12th Annual Otolaryngology Literature Update

Otology II

Ted R. McRackan, M.D., MSCR.
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Teddy McRackan, M.D., MSCR is the director of the Skull Base Center and medical director of the Cochlear Implant Program in the Department of Otolaryngology – Head and Neck Surgery. Dr. McRackan was born in Virginia and moved to Charleston to attend the College of Charleston. He received his medical degree from the Medical University of South Carolina and completed his residency at Vanderbilt University in Nashville, Tennessee. Afterward, he moved to Los Angeles for a fellowship in otology-neurotology and skull base surgery at the House Ear Clinic.

Dr. McRackan's clinical practice is focused on the comprehensive management of ear, hearing, balance, and skull base disorders in adults and children. Specific areas of interest include, but are not limited to: cochlear implantation; chronic ear surgery (cholesteatoma, chronic otitis media); acoustic neuroma and other skull base lesions; otosclerosis; facial nerve disorders and tumors; endoscopic ear surgery; implantable hearing aids; and vertigo.

Dr. McRackan has published a comprehensive neurotology textbook and has written over 100 peer-reviewed articles and book chapters. His research program has been supported by the National Institute on Deafness and Other Communication Disorders, National Center for Advancing Translational Sciences,American Cochlear Implant Alliance, and the Doris Duke Foundation.

His research focuses on a better understanding of the communication, health, social, and economic benefits of cochlear implantation in adults with hearing loss and the development of patient-centered interventions with a long-term goal of improving cochlear implant functional outcomes

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Medical University of South Carolina

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De Sousa KC, Manchaiah V, Moore DR, Graham MA, Swanepoel W. Effectiveness of an Over-the-Counter Self-fitting Hearing Aid Compared With an Audiologist-Fitted Hearing Aid: A Randomized Clinical Trial. JAMA Otolaryngol Head Neck Surg. 2023 Jun 1;149(6):522-530. doi: 10.1001/jamaoto.2023.0376. PMID: 37052929; PMCID: PMC10102918.

Ismail O, Sobhy O, Assal S, Sanghera P, Begg P, Irving R. Comparing Hearing Outcomes in Irradiated and Conservatively Managed Vestibular Schwannoma. Otol Neurotol. 2022 Mar 1;43(3):e374-e381. doi: 10.1097/MAO.0000000000003457. PMID: 35061638.

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McRackan TR, Hand BN; Cochlear Implant Quality of Life Development Consortium; Velozo CA, Dubno JR. Development and Implementation of the Cochlear Implant Quality of Life (CIQOL) Functional Staging System. Laryngoscope. 2022 Nov;132 Suppl 12(Suppl 12):S1-S13. doi: 10.1002/lary.30381. Epub 2022 Sep 9. PMID: 36082873; PMCID: PMC9650765.

Nassiri AM, Marinelli JP, Lohse CM, Carlson ML. Incidence of Cochlear Implantation Among Adult Candidates in the United States. Otol Neurotol. 2023 Jul 1;44(6):549-554. doi: 10.1097/MAO.0000000000003894. Epub 2023 May 18. PMID: 37205861.

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Disclosure

- Envoy Medical (Advisory Board)
- Funding:
  - NIH/NIDCD: R01DC020709

Topics to be discussed

- Cochlear Implantation
  - Low utilization
  - Improved understanding of real-world benefits
- Vestibular schwannomas (acoustic neuromas)
  - Hearing outcomes
- Over the counter hearing aids
- COVID vaccination and sudden hearing loss

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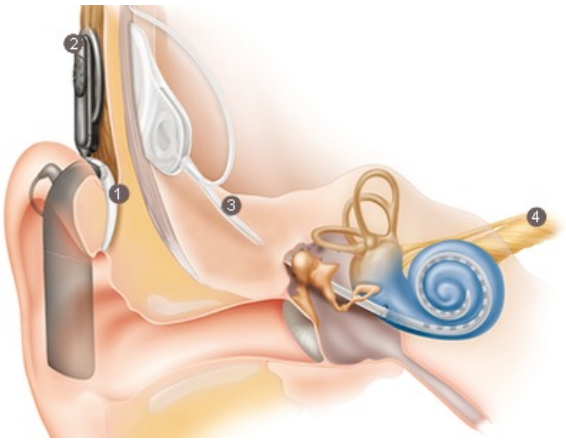
Cochlear implantation



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Cochlear implantation

- Period of drastic expansion of indications
  - CMS expansion to match FDA indications for bilateral hearing loss
    - Moderate to profound SNHL
    - <60% in best listening condition
  - FDA approval for single sided deafness (not CMS)
  - However, there is very poor market penetration

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Incidence of Cochlear Implantation Among Adult Candidates in the United States

*Ashley M. Nassiri, †John P. Marinelli, ‡Christine M. Lohse, and †Matthew L. Carlson

*Department of Otolaryngology-Head and Neck Surgery, University of Colorado School of Medicine, Aurora, Colorado; †Department of Otolaryngology-Head and Neck Surgery, Mayo Clinic, Rochester, Minnesota; and ‡Department of Quantitative Health Sciences, Mayo Clinic, Rochester, Minnesota

- Prior estimates of CI utilization were based on proprietary marketing models by private research firm
  - Utilization between 6-10% in adults
- Current study included prospectively maintained data from 2 of 3 CI manufacturers
    - Estimated third manufacturer data based on literature
  - Compared to National Health and Nutritional Examination Survey (NHANES) data
    - Conservative estimate (only severe to profound hearing loss)

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Incidence of Cochlear Implantation Among Adult Candidates in the United States

TABLE 1. *Summary of patient features, including data from two of the three US cochlear implant manufacturers (Cochlear Americas and Advanced Bionics)*

Feature	n (%)
Year of CI	
2015	4,598 (15)
2016	5,261 (18)
2017	6,173 (21)
2018	6,734 (22)
2019	7,300 (24)
Age at CI in years[a]	
20–29	1,093 (4)
30–39	1,537 (5)
40–49	2,130 (7)
50–59	3,542 (12)
60–69	6,370 (21)
70–79	8,800 (29)
≥80	6,594 (22)
Laterality of implant	
Unilateral or bilateral sequential	29,669 (99)
Bilateral simultaneous	397 (1)

[a]Median (interquartile range) age at CI was 70 (58–78) years.

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Incidence of Cochlear Implantation Among Adult Candidates in the United States

		US Residents ≥20 Yr Old		US Residents ≥20 Yr Old with Bilateral Severe-to-Profound Hearing Loss	
Age at CI, y	n	Population[a]	Incidence[b]	Population[c]	Incidence[d]
2015-2019					
20–29	1,286	226,406,339	0.6	—	—
30–39	1,808	215,620,278	0.8	172,445	1,048
40–49	2,506	202,663,005	1.2	—	—
50–59	4,167	216,110,701	1.9	1,491,118	279
60–69	7,494	183,390,553	4.1	1,852,197	405
70–79	10,353	107,566,831	9.6	3,399,066	305
≥80	7,758	62,311,150	12.5	4,691,922	165
Total	35,372	1,214,068,857	2.9	11,606,748	305

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Per 100,000 with severe to profound SNHL

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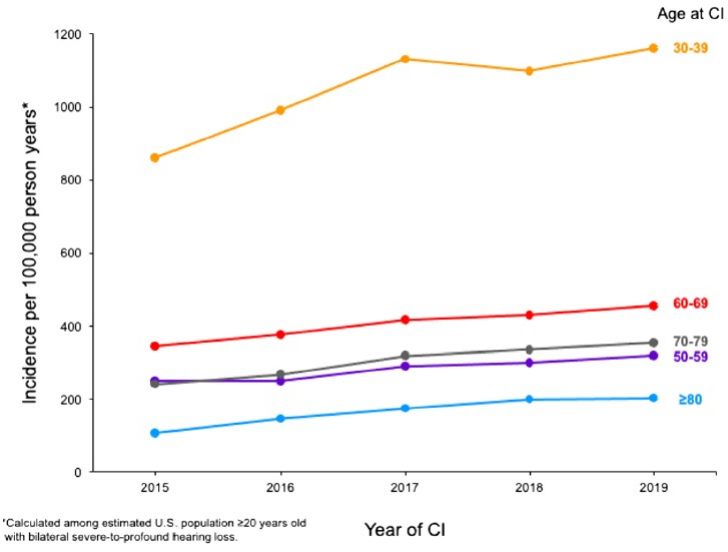
Incidence of Cochlear Implantation Among Adult Candidates in the United States



*Calculated among estimated U.S. population ≥20 years old with bilateral severe-to-profound hearing loss.

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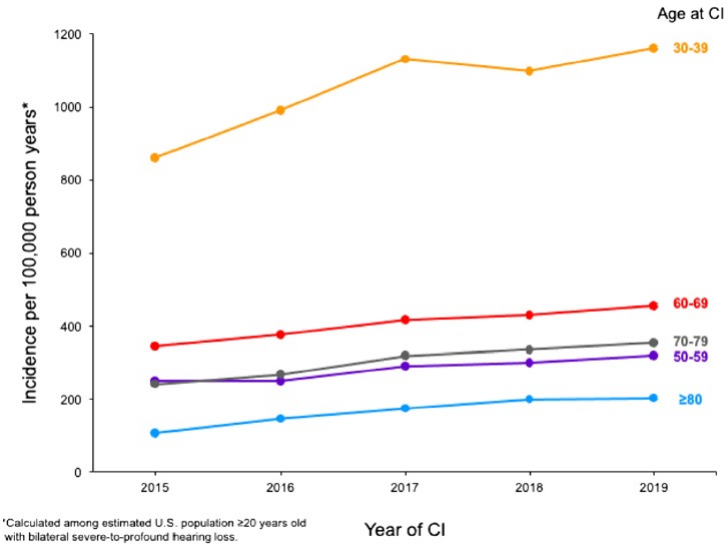
Incidence of Cochlear Implantation Among Adult Candidates in the United States



- Overall %57 increase in CI utilization during study period
- 50-59 cohort is only one that did not demonstrate growth
- Largest overall increase in number of CIs was >80 years

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- Despite substantial increases, CIs remain widely underutilized
  - Particularly in the elderly population
- More work needed to expand access to CIs

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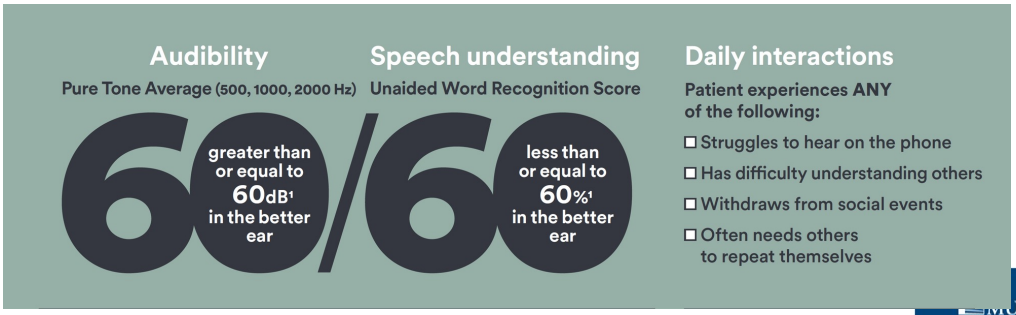

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Cochlear implant outcomes

- Cochlear implant outcomes have been traditionally measured solely using speech recognition outcomes
  - Word recognition (Example: CNC)
  - Sentence recognition (Example: AzBio)

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Development and Implementation of the Cochlear Implant Quality of Life (CIQOL) Functional Staging System

Theodore R. McRackan, MD, MSCR; Brittany N. Hand, PhD, OTR/L;
Cochlear Implant Quality of Life Development Consortium; Craig A. Velozo, PhD, OTR/L;
Judy R. Dubno, PhD

- Cochlear implant outcomes have been traditionally measured solely using speech recognition outcomes
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	Pre-op (SD)	12mo post-CI(SD)
Words in quiet	12.8% (±15.8)	59.5% (±22.2)
Sentences in quiet	20.2% (±20.3)	79.6% (±23.8)
Sentences in noise	21.6% (±19.2)	57.5% (±25.1)

Ma, Cheng, et al. Laryngoscope. 2021

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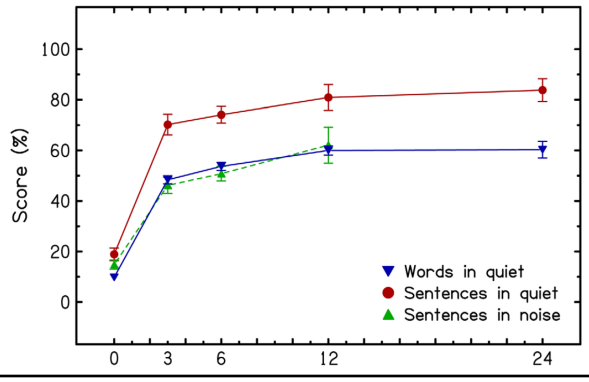

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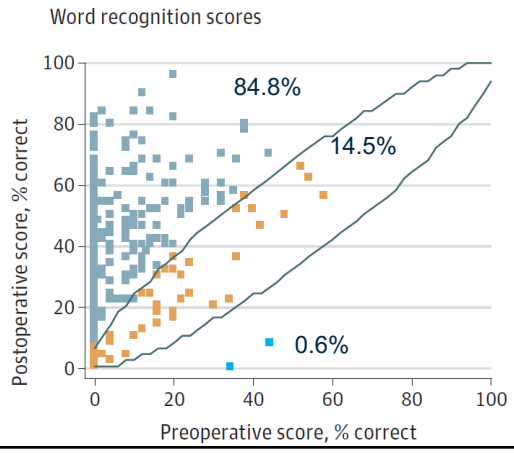

Dornhoffer JR, et al. JAMA-Oto. 2021
Dunn C, et al. AM J Aud. 2020
Lundberg EMH et al. Otol Neurotol 2021

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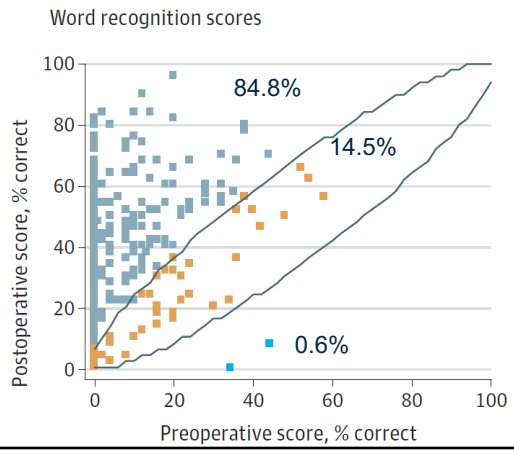

What does this mean regarding real-world functional ability?

Dornhoffer JR, et al. JAMA-Oto. 2021
Dunn C, et al. AM J Aud. 2020
Lundberg EMH et al. Otol Neurotol 2021

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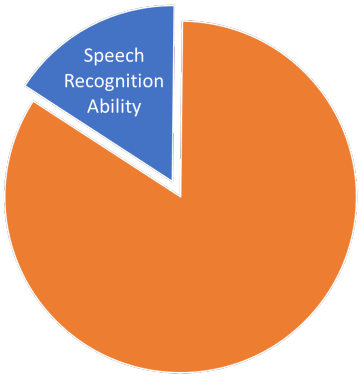

- Speech recognition only accounts for 4-16% of variance in patient self-reported communication ability
- Even lower in multivariable regression models (β=0.0 (0.0-0.1))

McRackan TR, et al. Ear and Hearing. 2021
McRackan TR, et al. Laryngoscope. 2018
McRackan TR, et al. Otol Neurotol. 2018

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Patient-reported outcome measures (PROMs)

- Instruments that capture a patient's perspective about their overall health or treatment
- Direct assessment of how a disease or intervention impacts functional abilities in real-world settings

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Patient-reported outcome measures (PROMs)

- Important because:
  - Removes clinicians' biases
  - Can efficiently measure multiple constructs
  - Regulatory standpoint:
    - Now required for FDA trials
    - Part of CMS Meaningful Measures Framework

Cochlear Implant QOL (CIQOL) Instruments

- Developed using rigorous development standards
- **No previous patient-reported outcome measure (PROM) has been validated in hearing loss or CI users that meets current standards**

https://education.musc.edu/ciqol

Cochlear Implant Quality of Life-35 Profile

ID:_____ Date:_____

INSTRUCTIONS: Think about your daily life with your cochlear implant (and/or hearing aid, if you also use one). Answer how often each of the following statements applies to your feelings and experiences. Answer how often each statement applies even if you don't use cochlear implants or hearing aids.

	Never	Rarely	Sometimes	Often	Always
1. I am able to have a conversation in a quiet place without asking the other person to repeat themselves					
2. Other people's voices sound clear and natural to me					
3. I am able to have a conversation with a group of three or more people					
4. I am able to have a conversation without asking the other person to repeat themselves					
5. I can hear and understand without looking at the person speaking					
6. I have to ask a lot of questions about what is being said in a conversation					
7. I can understand a conversation in a crowded environment (restaurant, party, etc.)					
8. I am able to have a conversation with someone in a noisy place without asking them to repeat themselves					
9. I can understand strangers without lip-reading in a noisy place					
10. I can follow the conversation in a group of five people in a crowded restaurant when I cannot see everyone					
11. I feel comfortable being myself					
12. My hearing loss makes me feel inadequate					
13. My hearing loss makes me irritable					
14. I keep quiet in a conversation to avoid saying the wrong thing					
15. I become frustrated when I cannot follow a conversation					
16. My hearing loss prevents me from listening to TV or radio					
17. I am able to enjoy listening to the radio and TV					
18. I am able to enjoy music					
19. I can recognize certain melodies in music					
20. Music sounds clear and natural to me					
21. Everyday sounds (birds chirping, rain, car horns, etc.) are clear to me					
22. Everyday sounds (microwave, birds chirping, rain, car horn) sound natural to me					
23. I am able to distinguish sounds in nature					
24. I am able to hear cars approaching in traffic					
25. I can hear someone approaching from behind					
26. I am able to follow a conversation with minimal effort					
27. I am able to ignore competing sounds and focus on the person who is speaking					
28. I can easily have a conversation in a noisy place (restaurant, party, store)					
29. I have to concentrate when having a conversation					
30. I have to concentrate when having a conversation with strangers when in a noisy place					
31. If I am interested, I will join family or friends for a social event					
32. I have the confidence to socialize					
33. I avoid socializing with friends, relatives, or neighbors due to my hearing loss					
34. I avoid social situations due to my hearing loss					
35. I feel left out when I am with a group of people due to my hearing loss					

Cochlear Implant Quality of Life-35 Profile

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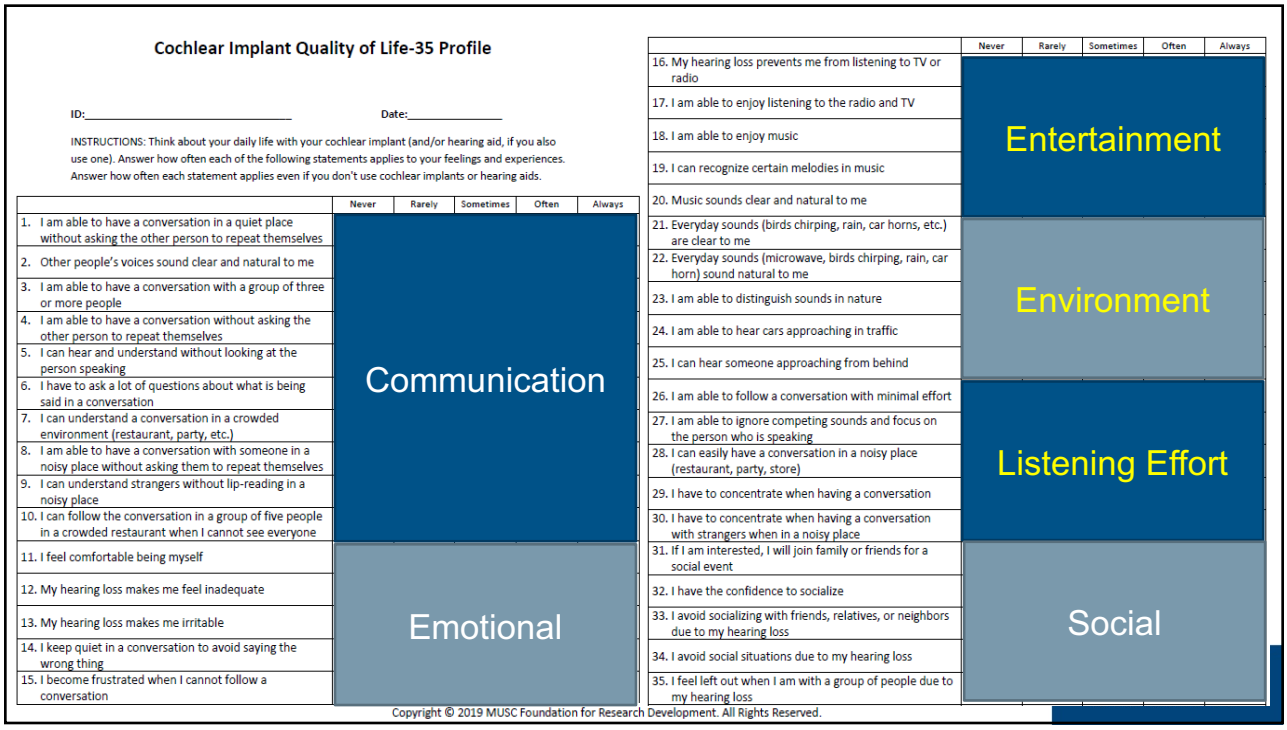

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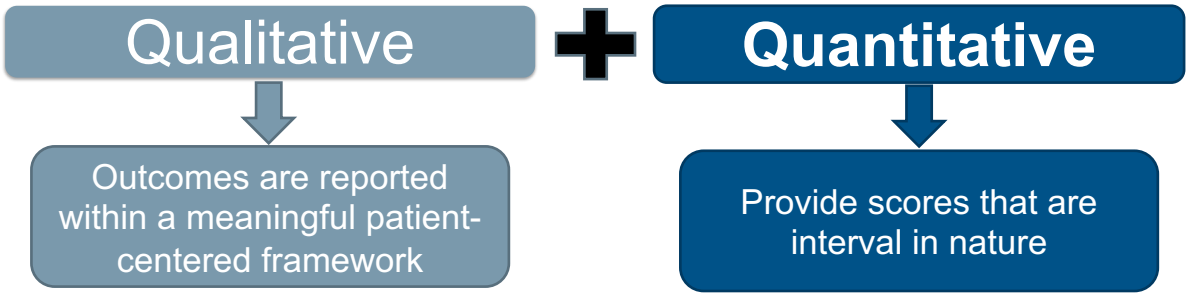
Rigorous mixed method approach helps overcome common interpretation problems with PROMs



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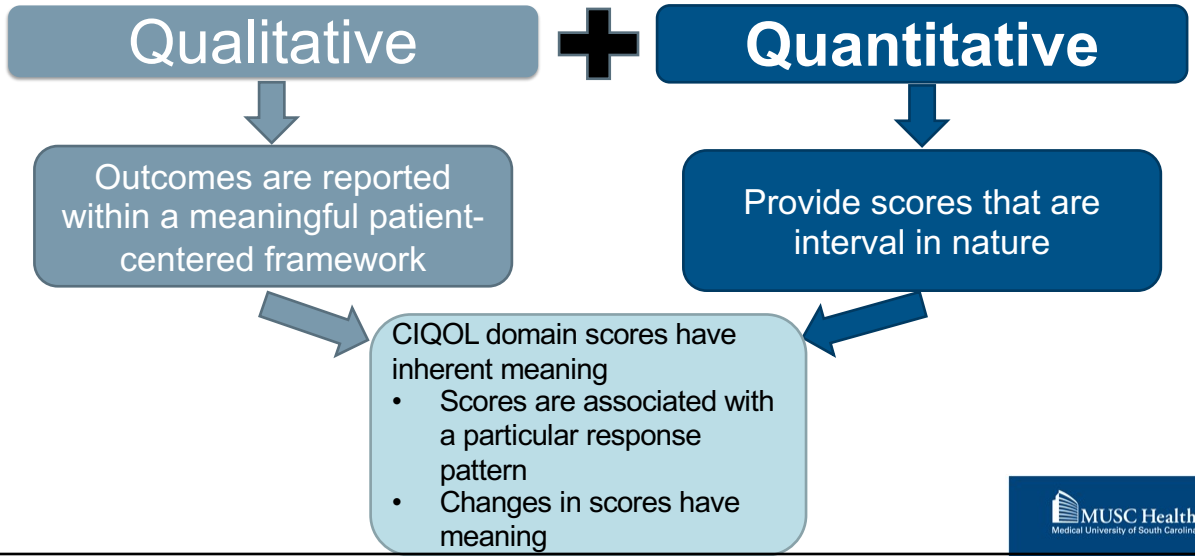

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Functional Staging Systems

- Enhance the interpretability of PROM scores
  - Provide detailed descriptions of patient-reported abilities via clinical vignettes
  - Maintain psychometrically derived (item response theory; IRT) hierarchy of quantitative scores

- Used in other health care settings

Tao W, et al. Arch Phys Med Rehabil 2008
Stineman MG, et al. Arch Phys Med Rehabil 2003
Jette AM, et al. J Rehab Med 2007

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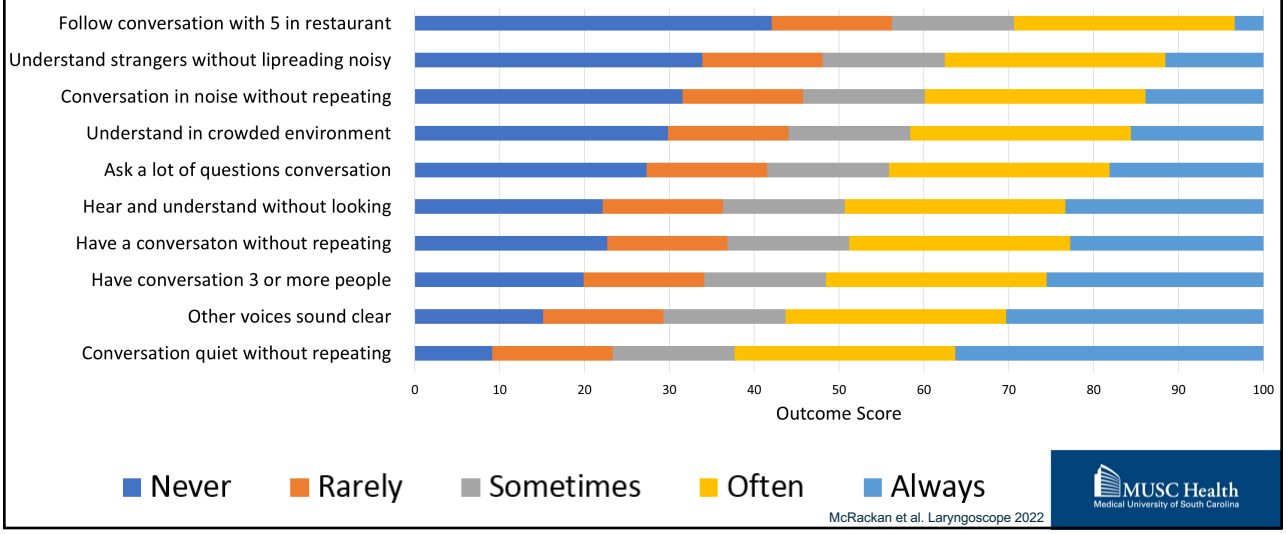
CIQOL-Communication example



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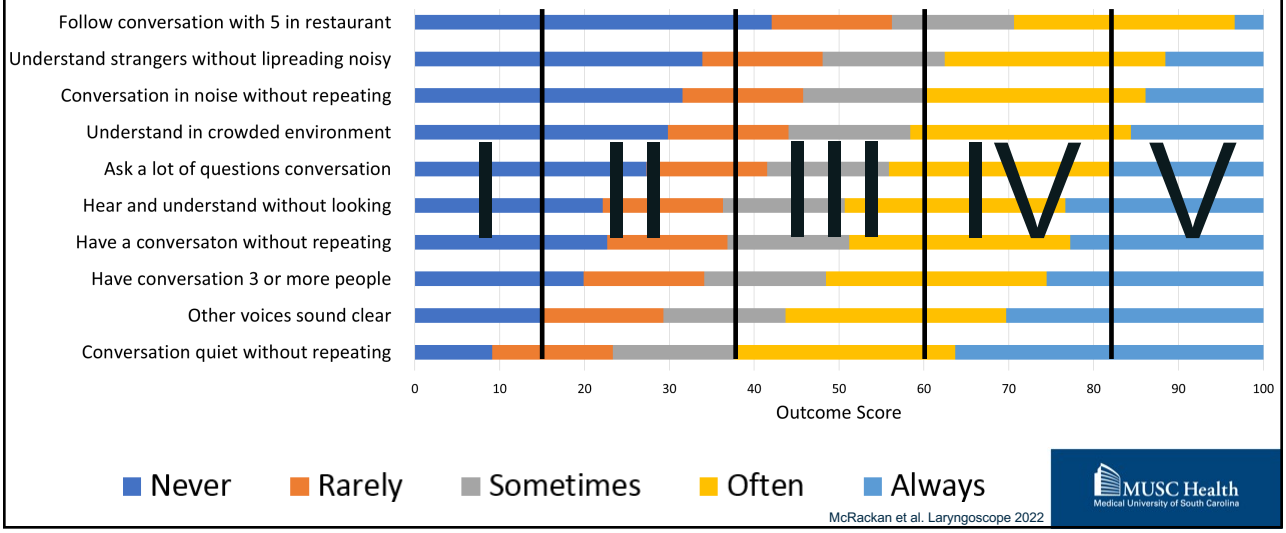
CIQOL-Communication Functional Staging System

- IRT analyses and expert opinion to identify cut-scores that separate stages
- Develop clinical vignettes



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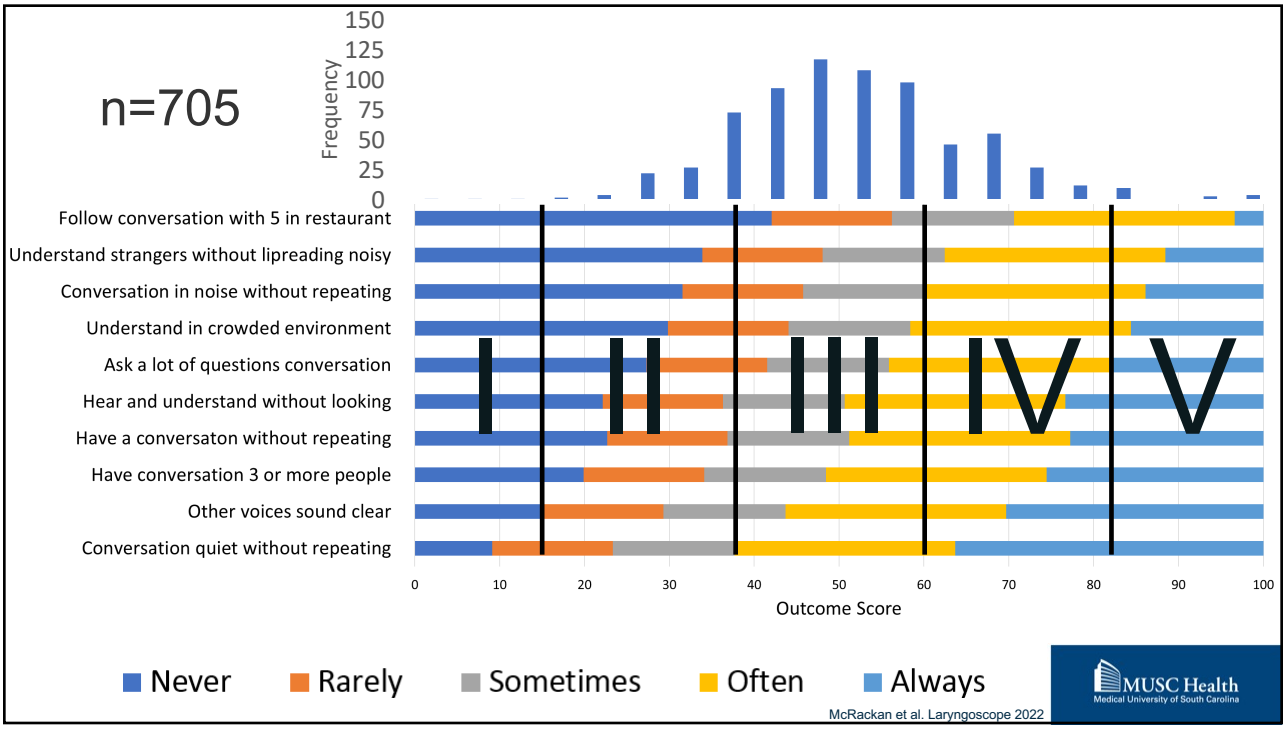
n=705



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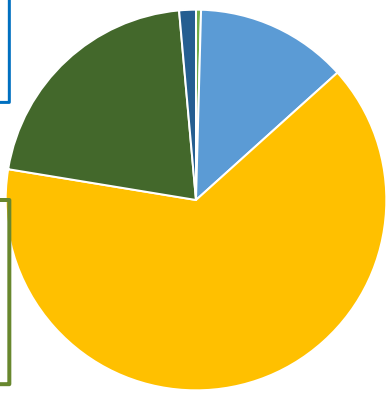
CIQOL-Communication Functional Staging System

I (0.4%):
- Unable to have a conversation in any listening environment

V (1.4%):
- Able to have a conversation in all listening environments with essentially no lip-reading



II (12.9%):
- Can sometimes have a conversation in quiet environments
- Need people to repeat themselves to understand conversation in quiet environments

IV (20.0%):
- Able to have a conversation in small groups in quiet
- Can sometimes have a conversation in noisy environments without lip reading

III (64.3%):
- Sometimes able to have a conversation in small group in quiet
- Has difficulty understanding, even with lip reading, in noisy environments

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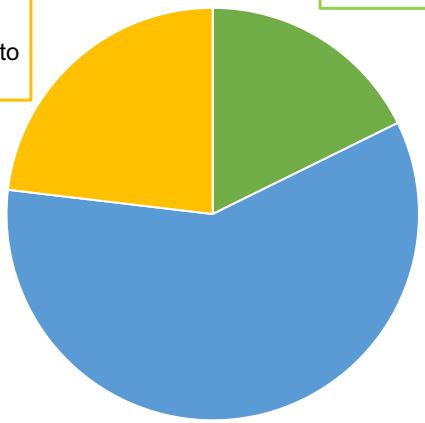
CIQOL-Entertainment Functional Staging System

III (23.1%):
- Usually able to enjoy music
- Music usually sounds clear and natural
- Hearing loss does not prevent them from listening to TV or radio

I (17.7%):
- Usually unable to enjoy music
- Unable to recognize melodies in music



II (59.1%):
- Hearing loss may prevent them from listening to TV or Radio
- Music does not always sound clear and natural

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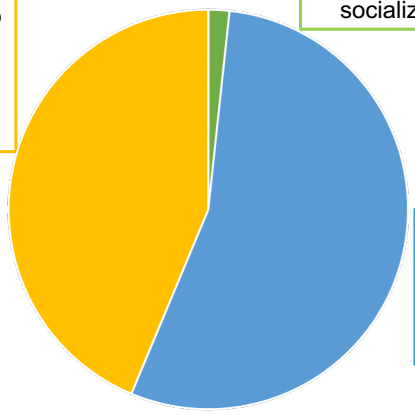
CIQOL-Social Functional Staging System

III (43.7%):
- Usually socializes and attends social events when interested
- Usually has the confidence to socialize
- Usually does not feel left out when with a group due to hearing loss

I (1.7%):
- Typically avoids socializing and social events due to hearing loss
- Usually does not have the confidence to socialize



II (54.6%):
- Can sometimes join family and friend for social events
- Can feel left out when with a group due to hearing loss

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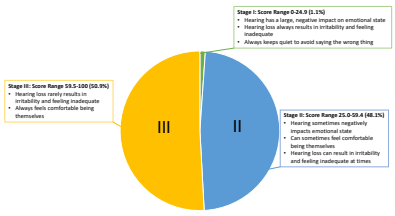
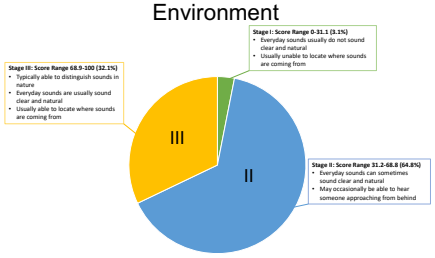
CIQOL Functional Staging System

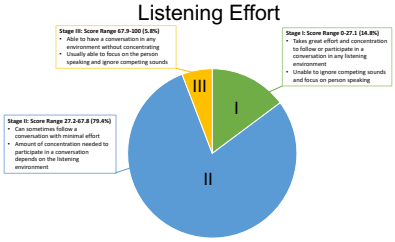
Emotional



Environment



Listening Effort



https://education.musc.edu/ciqol

McRackan et al. Laryngoscope 2022

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Development and Implementation of the Cochlear Implant Quality of Life (CIQOL) Functional Staging System

Theodore R. McRackan, MD, MSCR; Brittany N. Hand, PhD, OTR/L; Cochlear Implant Quality of Life Development Consortium; Craig A. Velozo, PhD, OTR/L; Judy R. Dubno, PhD

- Provide real-world understanding of functional abilities of CI users
  - Vast majority communicate well in quiet environments, but many have difficulty when there is background noise
  - 80% supplement auditory input with lip-reading
  - ~1 in 4 report music sounding clear and natural

McRackan et al. Laryngoscope 2022

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Development and Implementation of the Cochlear Implant Quality of Life (CIQOL) Functional Staging System

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- Provide real-world understanding of functional abilities of CI users

- Helpful for discussion with potential CI patients
  - Compare baseline abilities to normative data
  - Compare expectation to normative data

→ Evidence-based, shared decision making approach

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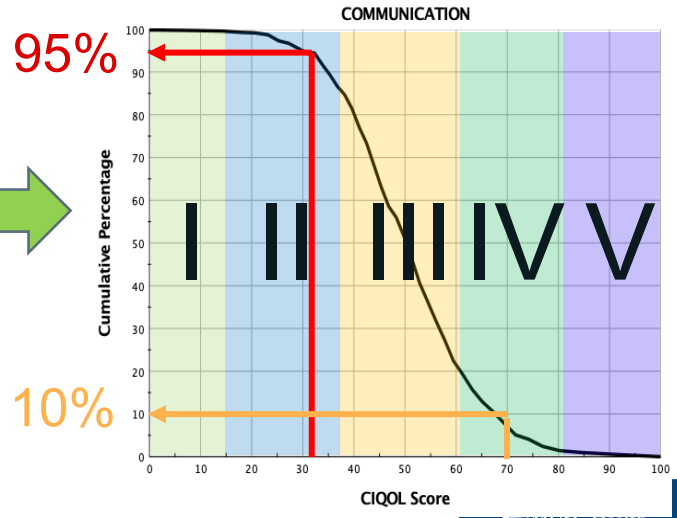
Pre-CI counseling

Baseline (pre-CI) CIQOL scores

+

CIQOL-Expectations



McRackan TR et al. JAMA-oto. 2022

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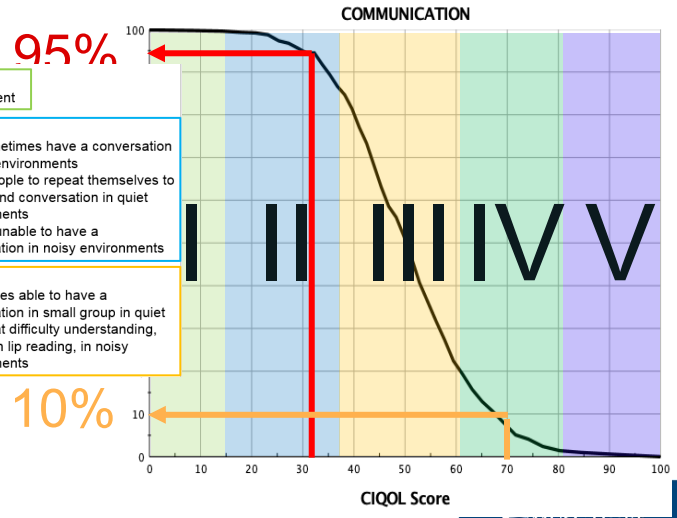
Pre-CI counseling

Baseline (pre-CI)



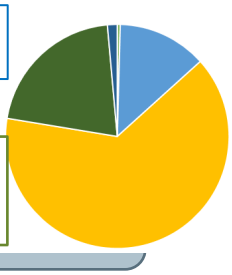
I (0.4%):
- Unable to have a conversation in any listening environment

II (12.9%):
- Can sometimes have a conversation in quiet environments
- Need people to repeat themselves to understand conversation in quiet environments
- Usually unable to have a conversation in noisy environments

III (64.3%):
- Sometimes able to have a conversation in small group in quiet
- Has great difficulty understanding, even with lip reading, in noisy environments

IV (20.0%):
- Able to have a conversation in small groups in quiet
- Can sometimes have a conversation in noisy environments without lip reading

V (1.4%):
- Able to have a conversation in all listening environments with essentially no lip-reading



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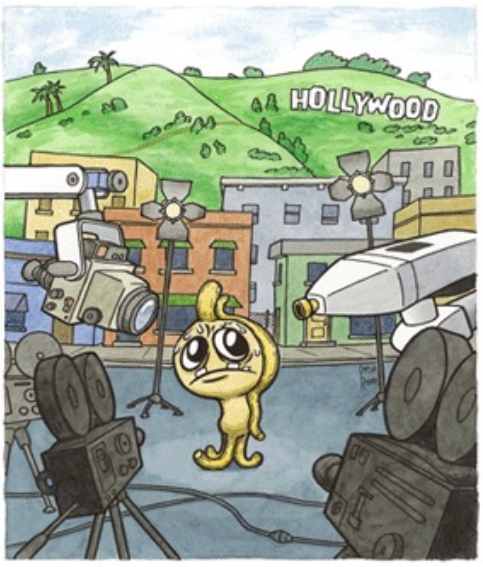
Vestibular schwannoma management



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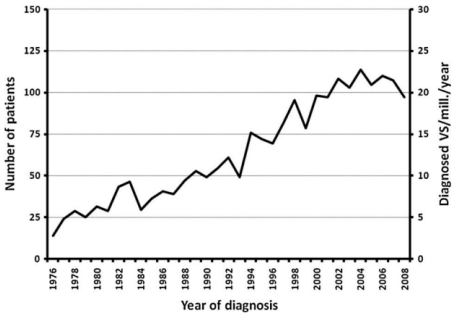
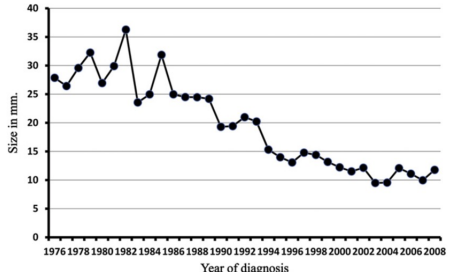
Vestibular Schwannomas

- Changes in treatment over time
  - Increased detection
    - 75% decrease in average tumor size at time of diagnosis
    - Being diagnoses in older patients
    - 1/500 people lifetime prevalence
    - 3-5/100,000 persons per year risk





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Vestibular Schwannomas

- Dramatic shift in practice patterns over time
- Focus on preservation of quality of life (balance, hearing, facial nerve) over tumor treatment
  - Hearing loss is often patients' primary concern as it is most common presenting symptom
    - Fairly small impact on long-term quality of life

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Hearing Preservation in Observed Sporadic Vestibular Schwannoma: A Systematic Review

*Karl R. Khandalavala, †Elias S. Saba, ‡Armine Kocharyan, ‡Ghazal S. Daher, §Christine M. Lohse, ¶John P. Marinelli, and ‡||Matthew L. Carlson

- Systematic review of available literature (2000-2020)
- Identify changes in hearing over time in patients with observed vestibular schwannomas

Hearing Class	PTA Hearing Level (dB)	WRS (%)
A	≤30	≥70
B	>30, ≤50	≥50
C	>50	≥50
D	any level	<50

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- 26 studies included (n=3,652 patients)
  - Mean age 58.8 years
  - Fairly even gender distribution
  - Mean follow up 49.2 months (SD 26.5!)
  - Substantial variability in how tumor size described
- Only patients with initial serviceable hearing were included in final analysis (n=1,674)

Hearing Class	PTA Hearing Level (dB)	WRS (%)
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- In total, 21% failed conservative management

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TABLE 2. *Summary of serviceable hearing maintenance rates over time*

Year	Studies Reporting	Originally SH That Had F/u Audio	NumberSH	Aggregate % SH[a]	Average % SH[b]	Max % SH	Min % SH
1	7	612	582	95	96	100	94
2	6	435	377	87	87	93	82
3	7	427	311	73	73	80	61
4	5	271	177	65	64	74	55
5	6	403	225	56	57	68	45
6	4	193	101	52	55	63	40
7	4	246	107	44	44	56	34
8	2	94	38	40	45	55	35
9	2	86	29	34	41	52	30
10	2	81	26	32	37	44	30

- Add table 2
- Then add figure 2 (stimated survival rates of maintaining SH were 96% at 1 year following diagnosis, 77% at 3 years, 62% at 5 years, and 42% at 10 years following diagnosis (Fig. 2).)

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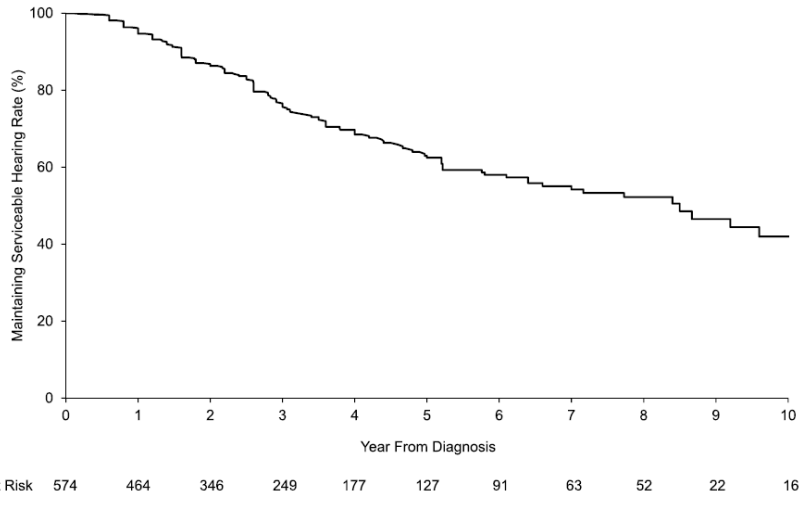

- K-M curve estimates of maintaining serviceable hearing:
  - 96% at 1 year
  - 77% at 3 years
  - 62% at 5 years
  - 42% at 10 years

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- Hearing loss (on average) occurs ~3.5dB per year
  - ?inevitable
- Hard to predict on individual patient basis (baseline hearing, initial tumor size)
- How does this compare to other treatment options?

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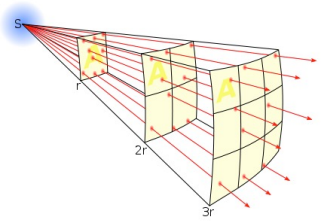
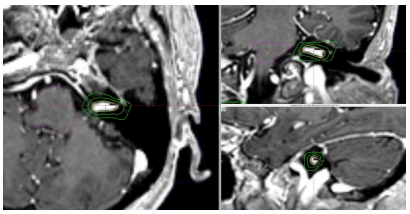
Comparing Hearing Outcomes in Irradiated and Conservatively Managed Vestibular Schwannoma

*†Omneya Ismail, †Ossama Sobhy, †Samir Assal, ‡Paul Sanghera, *§||Philip Begg, and *Richard Irving

- Stereotactic radiation (SRS) initially thought to be the holy grail
  - Gamma knife, LINAC, Cyberknife
- Definition of success in SRS





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*†Omneya Ismail, †Ossama Sobhy, †Samir Assal, ‡Paul Sanghera, *§||Philip Begg, and *Richard Irving

- Comparison of hearing outcomes in patients treated with SRS vs. Observation
- Inclusion criteria:
  - Tumors <2cm
    - Offered SRS when 2mm of linear growth noted
  - 3 years follow up
  - Used AAO-HNS hearing classification

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- N=247
  - 140 observation/107 SRS
  - Mean age 59.2 (obs) and 57.5 (SRS)

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TABLE 1. *Groups' demographic, tumor, and hearing characteristics*

	Conservative Group (n = 140)	SRS Group (n = 107)
Mean follow-up period, yrs ±sd	5.9 ± 1.6	7.1 ± 1.9
Mean age, Yrs ±sd	59.25 ± 13.16 ($p = 0.2855$)	57.5 ± 12.15
Sex (male/female)	M: 76 F: 64	M: 55 F: 52
Tumor side (right/left)	R: 71 L: 69 ($p = 0.915$)	R: 55 L: 52
Tumor location at diagnosis/Pre-SRS (intracanalicular/extracanalicular)	IC: 76 EC: 64 ($p < 0.001^a$)	IC: 26 EC: 81
Mean tumor size at diagnosis/pre-SRS, mm ±sd	9.59 ± 4.89	11.30 ± 5.02
Mean tumor size at last follow-up, mm ±sd	9.80 ± 5.44 ($p = 0.926$)	13.68 ± 4.96 ($p < 0.001^a$)
Mean PTA at diagnosis/pre-SRS, dBHL ± sd	50.55 ± 28.71	50.49 ± 27.90
Mean PTA at last follow-up, dBHL ± sd	61.75 ± 28.43 ($p < 0.001^a$)	83.27 ± 25.97 ($p < 0.001^a$)

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Mean PTA at last follow-up, dBHL ± sd	61.75 ± 28.43 ($p < 0.001^a$)	83.27 ± 25.97 ($p < 0.001^a$)

- Initial mean PTAs were similar for both groups
- Both groups had a significant deterioration of hearing over time
  - Observation: mean PTA showed average increase of 1.90 dB/yr
  - SRS: mean PTA showed average increase of 4.62 dB/yr

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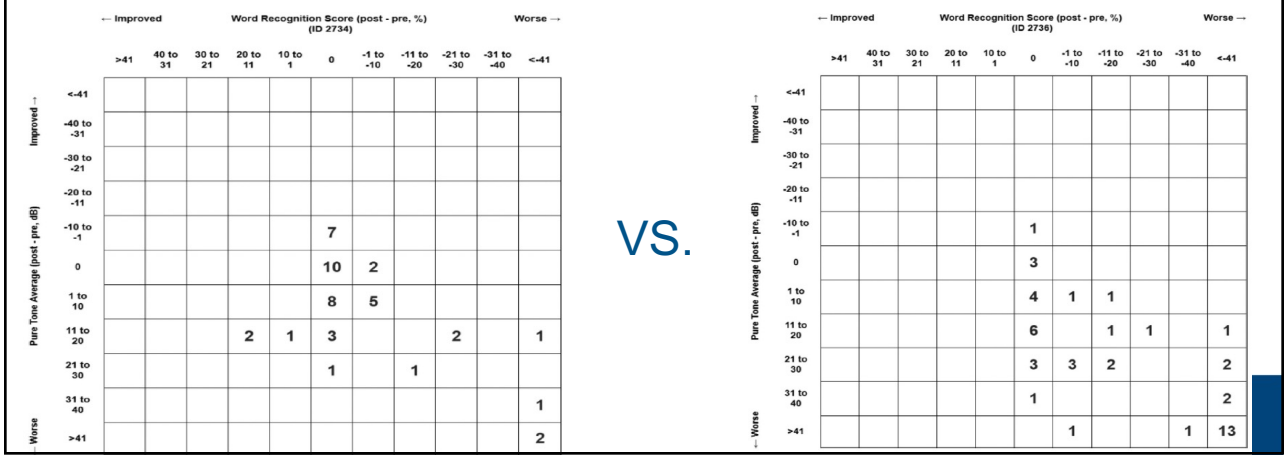
Comparing Hearing Outcomes in Irradiated and Conservatively Managed Vestibular Schwannoma

*†Omneya Ismail, †Ossama Sobhy, †Samir Assal, ‡Paul Sanghera, *§||Philip Begg, and *Richard Irving

- Which would you want?



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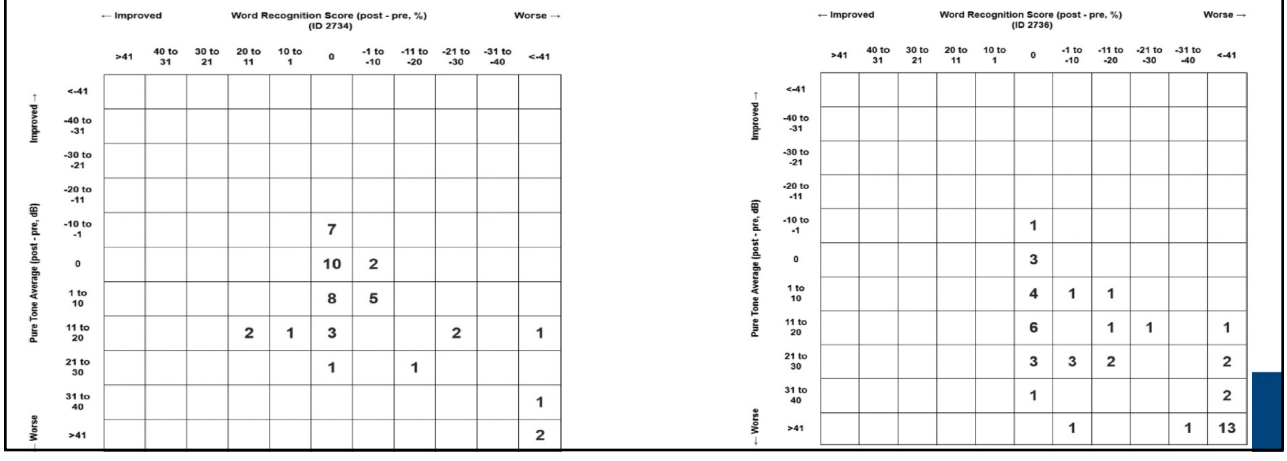
Observation

SRS



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	Tokyo Classification	Time of Diagnosis	Last Follow-up	*p* Value
Observation	Serviceable hearing	16 (34.8%)	11 (23.9%)	$^{McN}p = 0.025^a$
	Nonserviceable hearing	30 (65.2%)	35 (76.1%)	
SRS	Serviceable hearing	13 (27.7%)	2 (4.3%)	$^{McN}p = 0.001^a$
	Non-serviceable hearing	34 (72.3%)	45 (95.7%)	

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- Significant hearing deterioration in both cohorts
  - More substantial in patients undergoing SRS
    - Caveat #1: selection bias as these were growing tumors
    - Counter caveat: only 3 year follow up
  - Literature overall supports better hearing outcomes with conservative management
    - Hearing preservation surgery?

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Questions?