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MARKET RESEARCH

Health Care Professionals' feedback on the intra-operative use of the AIM System: Integration, Performance and Utility

INTRODUCTION

In 2018, Advanced Bionics (Valencia, CA, USA) introduced the AIM™ System, which includes in the OM Suite software a comprehensive suite of objective measures that can be performed intra-operatively and post-operatively. The system records intracochlear potentials generated from the different structures of the cochlea and auditory nerve in response to sound, providing insights about the patient's cochlear health.

The AIM System offers three electrocochleography (ECochG)-related measures:

1. **Real-time ECochG insertion monitoring,** which is performed while the electrode array is being inserted into the cochlea, giving surgeons real-time feedback during the insertion. A sudden amplitude drop in intracochlear ECochG measurement in the late phase of insertion is associated with cochlear trauma.[1,2] Studies suggest that ECochG measurements can be used to optimize the insertion of a lateral wall electrode and real-time monitoring is the most effective approach for hearing preservation.[1,2,3]
2. **Electrode Sweep** allows for ECochG measurements from different recording electrodes and provides information about electrode location with respect to acoustic stimulation frequency and sources of ECochG responses. This measure provides insight to clinicians regarding the frequency-to-place mapping or tonotopic region of the electrodes in the cochlea.
3. **ECochG Threshold,** which allows for fast, objective, and convenient audiometric thresholds without needing any patient feedback may help monitor residual hearing over time. Recent studies have demonstrated that conventional behavioral thresholds and ECochG thresholds are significantly correlated.[4,5,6]

Additionally, the AIM System supports objective measures such as impedance measurements, **Neural Response Imaging (NRI)** and **Electrical Stapedius Reflex Threshold (ESRT)** *(see Table 1)*.

MEASURE	CLINICAL BENEFIT
Impedances	• Impedance measurements are color-coded to indicate valid, short, or open impedances in green, purple, and gold, respectively. • The OM Suite allows impedance measurements using the case ground, ring ground or both.
Neural Response Imaging (NRI)	• NRI measures the responsiveness of the auditory nerve to electrical stimulation. • NRI can provide a method of verification of program settings and is particularly helpful with young children and difficult to program individuals. • The OM Suite offers a fast, objective, and automatic measure of NRI.
Electrically-evoked Stapedius Reflex Threshold (ESRT)	• ESRT testing is a useful objective measure to assist clinicians with fitting CI recipients, who are unable to provide reliable subjective feedback about loudness levels. • Although ESRTs are sometimes more difficult to obtain than NRI, they generally show a stronger correlation with behaviorally set M levels.[7] • The AIM System makes measuring ESRT an easier procedure.

Table 1: list of objective measures and clinical benefits

Here we present the results of an international survey of health care professionals from Europe and the United States on the integration, performance, and utility of the AIM System during intra-operative use. Respondents were either surgeons using the AIM System during electrode insertion or other operating room staff assisting with the AIM System during surgery.

SURVEY CONDUCTION AND PARTICIPANTS

The survey was conducted via SurveyMonkey®. The link to the survey was provided to professionals via AB field staff. Responses were obtained from twelve ENT surgeons and eleven other operating room staff supporting the surgery (N=23). The survey revealed their impressions of using the AIM System, including: setting up the hardware, handling the tablet, and giving feedback to the surgeon during electrode array insertion. Seventy percent of the respondents reported no previous experience with intra-operative measurement tools.

SURVEY OUTCOMES

Surgical routine: considerations for cochlear structure preservation

Surgeons were asked to provide information on their general experience implanting cochlear implants (CI), their usual surgical routine, and specific feedback about the AIM System from their perspective. Most surgeons (75%) reported more than ten years experience implanting CIs, while one surgeon each reported 6-10 years and 1-5 years experience. In the last 12 months, most surgeons (58%) performed more than 50 implantations, and 33% of the surgeons performed between 26 and 50 surgeries. The number of surgeries in the last 12 months on candidates with low-frequency residual hearing (audiometric threshold at 500 Hz better than 80 dB HL) in the ear to be implanted was reported as more than 10 by 50% of the surgeons.

All surgeons answered that they take some specific consideration or surgical technical adaptations to help preserve cochlear structures for all candidates. Ninety-two percent or more of them select specific electrode array and limit the speed of insertion. A breakdown of the considerations is presented in *Figure 1*.

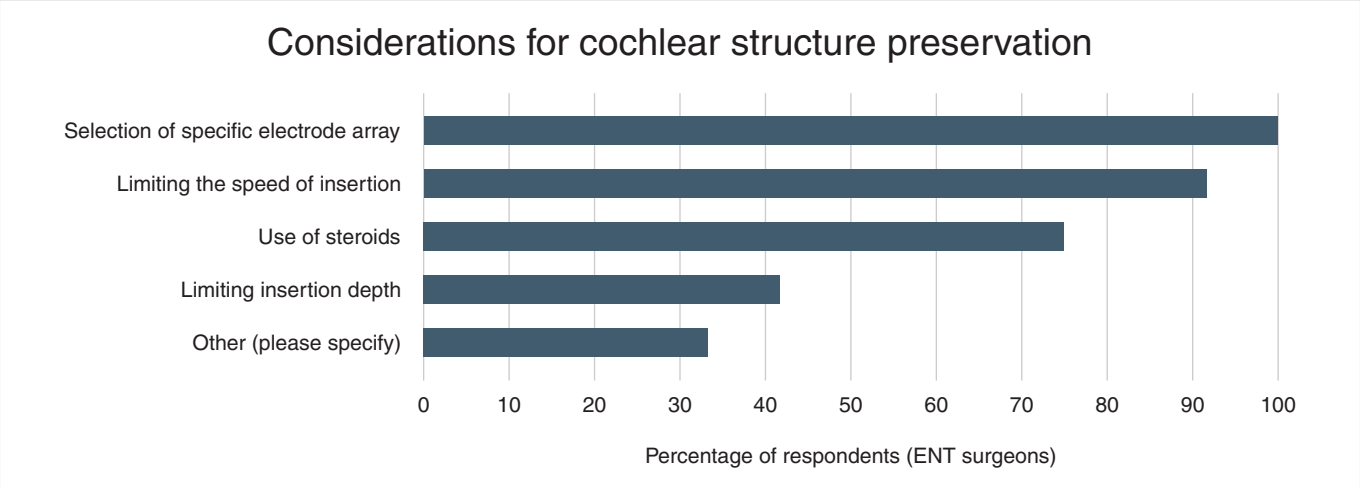

Fig. 1: Considerations for cochlear structure preservation. Multiple selections were possible.

"Other" considerations included atraumatic drilling at low speed at the round window, the use of Robotol, a surgical robot for minimally invasive surgery, and round window insertion with limited suction at the level of the round window. Ninety-two percent of the surgeons indicated their preference for round window insertions and preferred AB's lateral wall HiFocus™ SlimJ electrode for AIM-assisted surgeries.

AIM System: easy and impactful integration into surgical procedure routine

The electrode insertion time before the use of the AIM System varied greatly across surgeons. It was reported as less than 60 seconds by 66% of the surgeons *(Figure 2, top panel)*. With the AIM System, 58% of the surgeons reported longer insertion times, and 33% reported the same insertion time. Only one surgeon reported a much shorter insertion time using AIM System *(Figure 2, bottom panel)*.

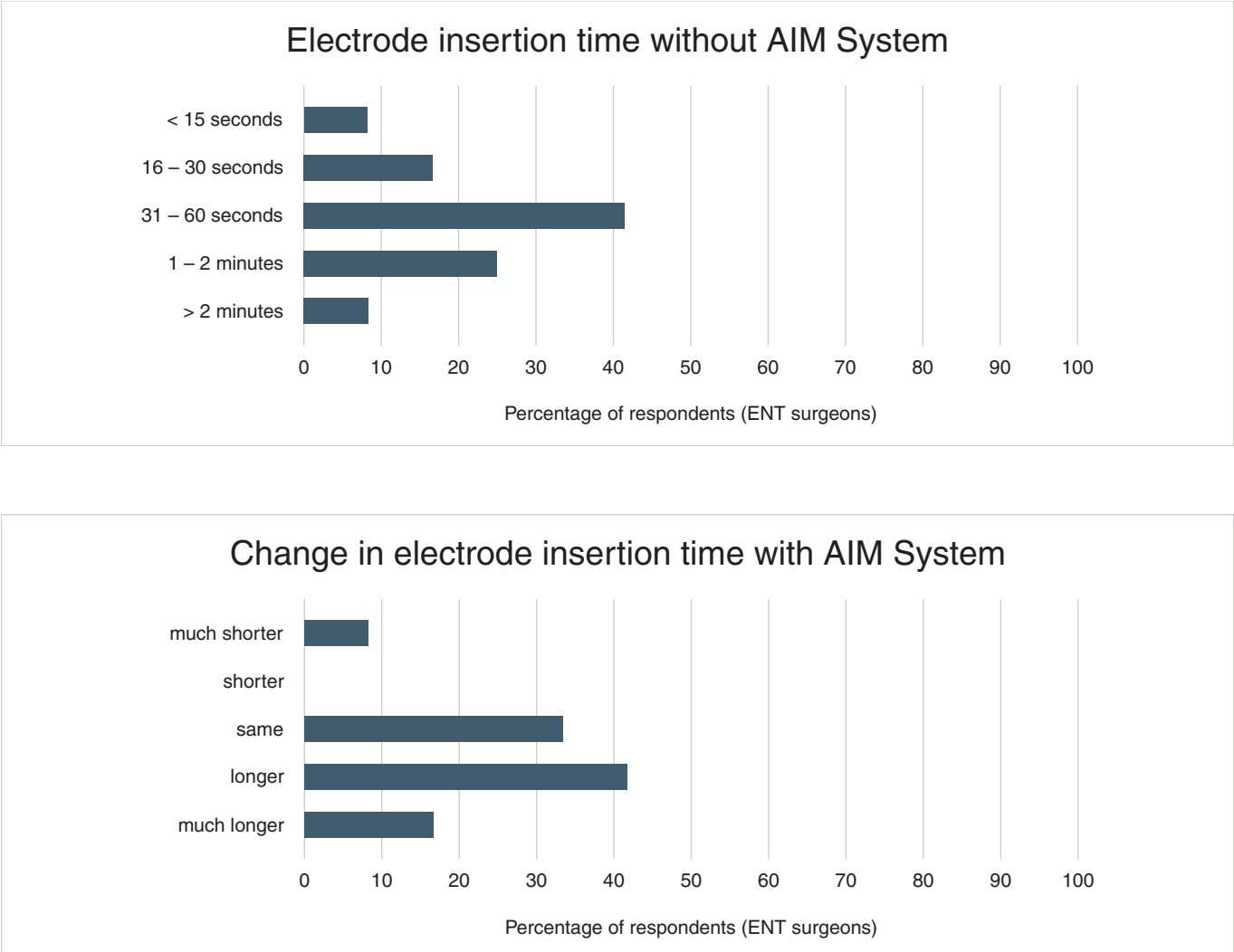

Fig. 2: Electrode insertion time without the use of the AIM System (top panel) and change in insertion time with the use of the AIM System (bottom panel).

The time added by the use of the AIM System to the normal surgical routine was reported 10 minutes or less by 67% of surgeons *(see Figure 3)*. All surgeons considered this additional time acceptable.

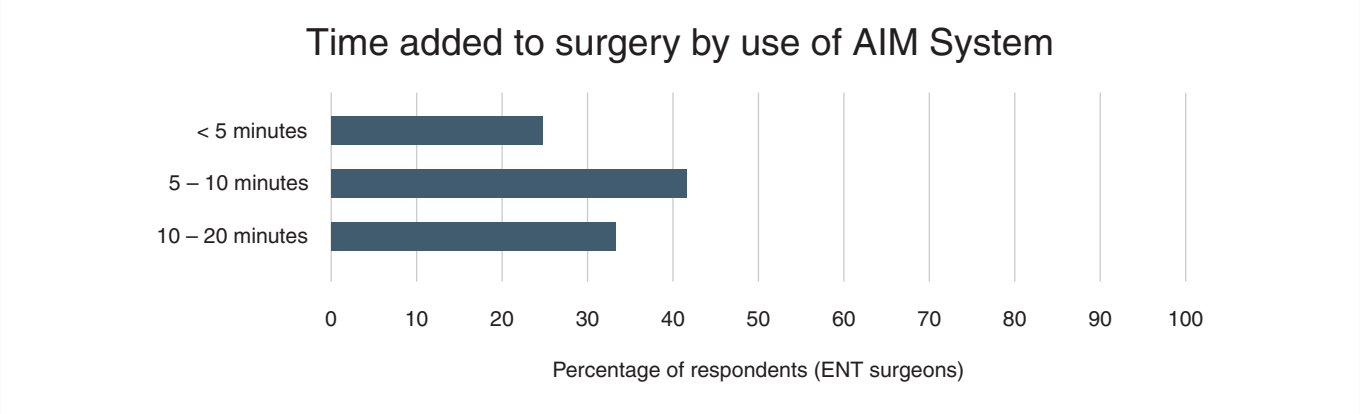

Fig. 3: Time added to the duration of surgery by the use of AIM System.

The AIM System was mostly recommended for electro-acoustic stimulation (EAS) candidates and patients with residual hearing not meeting formal EAS criteria.* However, 42% of the surgeons recommend the use of the AIM System for all patients *(see Figure 4)*.

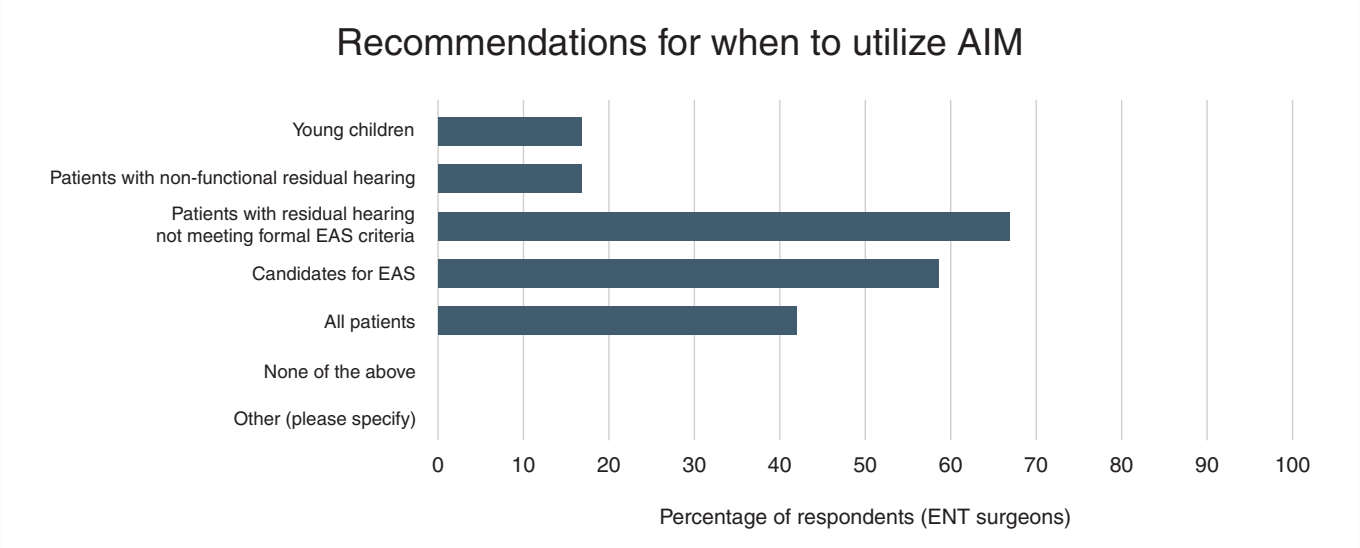

Fig. 4: Patient groups for whom the use of AIM System is recommended. Multiple selections were possible.

**Electro-acoustic stimulation (EAS) is not approved by FDA. Please contact your local AB representative for regulatory approval and availability in your region.*

Integration of the AIM System into the surgical procedure and the placement of the sterile insert into the ear were rated by sixty-six percent of the surgeons as “very easy” or “easy”. The surgical preparation/draping procedure was rated as “very easy” or “easy” by fifty-percent of the surgeons. *(see Figure 5)*.

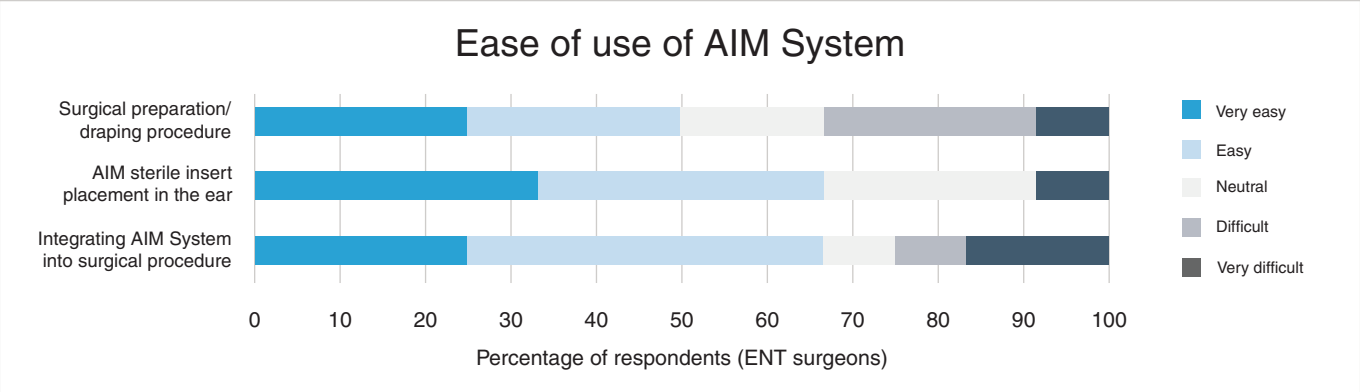

Fig. 5: Surgical ease of use of the AIM System.

AIM System: a valuable intra-operative tool

The majority of the surgeons (seventy-five percent or more) strongly agreed or agreed that the AIM System provides surgeons with valuable insights during surgery and the real-time feedback about cochlear function leads to better understanding the impact of surgical procedure on patient outcomes *(see Figure 6)*.

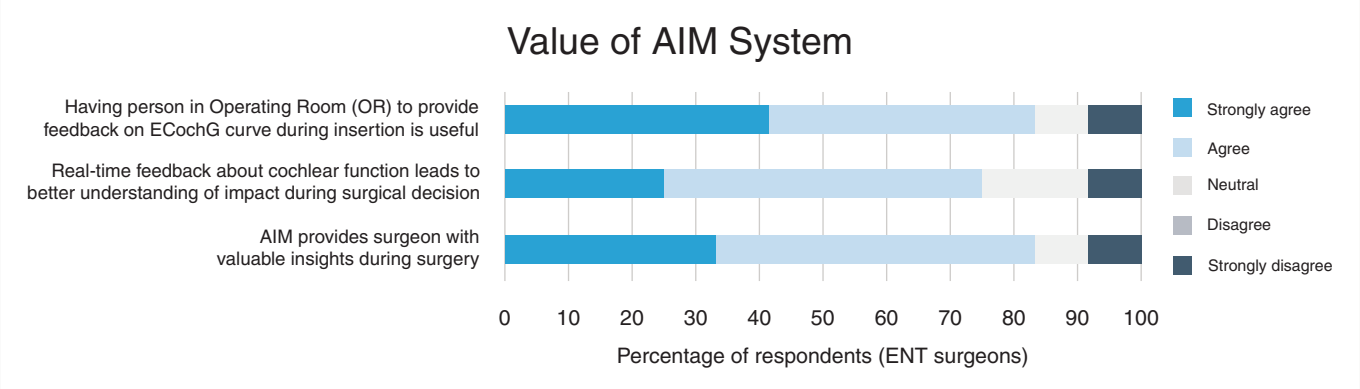

Fig. 6: Value of AIM System during surgery.

When asked about their recommendations, all surgeons recommended their colleagues try the AIM System noting the use of the AIM System during CI surgery to benefit both CI surgeons and their patients.

AIM System: a useful and well-designed tool for the OR

In addition to the questions related explicitly to surgical considerations that were only posed to the ENT surgeons responding to the survey, all survey participants, ENT surgeons, and other OR staff, were queried on the usefulness of and their satisfaction with the AIM System. The usefulness ratings of several features of the AIM System are presented in *Figure 7*.

Most of the features were rated as “useful” or “very useful” by the majority of respondents. The recording of real-time ECochG potentials during electrode insertion, the measurement of ECochG thresholds after insertion, and the NRI measurement were rated as “useful” or “very useful” by 86% or more of the respondents. The intra-operative ESRT presented a lower rating, which is likely a consequence of the need to use a separate immittance bridge in parallel to measure ESRT in AIM System, which is often not available in operating theatres. Although intra-operative ESRTs could be a guide for determining the maximum electrical stimulations levels,[8] it is more commonly used to assist clinician post-operatively with fitting CI recipients. As a reminder this survey was completed by surgeons and operating room staff, so it can be assumed that a fair number of those surveyed do not routinely use ESRT in the intra-operative environment.

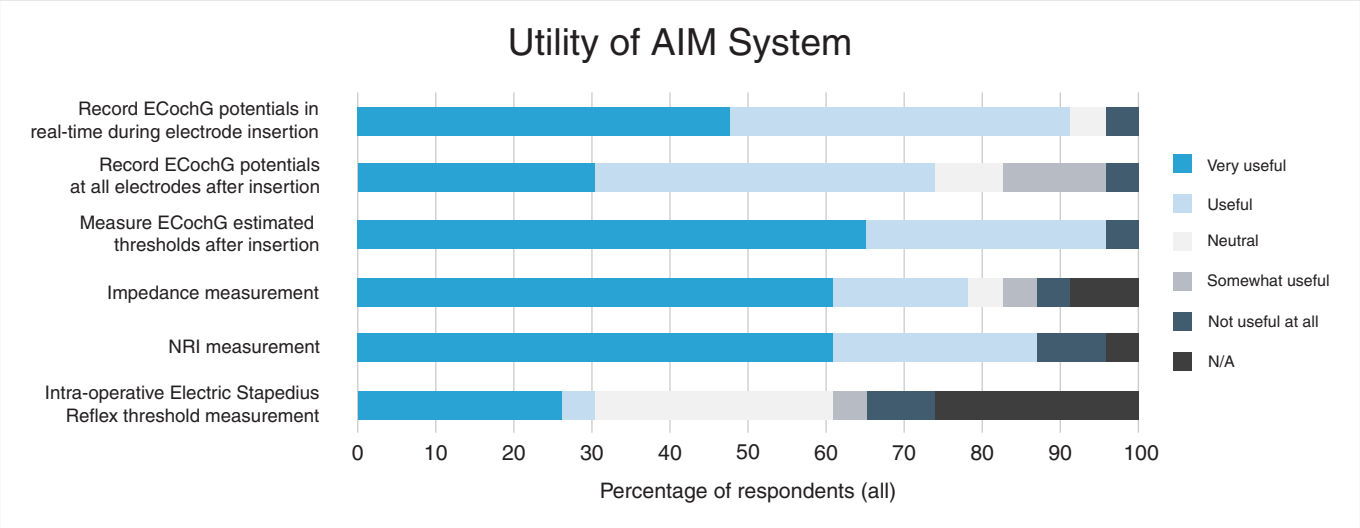

Fig. 7: Ratings of the usefulness of AIM System features.

The respondents’ satisfaction was rated for several aspects of the AIM System *(see Figure 8)*. The majority of users were “satisfied” or “very satisfied” with their experience. The compactness and portability of the AIM System, as well as the overall workflow/intuitiveness of the AIM System software, were especially well received, with 87% and 78% favorable ratings, respectively. The “Scanning license QR code, filling demographics information” and “Transferring data into fitting software” have indicated some room for improvement.

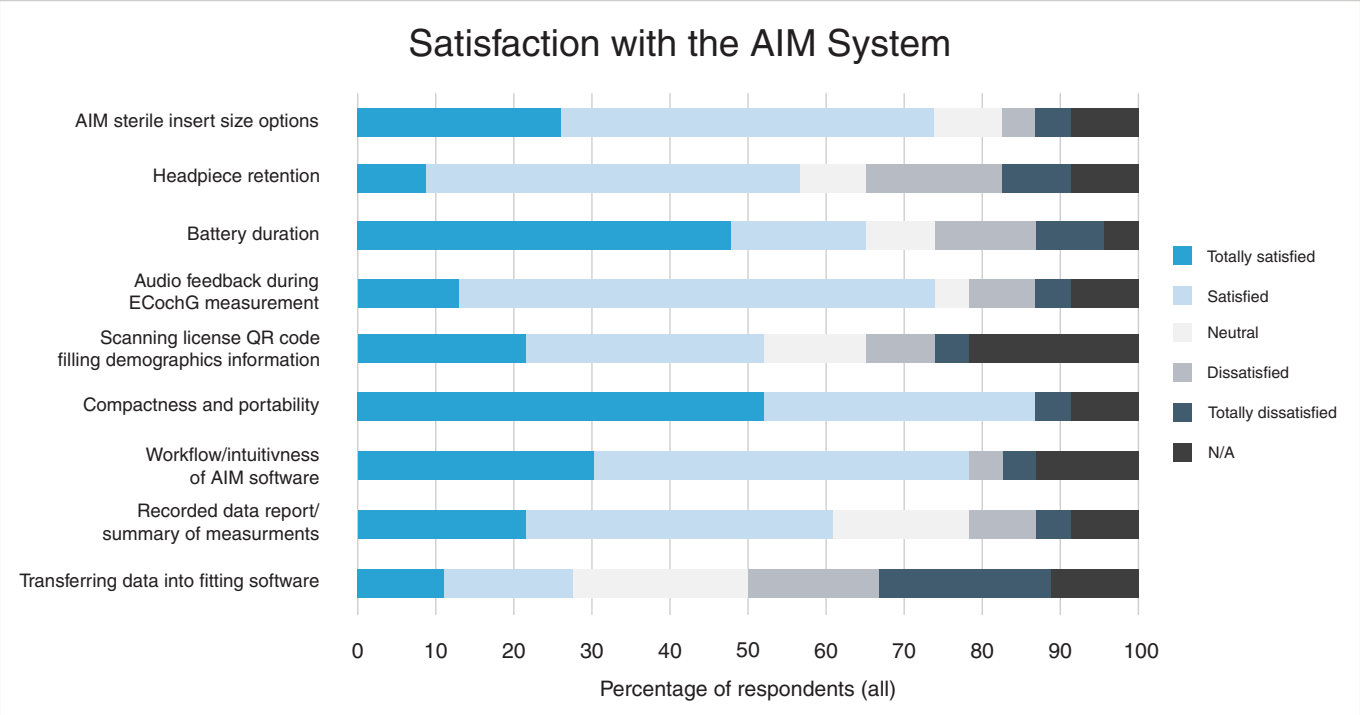

Fig. 8: Ratings of satisfaction with several usability aspects of the AIM System.

SUMMARY

The surgeons responding to this survey were very experienced with the majority reporting 10 or more years experience implanting CIs. The system was found to be easy to incorporate into the surgical routine, with the additional time required for use of the AIM System being rated as acceptable by all surgeons.

There is a global trend in expanding CI candidacy to include those with more residual hearing.[9] The AIM System was mostly used during surgeries with patients presenting with some residual hearing and particularly EAS candidates, providing real-time insight about the cochlear health during the insertion.* Most surgeons reported longer insertion times while using the AIM System. A recent study has indicated surgical intervention in response to intraoperative ECochG measurement can reduce trauma and save residual hearing during cochlear implantation, as demonstrated in a randomized clinical trial.[1]

The questions posed to all respondents revealed ECochG-based measurements to be as useful as other objective measures such as NRI and impedance measurements. While the transfer of data could be streamlined for ease of use, the handling of the AIM System was overall rated very favorably.

The AIM System was generally very well-received, with all surgeons valuing the benefits during surgery with real-time feedback, suggesting their peers try the system, and recommending it to all CI surgeons.

**Electro-acoustic stimulation (EAS) is not approved by FDA. Please contact your local AB representative for regulatory approval and availability in your region.*

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ADVANCED BIONICS LLC
28515 Westinghouse Place
Valencia, CA 91355, United States
T: +1.877.829.0026
T: +1.661.362.1400
F: +1.661.362.1500
info.us@advancedbionics.com

ADVANCED BIONICS AG
Laubisrütistrasse 28
8712 Stäfa, Switzerland
T: +41.58.928.78.00
F: +41.58.928.78.90
info.switzerland@advancedbionics.com

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