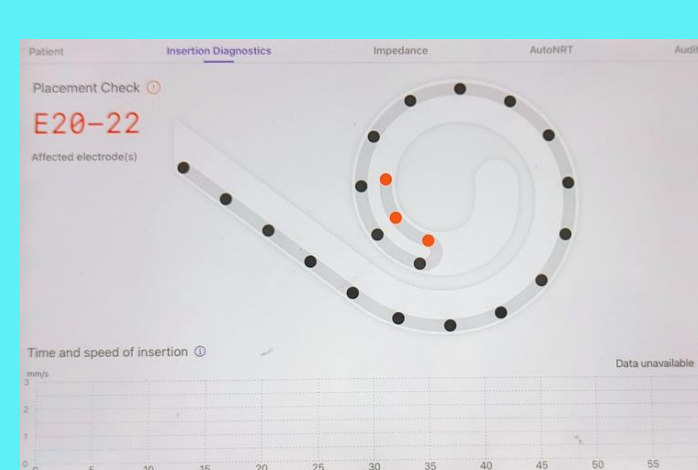
- Placement check was used during every surgery to ensure accurate positioning. As our experienced surgeons grew comfortable with the software, not all active real-time insertional diagnostics were utilized.
- Mean insertion time (n=14)= 1 minute 20 seconds
- Mean insertion speed (n=14)= 0.28 mm/s

Conclusions and Clinical considerations

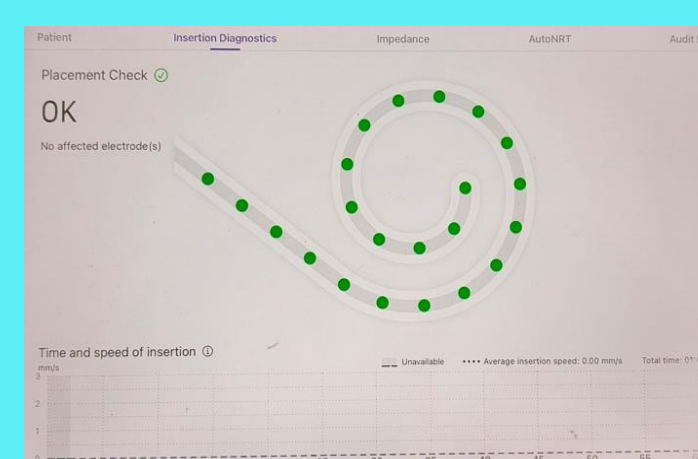
- Intra-operative impedances from the SmartNav are significantly lower than post-operative impedances even after over 3 months of implant usage and stimulation. Higher responses were expected at Switch on due to the absence of consistent implant stimulation, but unexpected at surgery. This trend is different from our experiences with the CR220 remote and CS EP software previously. A possible explanation may be due to the electrode conditioning from the insertional diagnostic testing, immediately prior to impedance telemetry measures.
- The trend from the SmartNav autoNRT suggests it is visibly similar in profile but significantly different from autoNRT at Switch on. This may be due to difference in intra-operative default NRT parameters. Careful consideration should be taken when using intra-operative autoNRTs during initial audiological programming. Repeat NRT responses should be obtained where possible, especially when the patient is unable to be mapped behaviourally.
- More in-depth review into the differences between the default intra-operative and post-operative recording parameters should be conducted, to ascertain if a closer set of parameters would enable better translatability of the intra-operative responses for post-operative programming.

Placement check case study:

- One patient notably had a tip foldover detected during SmartNav's electrode placement check which occurred upon 3 attempted insertions:



- Upon the 4th attempt with the same electrode, full insertion was achieved with correct positioning, confirmed by impedance and autoNRT



- Post-operative X ray results also confirmed full insertion of implant

Clinical perspectives:

- SmartNav required patient pre-registration to enable cloud-based data storage and sharing to software. Our service identified through trial and error that the most optimal time was to register patients prior to surgery
- This led to significant reduction in clinical admin post-operatively. No implant details, patient profile creation was required
- Further remote care (E.g. Remote check and Remote Assist) options became immediately available.
- Electrode placement check has been very effective at identifying placement issues in real time. Our surgical team has developed confidence in the SmartNav during its implementation, which led to omitting the post-operative X-ray for standard patient pathway; improving surgical time and post-op efficiency.