Outcomes of Open Canal vs. Traditional Custom Hearing Aids: *A Randomized Controlled Trial*

Advances in Audiology

Tomorrow's Solutions for Today's Challenges

2nd – 5th of December 2012

Session II: Factors in Hearing Instrument Adoption & Use

Presented by:

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USF
UNIVERSITY OF
SOUTH FLORIDA

Acknowledgements

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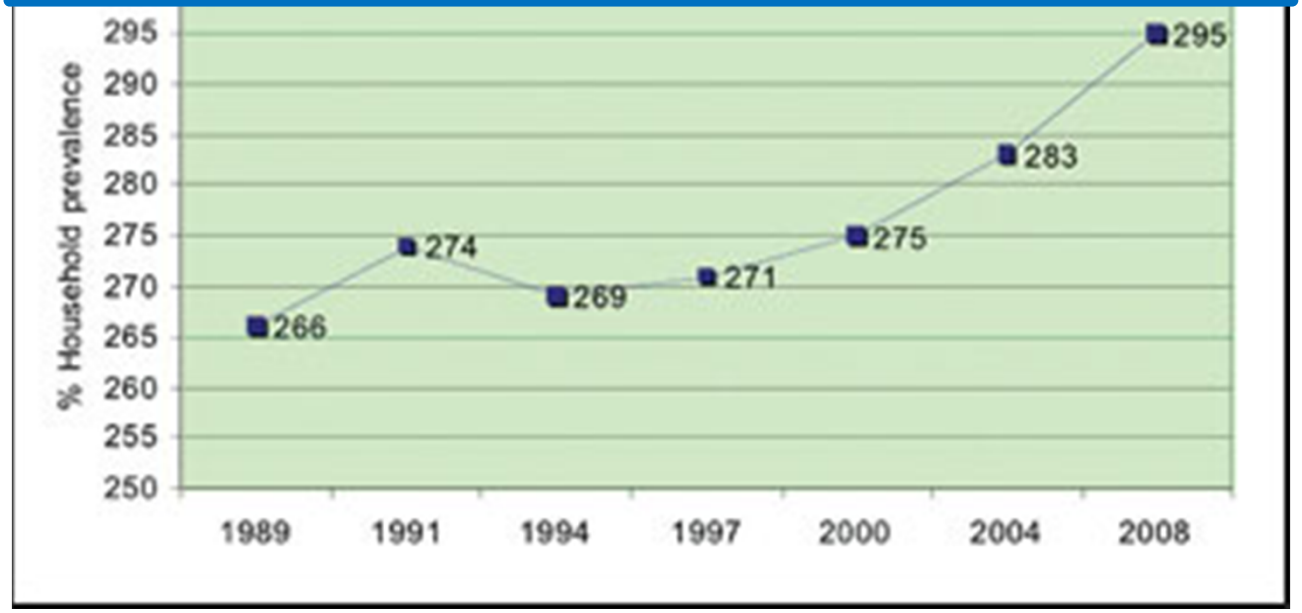
- The contents do not represent the views of the Department of Veterans Affairs or the United States Government

Impetus for Study

34 million Americans with Adult Onset Hearing loss



S. Kochkin. MarkeTrak VIII: 25 year trends in the hearing health market. The Hearing Review, Vol. 16 (11), October 2009, pp.12-31.

Hearing Aids

Primary Treatment Option

Low Prevalence of Hearing Aid Use

Only 22% of those over the Age of 50 y/o with HL > 25 dB HL use Hearing Aids

Chien & Lin (2012)

Table. Prevalence and Number of Individuals 50 Years or Older With Hearing Loss[a] Using Hearing Aids in the United States[b]

	Prevalence of Hearing Aid Use Among Adults With Hearing Loss[a] ≥25 dB, % (95% CI)[c]						
	Sex		Hearing Loss Severity[d]		Total		
Variable	Male	Female	Mild (25-40 dB)	Moderate or Greater (>40 dB)	Overall Prevalence of Hearing Aid Use	No. With Hearing Aids (in Millions)	No. With Hearing Loss[a] ≥25 dB (in Millions)
Age, y							
50-59	4.3 (0-9.5)	4.5 (0-13.5)	2.7 (0-6.6)	11.8 (0-27.5)	4.3 (0-8.8)	0.2	4.5
60-69	7.3 (2.5-12.1)	7.2 (1.4-13.0)	2.6 (0-5.2)	23.9 (10.6-37.2)	7.3 (3.6-10.9)	0.4	6.1
70-79	21.1 (14.5-27.6)	12.7 (6.0-19.5)	3.4 (0.3-6.5)	47.8 (37.0-58.6)	17.0 (12.4-21.6)	1.5	8.8
≥80	28.1 (20.3-35.9)	17.9 (11.2-24.7)	3.4 (0-7.7)	35.7 (28.7-42.7)	22.1 (18.5-25.8)	1.6	7.3
Estimated total No. of individuals with hearing aids and with hearing loss (in millions)						3.8[d]	26.7

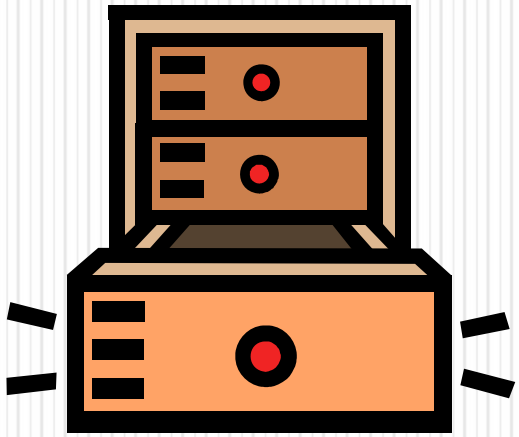
[a] Hearing loss was defined as a speech frequency pure tone average of hearing thresholds at 0.5-, 1-, 2-, and 4-kHz tones presented by air conduction in the better hearing ear of 25 dB or greater.

[b] Data were derived from the 1999-2006 National Health and Nutrition Examination Survey.

[c] All values represent prevalence percentage unless otherwise noted.

[d] Numbers do not sum to group total because of rounding.

12.4% of Adults Who Try Hearing Aids



Kochkin S. MarkeTrak V: Why my hearing aids are in the drawer: The consumer's perspective. *Hear Jour.* 2000;53(2):34-42.

Factors Associated with Non-Use and Discontinued Use of Traditional Hearing Aids

- Poor fit, comfort and/or cosmetics
- Lack of ease of use
- “A plugged up sensation” related to occlusion
- Poor sound quality of own voice
- Negative side effects of whistling feedback
- Difficulty understanding speech in noise

Popularity of Open Ear Fittings

Improved comfort and cosmetics

Reduced effects of occlusion

May reduce the amount of under and un-use of hearing aids

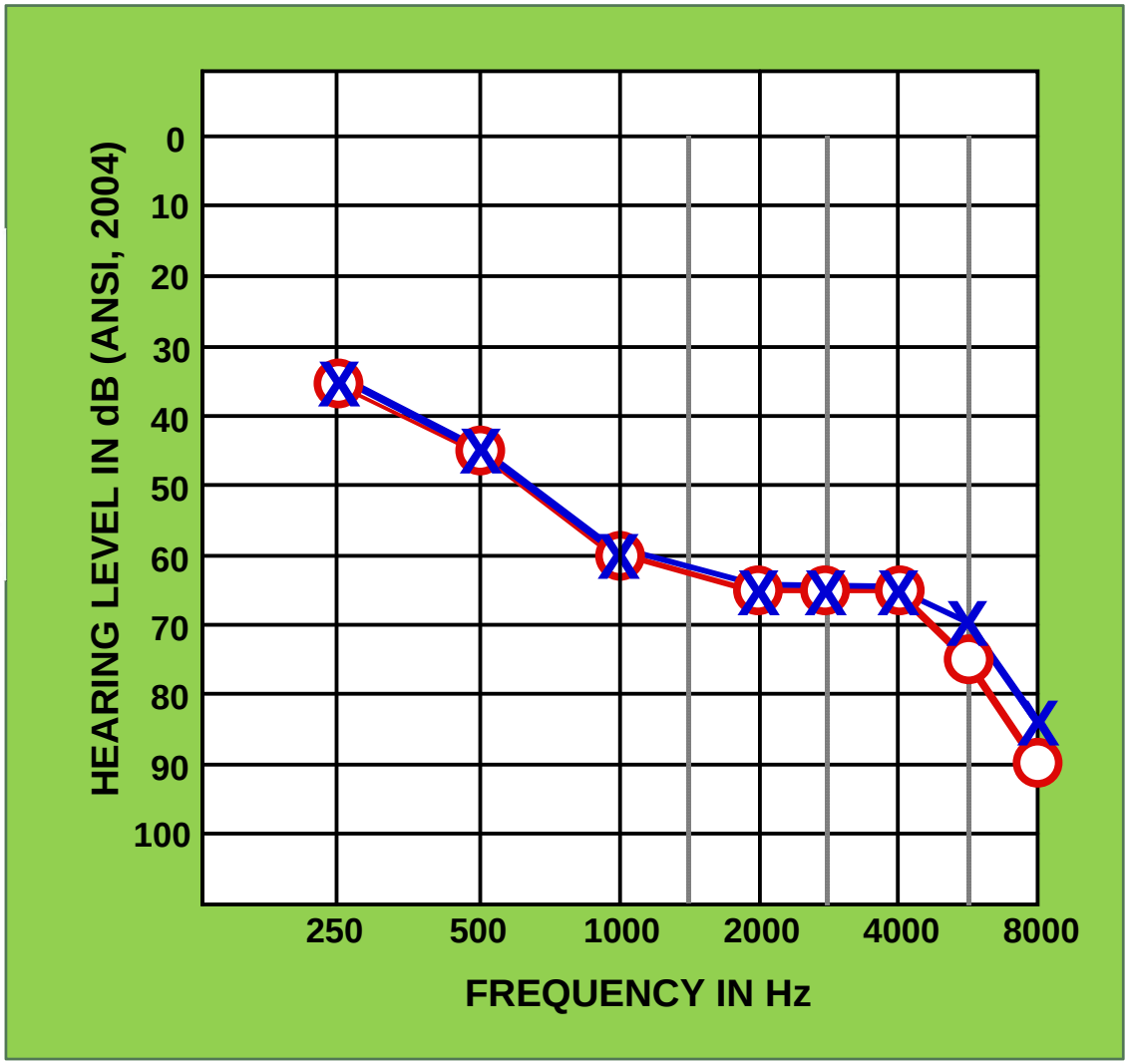
Potential Limitations/Trade-Offs

Open Ear (OE)

Traditional Custom (TC)

- Maximum low- and high-frequency gain available may be less in OE than in TC fitting
  - Difficulty in meeting targets
  - Reduced speech recognition
- Decreases in Directional Microphones benefits with OE fittings may occur due to decrease in low-frequency gain

What would you fit?



Our Team

- Gene Bratt and Richard Wilson
  - Co-Principal-Investigators
- Mia Rosenfeld
  - Study Coordinator/ Research Audiologist
- Theresa Chisolm, Rachel McArdle, Todd Ricketts, Sherri Smith
  - Co-Investigators
- Ginny Alexander, Elizabeth Talmage, Erin Coomes
  - Research Audiologists

Multi-Site Study

Nashville VA Medical Center

James H. Quillen, VAMC,
Mt. Home, TN

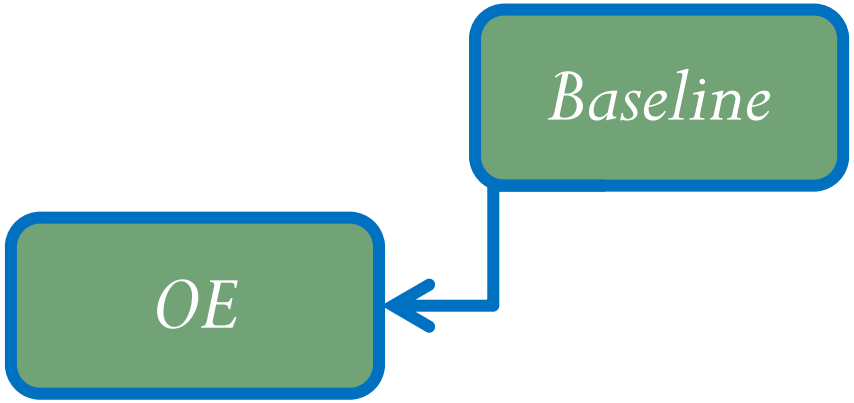
VAHC – Bay Pines, Florida

3-Period Crossover Design

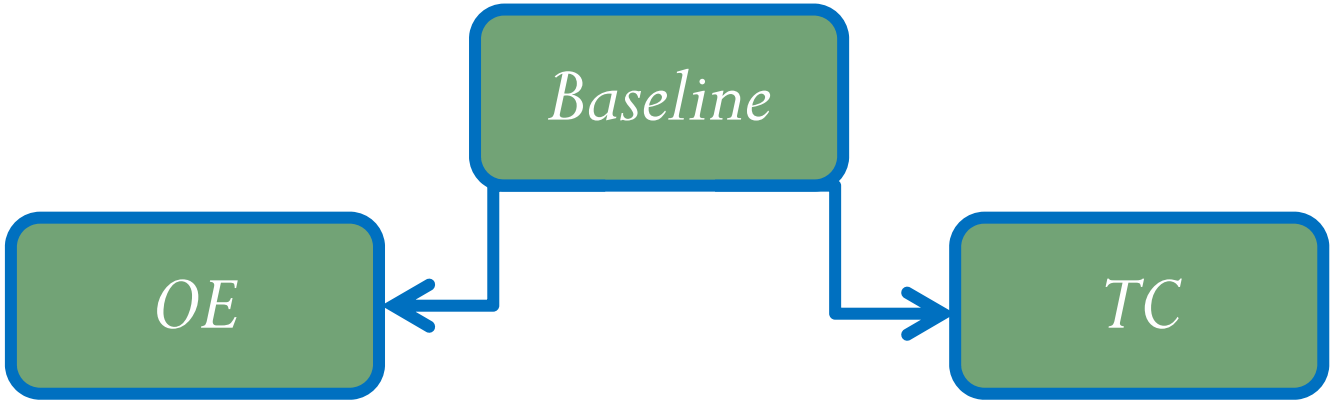
3-Period Crossover Design

Baseline

3-Period Crossover Design



3-Period Crossover Design



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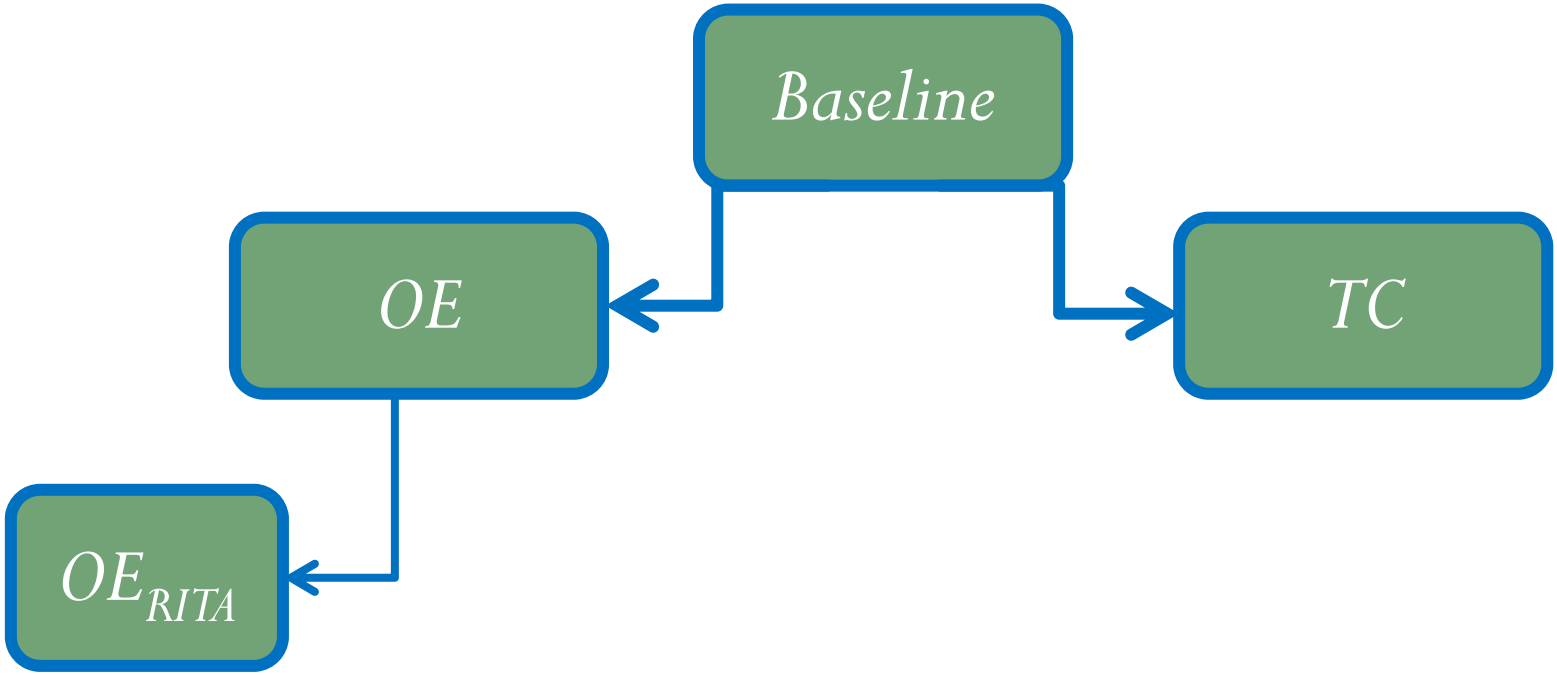

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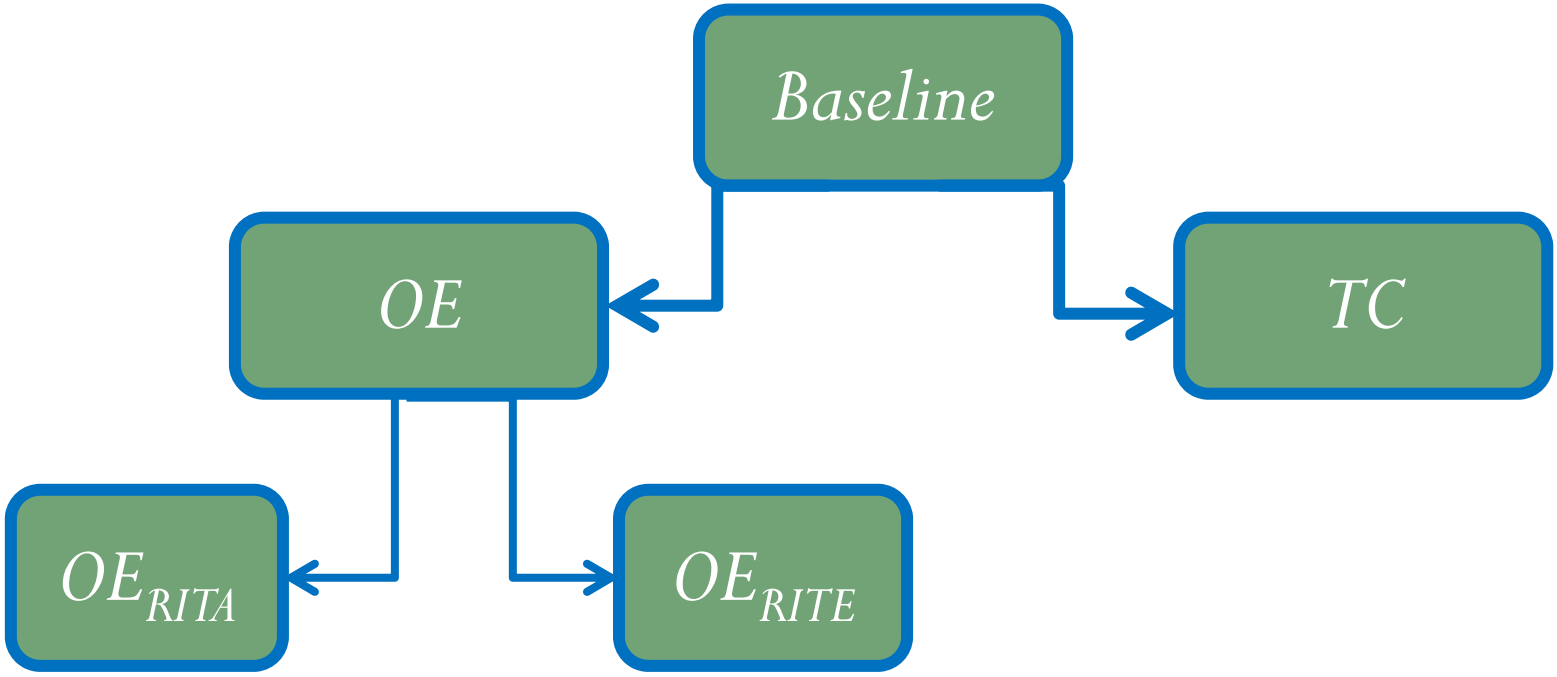

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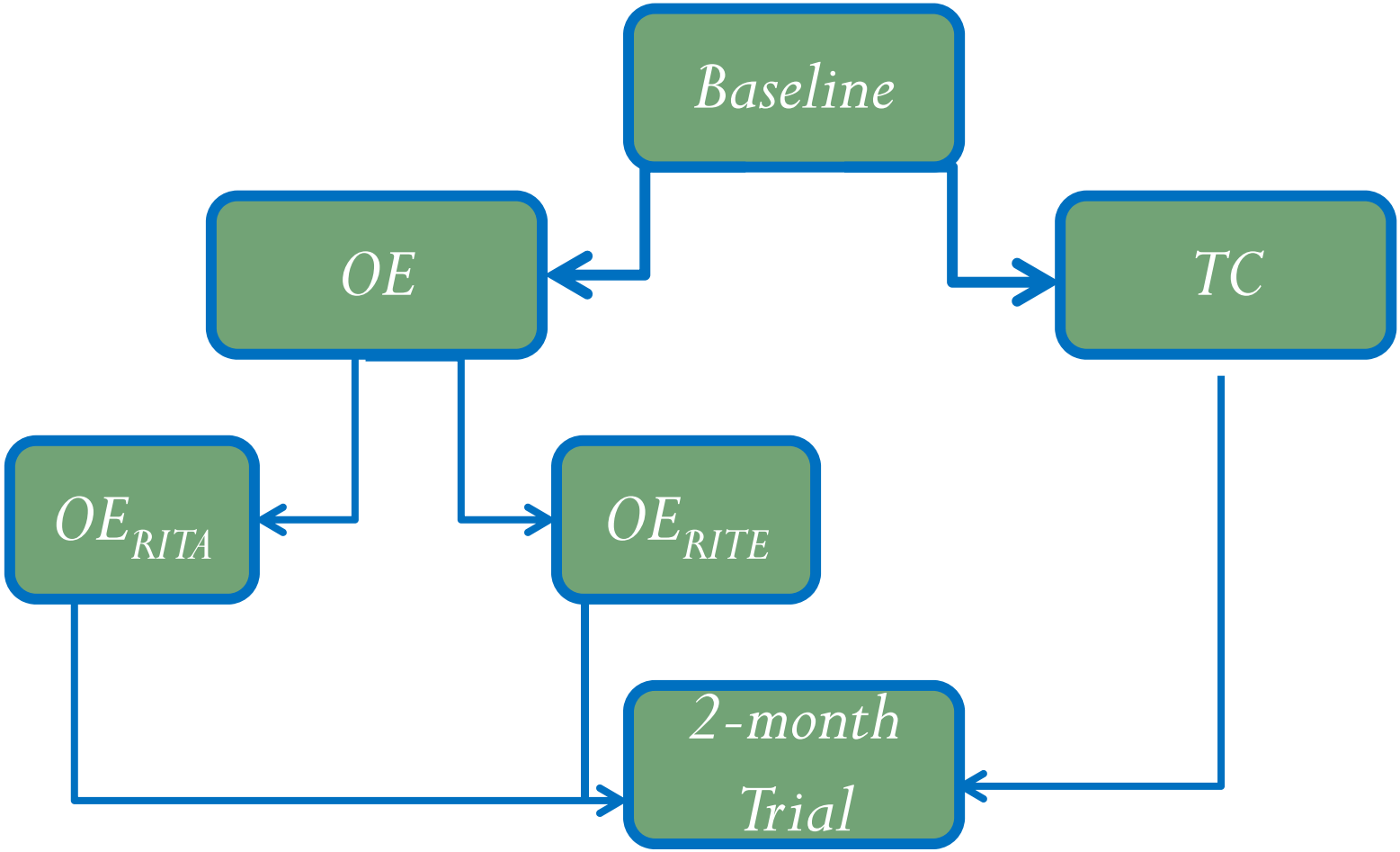

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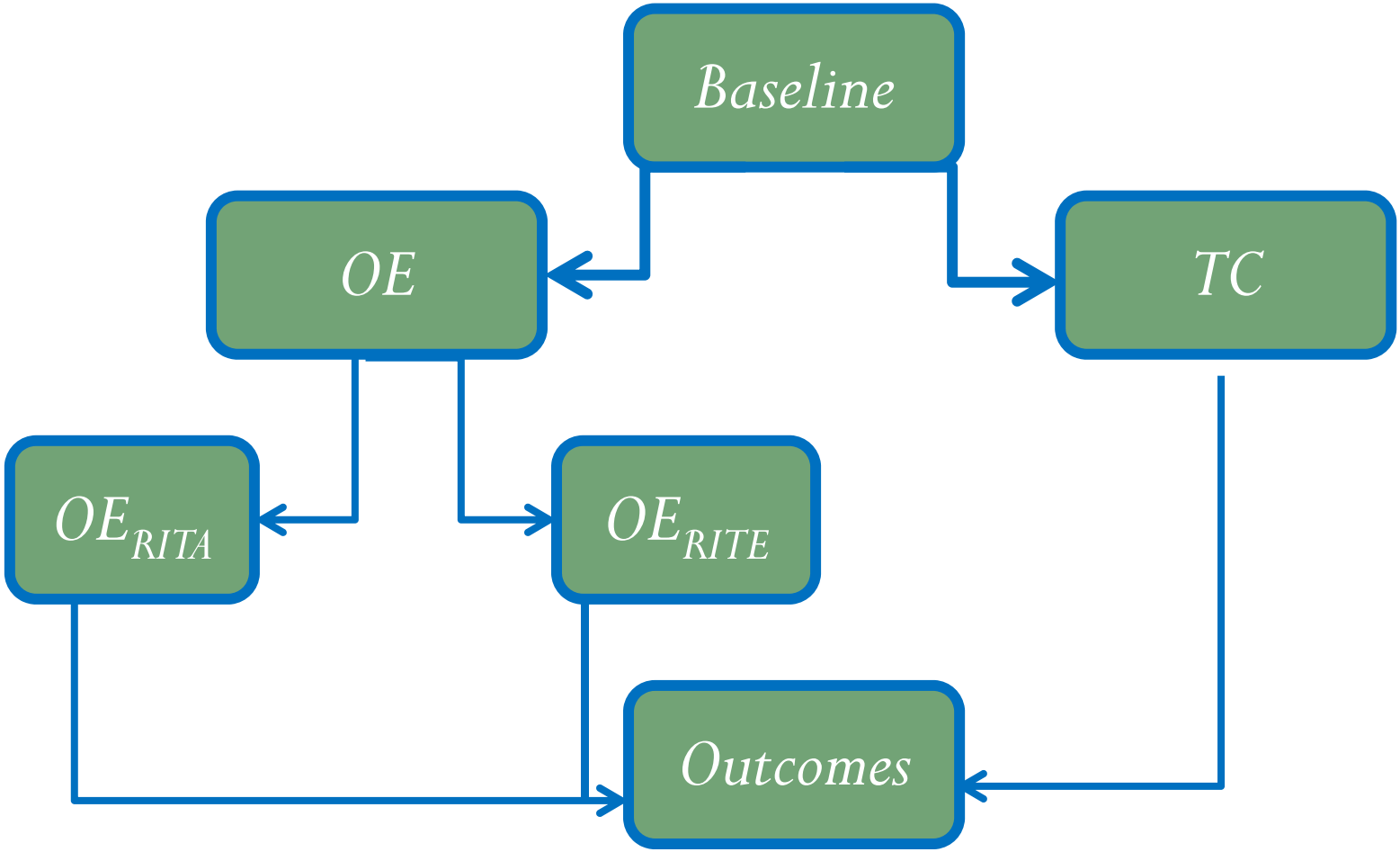

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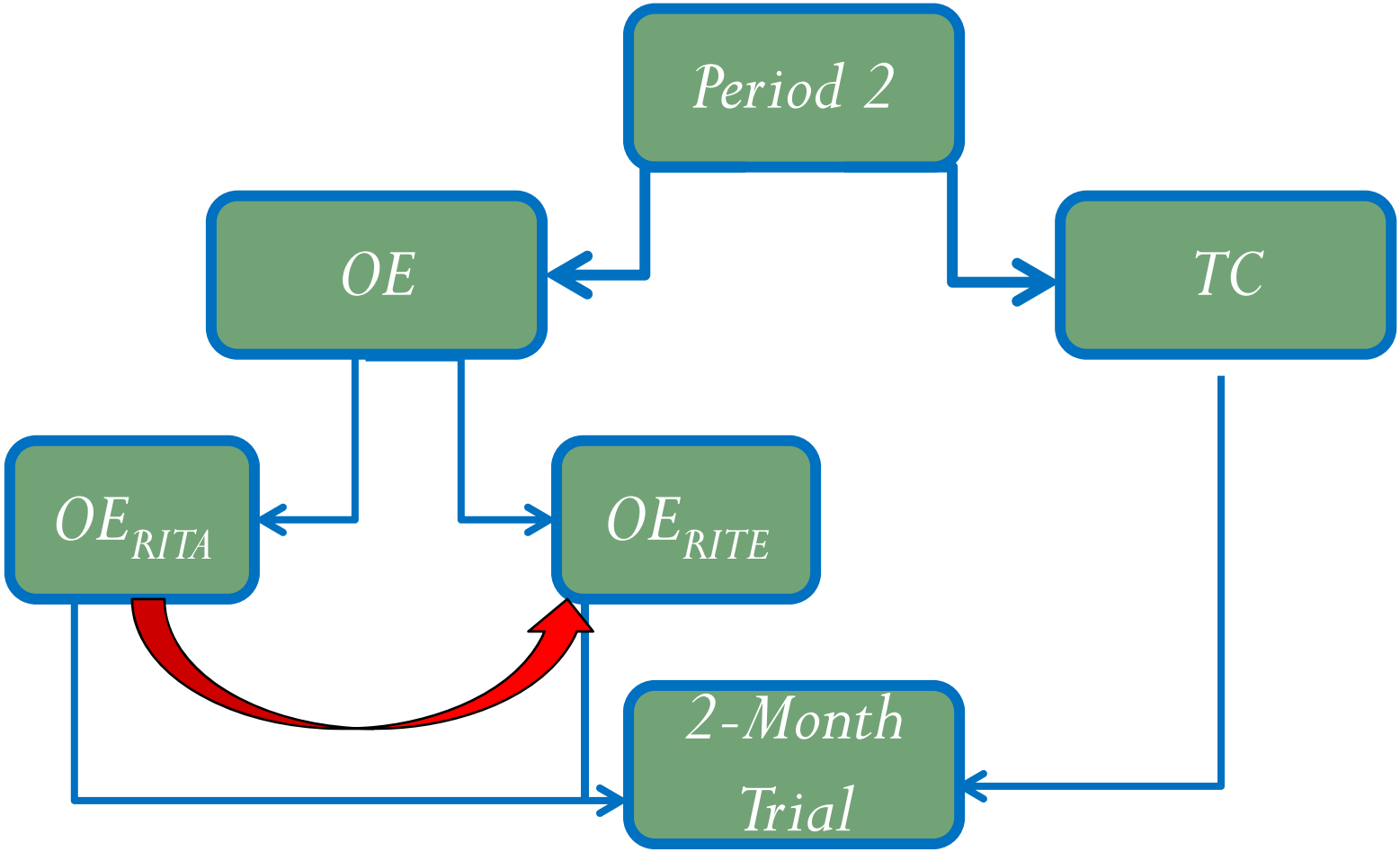

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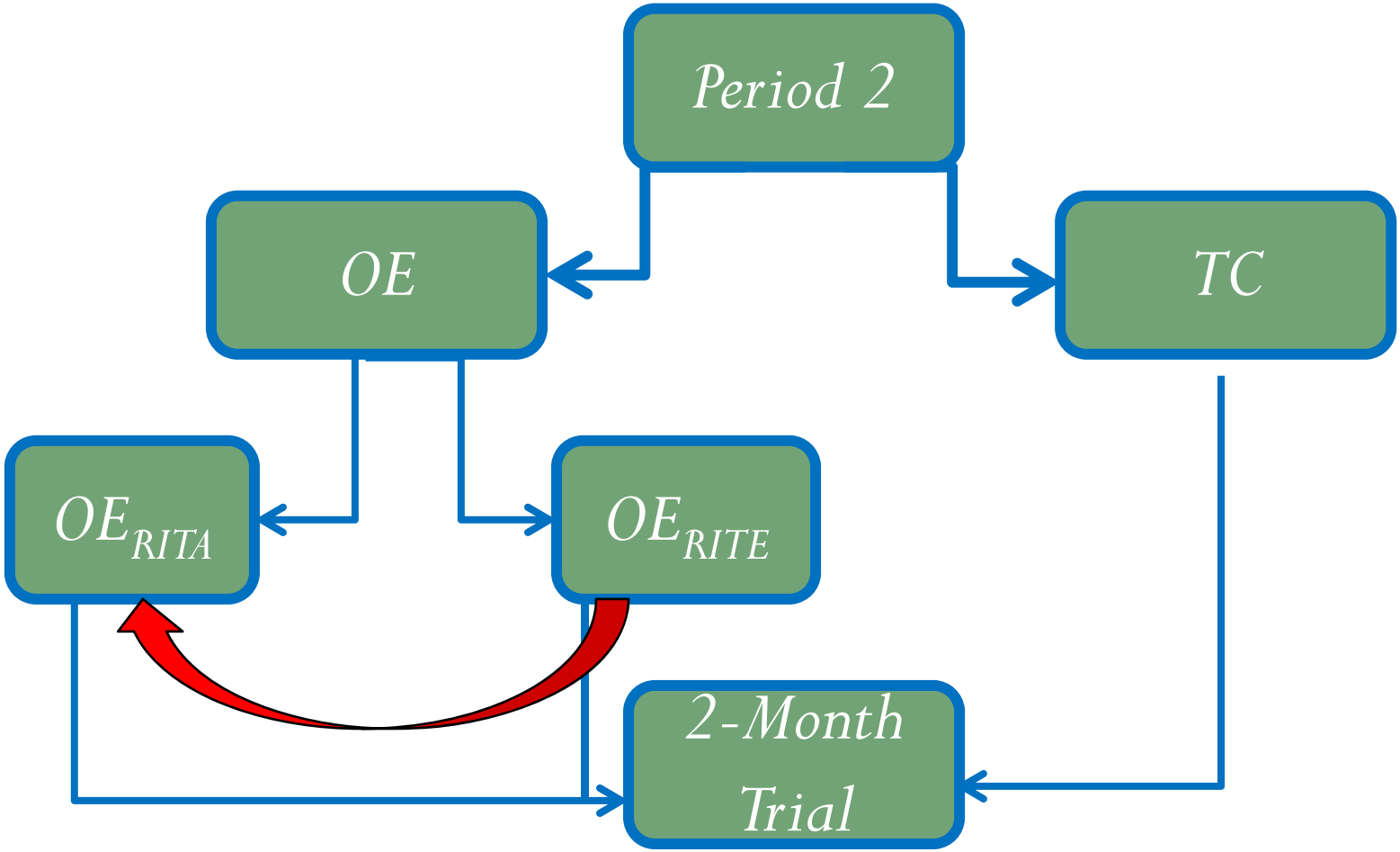

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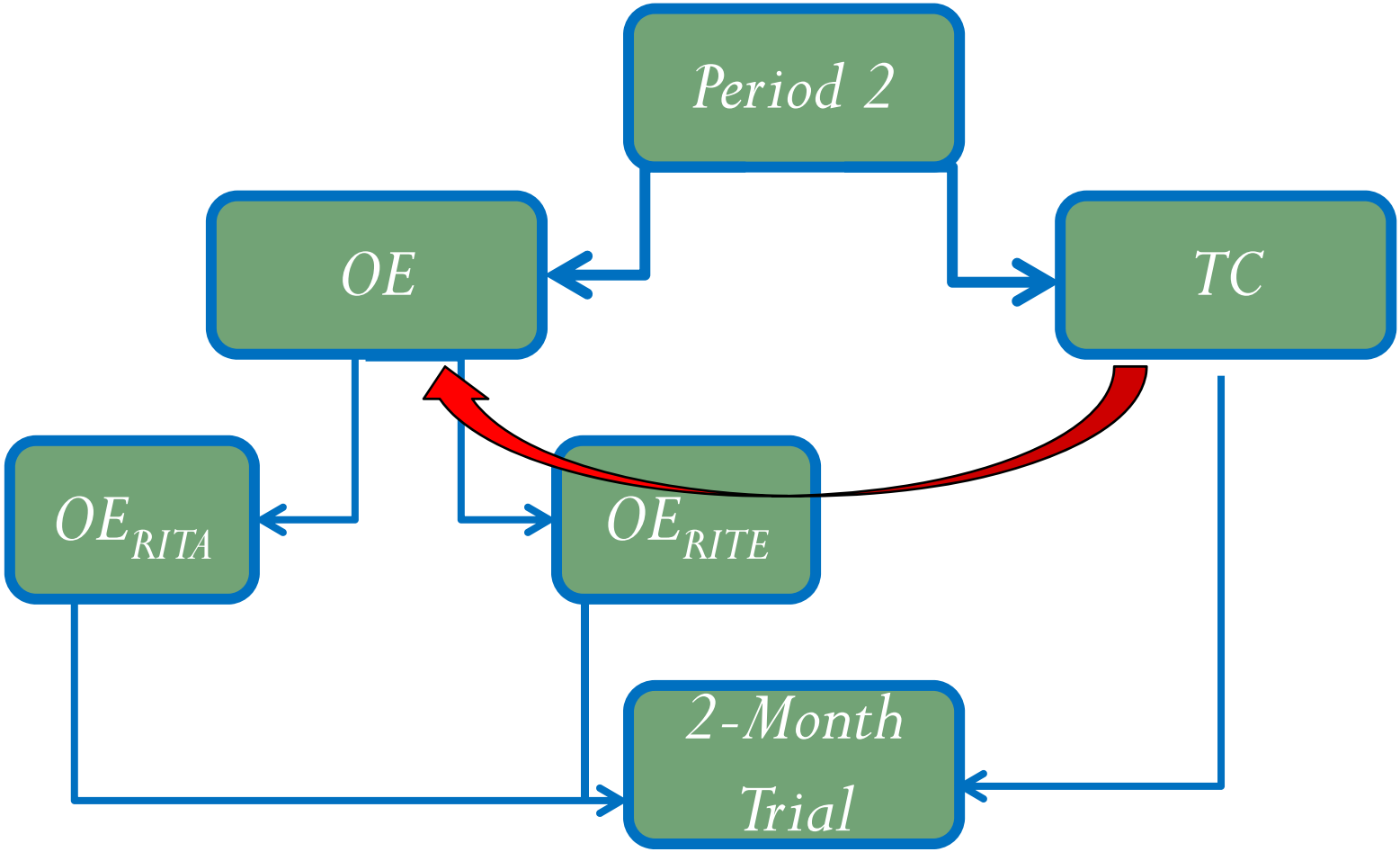

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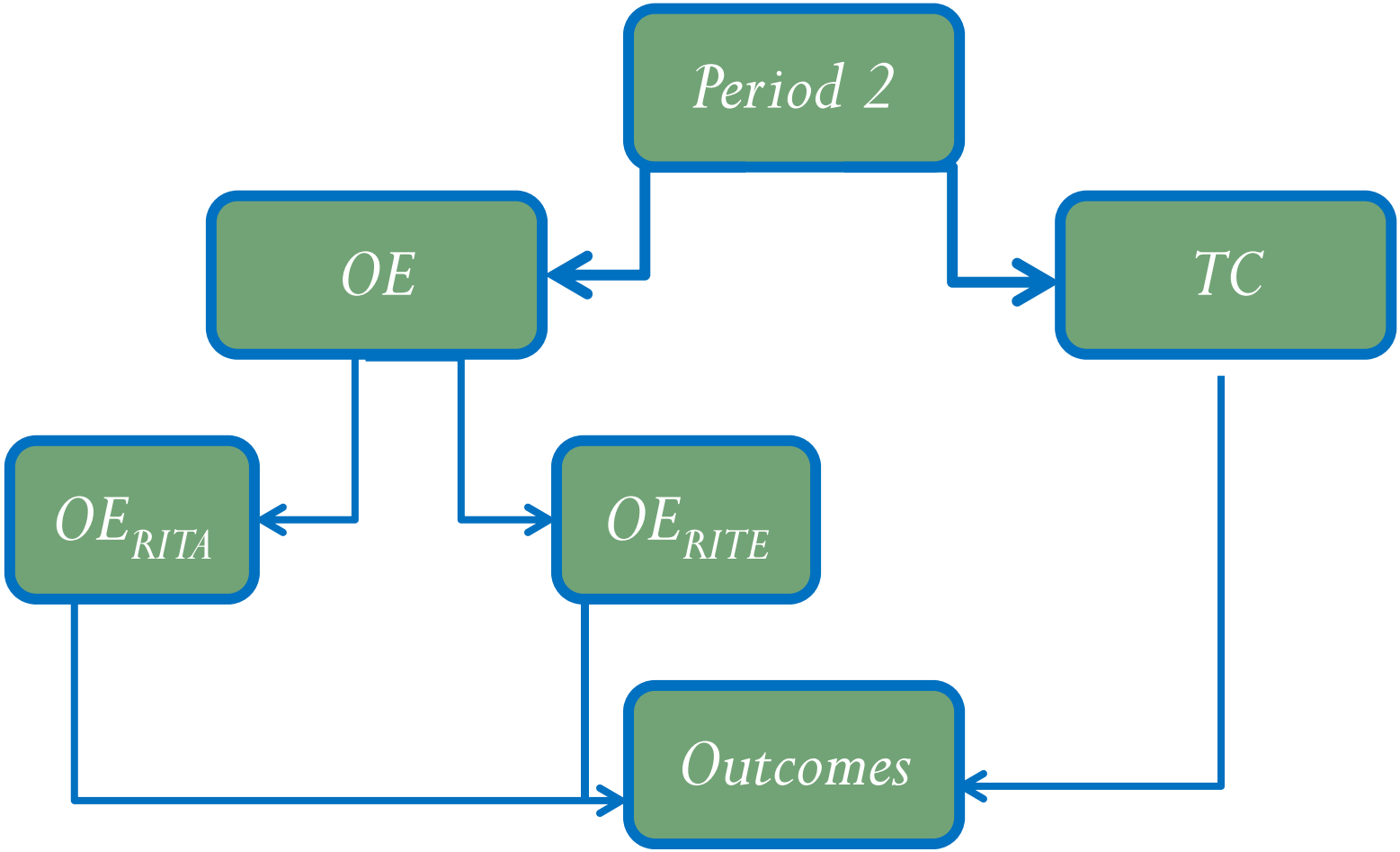

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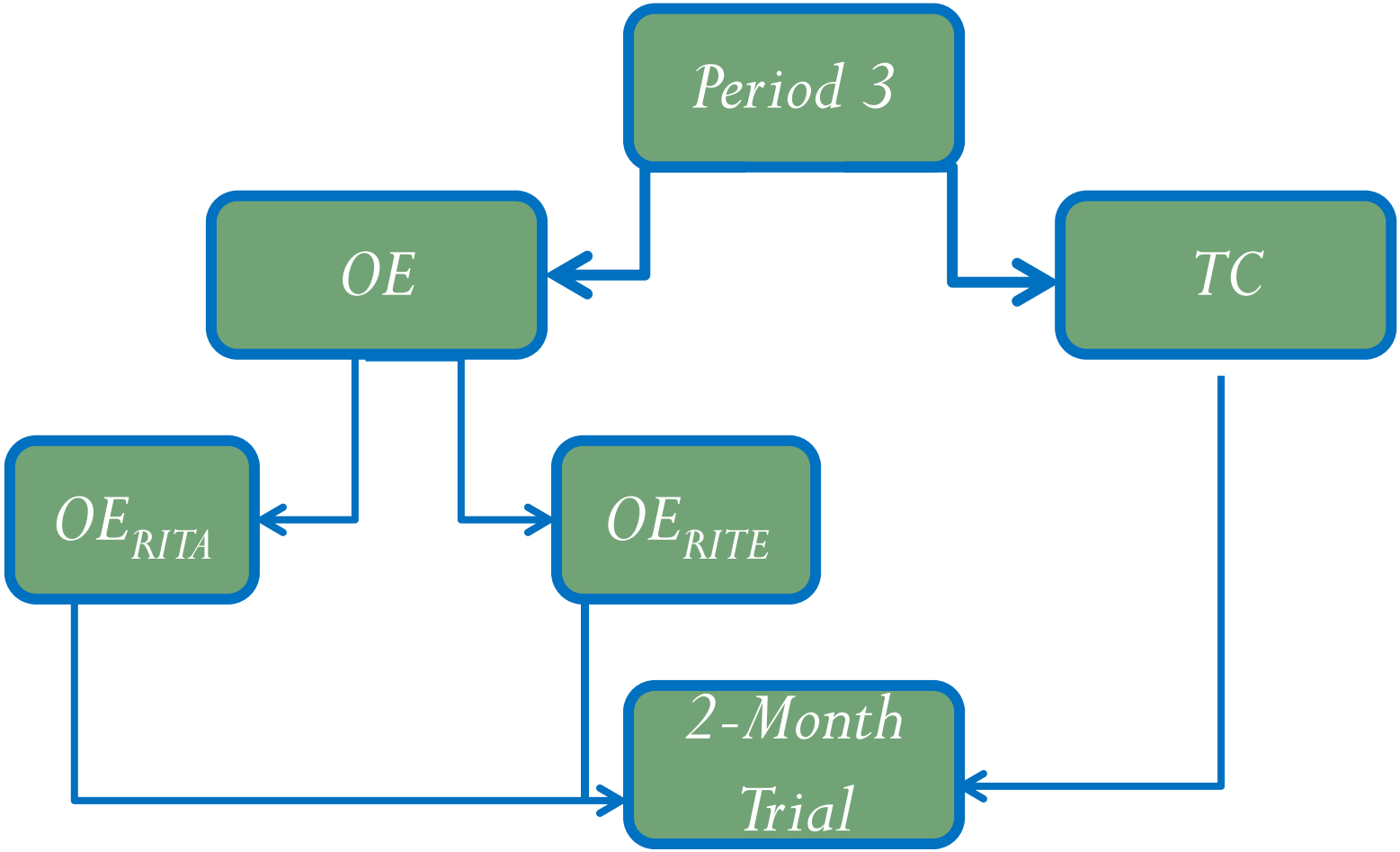

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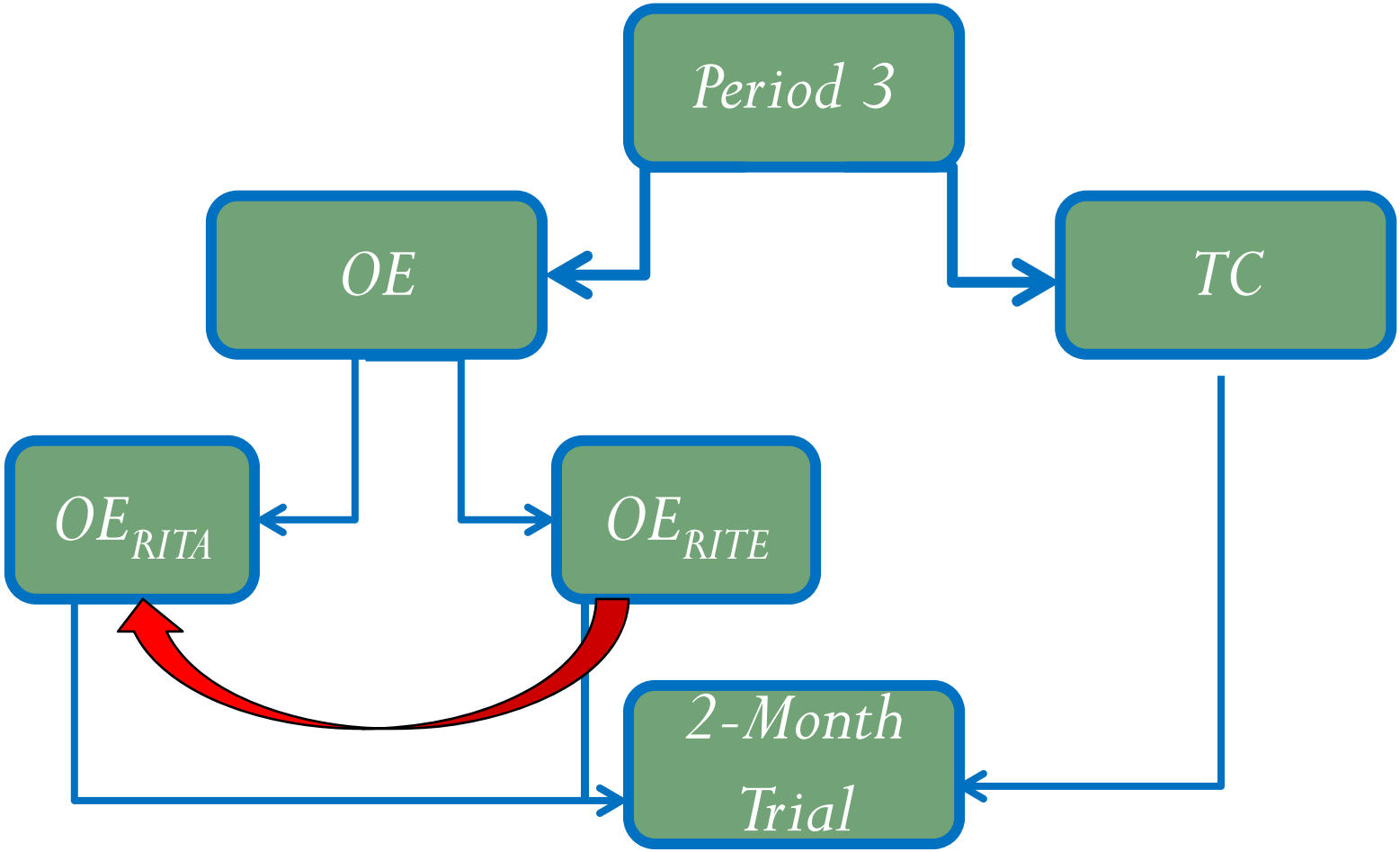

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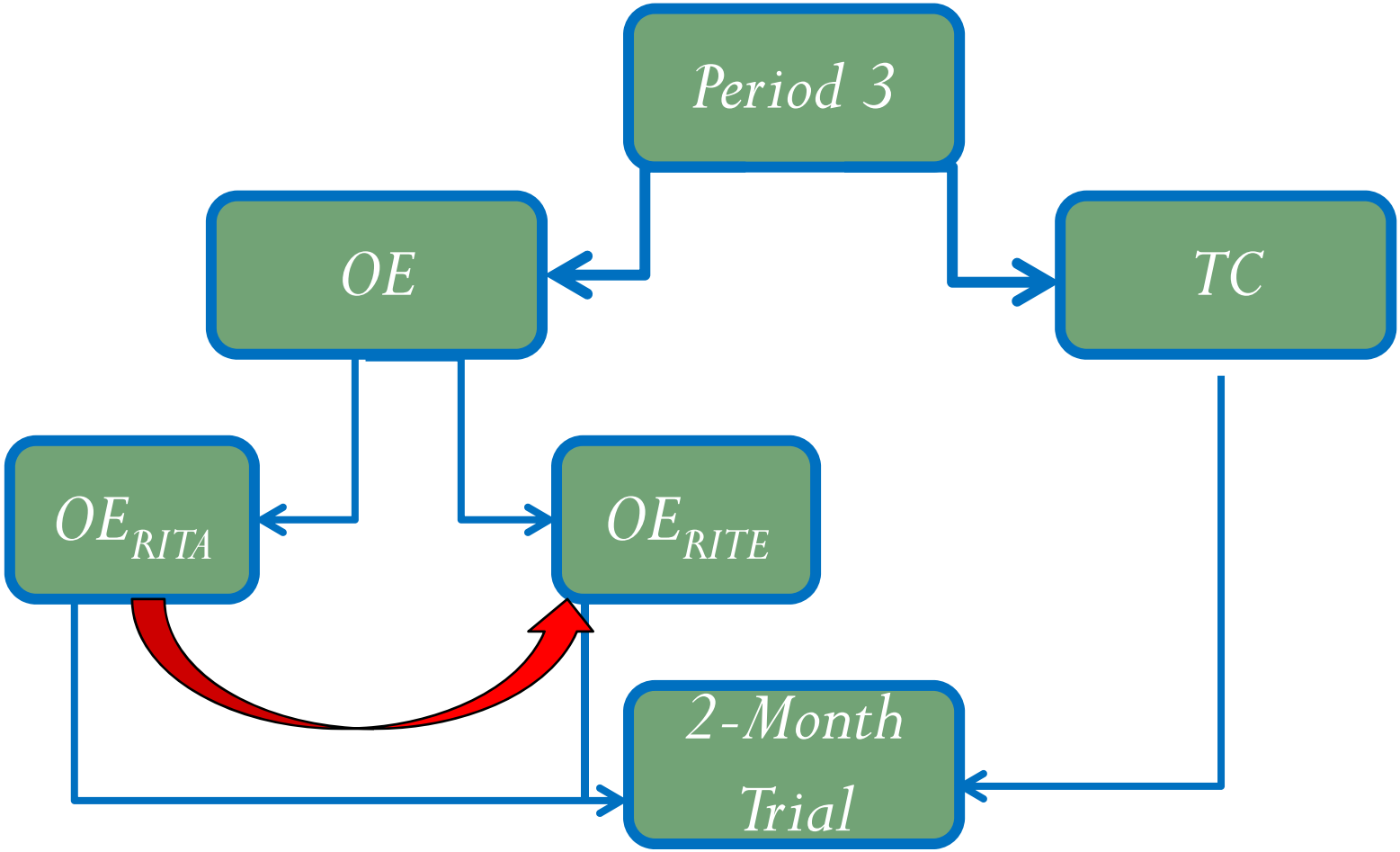

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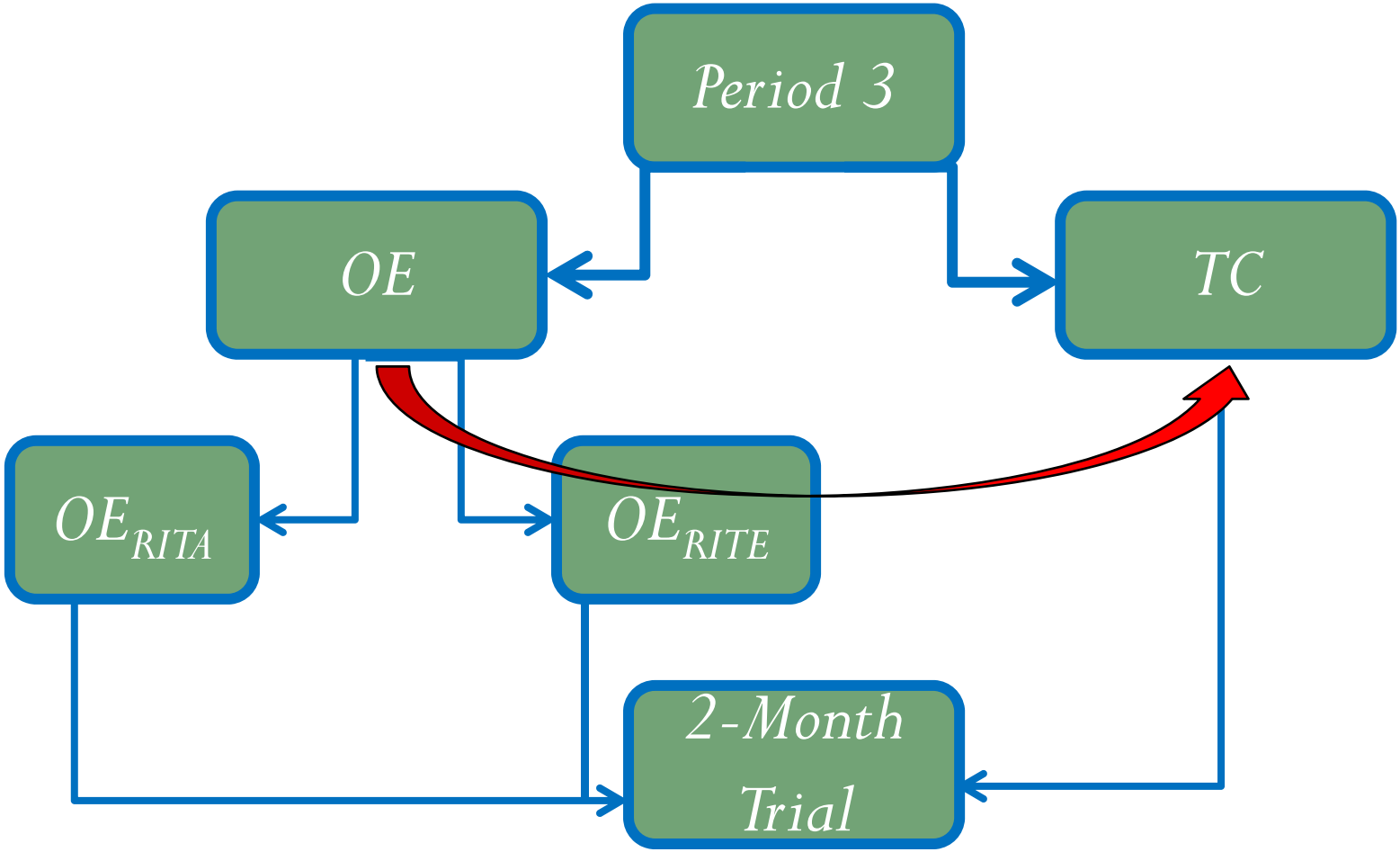

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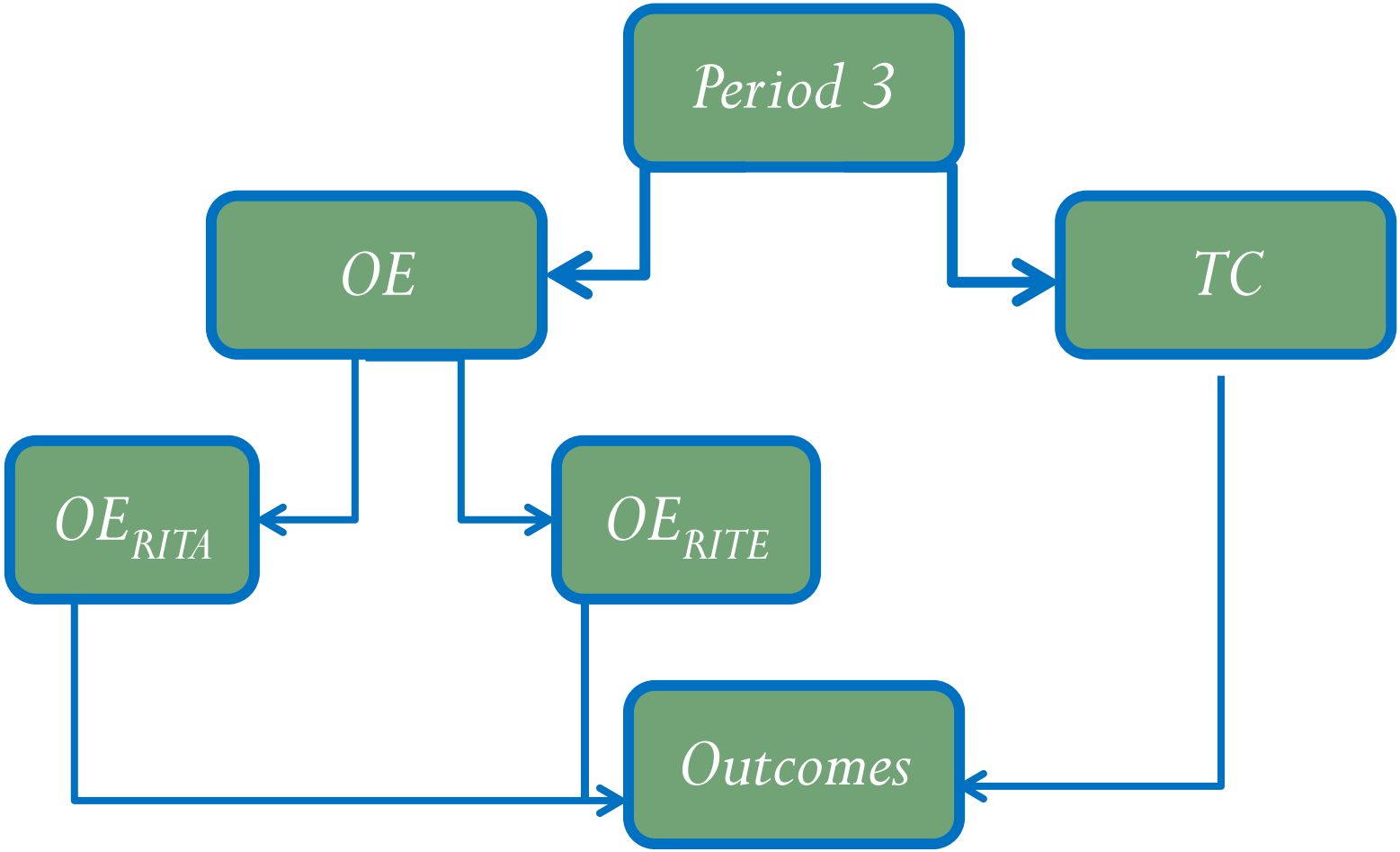
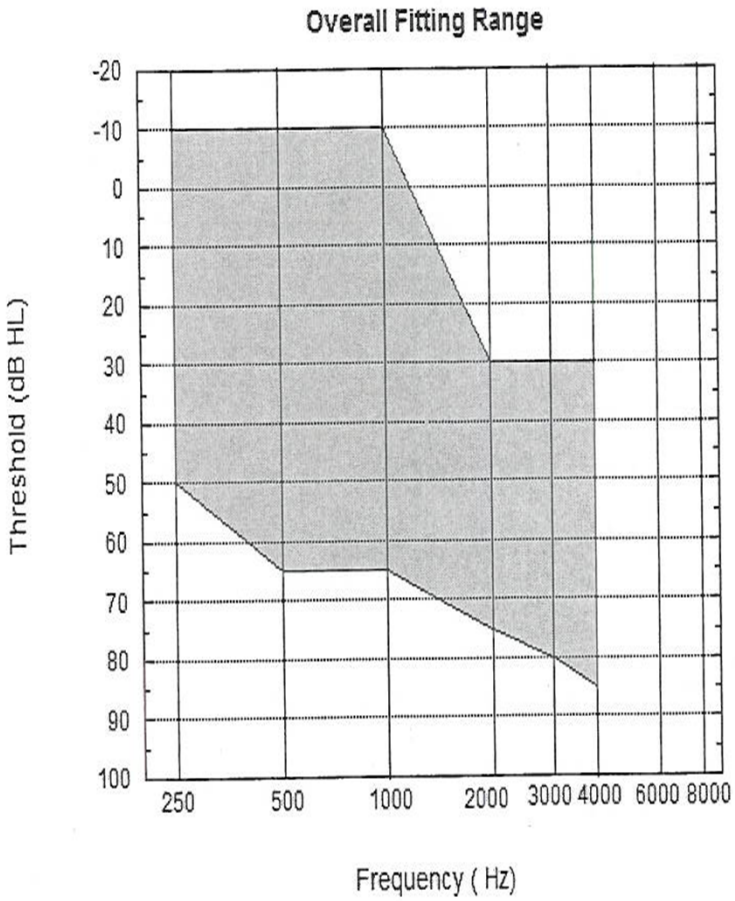


Rank Preferences for Hearing Aid Styles

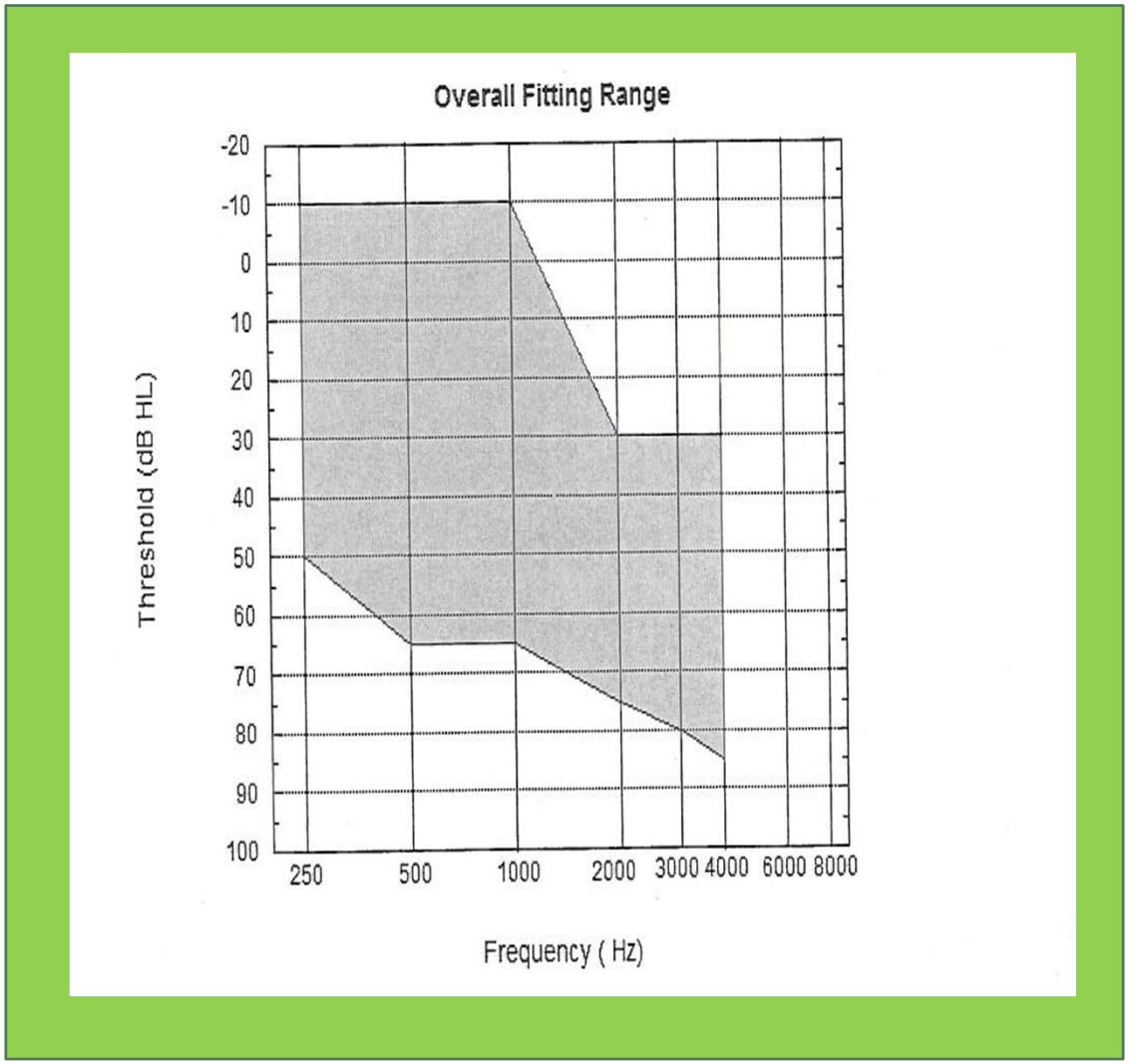
#1 Ranked Style to be Used at End of Study Protocol

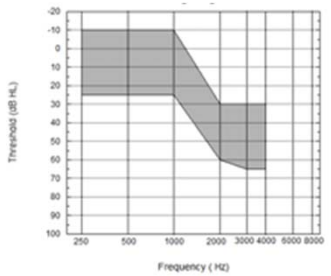
Participant Characteristics
(*n* = 263)

- 255 males, 8 females
- Roughly symmetrical (PTA within 15 dB) SNHL
- 139 New Hearing Aid Users
  - 16 (11.5%) tried hearing aids in last 10 years but had rejected them
- 124 Experienced Hearing Aid Users
  - 1-30 years, mean = 7.82 years
- Age
  - New Hearing Aid Users: 66.35 years (SD = 8.69)
  - Experienced Hearing Aid Users: 70.33 years (SD = 8.49)


Overall Fitting Range
Threshold (dB HL)
-20
-10
0
10
20
30
40
50
60
70
80
90
100
250
500
1000
2000
3000
4000
6000
8000
Frequency (Hz)

Recruited to fit into 1 of 3 Hearing Loss Groups





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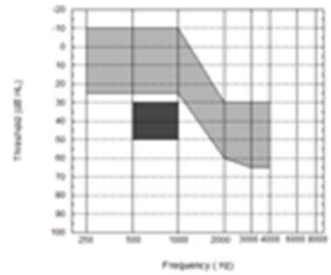

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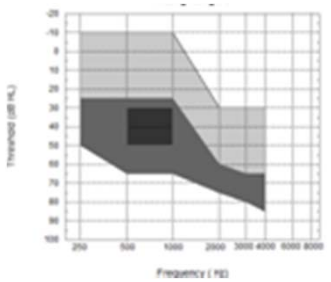

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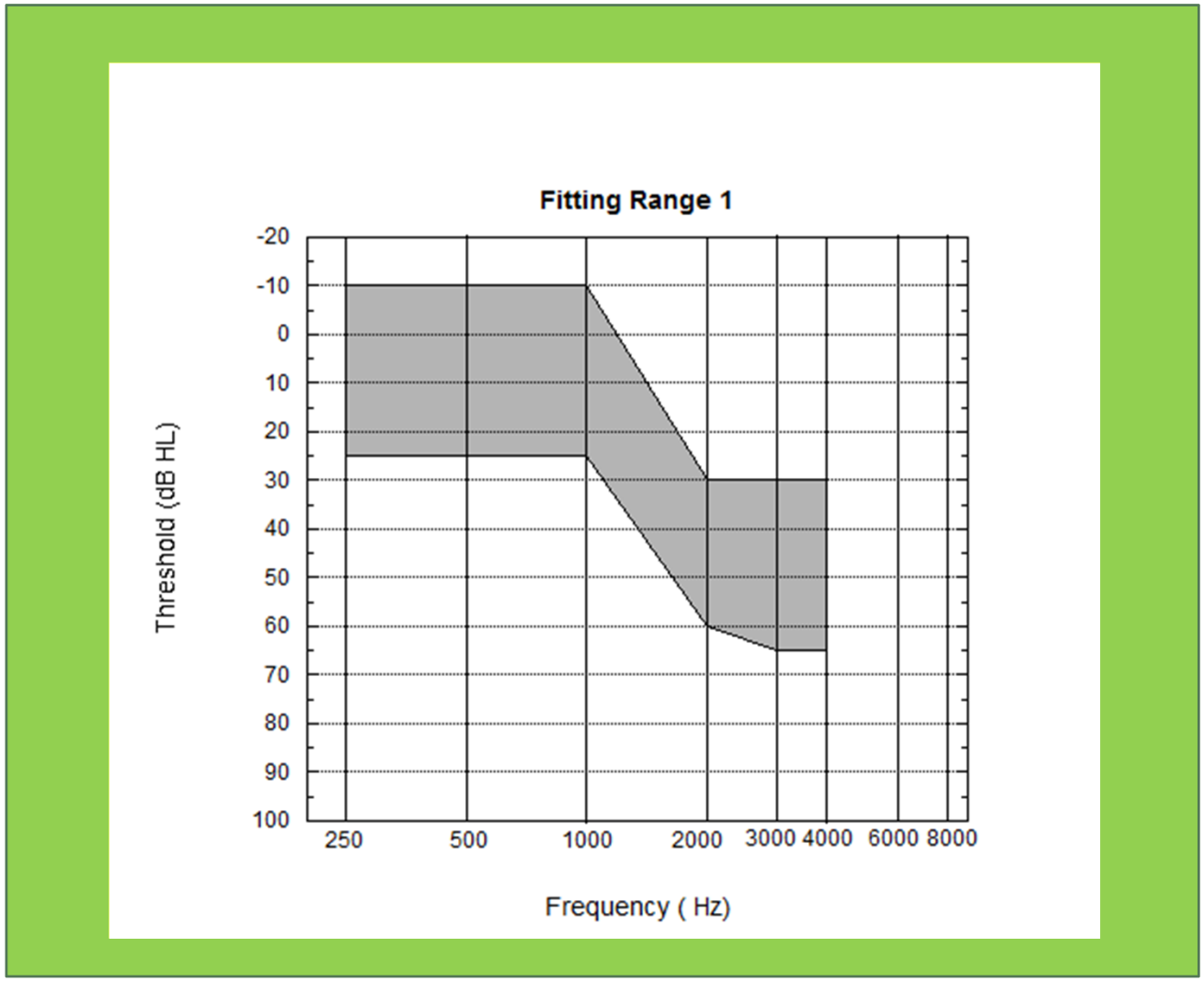
Group 1 Fitting Range

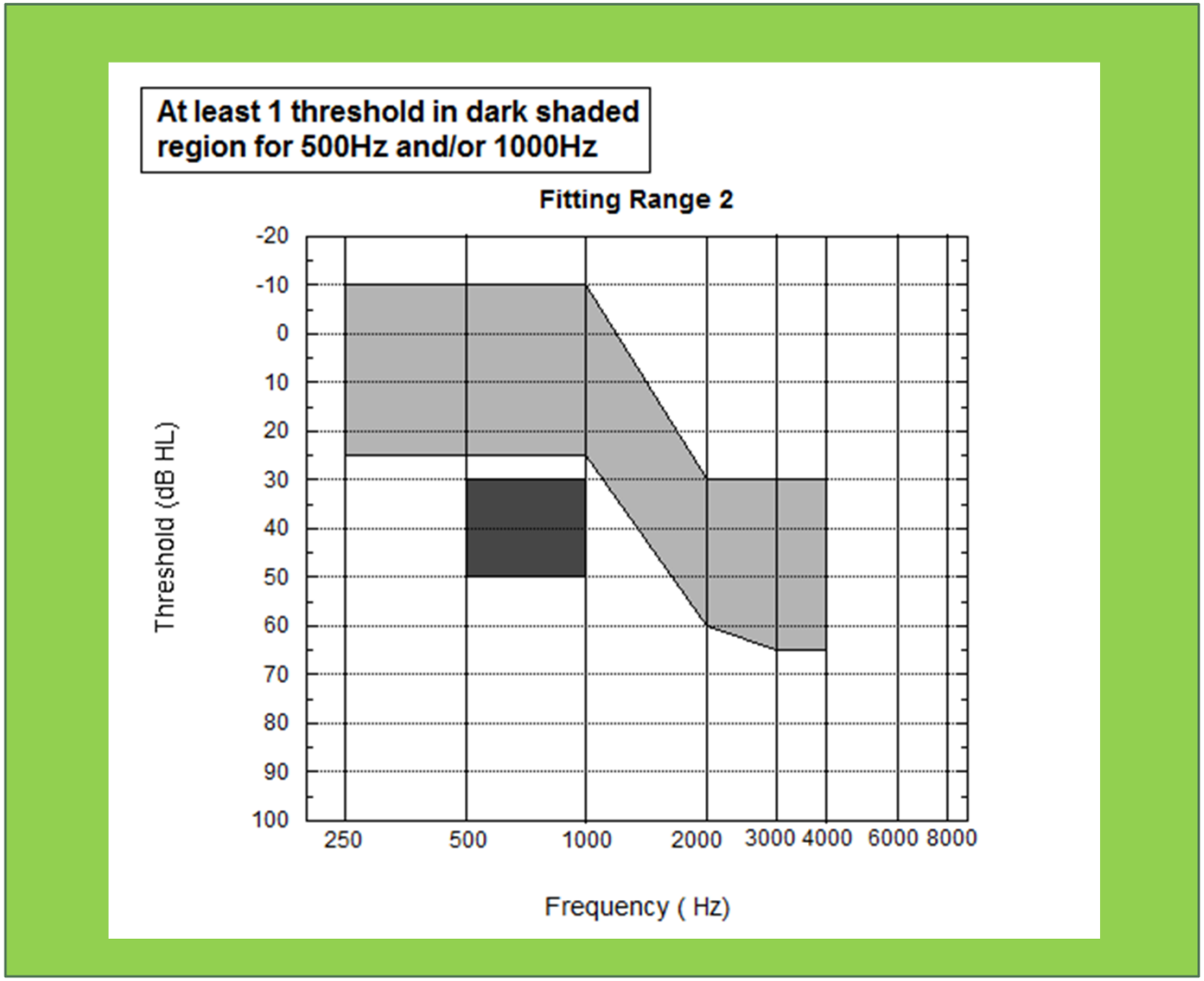
n = 61 (43 New; 18 Experienced)



V1

Group 2 Fitting Range

n = 62 (39 New; 23 Experienced)

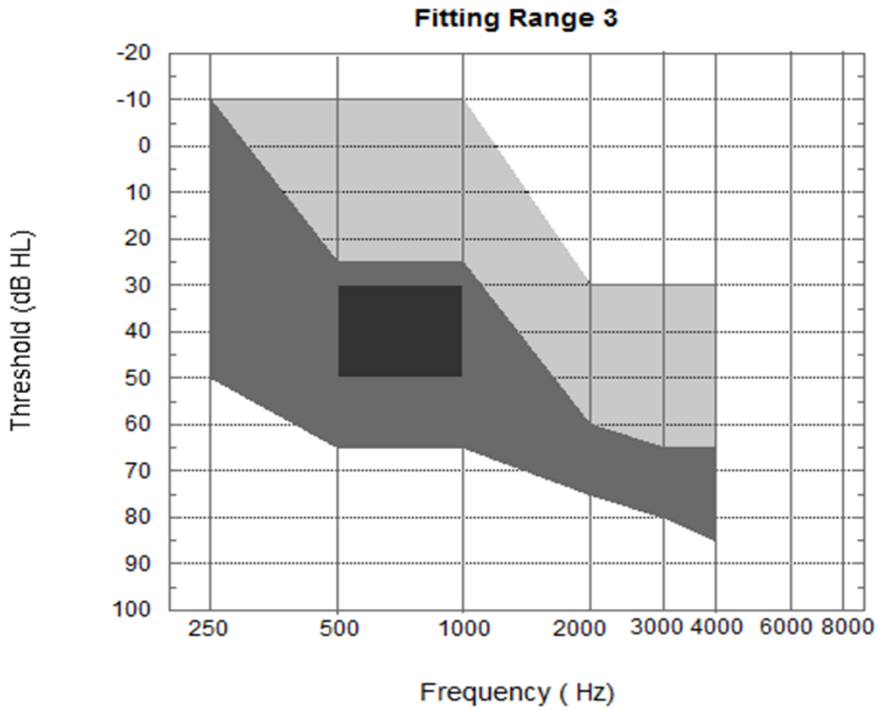


Slide 35

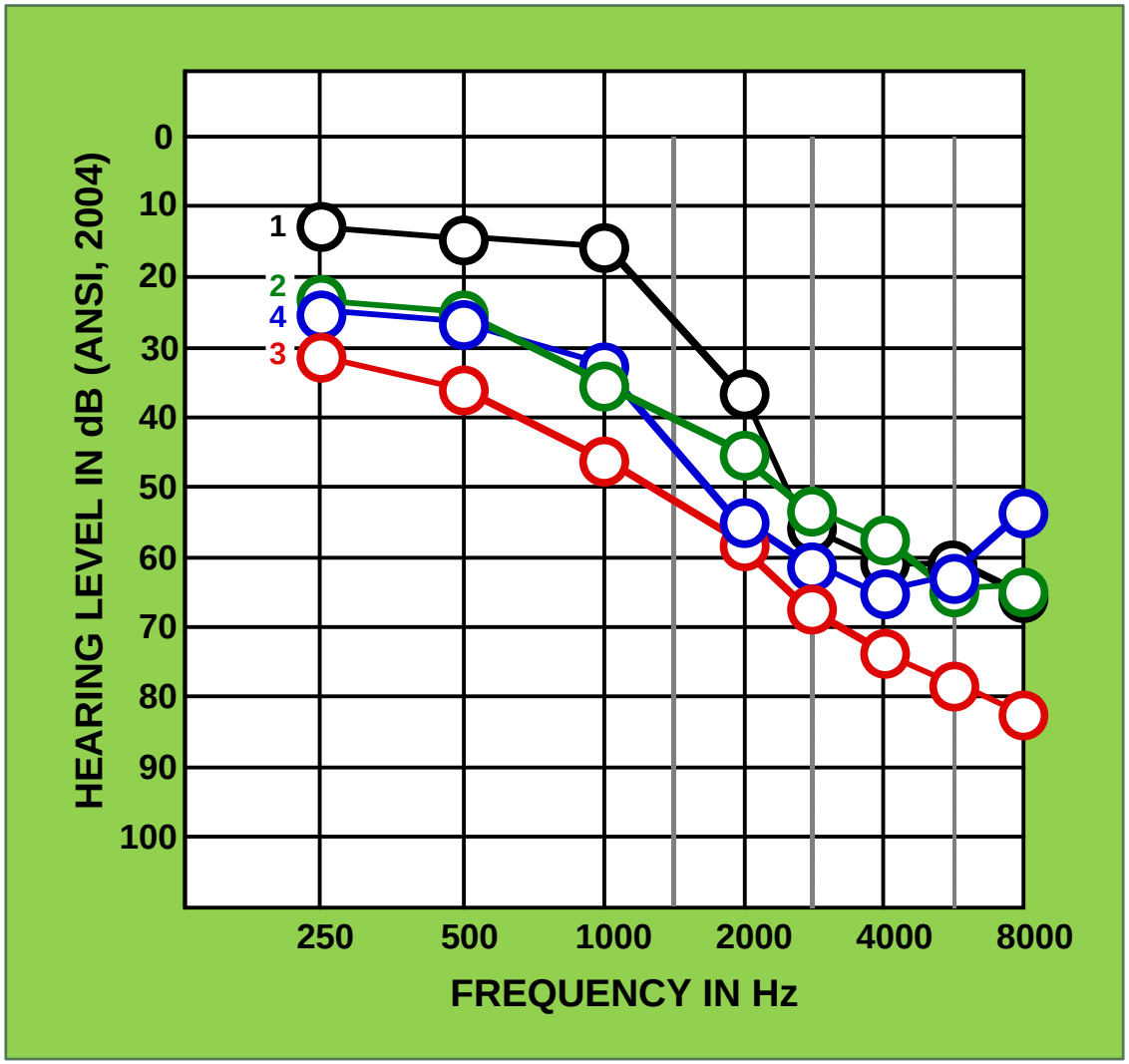
V1 a space is needed between 500 and Hz; likewise between 1000 and Hz
VHAMOUWILSOR; 13.02.2010

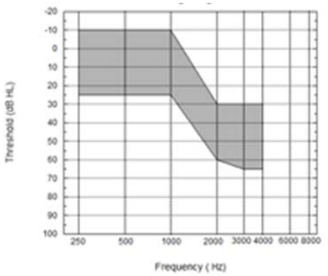
Group 3 Fitting Range

n = 82 (28 New; 54 Experienced)



At least 1 threshold in the dark shaded box for 500Hz and/or 1000Hz and at least 3 thresholds in the lower region


HEARING LEVEL IN dB (ANSI, 2004)
0
10
20
30
40
50
60
70
80
90
100
1
2
4
3
250
500
1000
2000
4000
8000
FREQUENCY IN Hz



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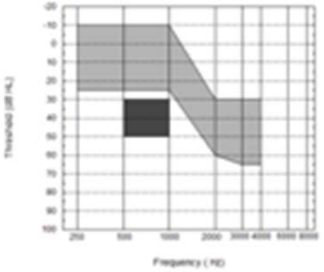

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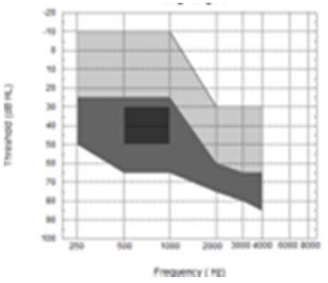

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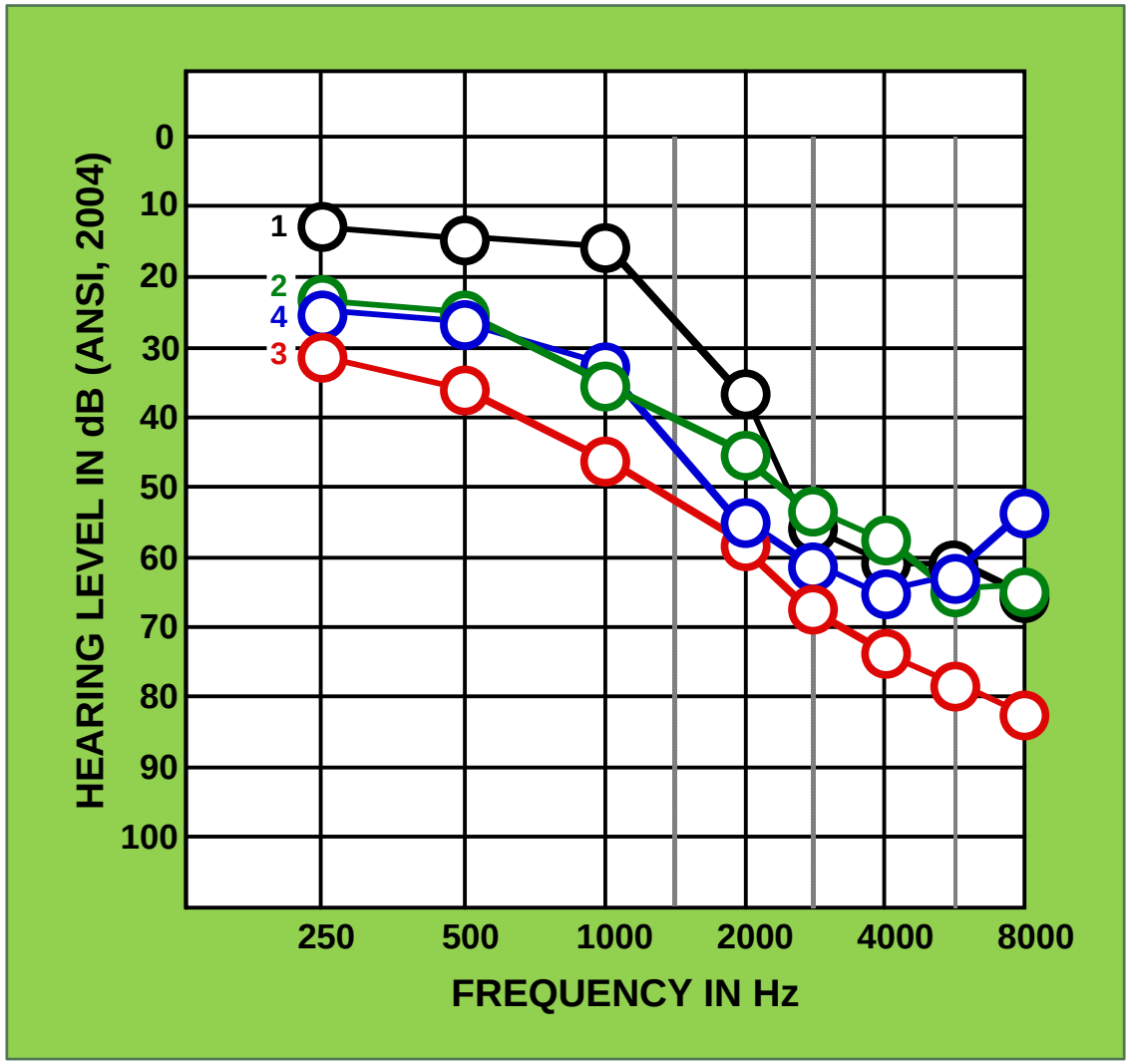
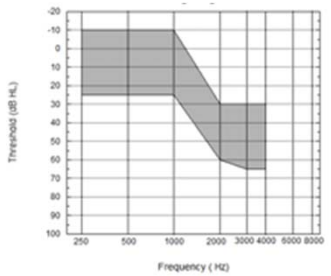
Group 4 (Other)

n = 58 (29 New; 29 Experienced)





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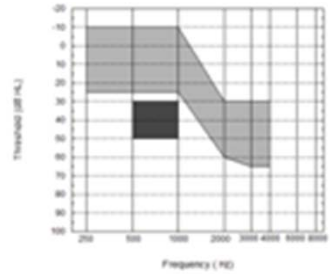

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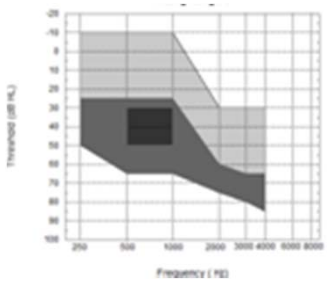

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Hearing Aids

1. Maintaining consistency of circuit type across the three styles
2. Feedback control system that would maximize ability to meet/approximate target in open fit configuration.

- Traditional Custom
  - Starkey Destiny 1200

Hearing Aids

- OE_{RITA}
  - Destiny 1200 mini or full BTE, fit with slim tubing and open dome

- OE_{RITE}
  - Zon .7, fit with open dome

Hearing Aids

- Set to dynamic mode, other noise reduction features disabled
- Any manual controls disabled
- Telephone program options individually selected
- Goal: Match REAR (65dB input, DigSpeech) to NAL-NL1 REAR targets

Best Fit vs. User Fit

- Some patients prefer gain settings lower than NAL-NL1 target
- In these cases, gain reductions made to the patient preferred levels
- Documented “best fit” (closest to NAL-NL1 prior to feedback) and “user fit” (as worn)
- Preliminary data for Best Fit (*n* = 111 participants)


Target
RITE
RITA
TC

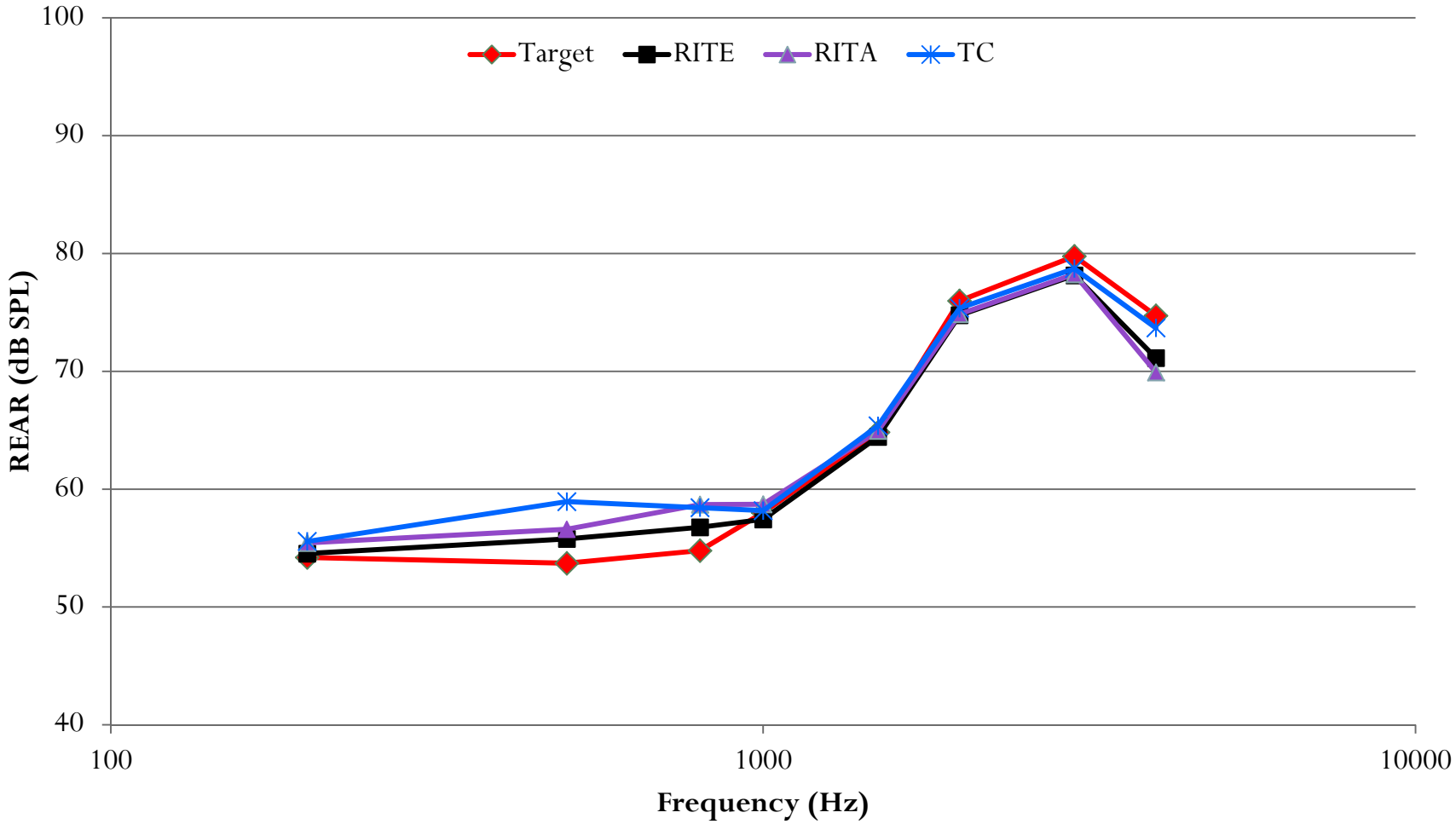

Target
RITE
RITA
TC


Target
RITE
RITA
TC

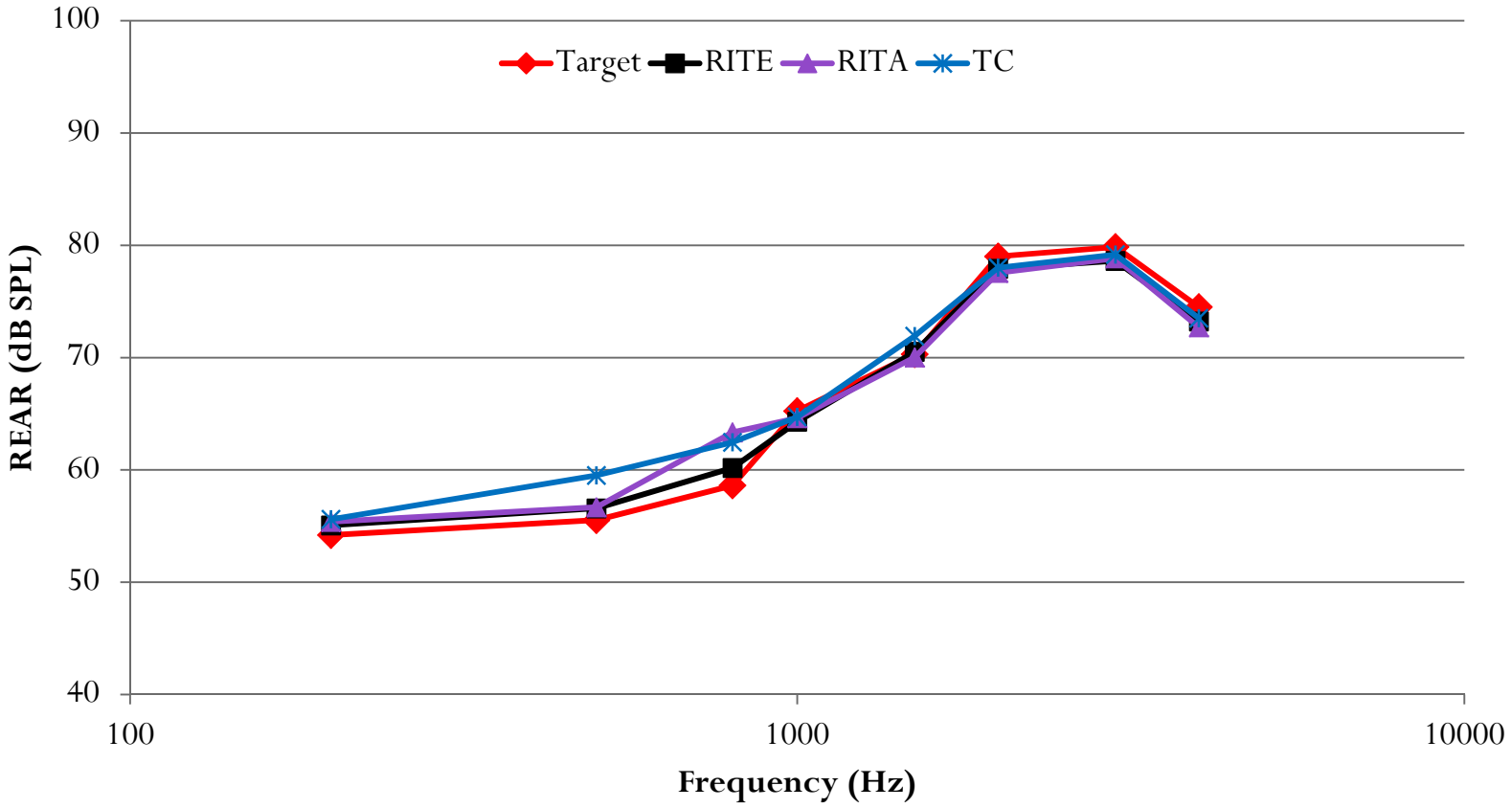

Target
RITE
RITA
TC


Target
RITE
RITA
TC

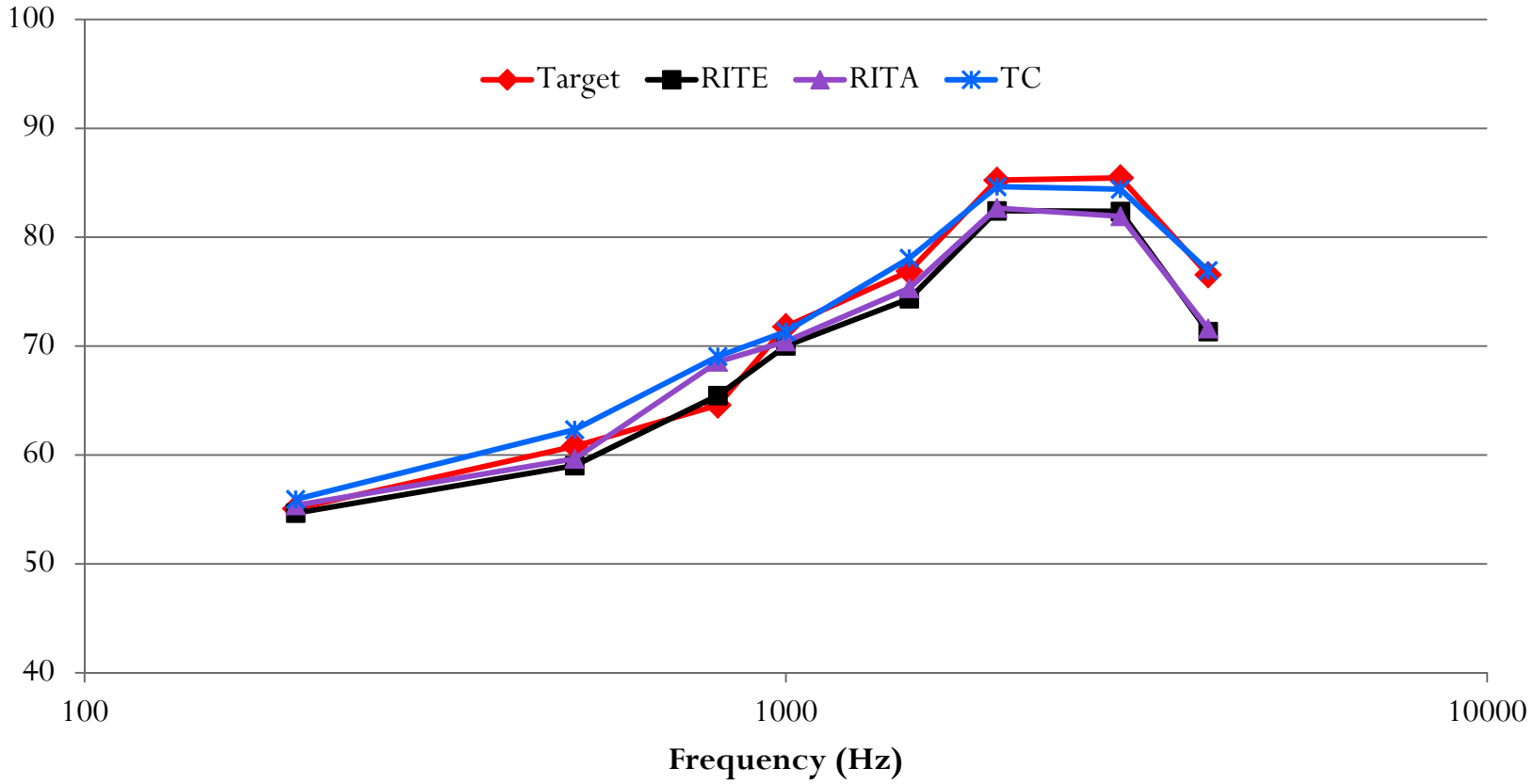
Group 1 REAR


100
90
80
70
60
50
40
REAR (dB SPL)
Target
RITE
RITA
TC
100
1000
10000
Frequency (Hz)

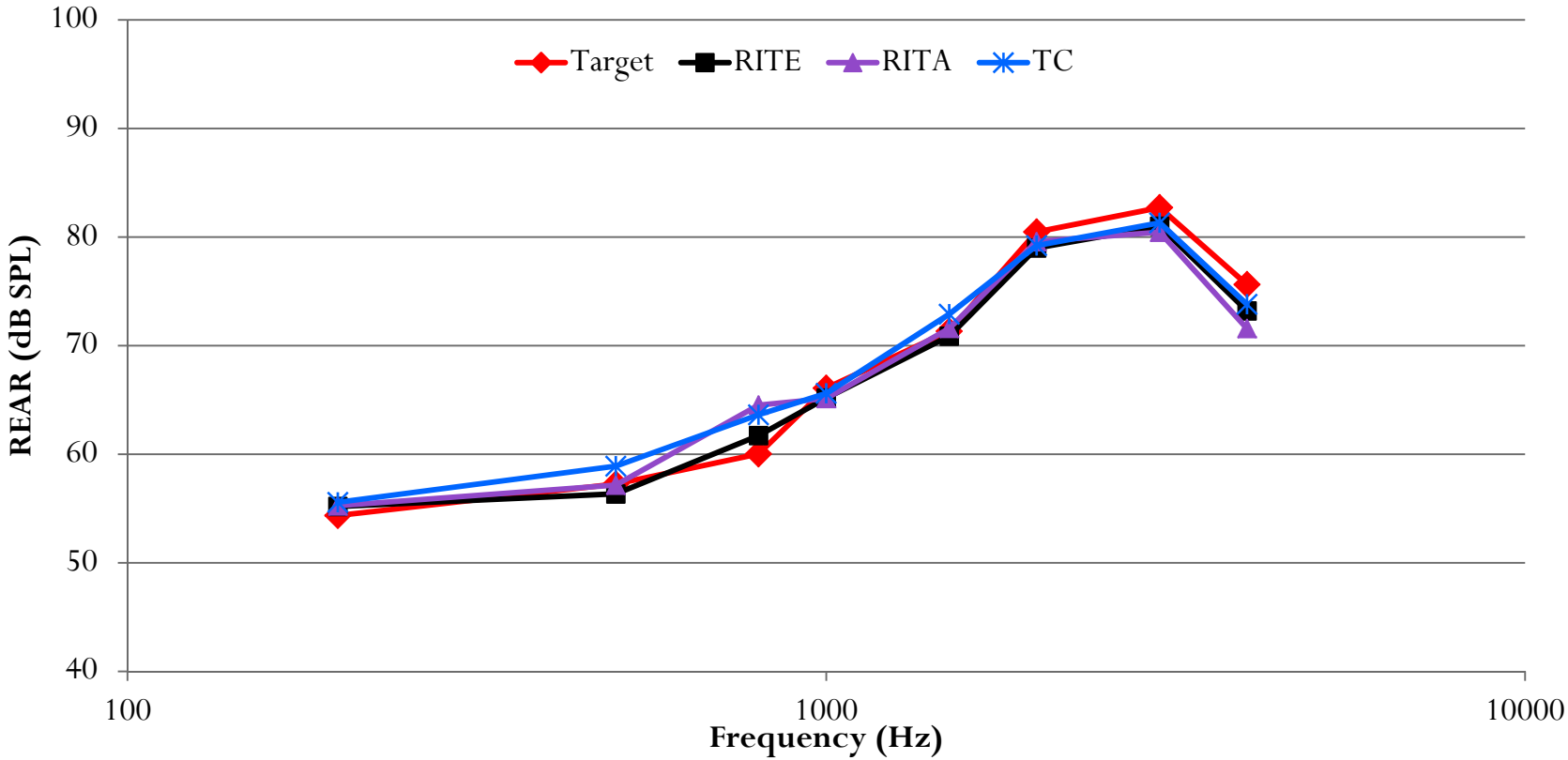
Group 2 REAR


100
90
80
70
60
50
40
REAR (dB SPL)
Target
RITE
RITA
TC
100
1000
10000
Frequency (Hz)

Group 3 REAR


100
90
80
70
60
50
40
Target
RITE
RITA
TC
100
1000
10000
Frequency (Hz)

Group 4 REAR


100
90
80
70
60
50
40
REAR (dB SPL)
Target
RITE
RITA
TC
100
1000
10000
Frequency (Hz)

All 3 Hearing Aid Styles

- Able to fit a wide range of hearing loss with appropriate match to target
- Can match to target through 3000 Hz
- Open-fit BTE's may undershoot at 4000 Hz, we could frequently meet target even with substantial hearing loss

Outcome Measures

- **Subjective**
  - Style Preference Survey (SPS; Smith, et al., *JAAA*, in press)
- **Objective**
  - Words-in-Noise (WIN; Wilson 2003)
    - Aided SNR-50
- **Preferred Hearing Aid Style**

Subjective Outcomes

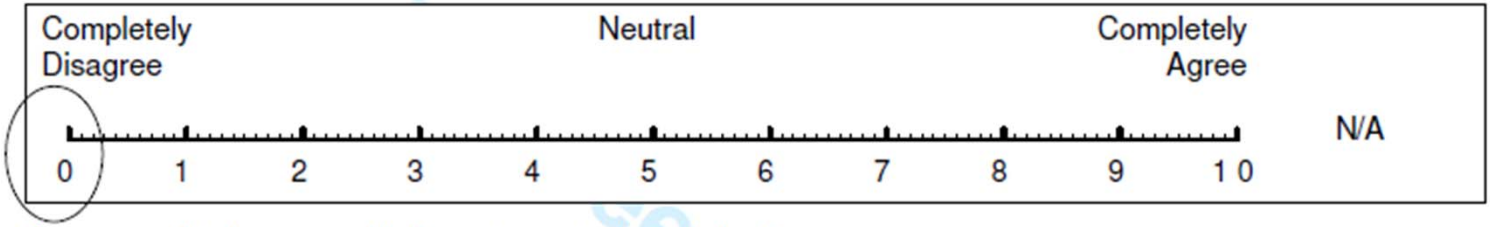
Style Preference Survey

Style Preference Survey

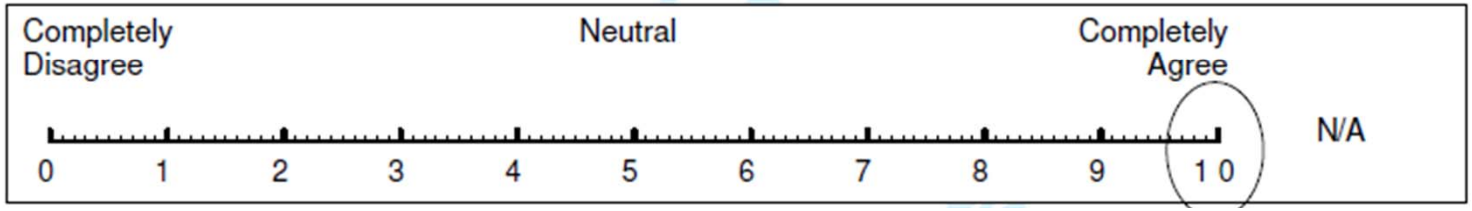
- 35 items encompassing five subscales related to:
  - (1) Fit, Comfort, and Cosmetics
  - (2) Localization
  - (3) Ease of Use
  - (4) Subjective Occlusion/Own Voice Effects
  - (5) Feedback

Style Preference Survey

Please read each question carefully. Circle a number from 0 to 10 that best represents your agreement with the statement made.
If you completely disagree with the statement, then circle 0.

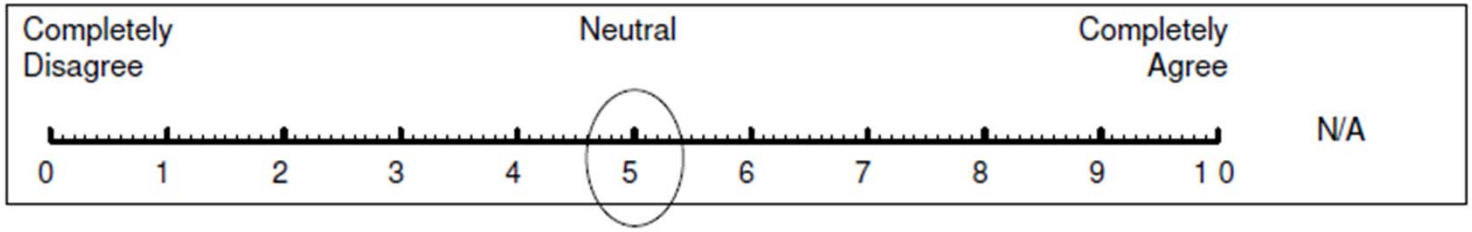


If you completely agree with the statement, then circle 10.

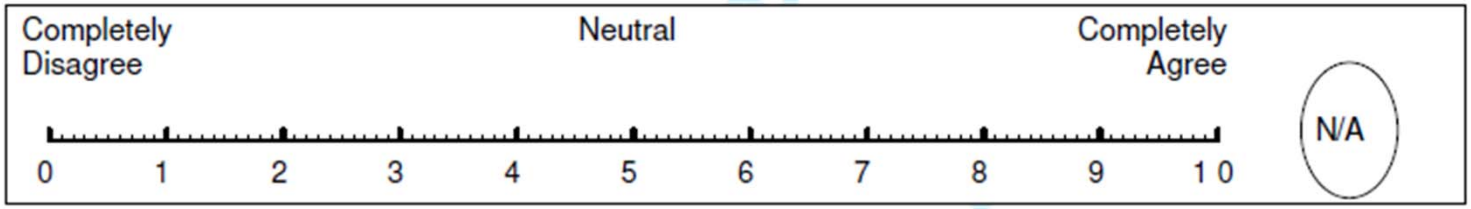


Style Preference Survey

If you neither agree or disagree, then circle 5.



Style Preference Survey



Style Preference Survey

- 35 items encompassing five subscales related to:
  - (1) Fit, Comfort, and Cosmetics
  - (2) Localization
  - (3) Ease of Use
  - (4) Subjective Occlusion/Own Voice Effects
  - (5) Feedback

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  - (4) Subjective Occlusion/Own Voice Effects
  - (5) Feedback
    - No significant main effects or interactions
    - Feedback algorithms effective

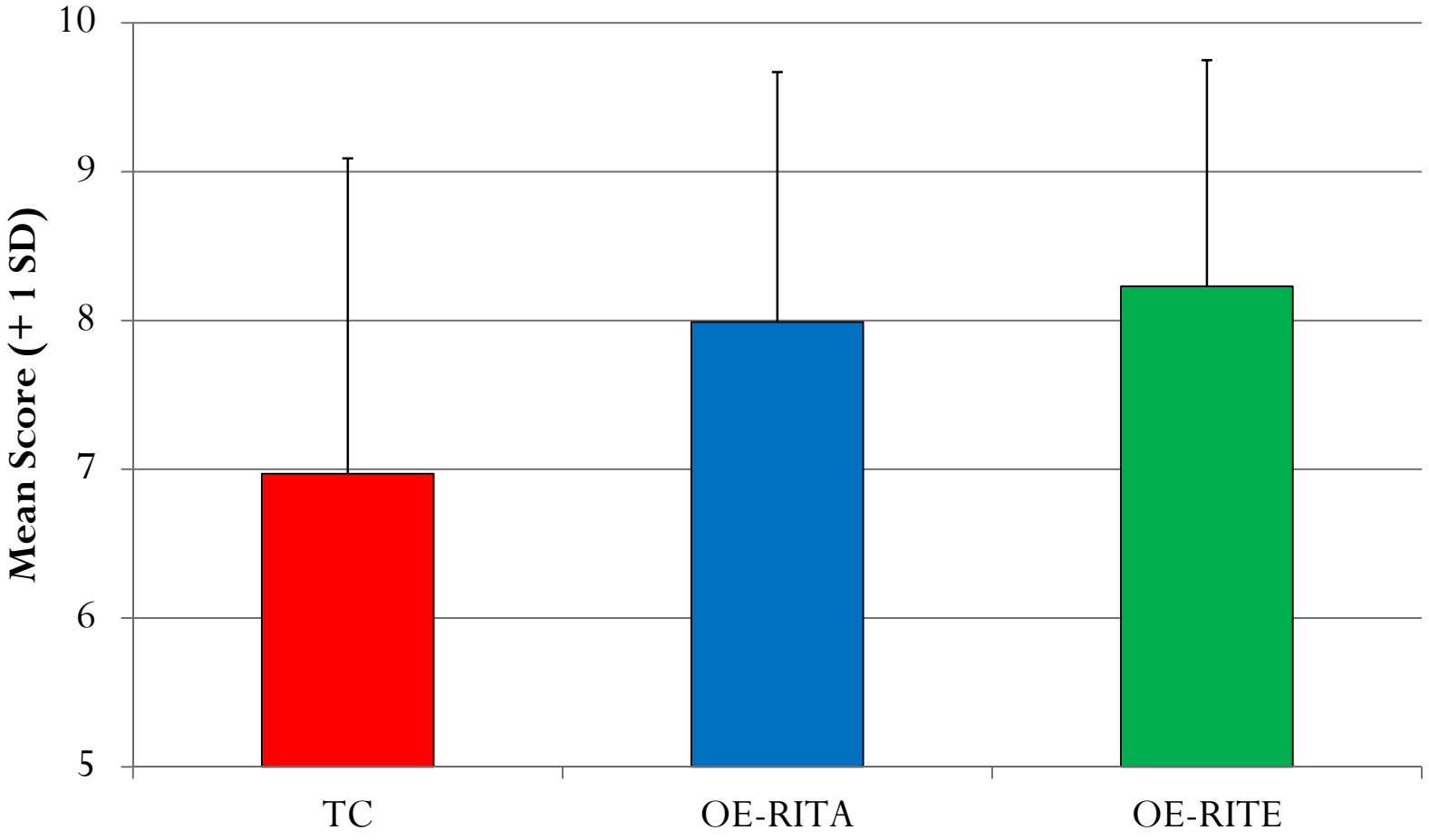
Repeated Measures ANOVAs

1 Within Groups Factor:	Hearing Aid Style
2 Between Groups Factors:	Hearing Loss Group
	Hearing Aid Experience

Fit, Comfort, Cosmetics

SPS: Fit, Comfort, & Cosmetics

]



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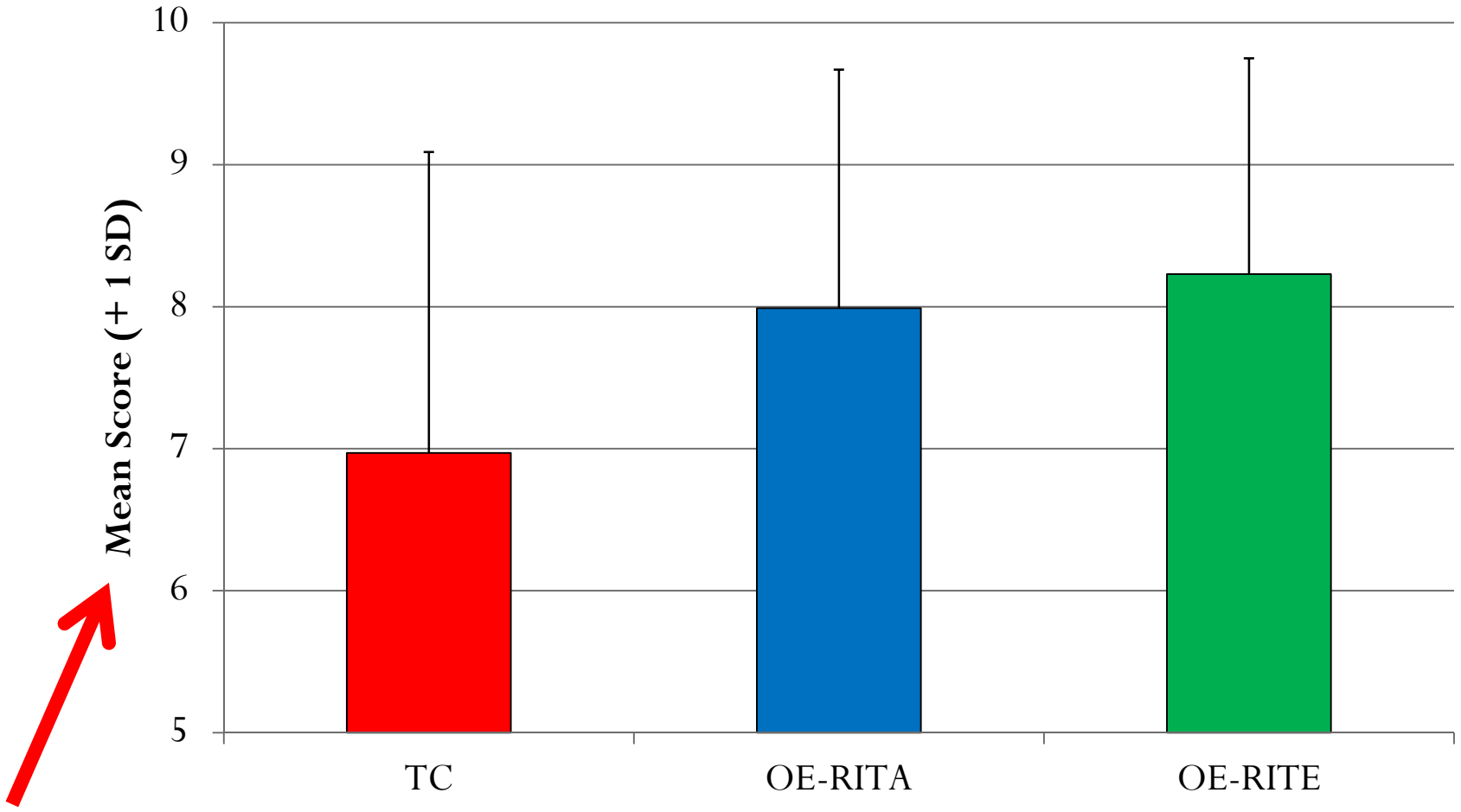

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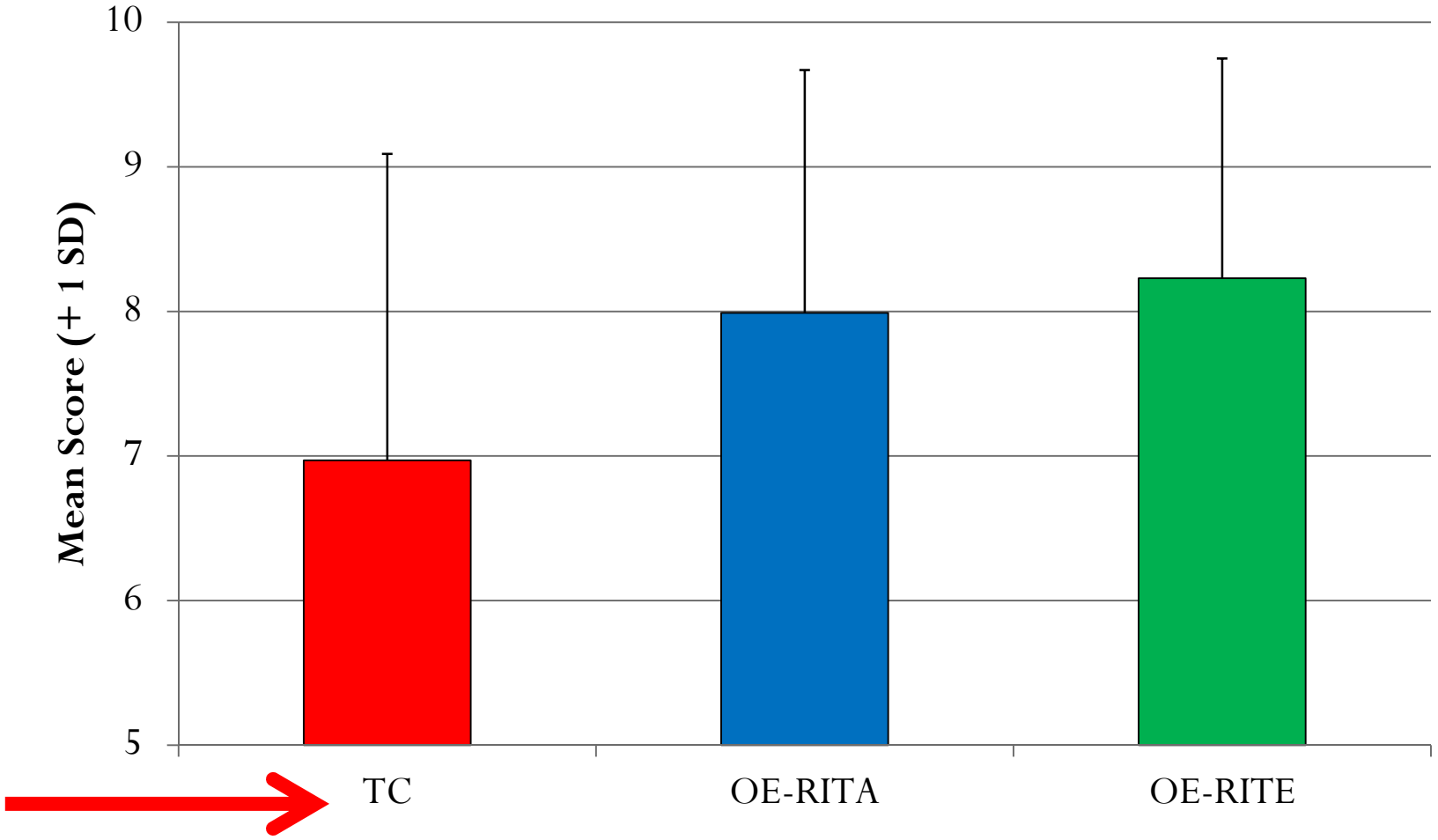

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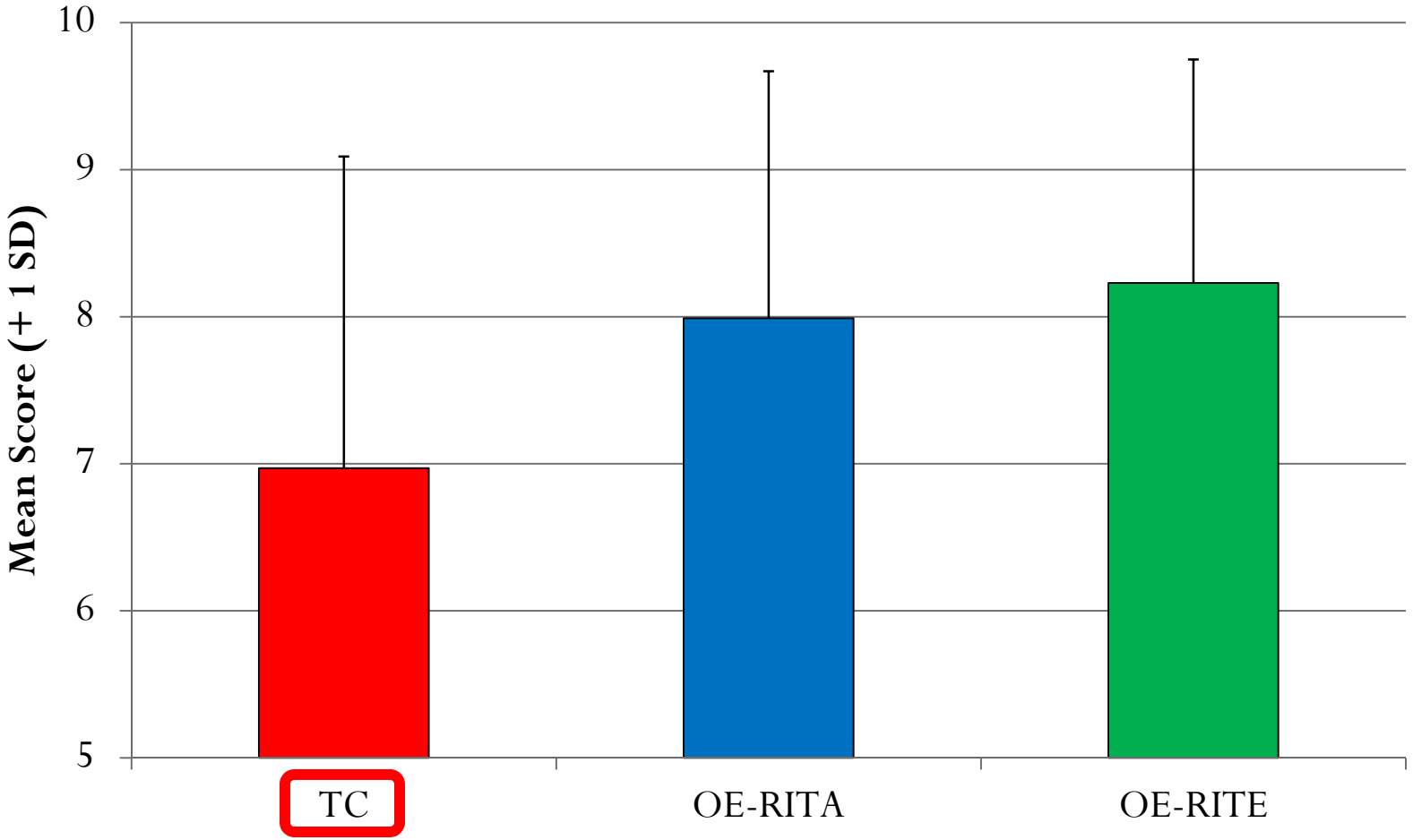

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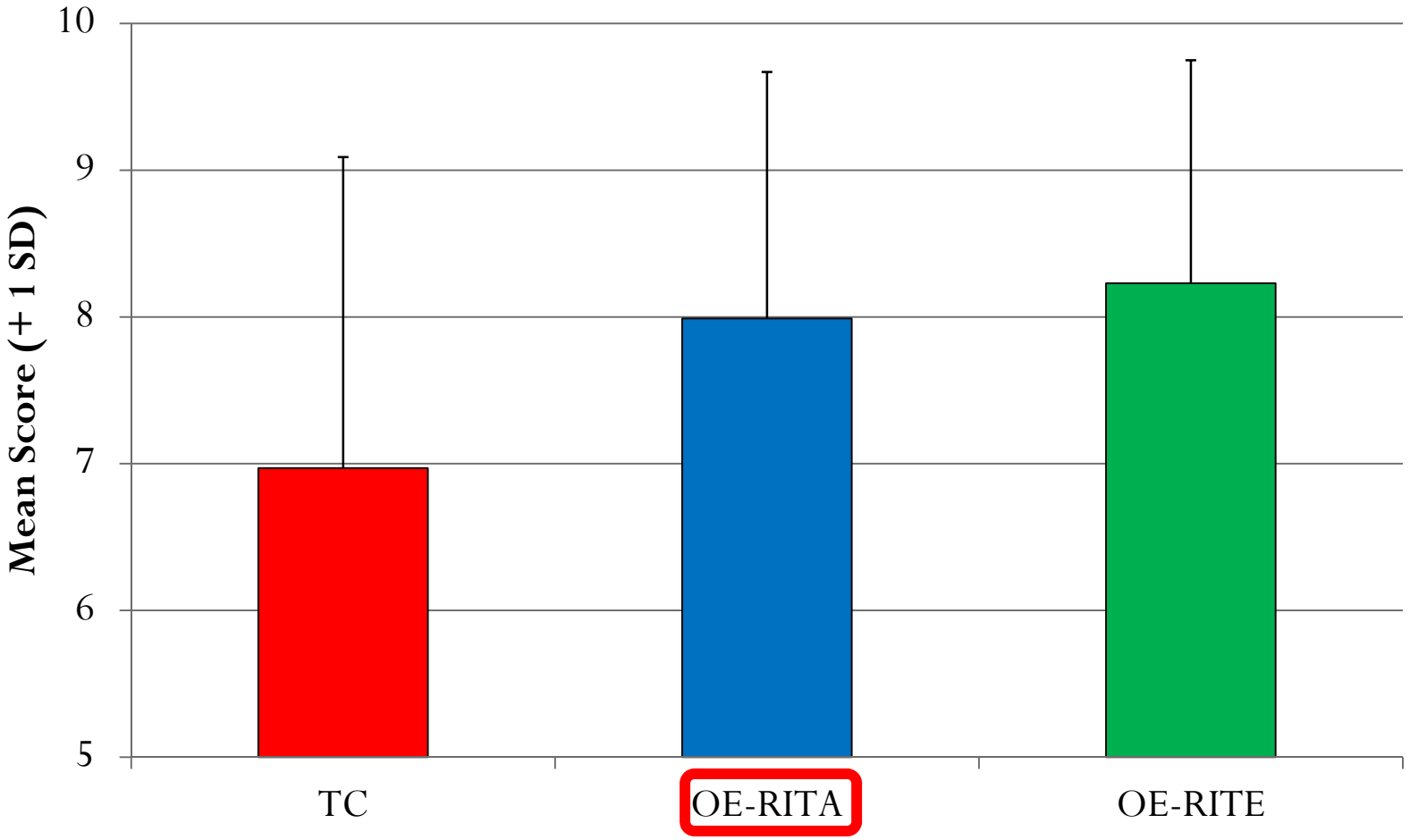

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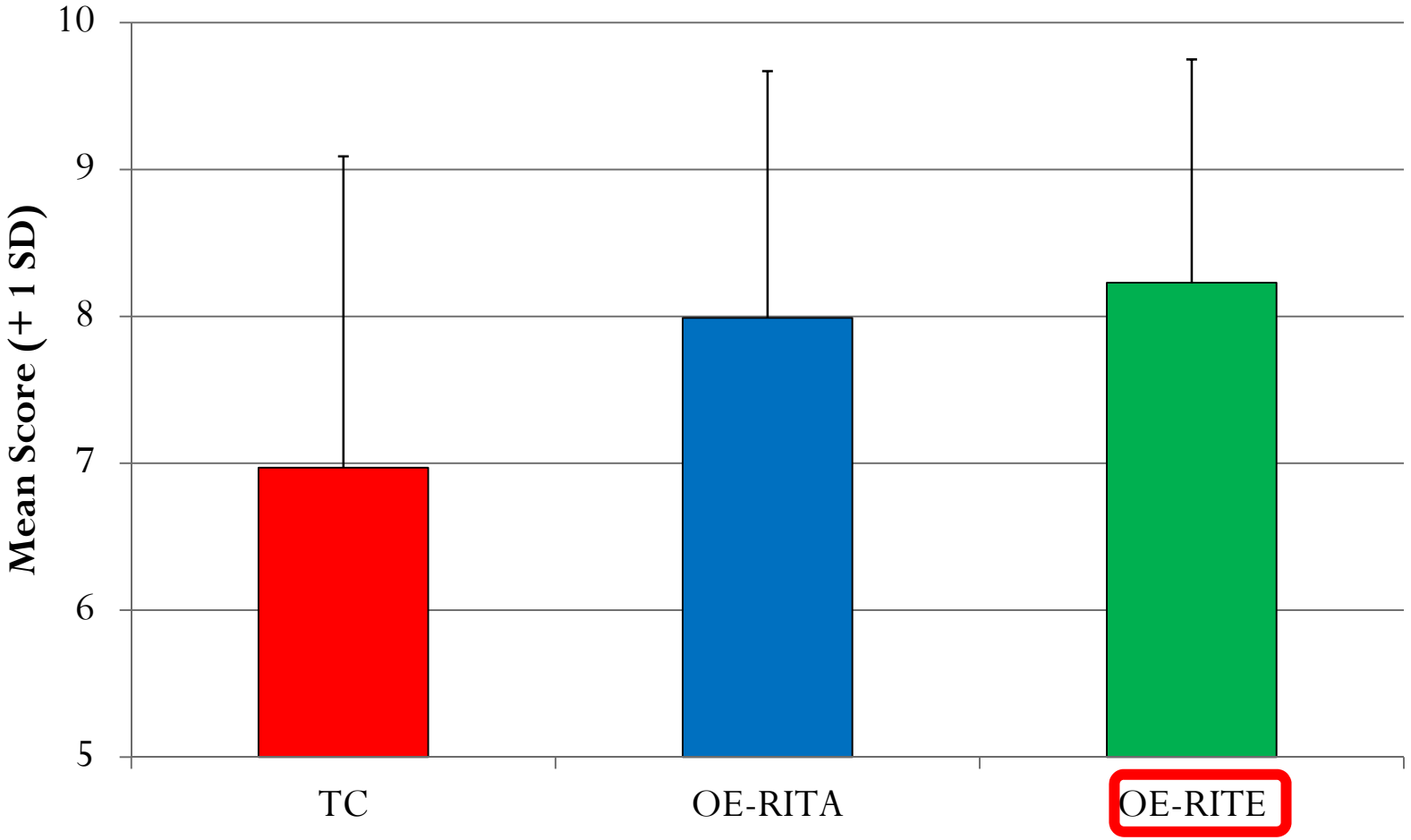
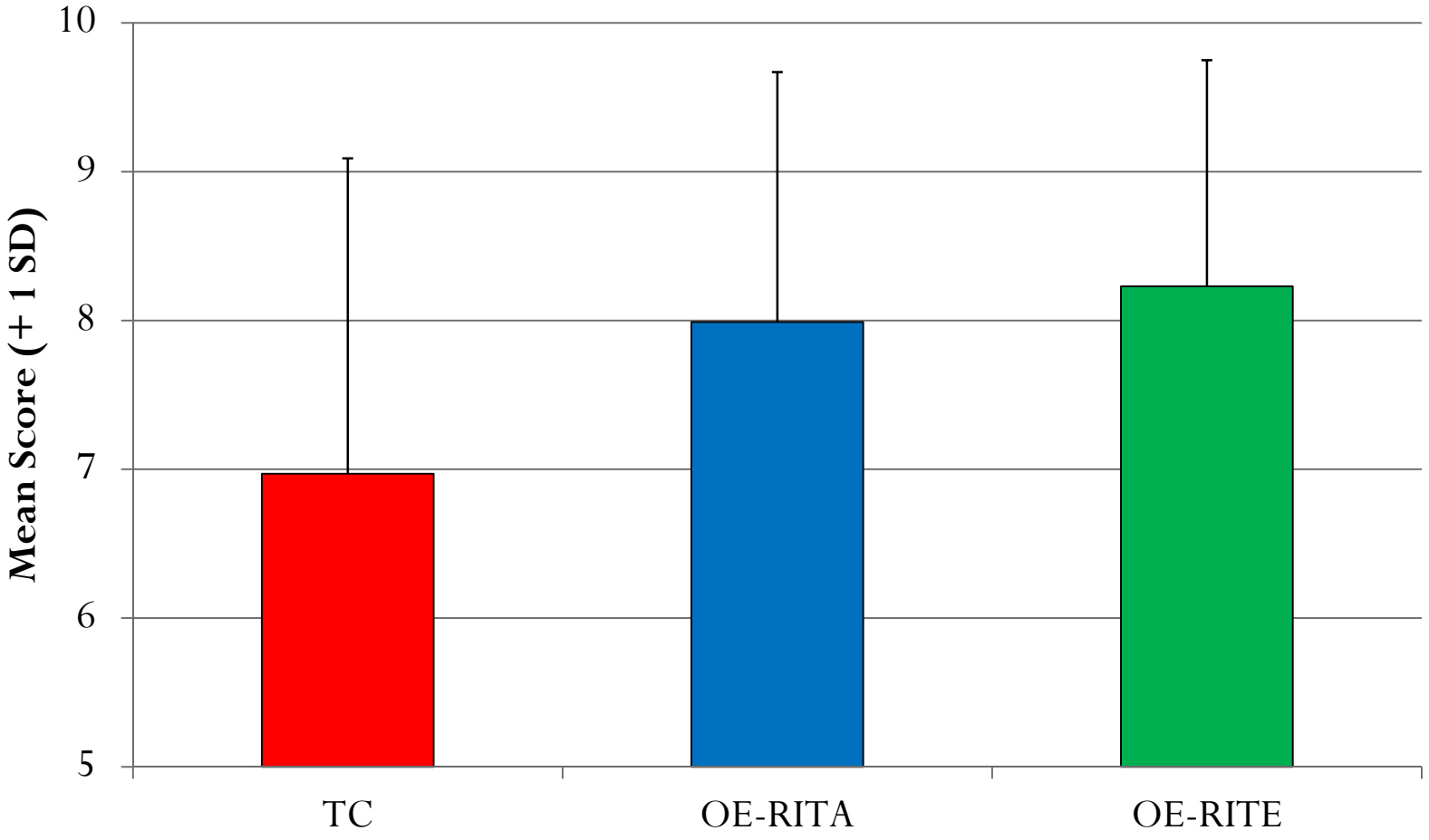


SPS: Fit, Comfort, & Cosmetics

[Style: F (2, 510) = 60.58, p = .000, ηp^2 = .192]



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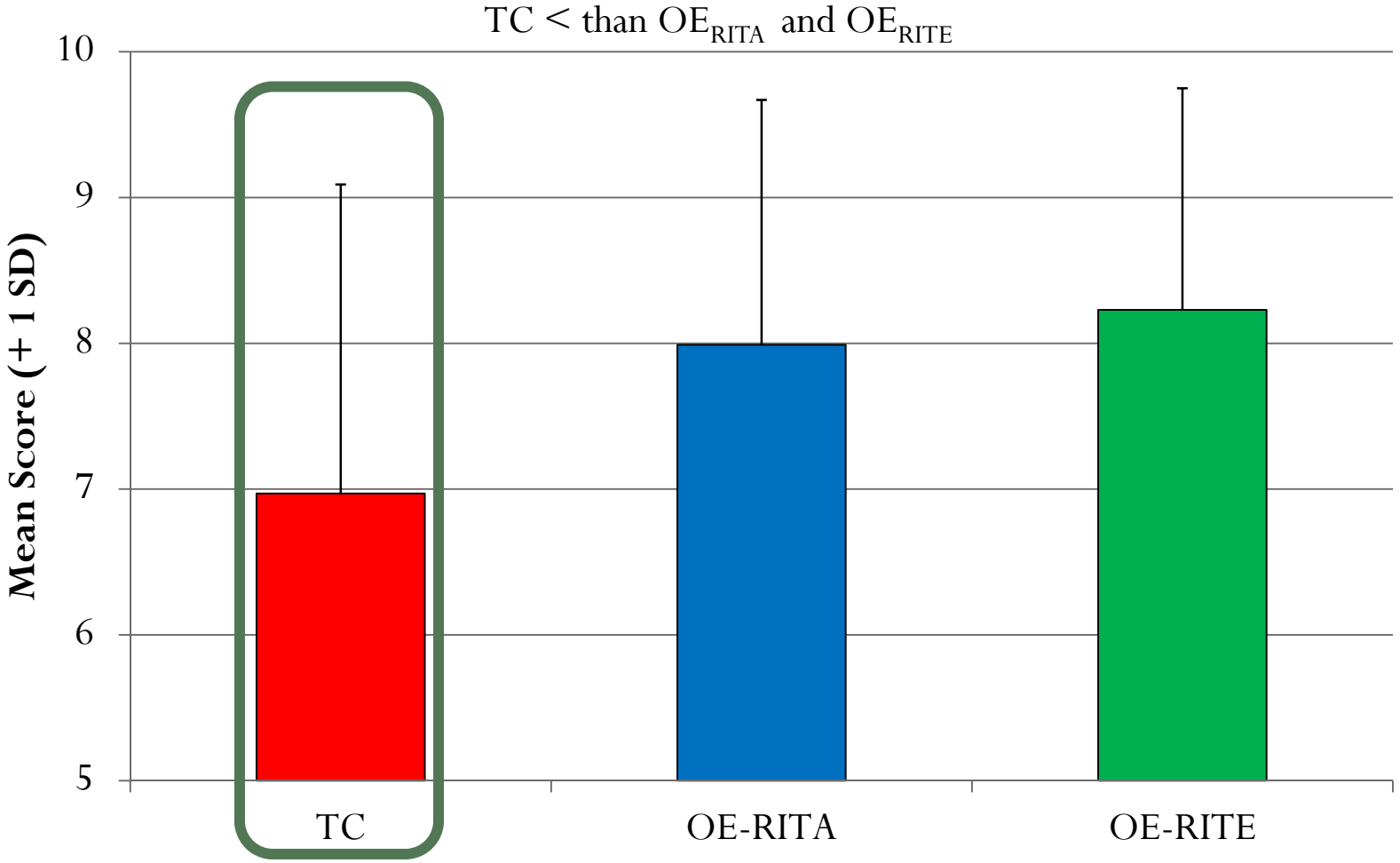

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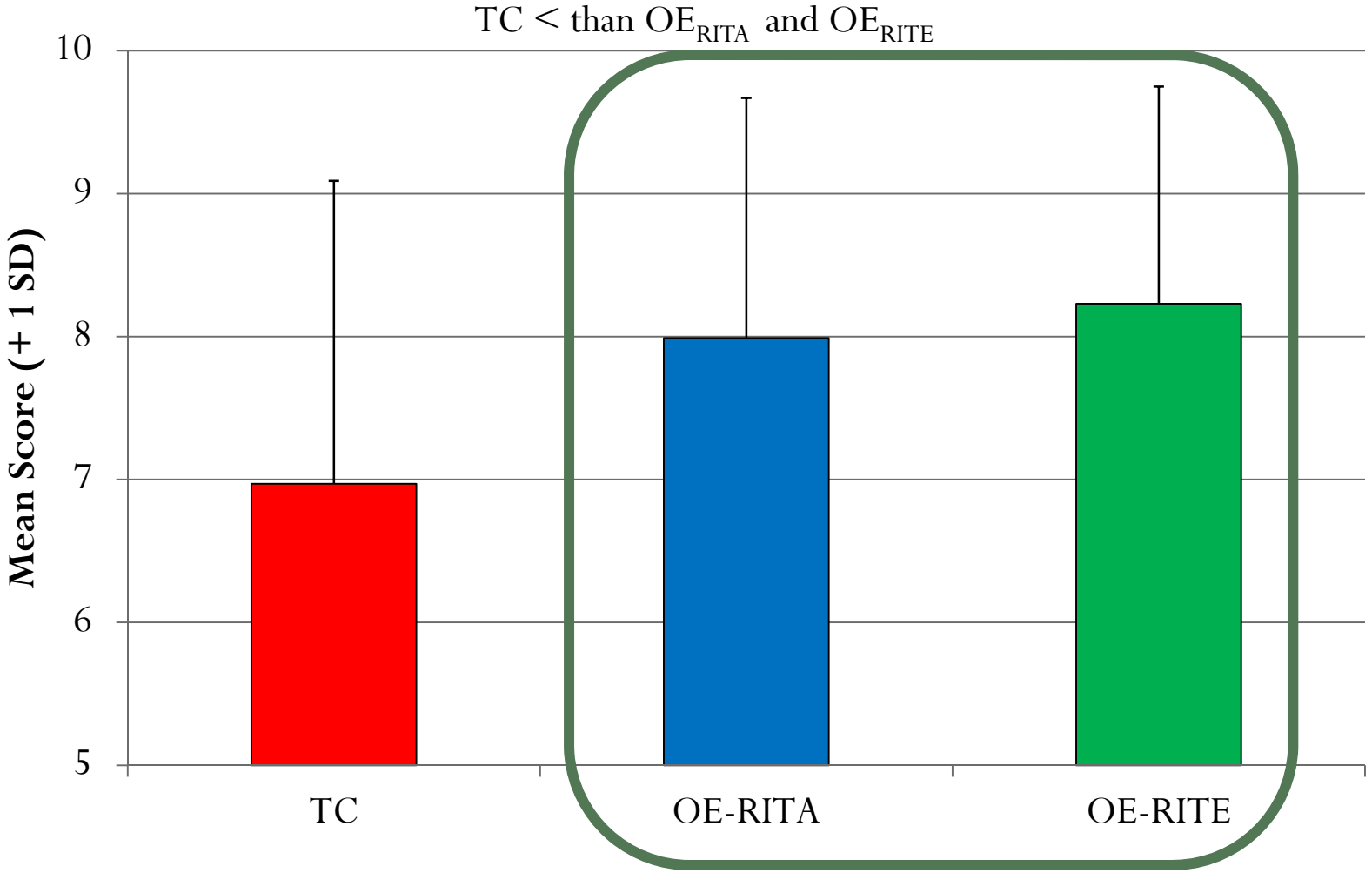

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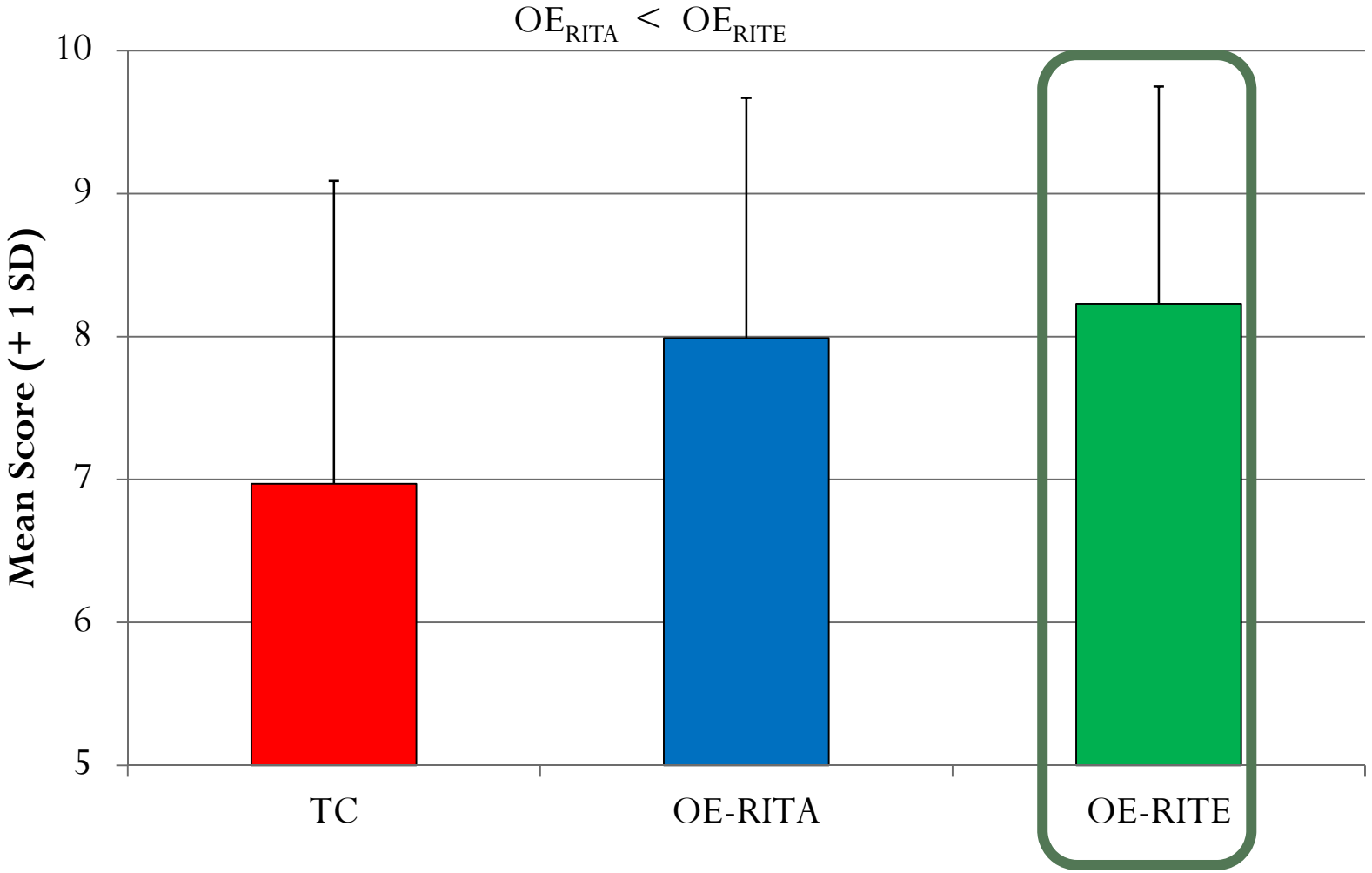

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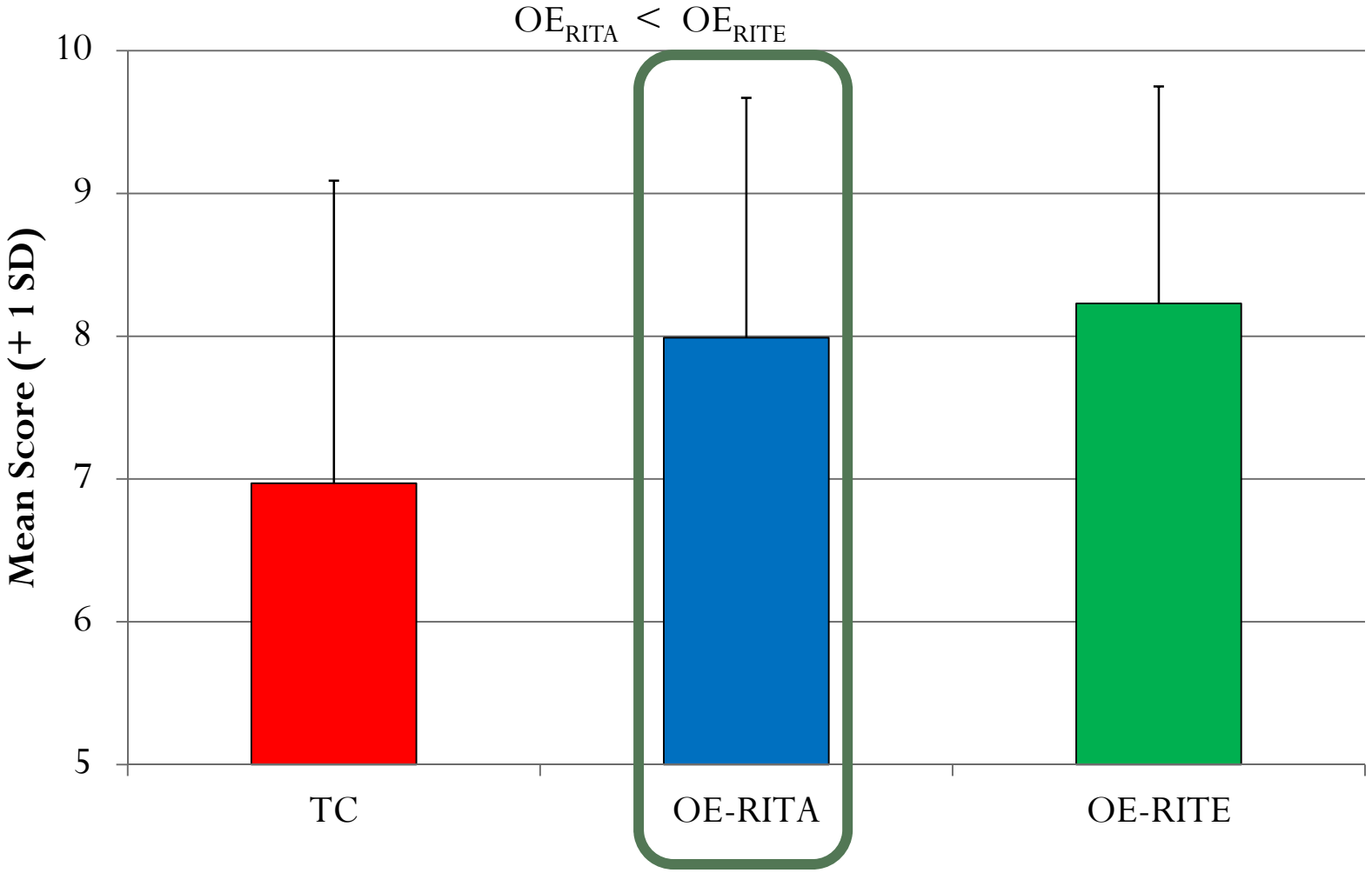


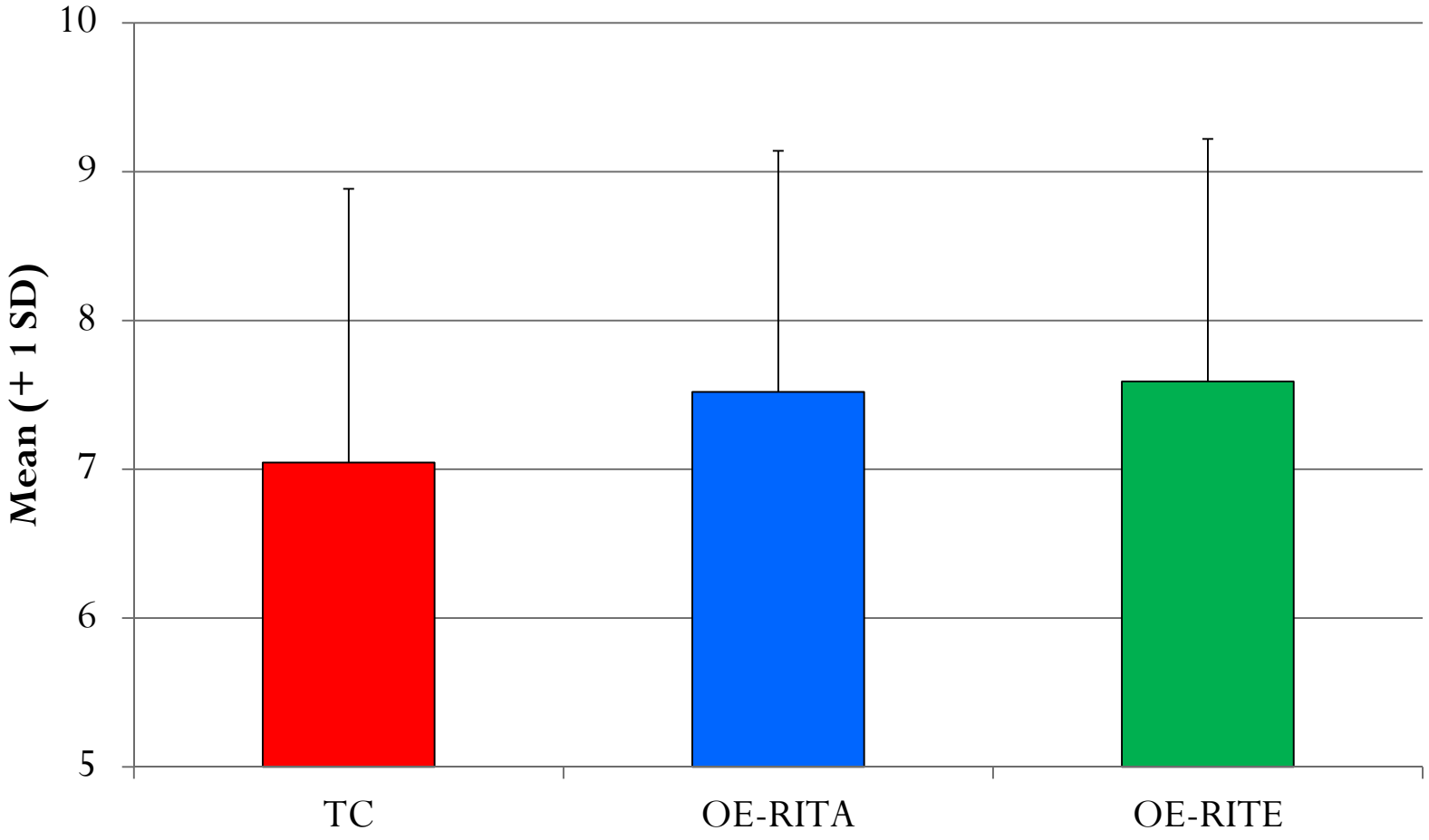
Fit, Comfort, Cosmetics

No other significant findings

Localization

SPS: Localization

[Style: F (2, 510) = 31.40, p = .000, ηp^2 = .110]



SPS: Localization

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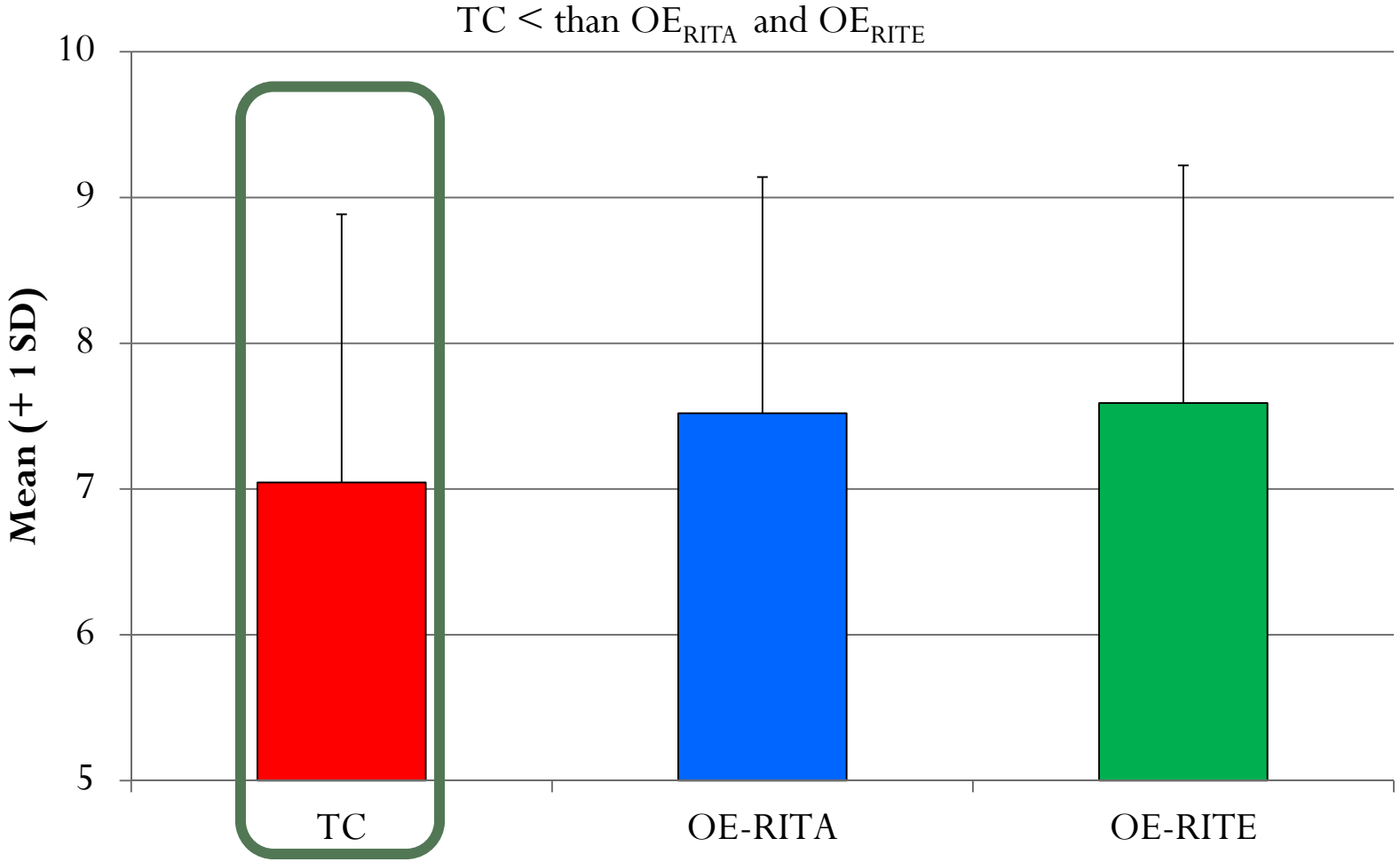

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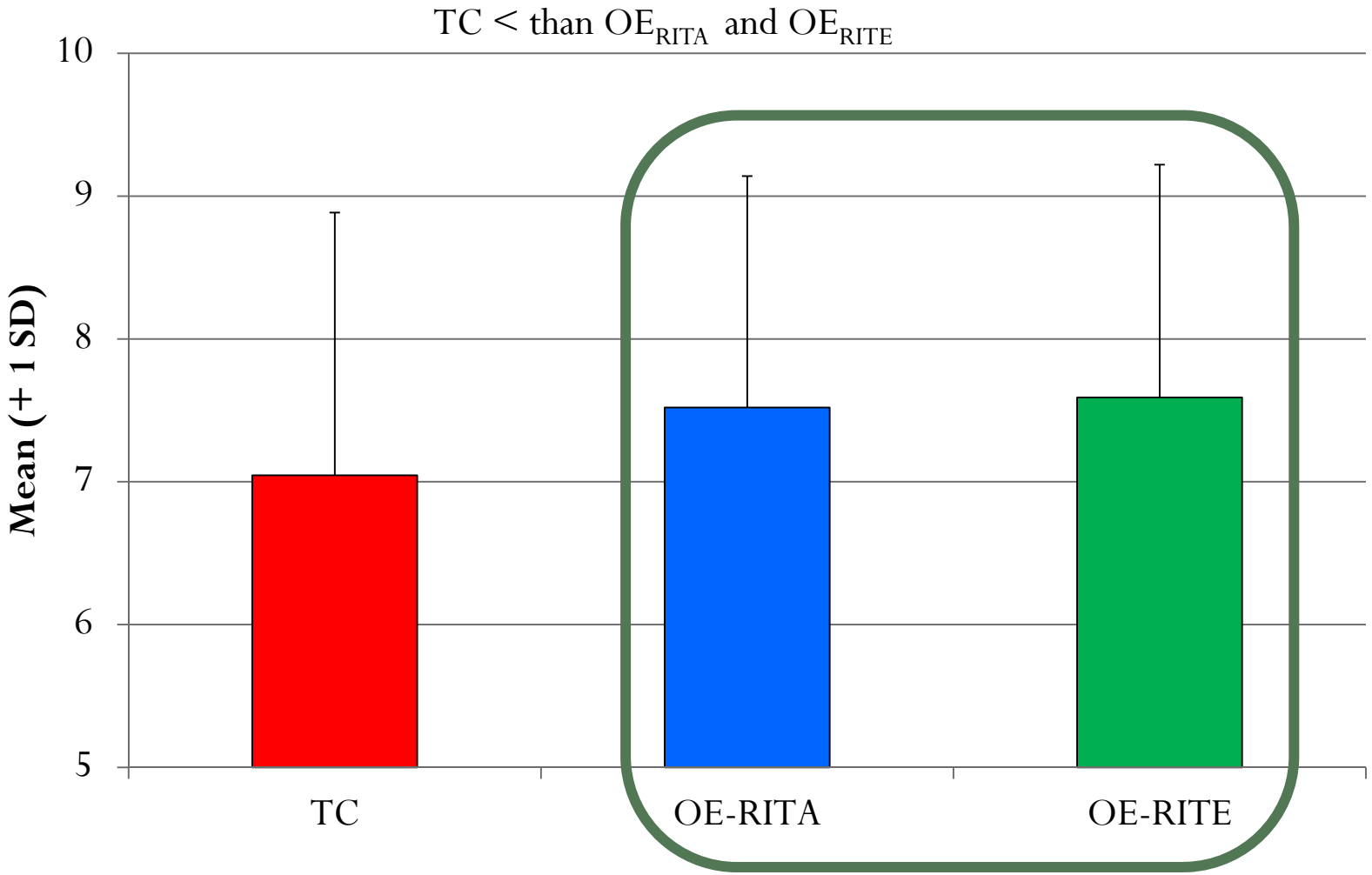

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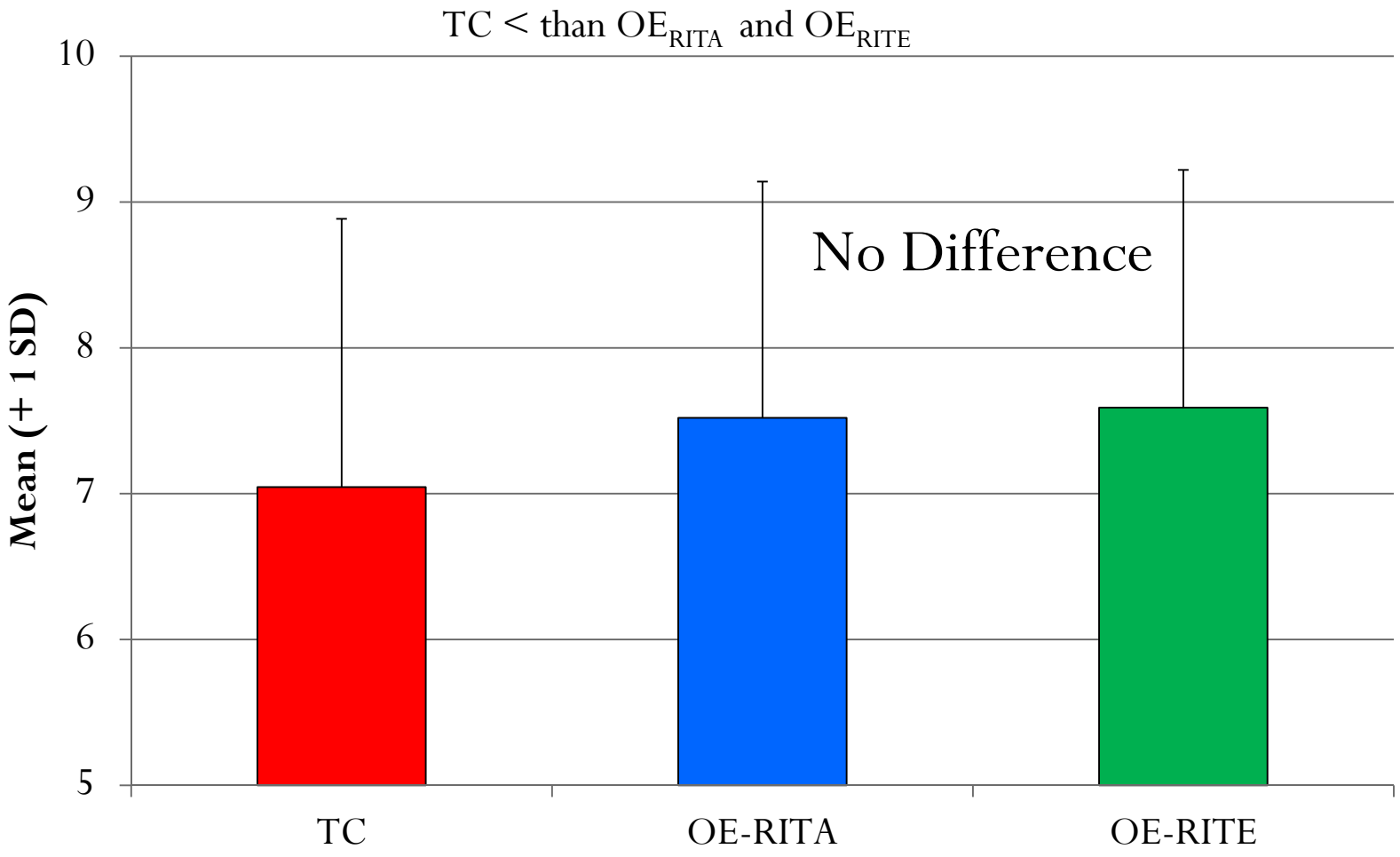


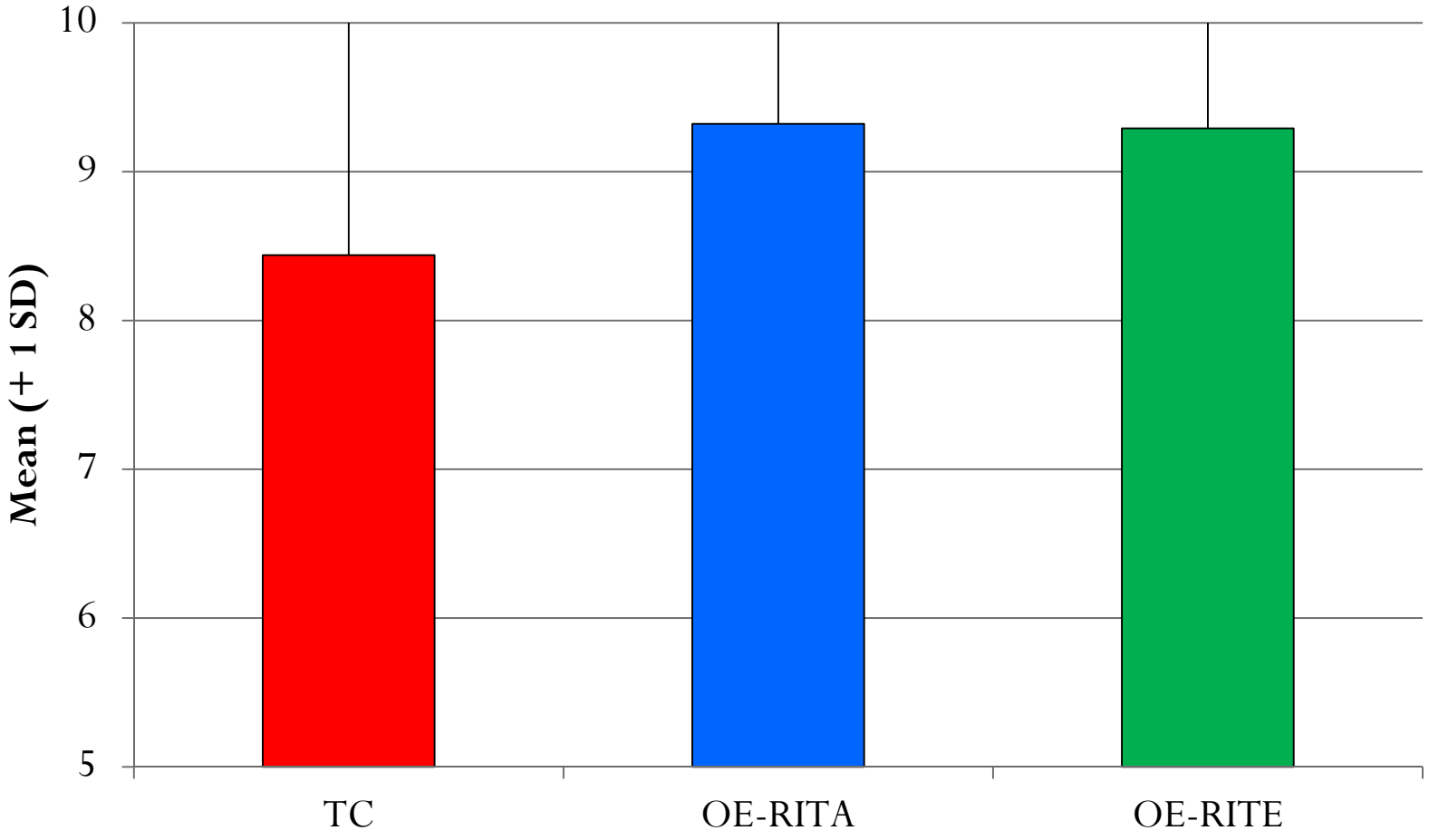
Localization

No other significant findings

Ease of Use

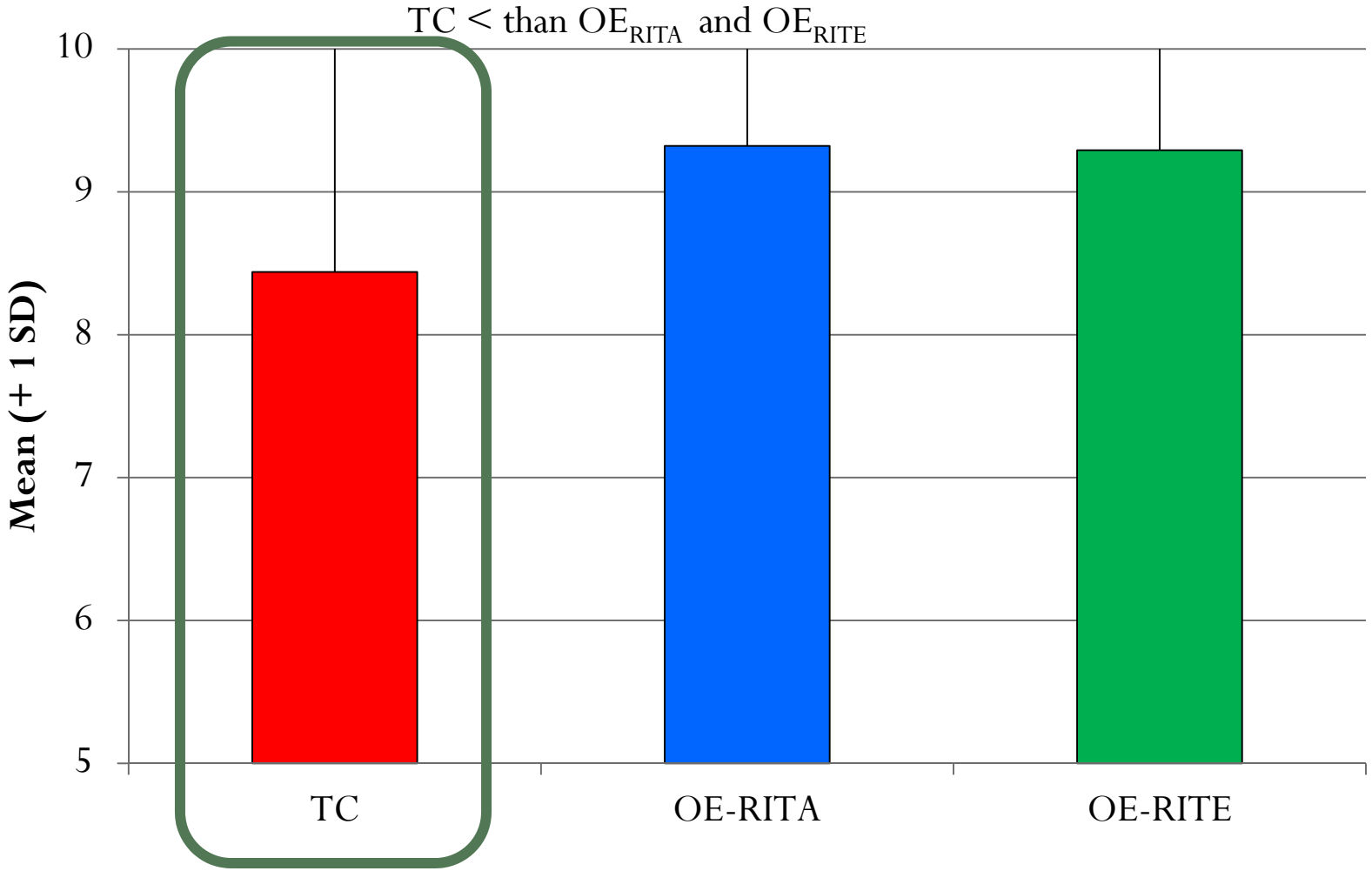
SPS: Ease of Use

[Style: F (2, 510) = 42.39, p = .000, ηp^2 = .143]



SPS: Ease of Use

[Style: F (2, 510) = 42.39, p = .000, ηp^2 = .143]



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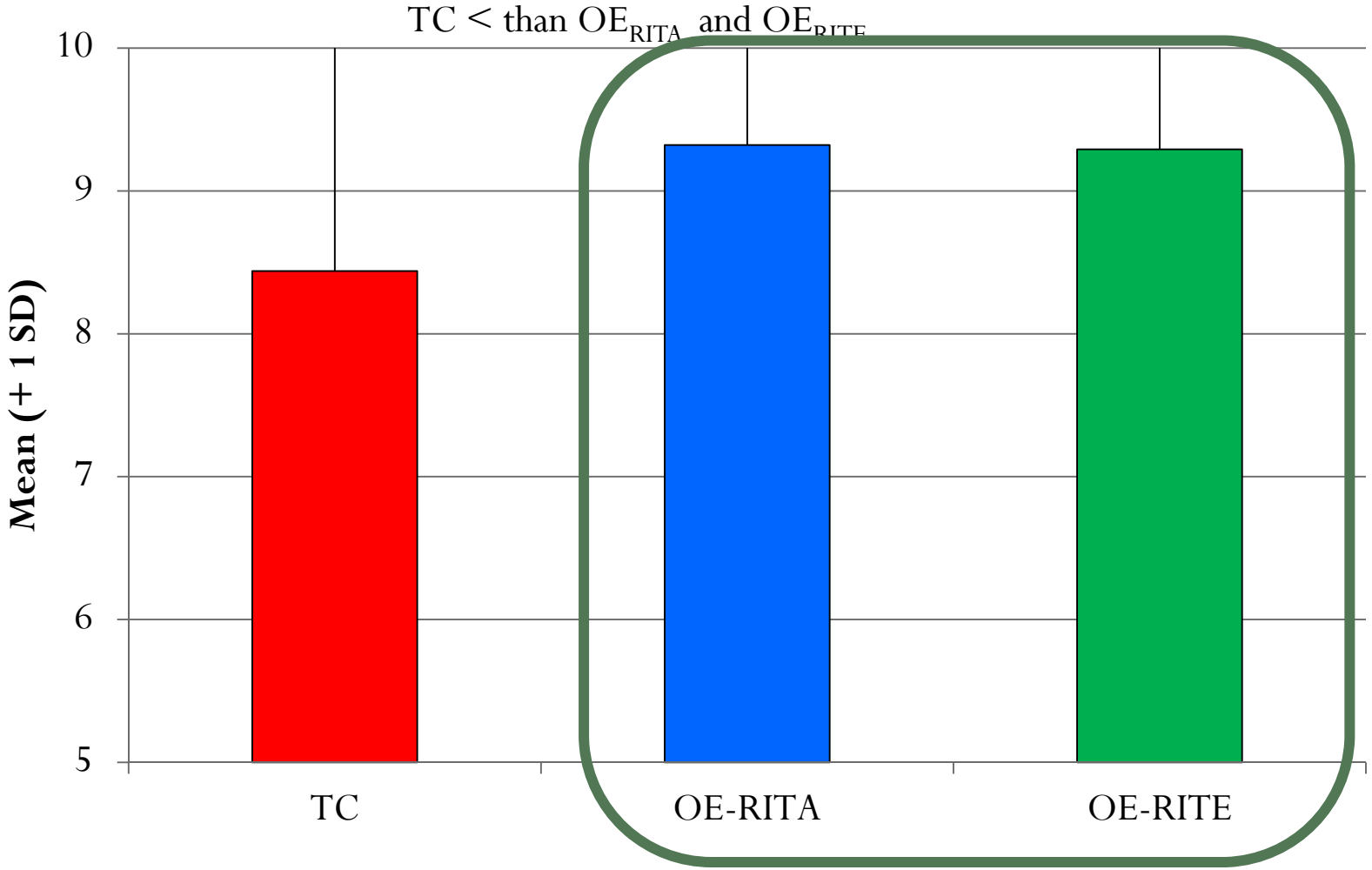

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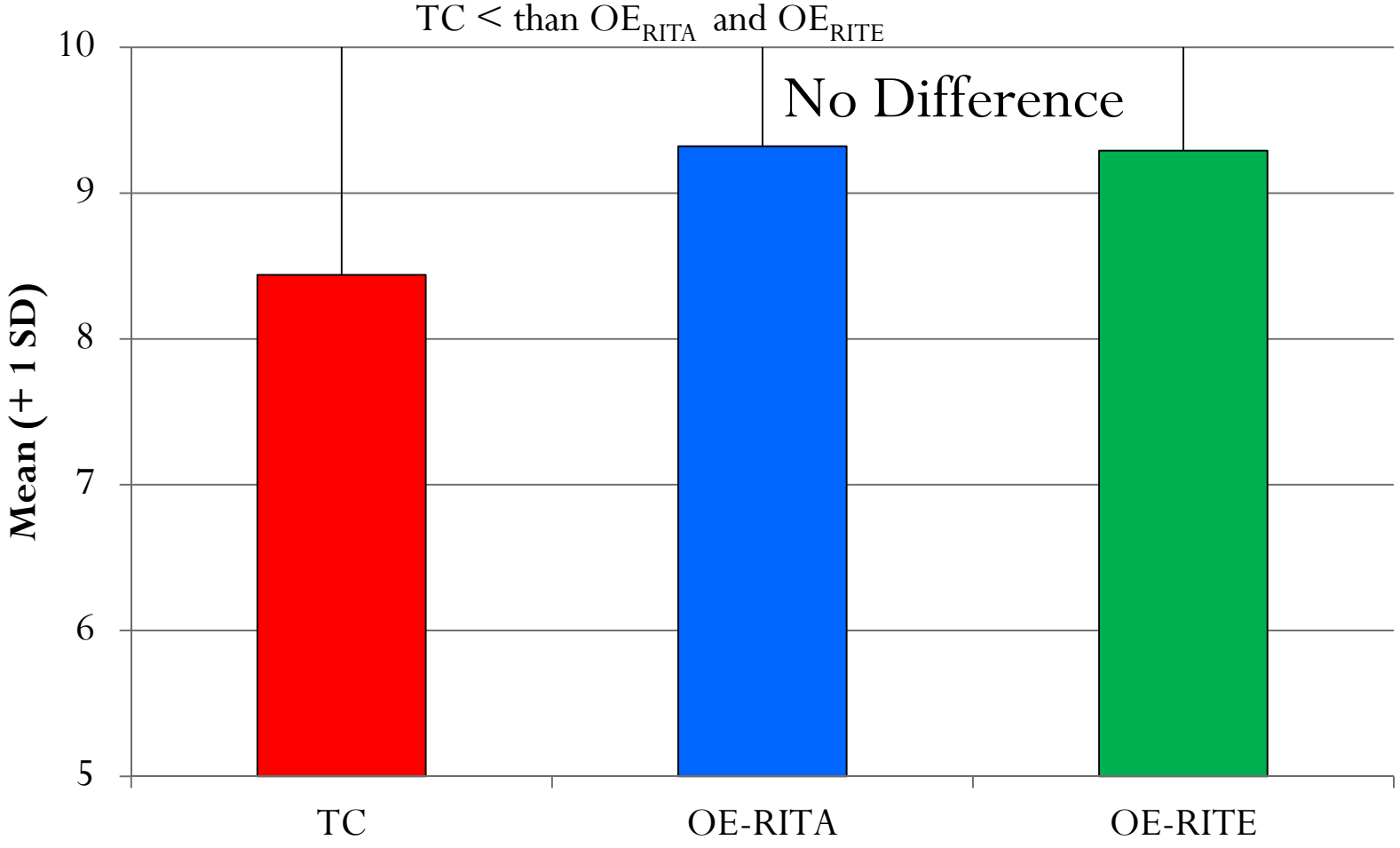


Ease of Use

No other significant findings

Subjective Occlusion/Own Voice

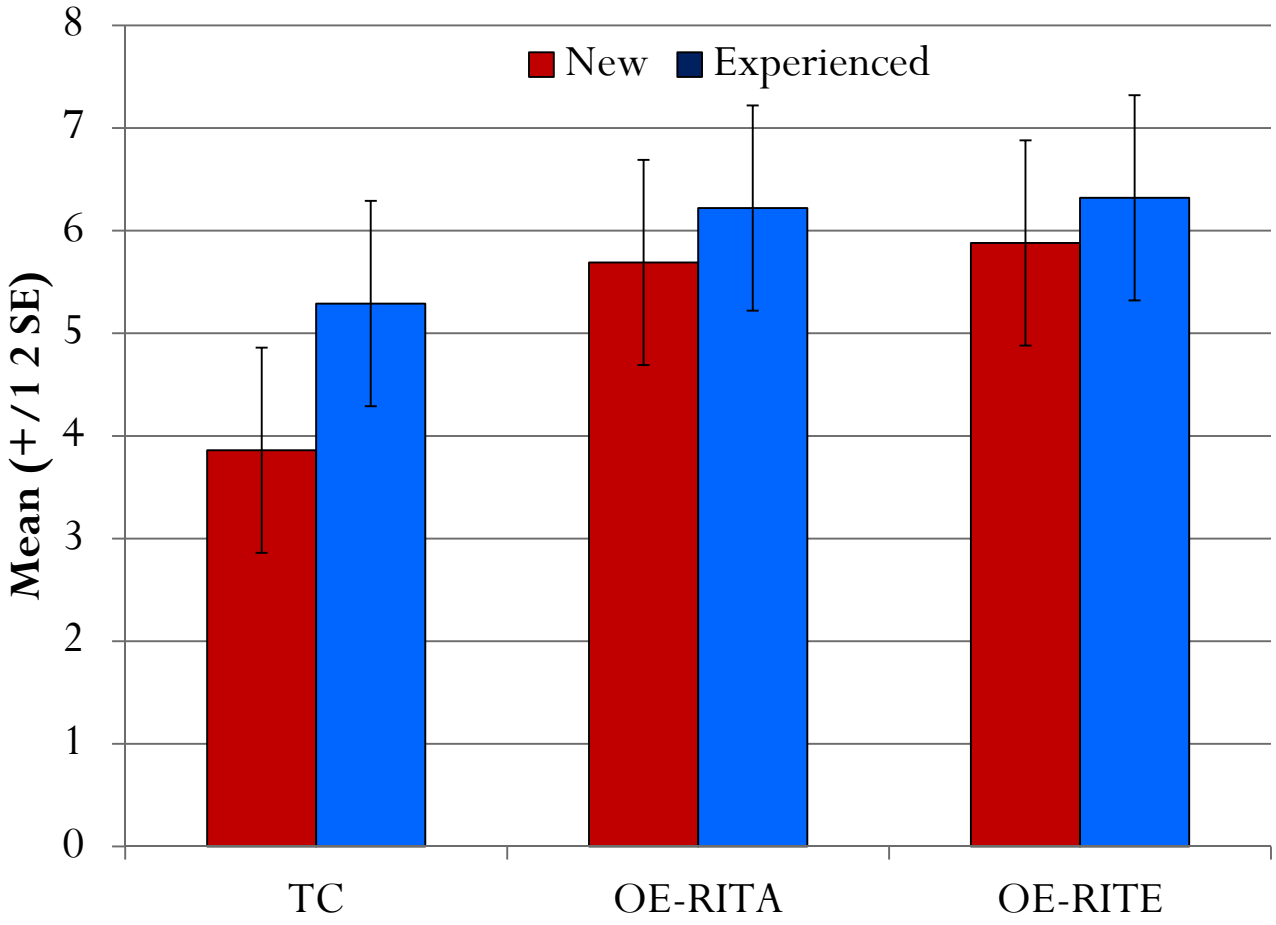
Significant Main Effect of Style

Significant Main Effect of Hearing User Status

SPS: Subjective Occlusion/Own Voice

Style X User Experience

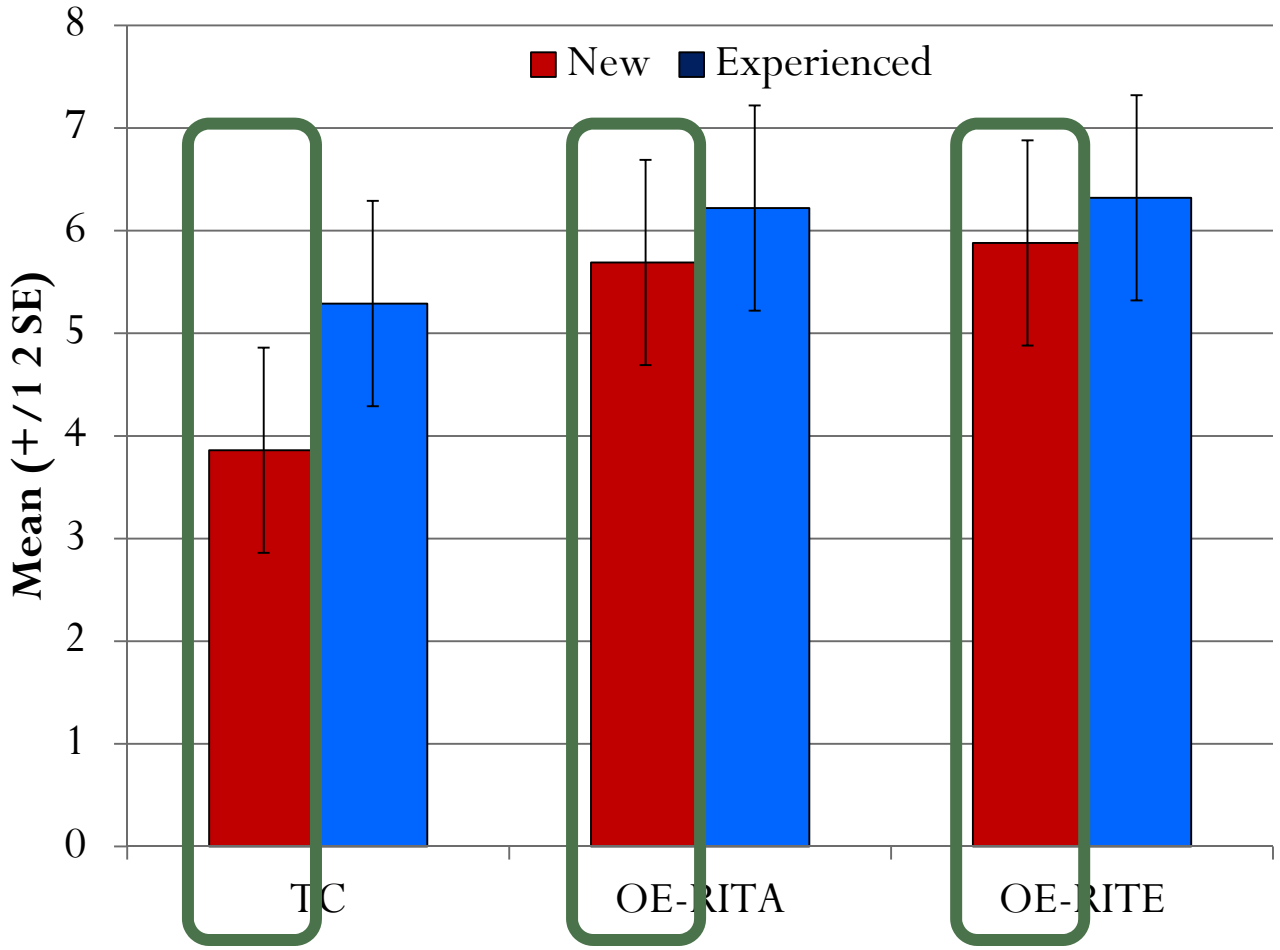
[F (1, 255) = 11.86, p = .000, ηp^2 = .044]



SPS: Subjective Occlusion/Own Voice

Style X User Experience

[F (1, 255) = 11.86, p = .000, ηp^2 = .044]



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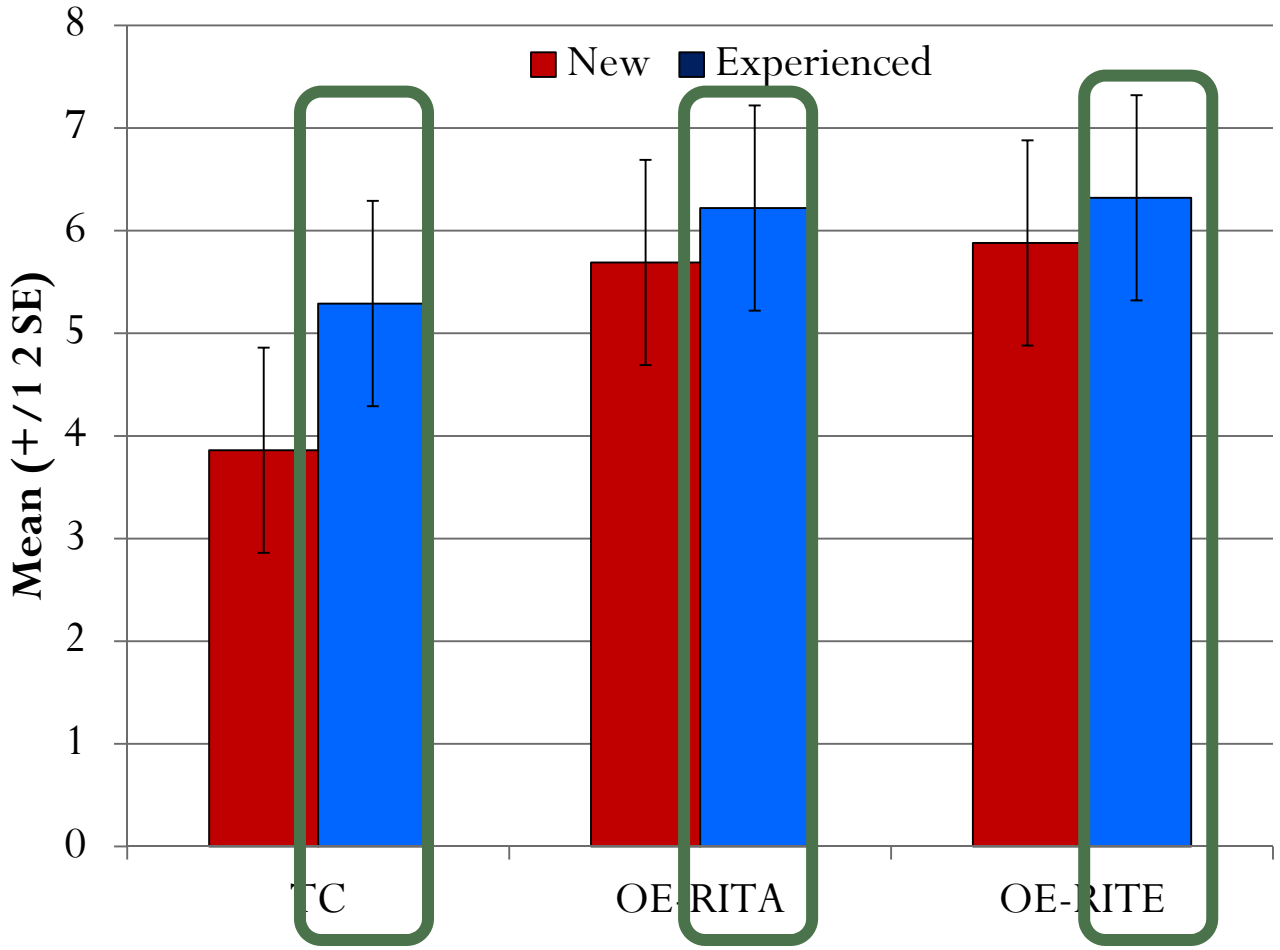

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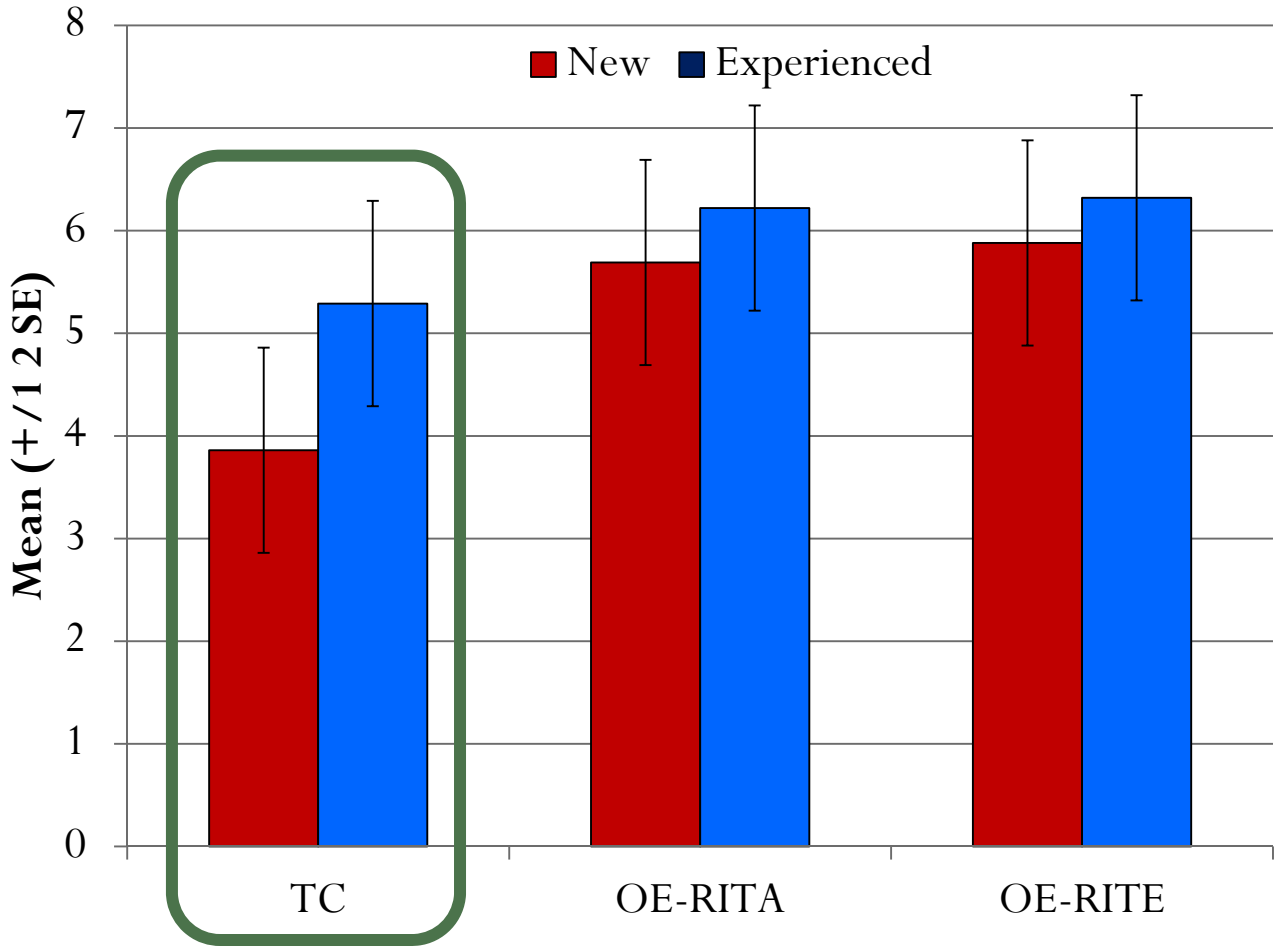

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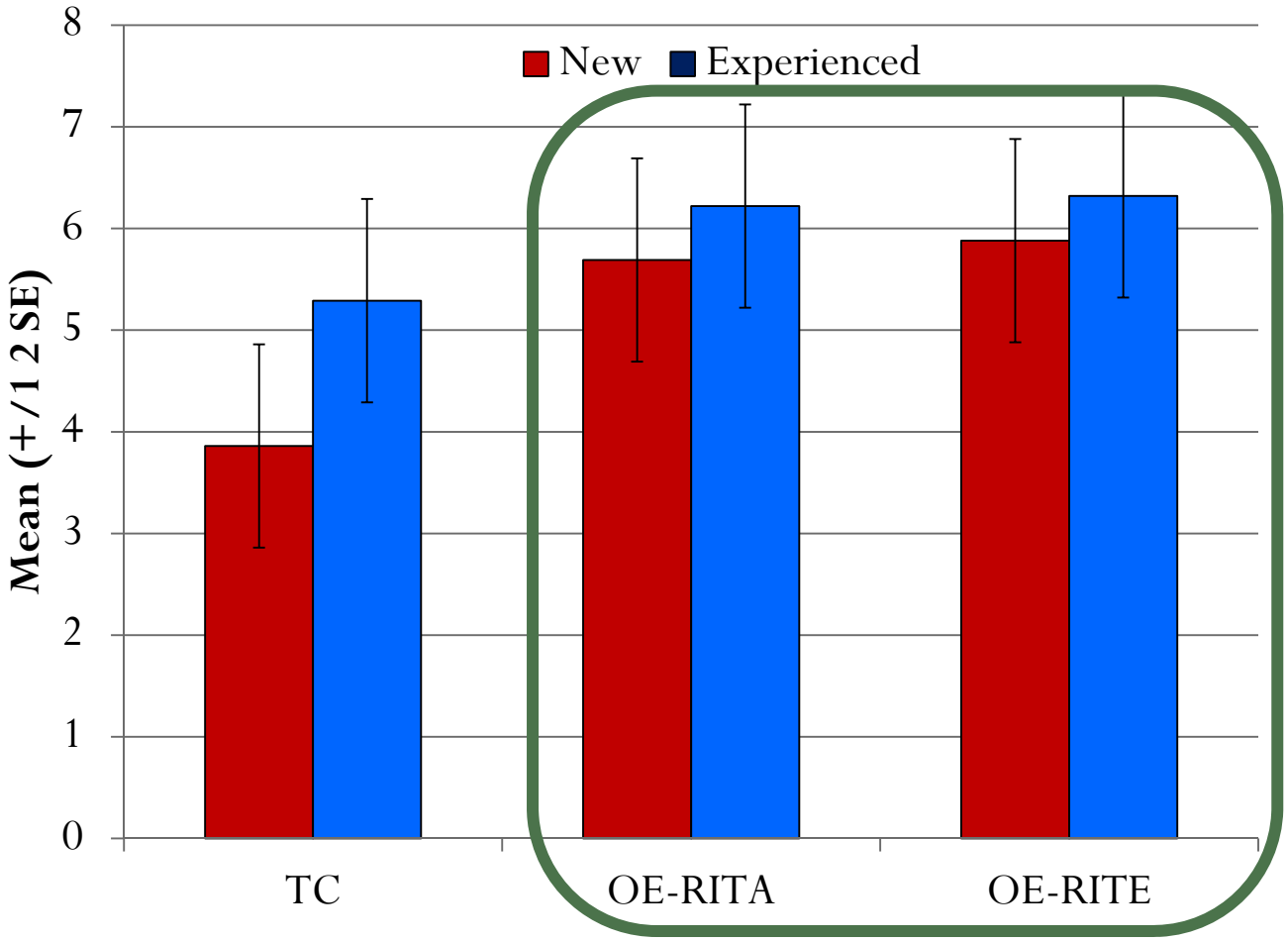

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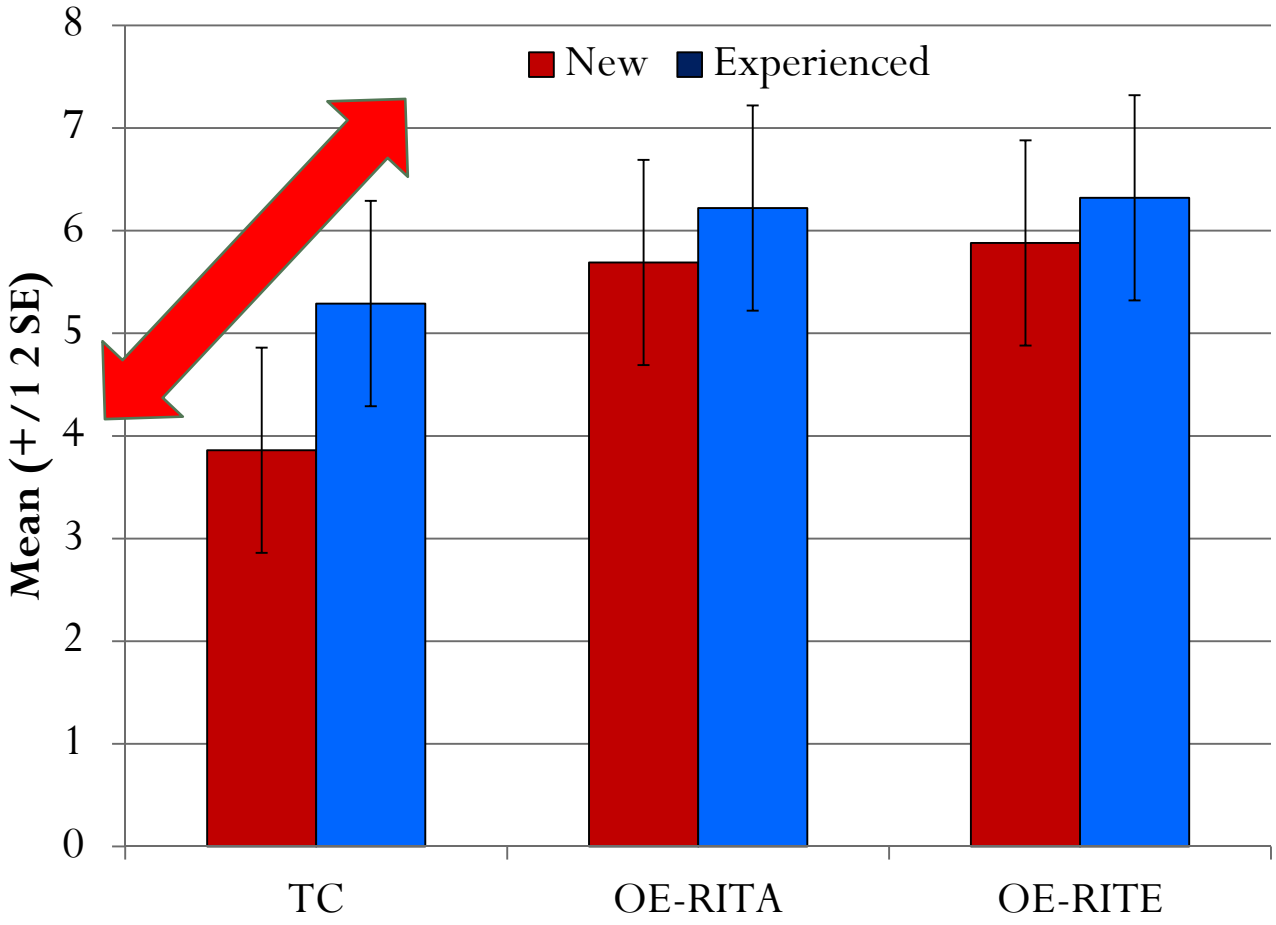

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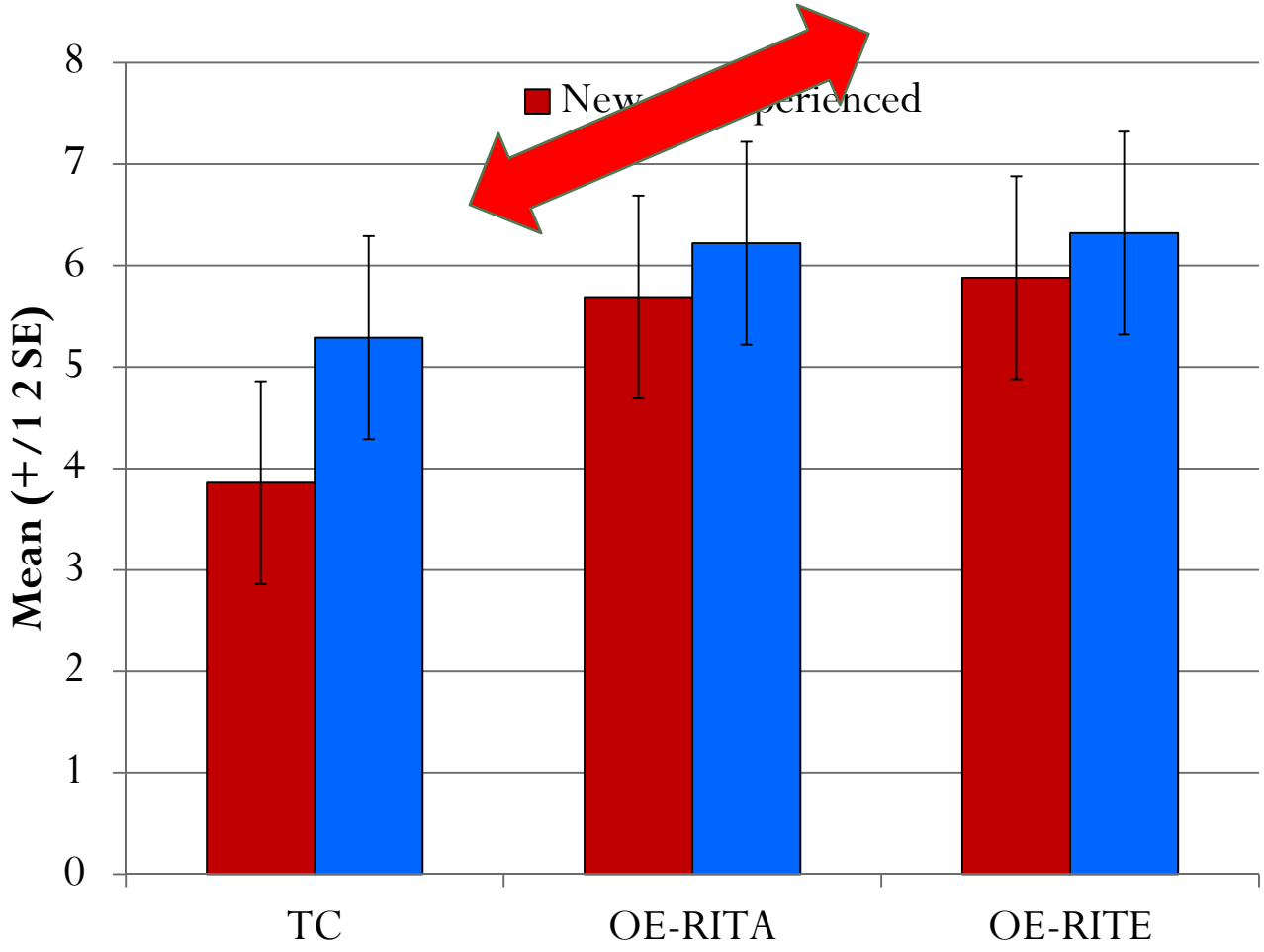

SPS: Subjective Occlusion/Own Voice

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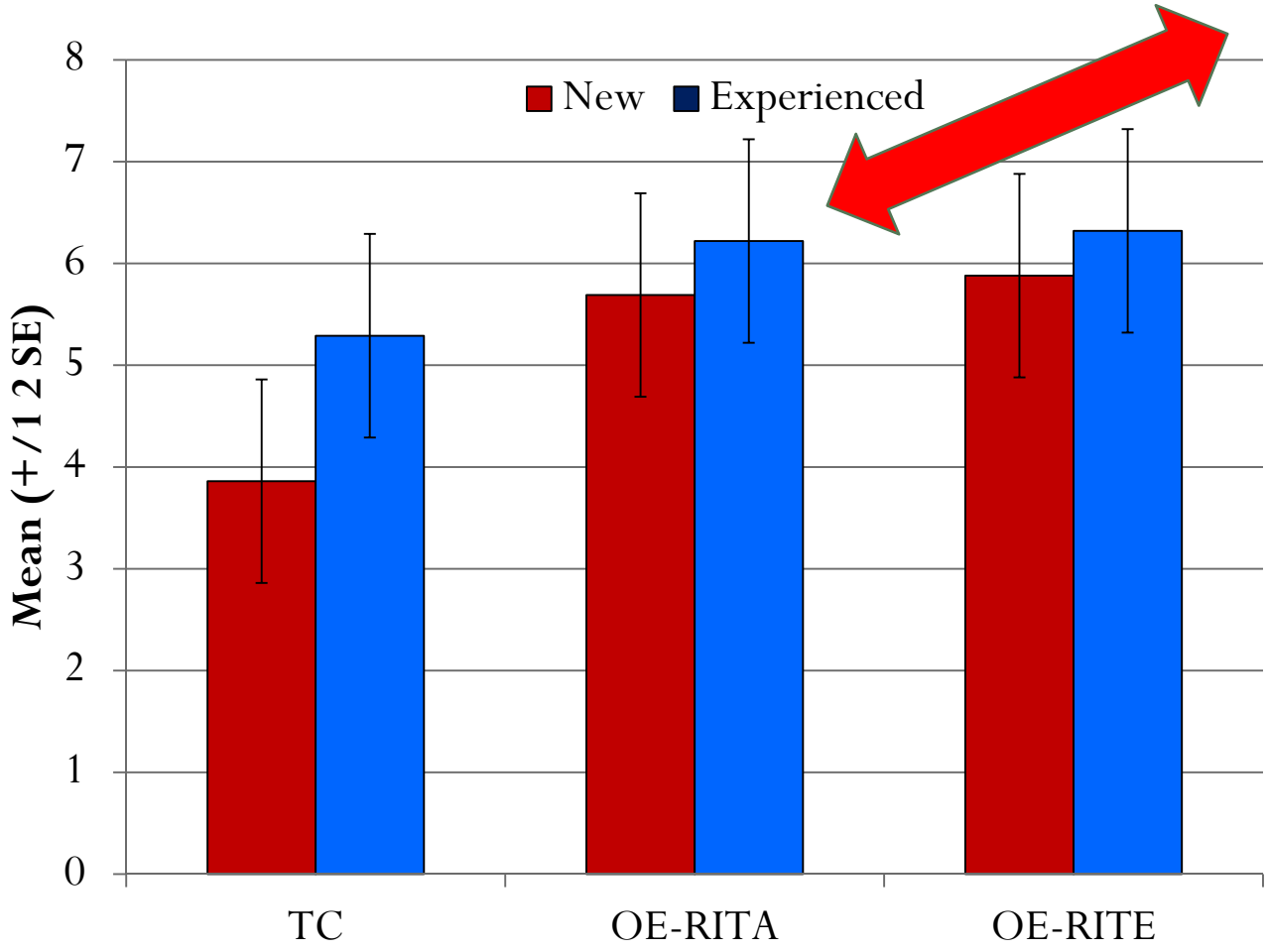
[F (1, 255) = 11.86, p = .000, ηp^2 = .044]



Subjective Occlusion/Own Voice

Main Effect of Style
Main Effect of Hearing Status
Interaction of Style x Hearing Status

No other factors significant

Summary

Subscale	Style	HL Group	User Status	Interactions
Fit, Comfort, Cosmetics	TC < OE RITA < RITE	NS	NS	NS
Localization	TC < OE RITA = RITE	NS	NS	NS
Ease of USE	TC < OE RITA = RITE	NS	NS	NS
Subjective Occlusion	TC < OE RITA = RITE	NS	New < Experienced	New < Experienced ONLY for TC
Feedback	NS	NS	NS	NS

Summary

Subscale	Style	HL Group	User Status	Interactions
Fit, Comfort, Cosmetics	TC < OE RITA < RITE	NS	NS	NS
Localization	TC < OE RITA = RITE	NS	NS	NS
Ease of USE	TC < OE RITA = RITE	NS	NS	NS
Subjective Occlusion	TC < OE RITA = RITE	NS	New < Experienced	New < Experienced ONLY for TC
Feedback	NS	NS	NS	NS

Objective Outcome Measures

Words-in-Noise Test

Words-in-Noise Test (WIN)

- 35 NU No. 6 monosyllabic words (female speaker)
  - Presented in soundfield at 0^{o} azimuth
- Multitalker babble
  - Presented at 180^{o} azimuth at 70 dB HL
- Descending paradigm
  - 5 words per each of 7 signal-to-babble ratios from 24-to 0-dB S/N, 4-dB decrements
- Scored in terms of signal-to-noise ratio at the 50% point (Spearman-Kärber equation)

Example: Say the word <u>voice</u>

Wilson, Journal of the American Academy of Audiology, 2003

WIN Results

WIN Results

Hearing Loss Group

$F(3, 255) = 34.23, p = .000, \eta\rho^2 = .287$

Group 1: 10.36 (SE = .31)

Group 2: 12.34 (SE = .29)

Group 3: 14.44 (SE = .26)

Group 4: 11.93 (SE = .30)

WIN Results

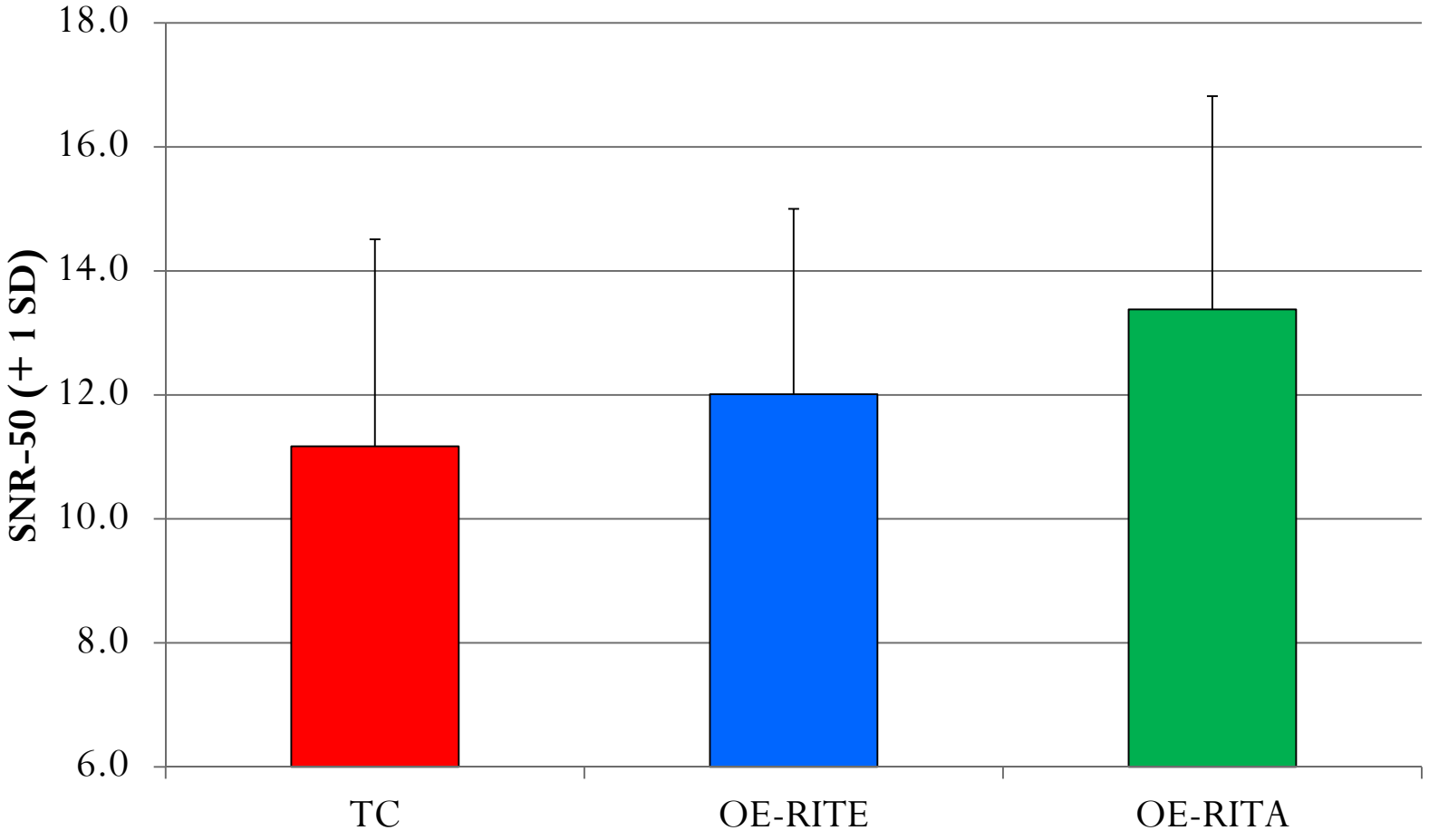
HA Experience

$F(1, 255) = 26.13$, $p = .000$, $\eta p^2 = .093$]

New Users	11.51 (SE = .19)
Experienced	13.02 (SE = .21)

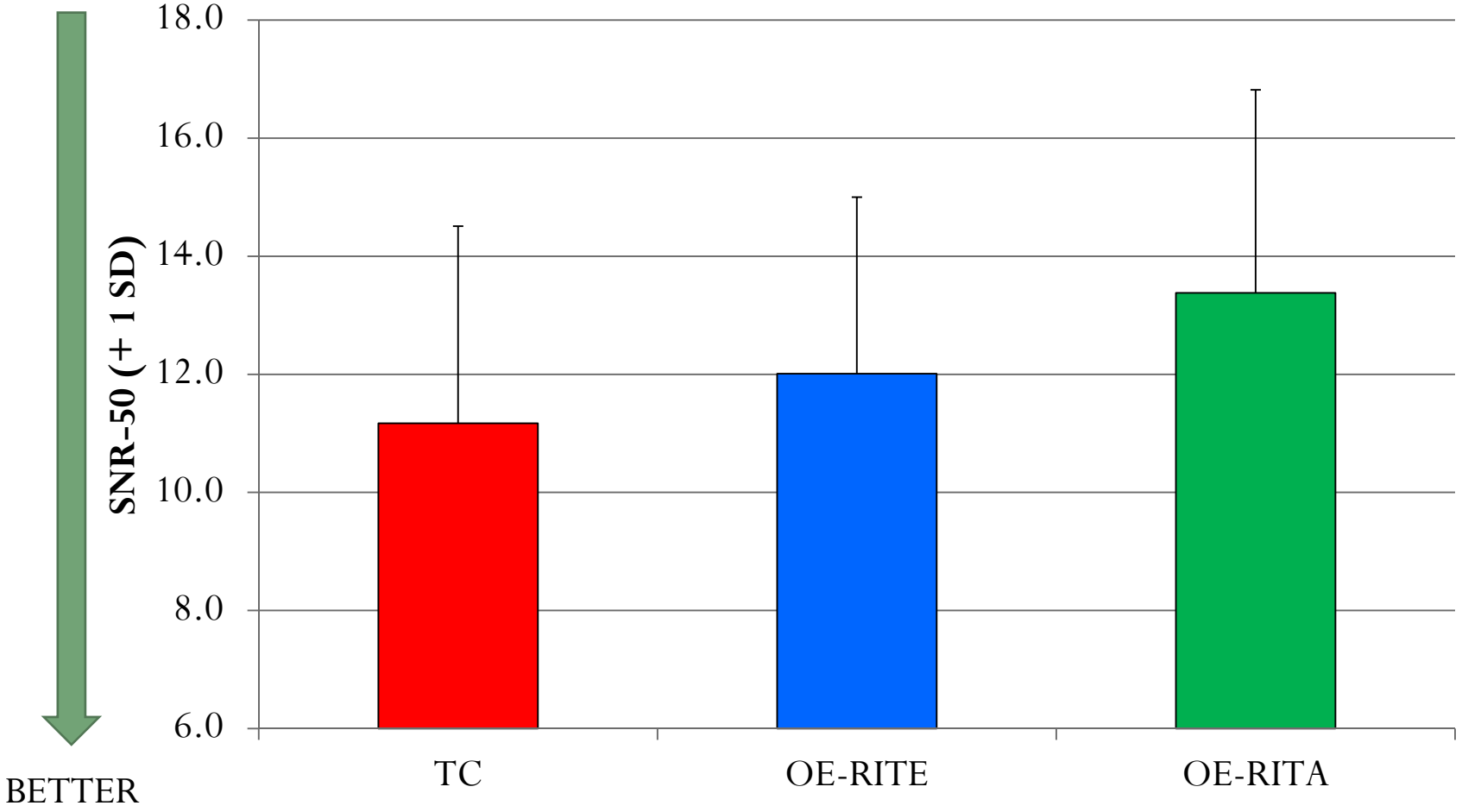
WIN

[Style: F (2, 510) = 117.68, p = .000, ηp^2 = .316]



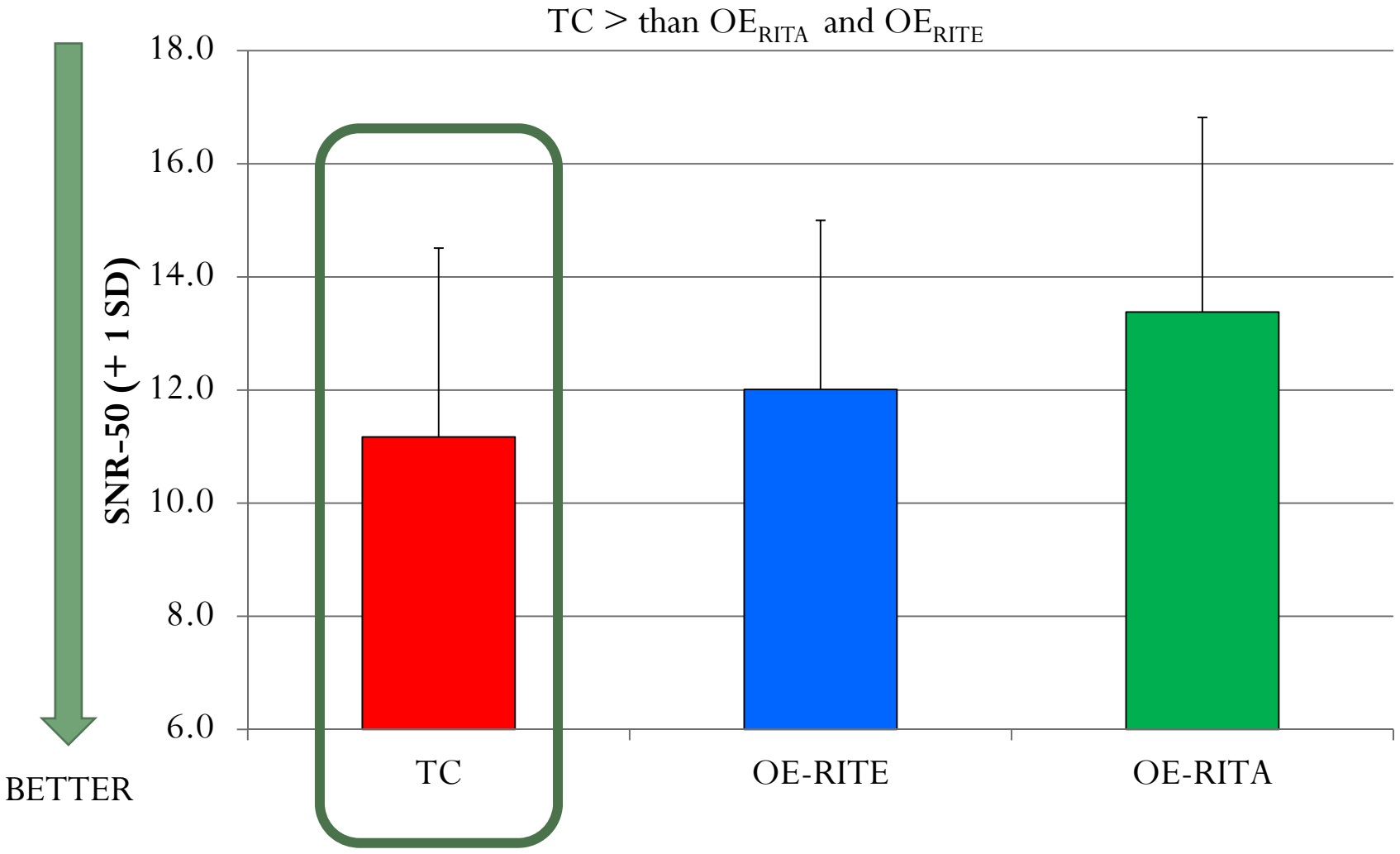
WIN

[Style: F (2, 510) = 117.68, p = .000, ηp^2 = .316]



WIN

[Style: F (2, 510) = 117.68, p = .000, ηp^2 = .316]



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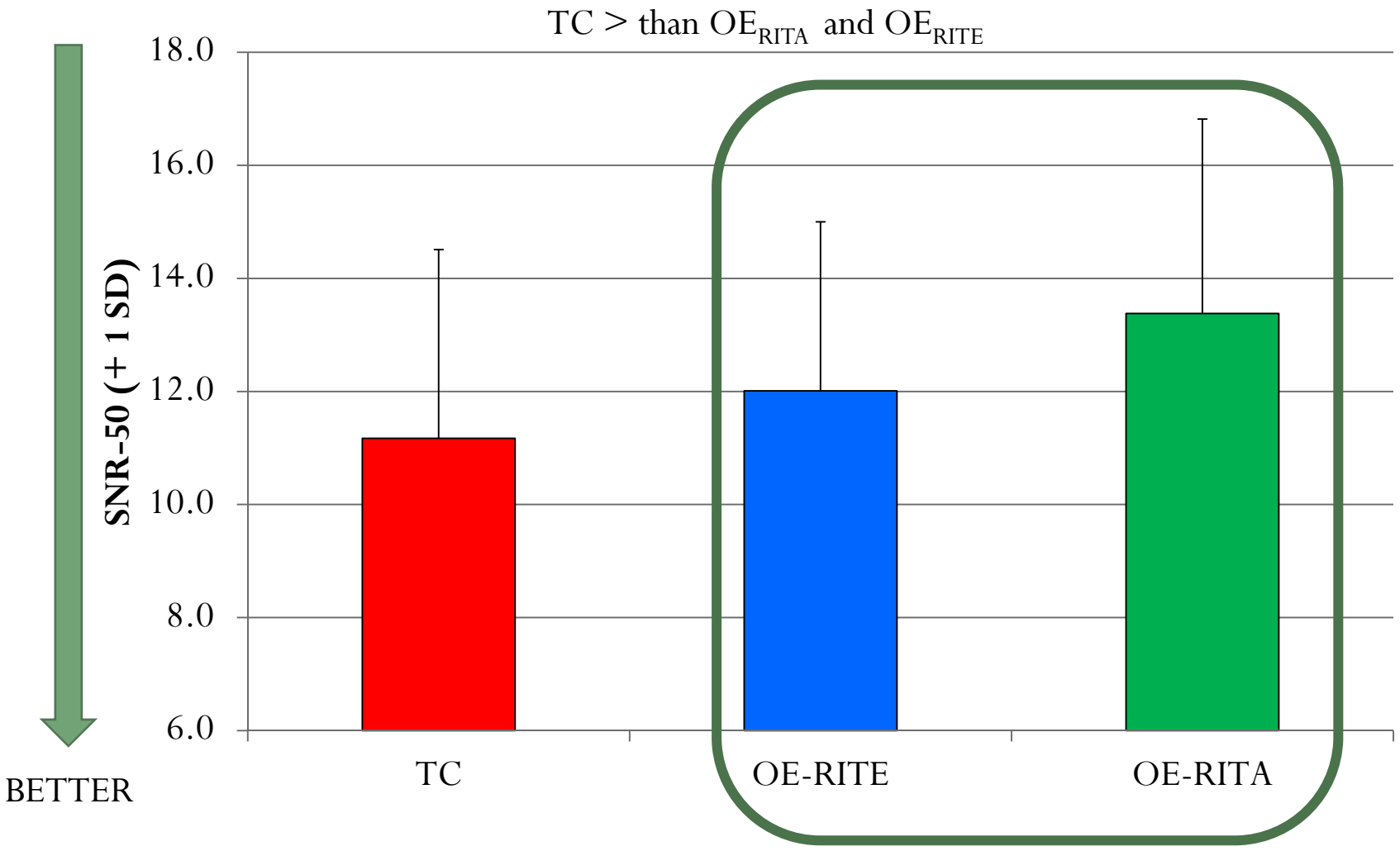

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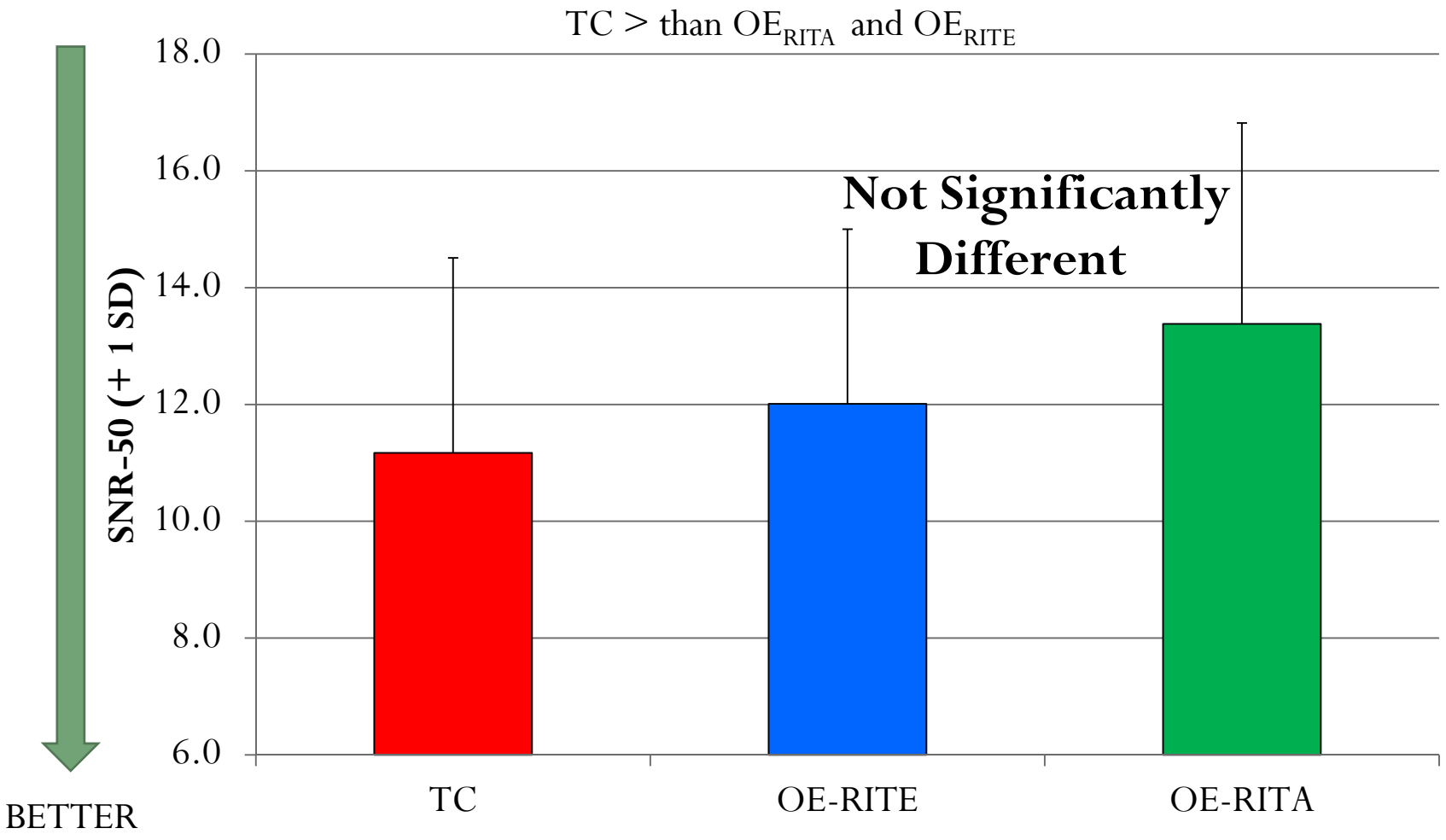


Trade-Off

Subjective OE > TC

- Fit, Comfort, Cosmetics
- Localization
- Ease of Use
- Subjective Occlusion

Objective TC > OE

- Speech understanding in noise

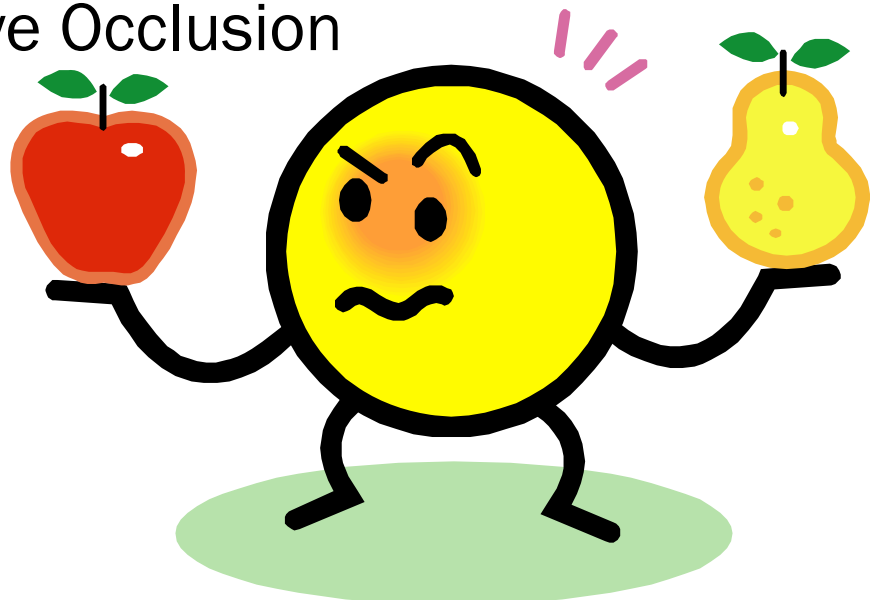
Which Drives Patient Preference?

Subjective OE > TC

- Fit, Comfort, Cosmetics
- Localization
- Ease of Use
- Subjective Occlusion

Objective TC > OE

- Speech understanding in noise



Preferred Hearing Aid Style

Style	*n* = 263	Percent
Traditional Custom		
OE-RITA		
OE-RITE		

Preferred Hearing Aid Style

Style	*n* = 263	Percent
Traditional Custom	52	19.7%
OE-RITA		
OE-RITE		

Preferred Hearing Aid Style

Style	*n* = 263	Percent
Traditional Custom	52	19.7%
OE-RITA	85	32.3%
OE-RITE		

Preferred Hearing Aid Style

Style	*n* = 263	Percent
Traditional Custom	52	19.7%
OE-RITA	85	32.3%
OE-RITE	126	48.0%

BUT….

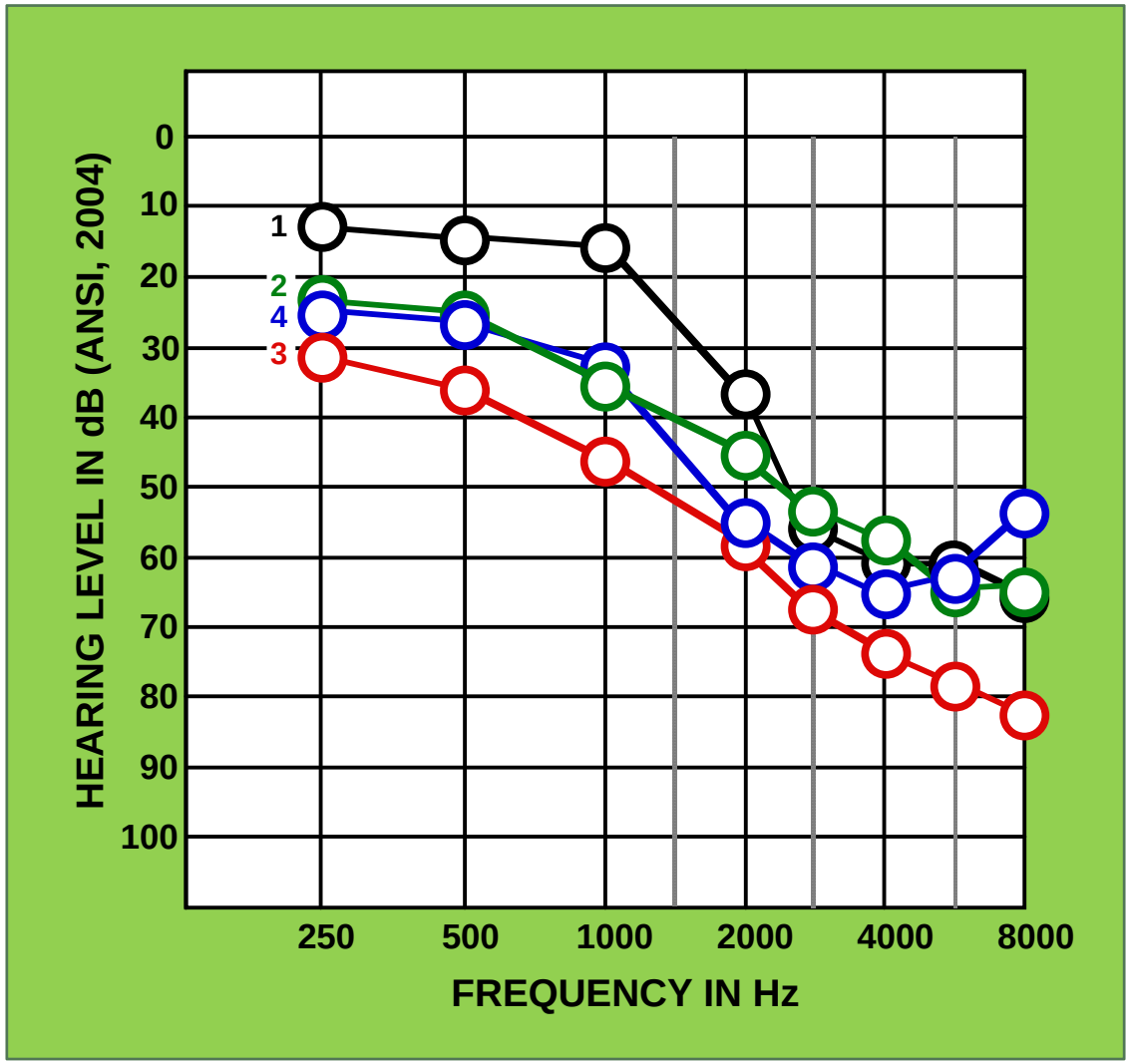
Without a 3-arm crossover trial, how do you know what style to recommend to your patients?

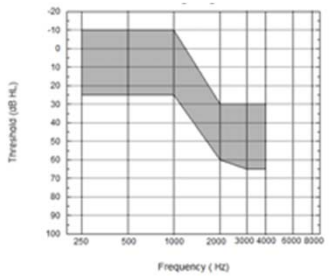
BUT….

Without a 3-arm crossover trial, how do you know what style to recommend to your patients?

Can you make the decision based on the audiogram?

Does Style Preference Differ as a Function of Hearing Loss Category?





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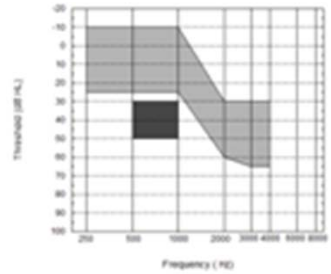

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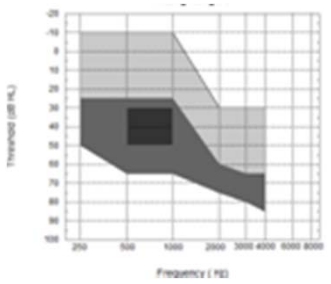
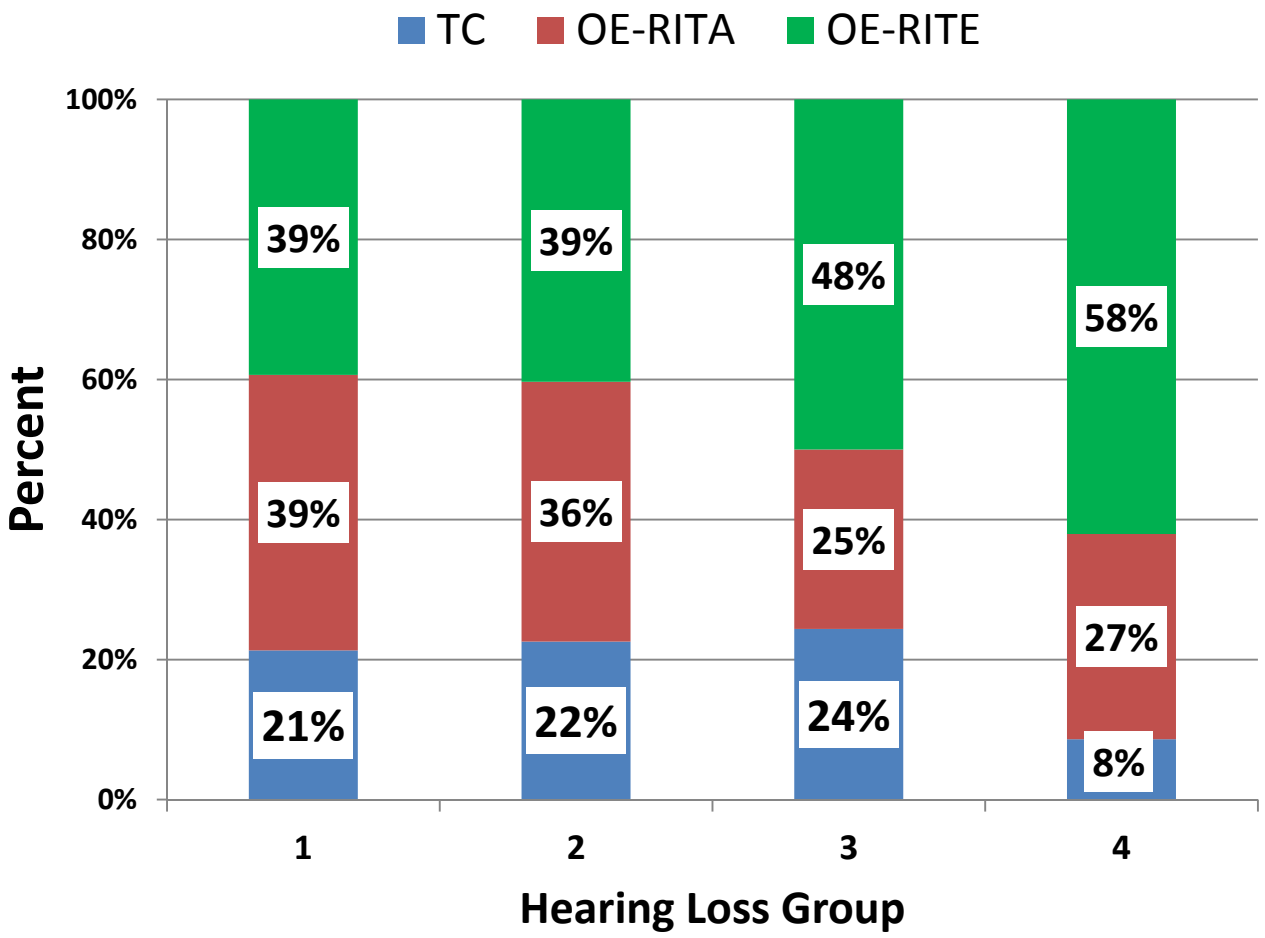
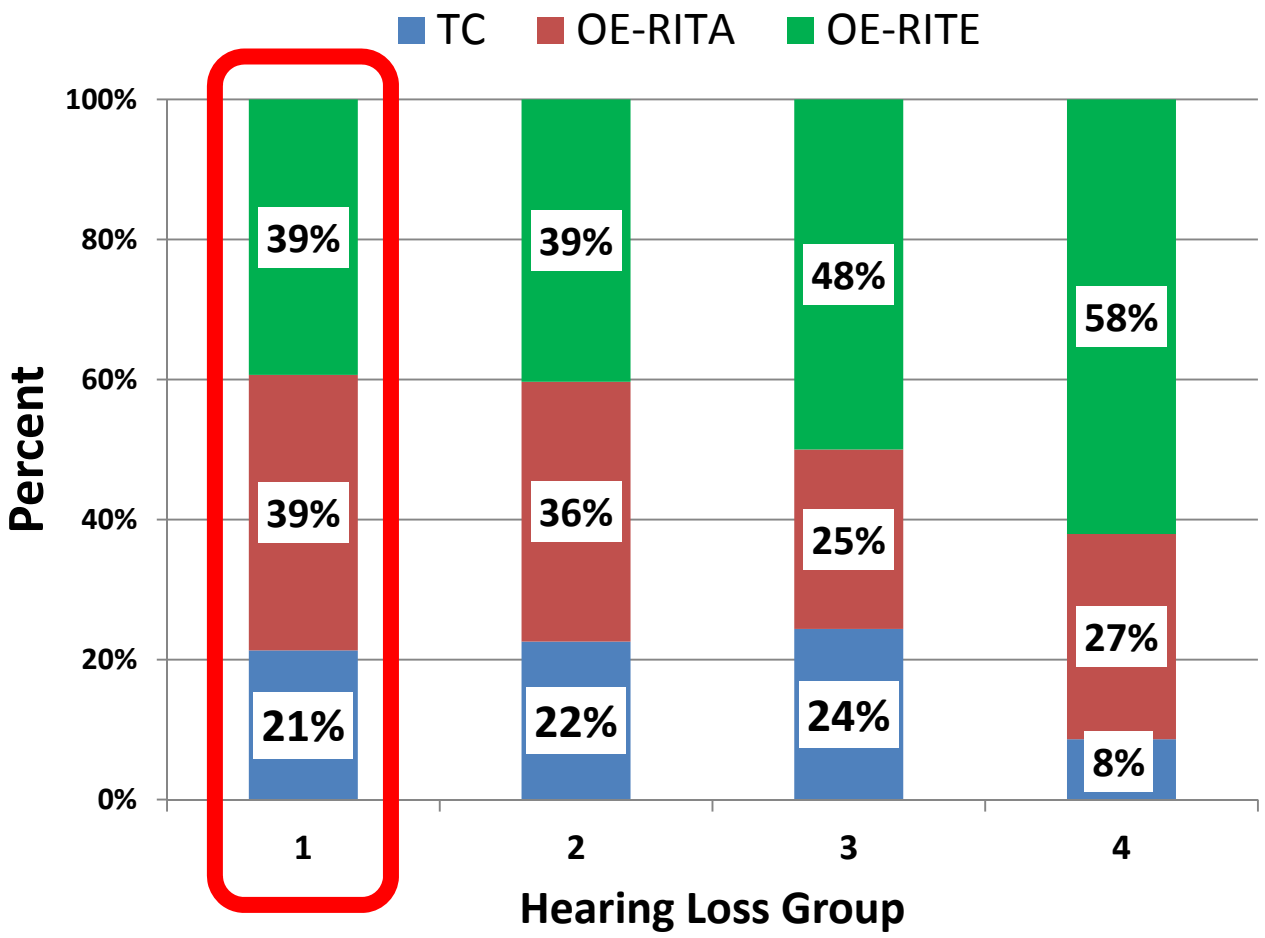


= 3

Percentage Preferring Each HA Style within each HL Group



Percentage Preferring Each HA Style within each HL Group



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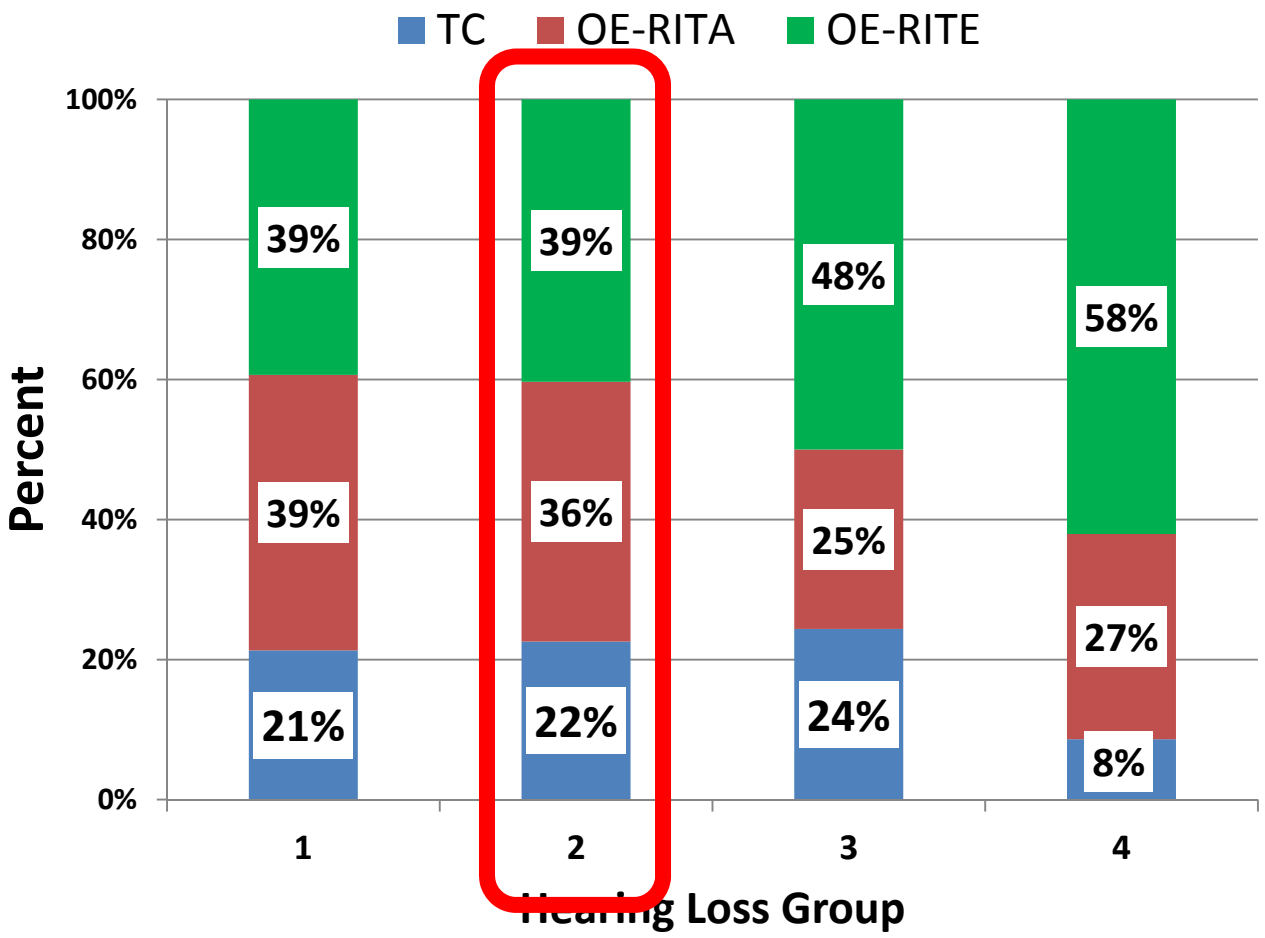

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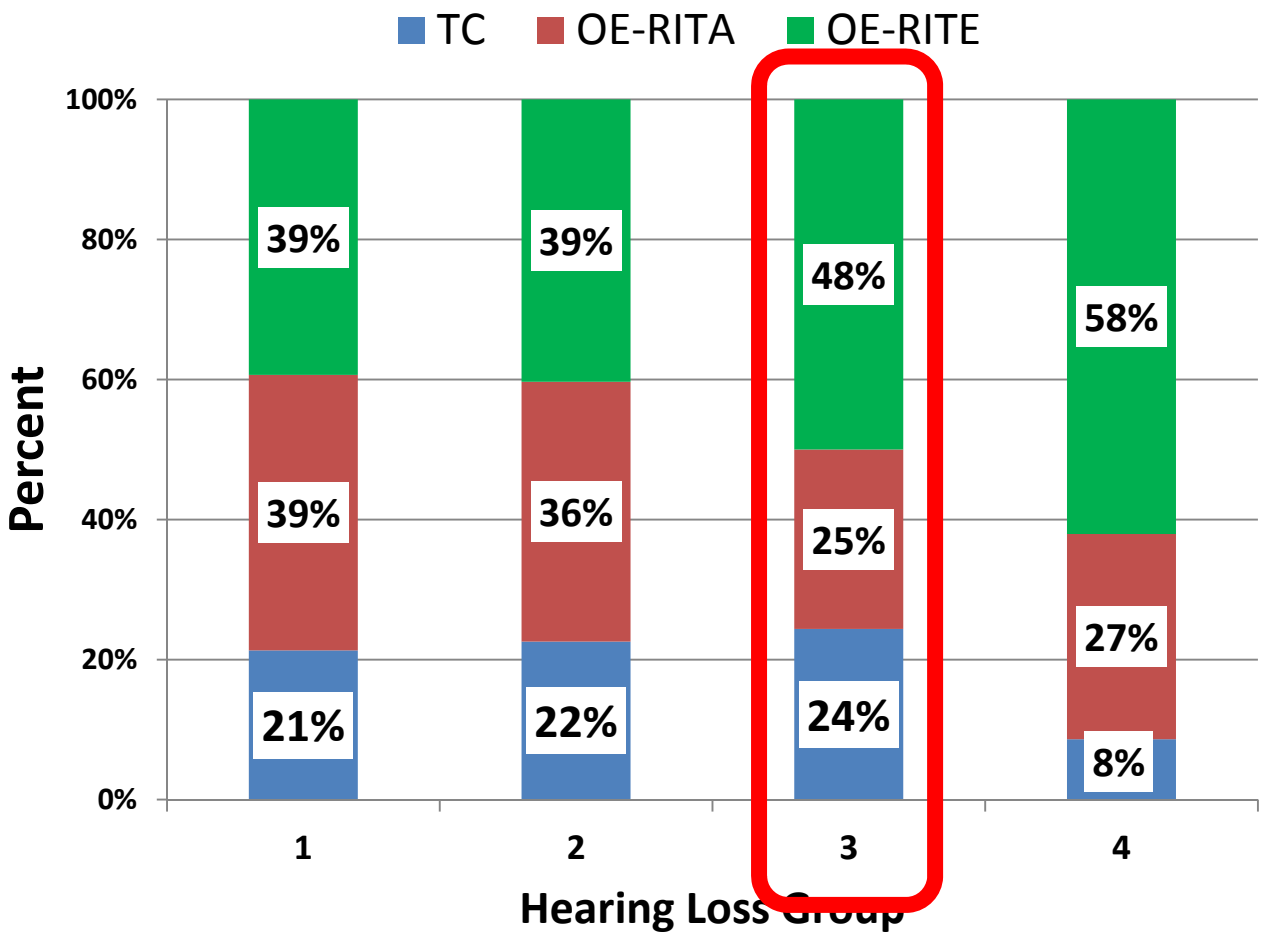
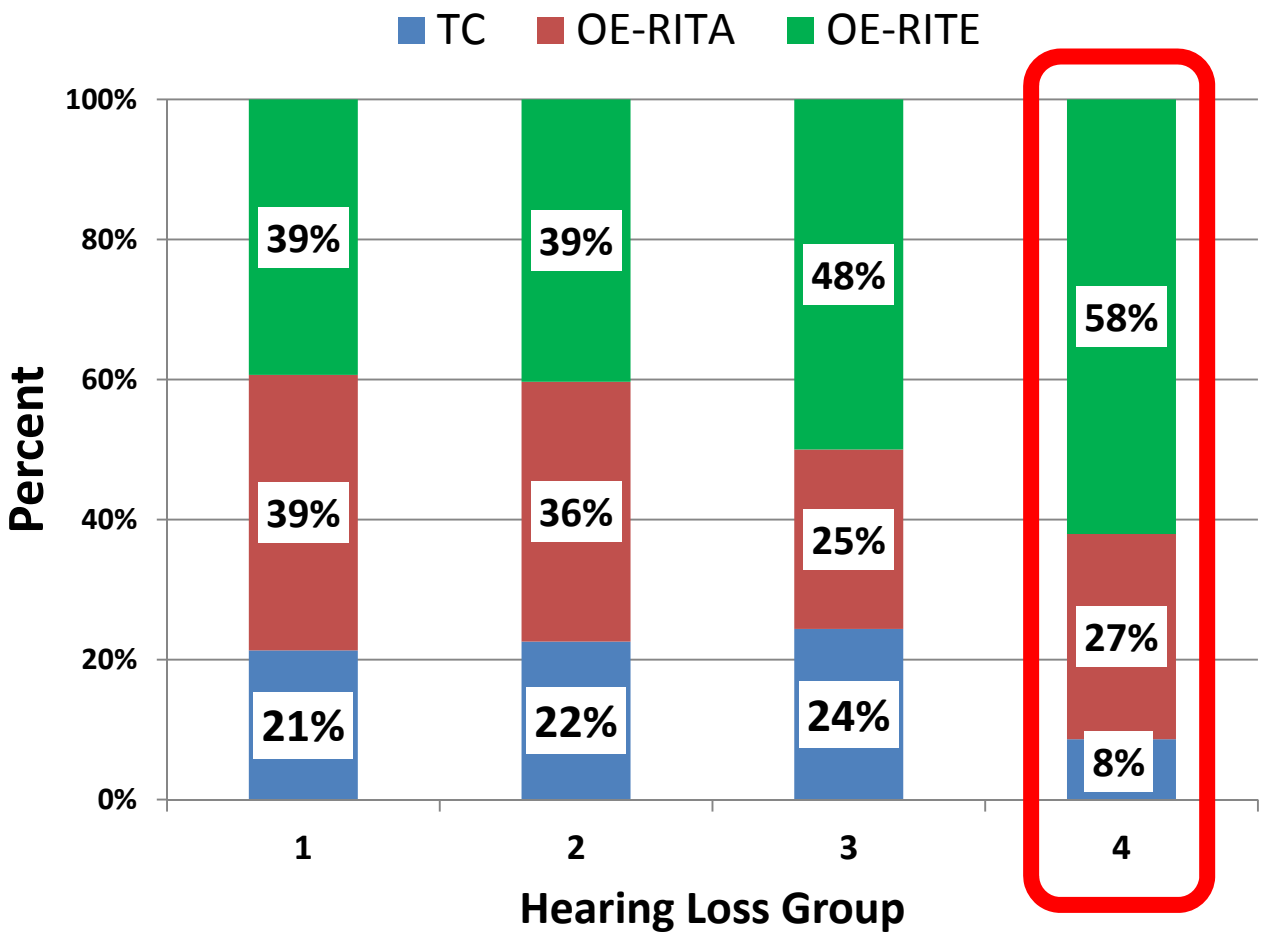
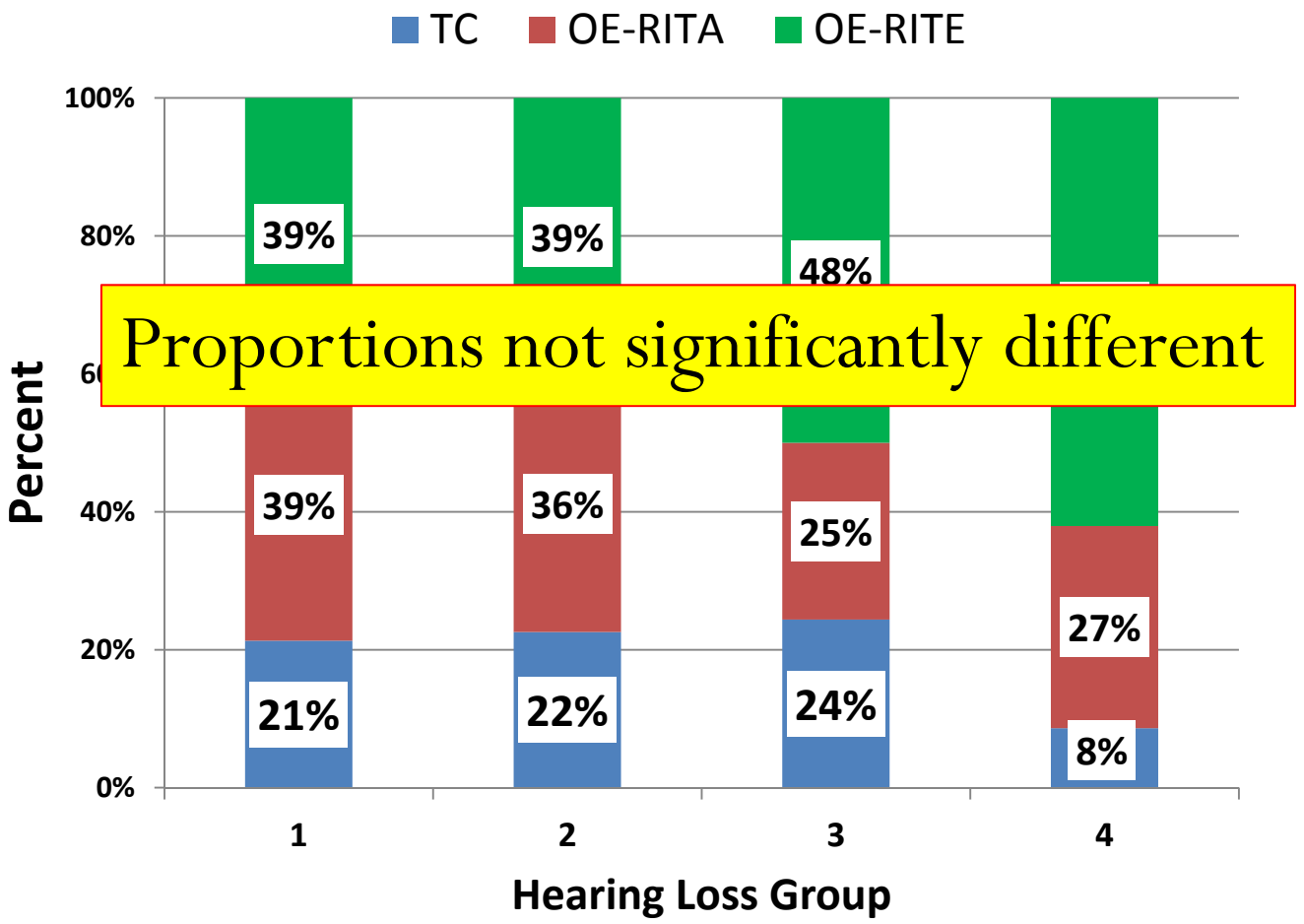


Percentage Preferring Each HA Style within each HL Group



Percentage Preferring Each HA Style within each HL Group

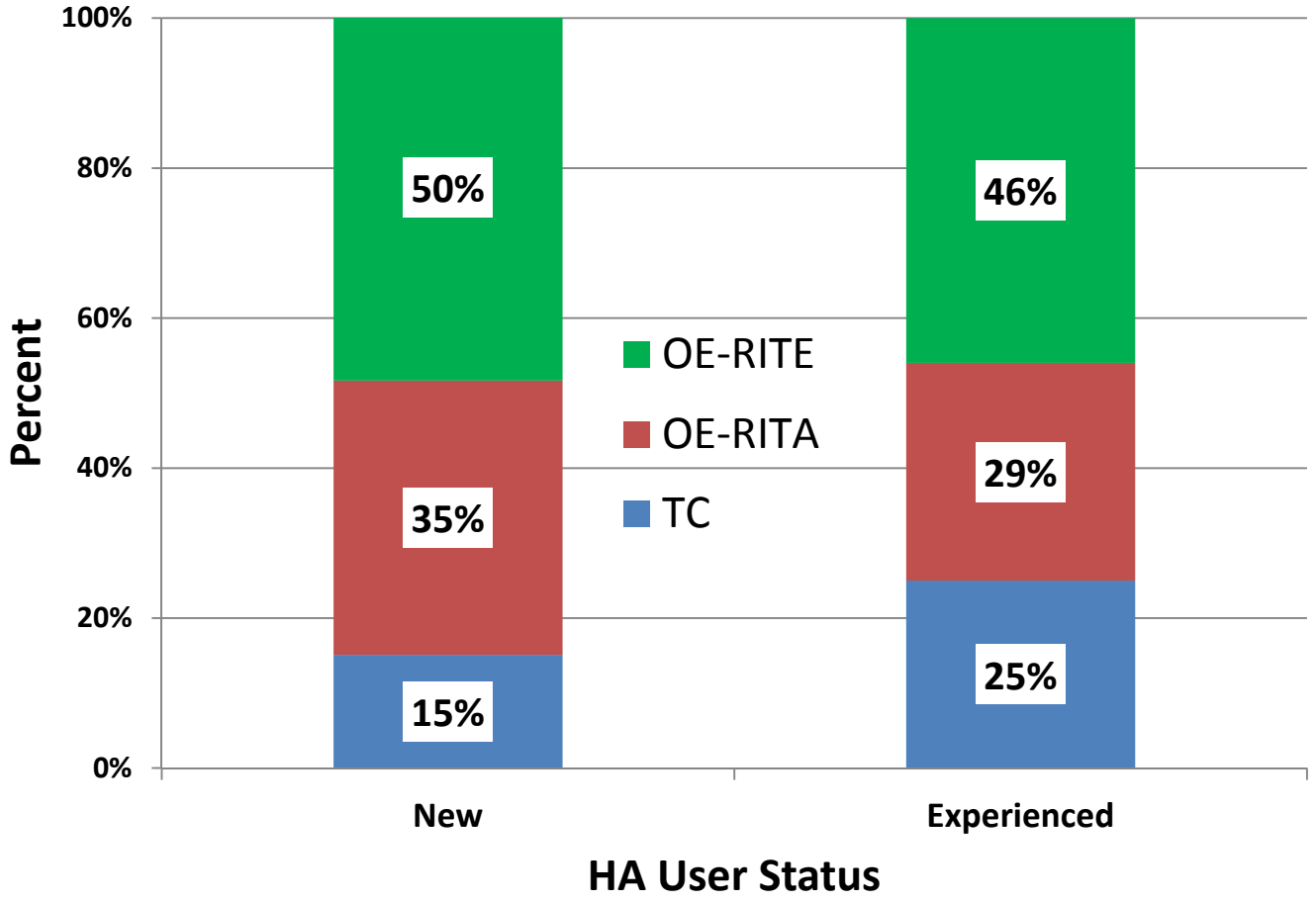


BUT….

Without a 3-arm crossover trial, how do you know what style to recommend to your patients?

Can you make the decision based on **hearing aid experience**?

Percentage Preferring Each Style as a Function of HA Experience



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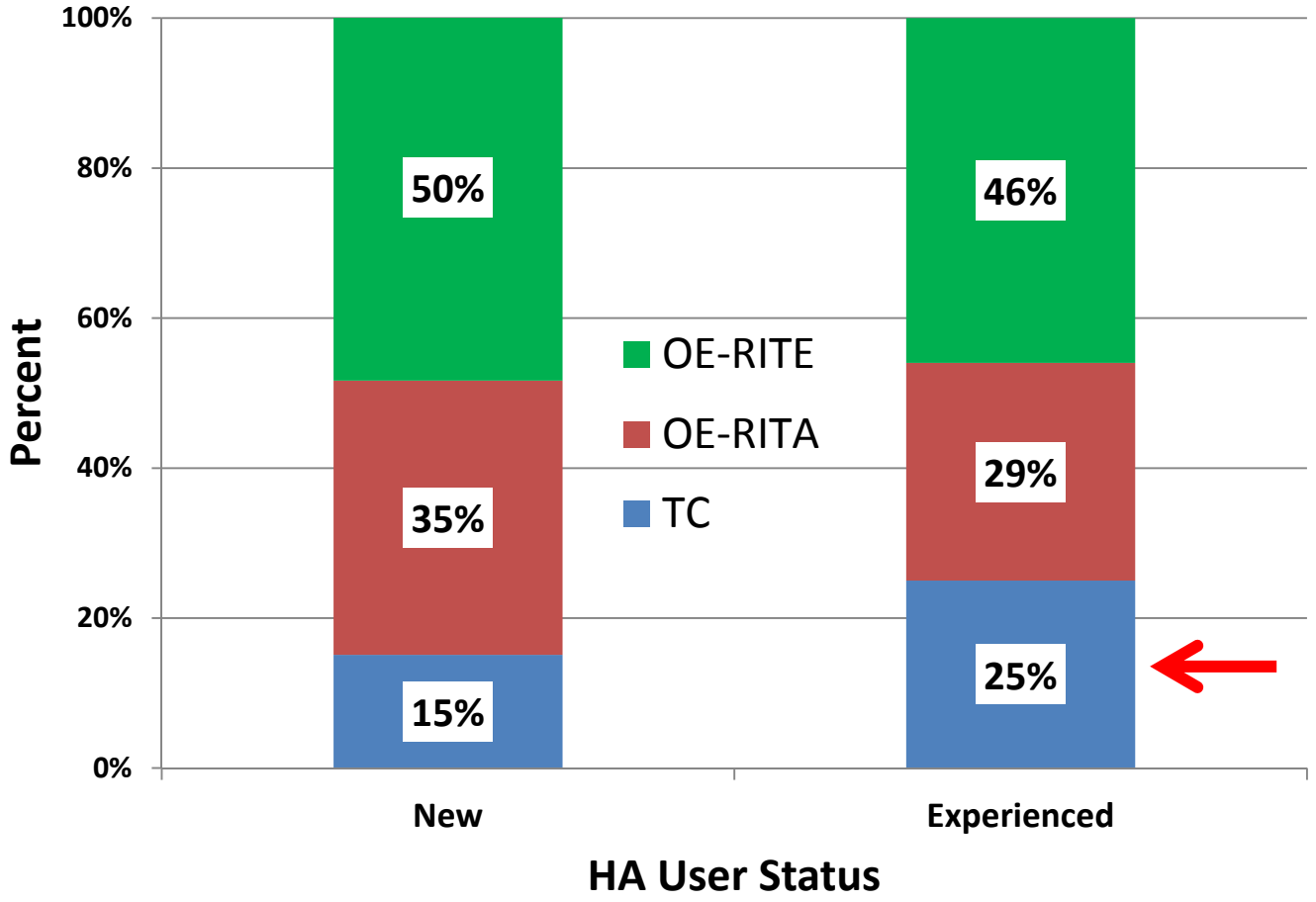
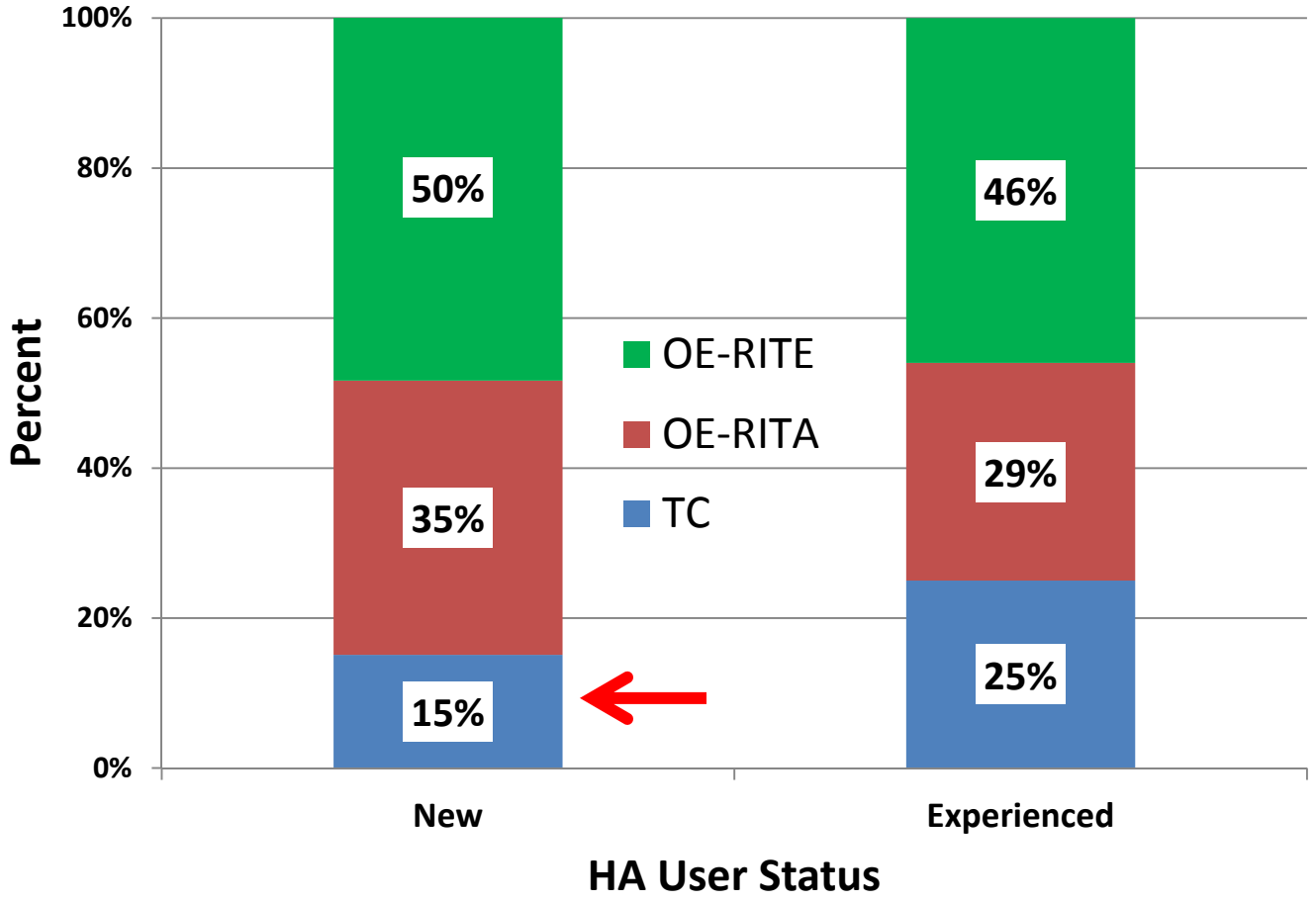


Percentage Preferring Each Style as a Function of HA Experience



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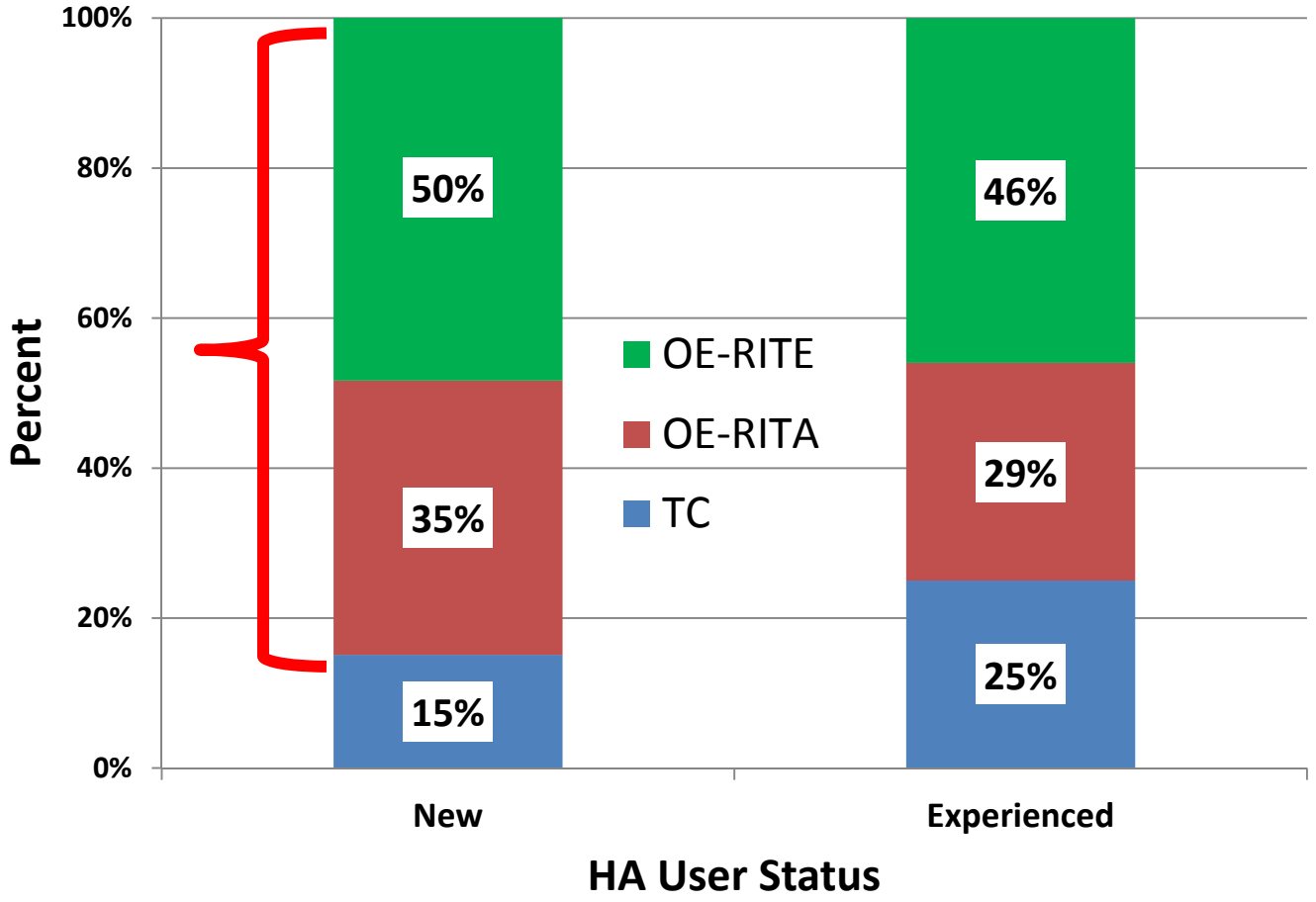

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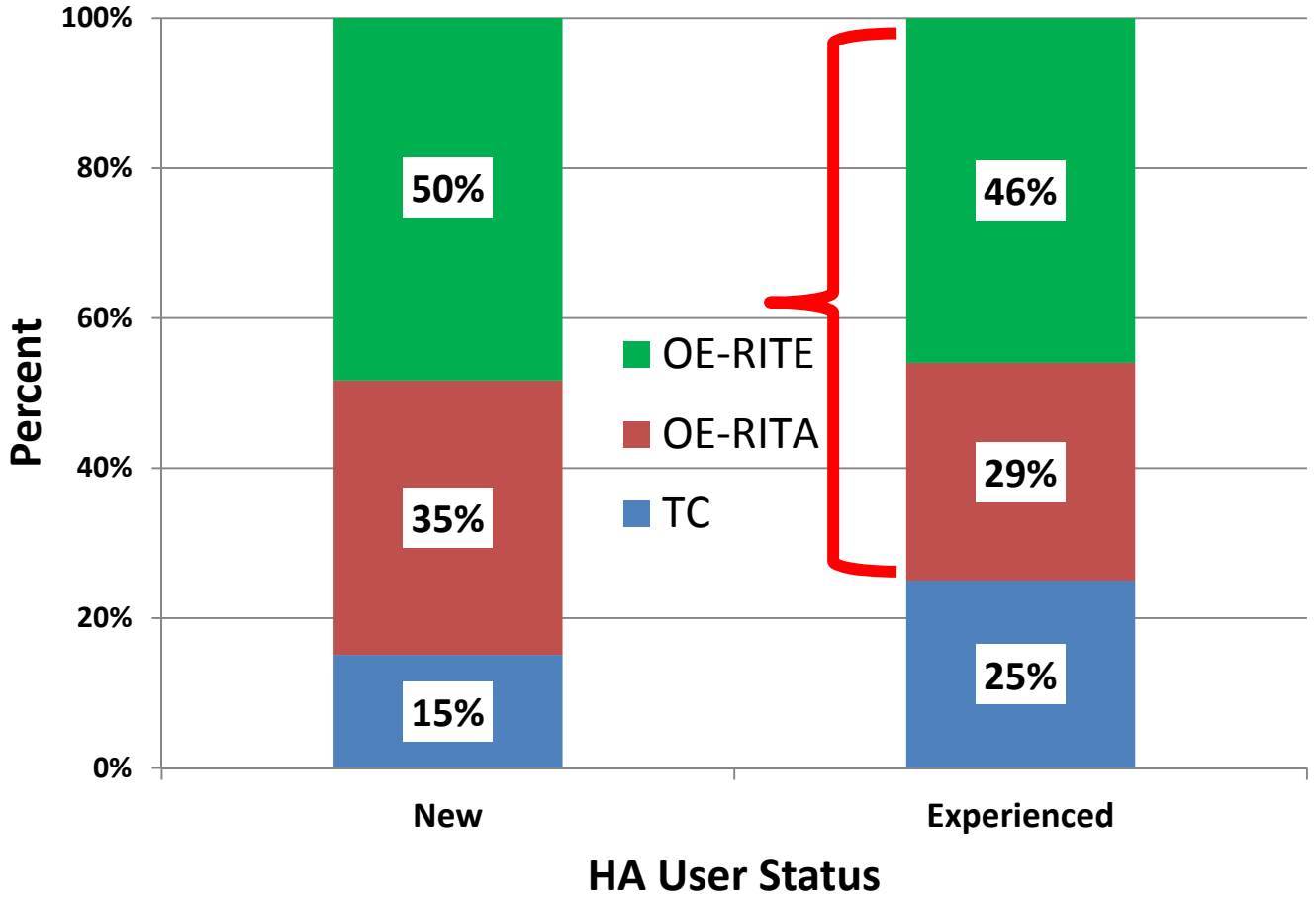
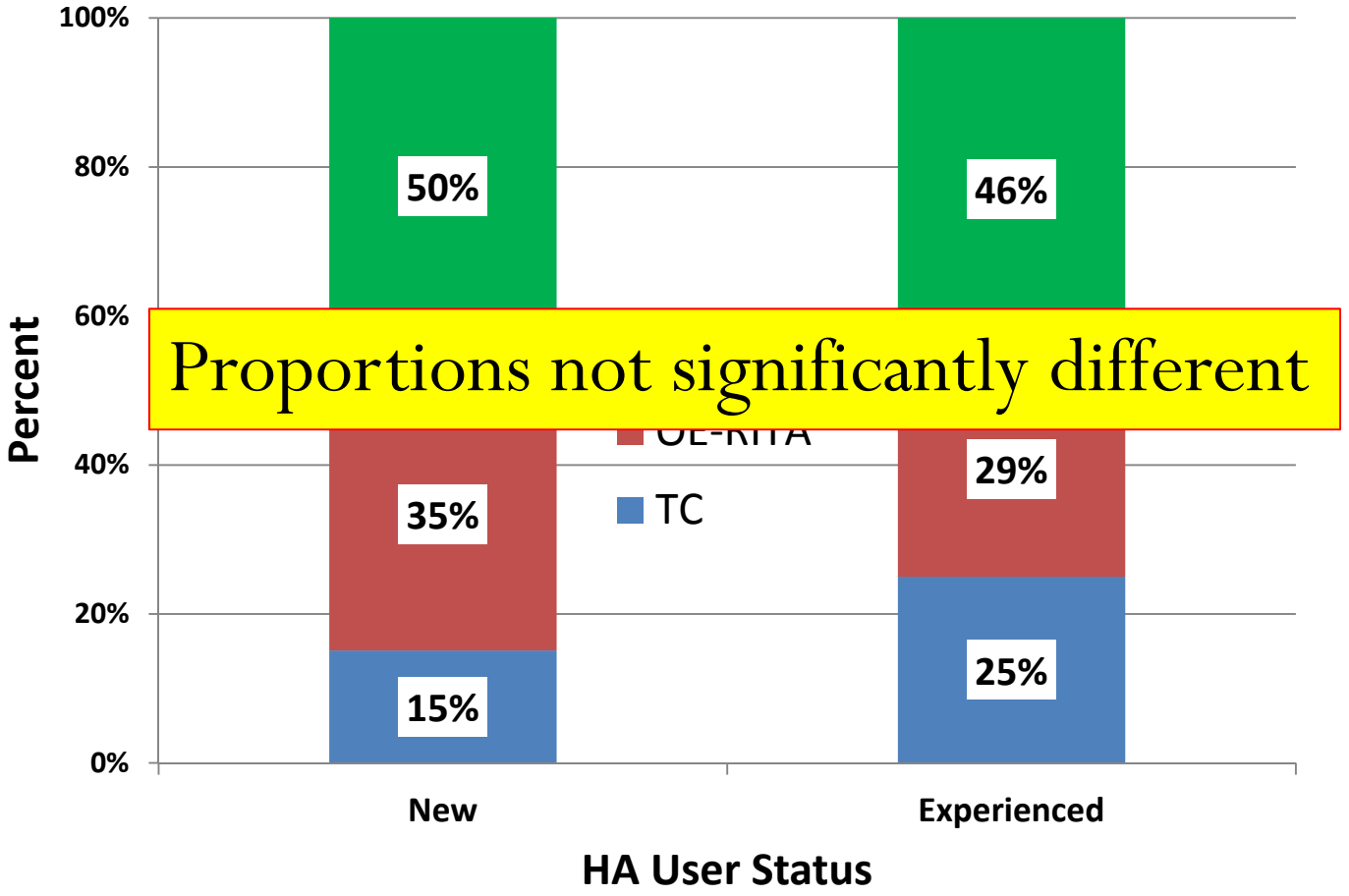


Percentage Preferring Each Style as a Function of HA Experience



Proportions not significantly different

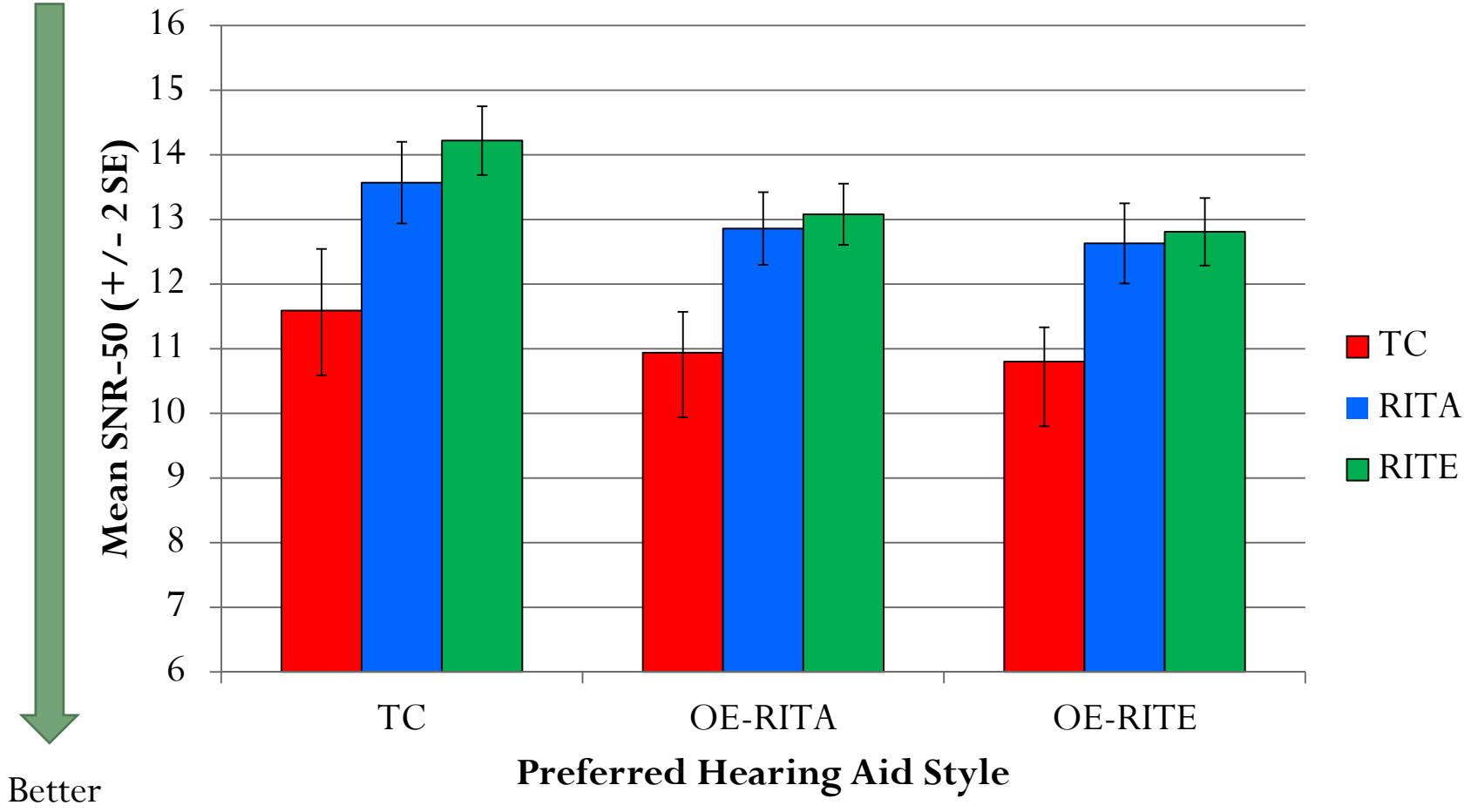
BUT….

Without a 3-arm crossover trial, how do you know what style to recommend to your patients?

Can you make the decision based on speech understanding in noise?

Aided or Unaided?

Aided WIN as a Function of Preferred Hearing Aid Style



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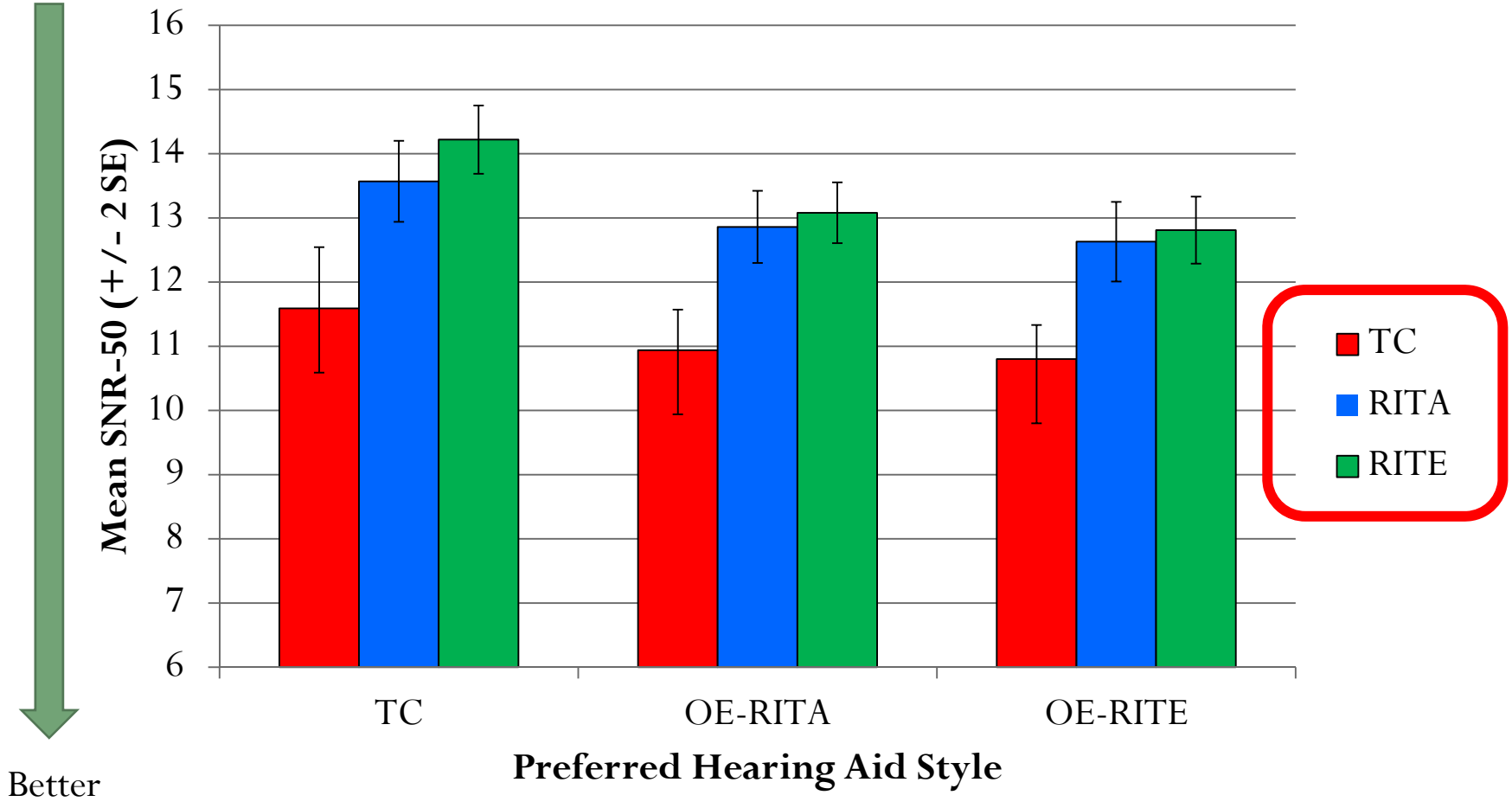
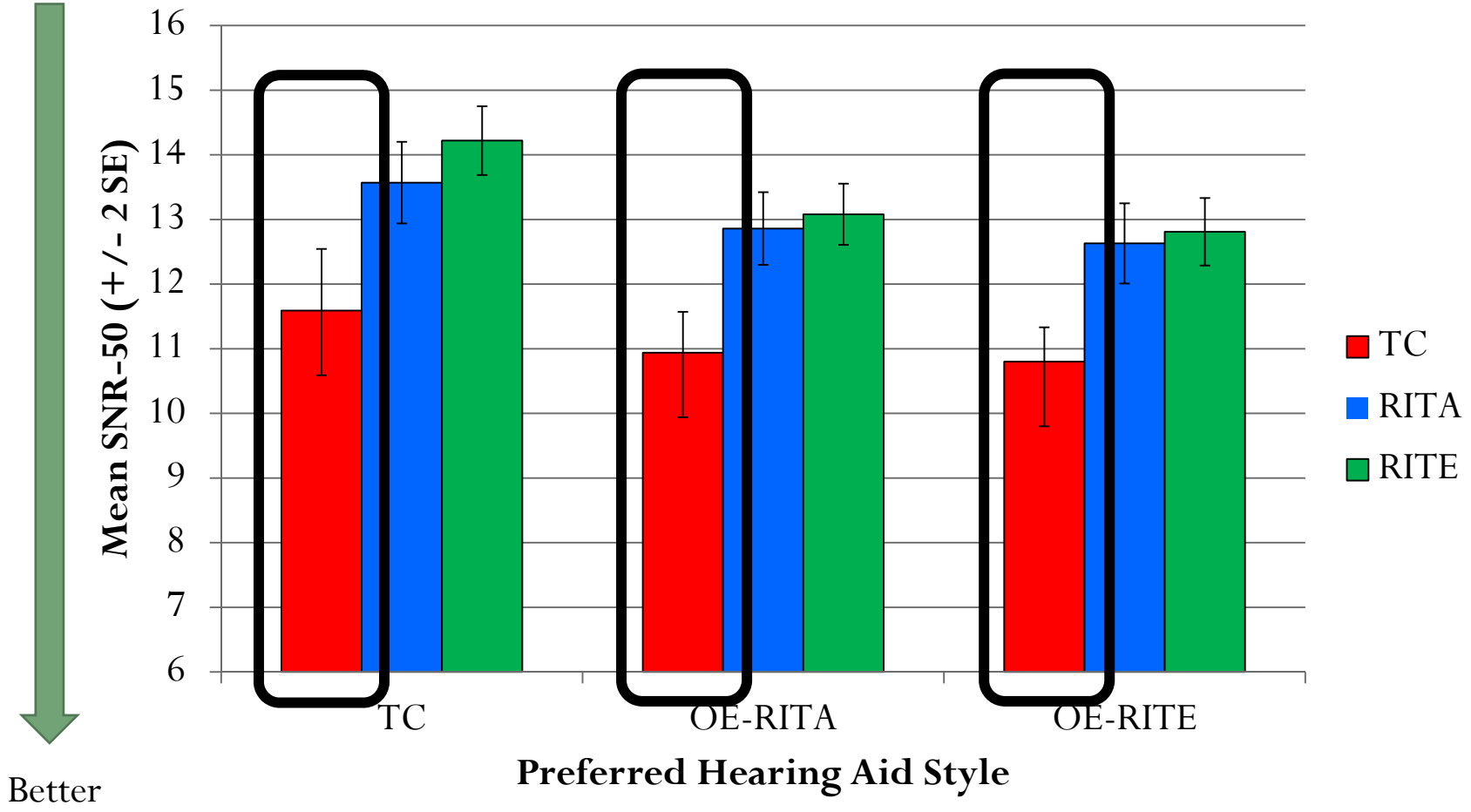


Aided WIN as a Function of Preferred Hearing Aid Style



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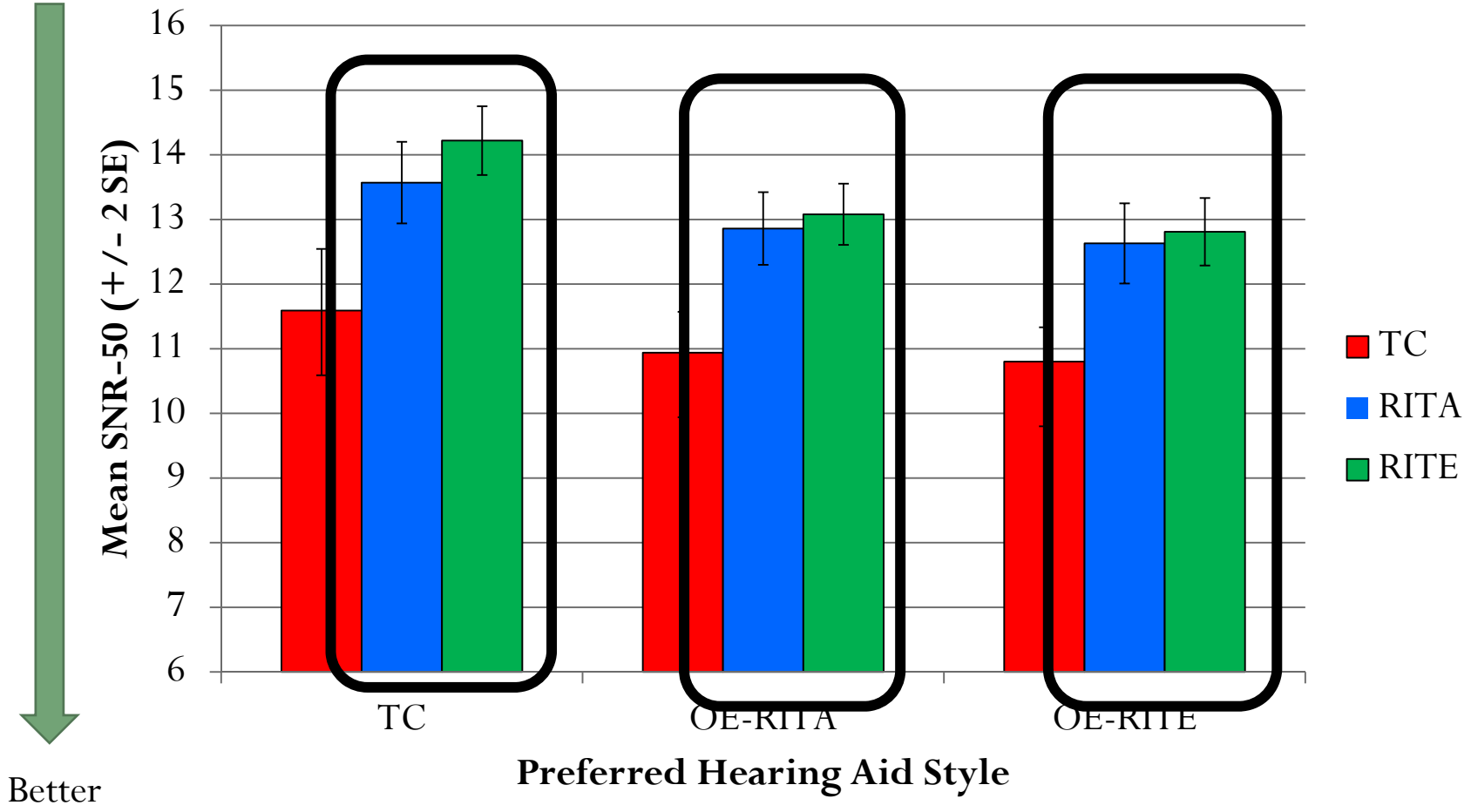

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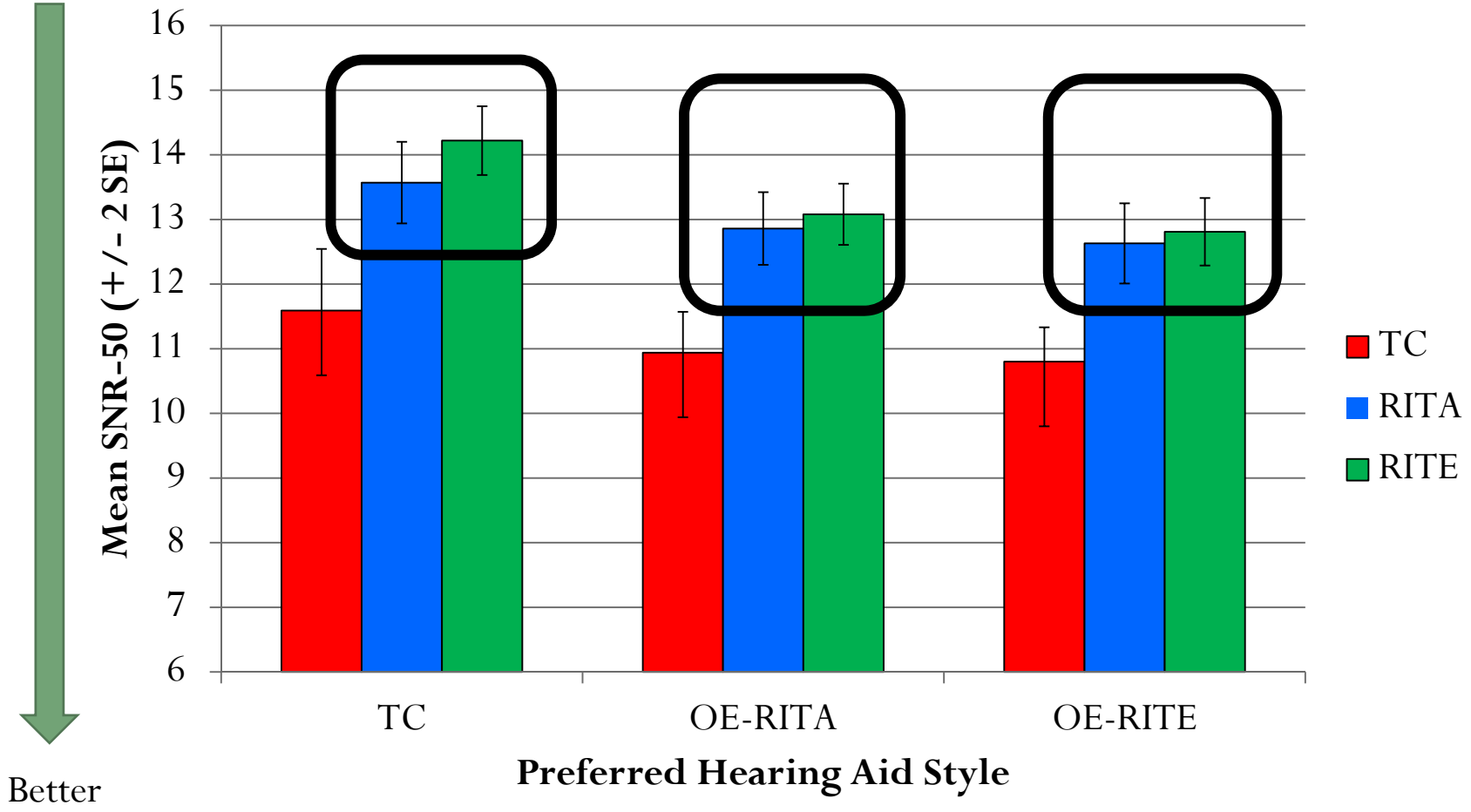

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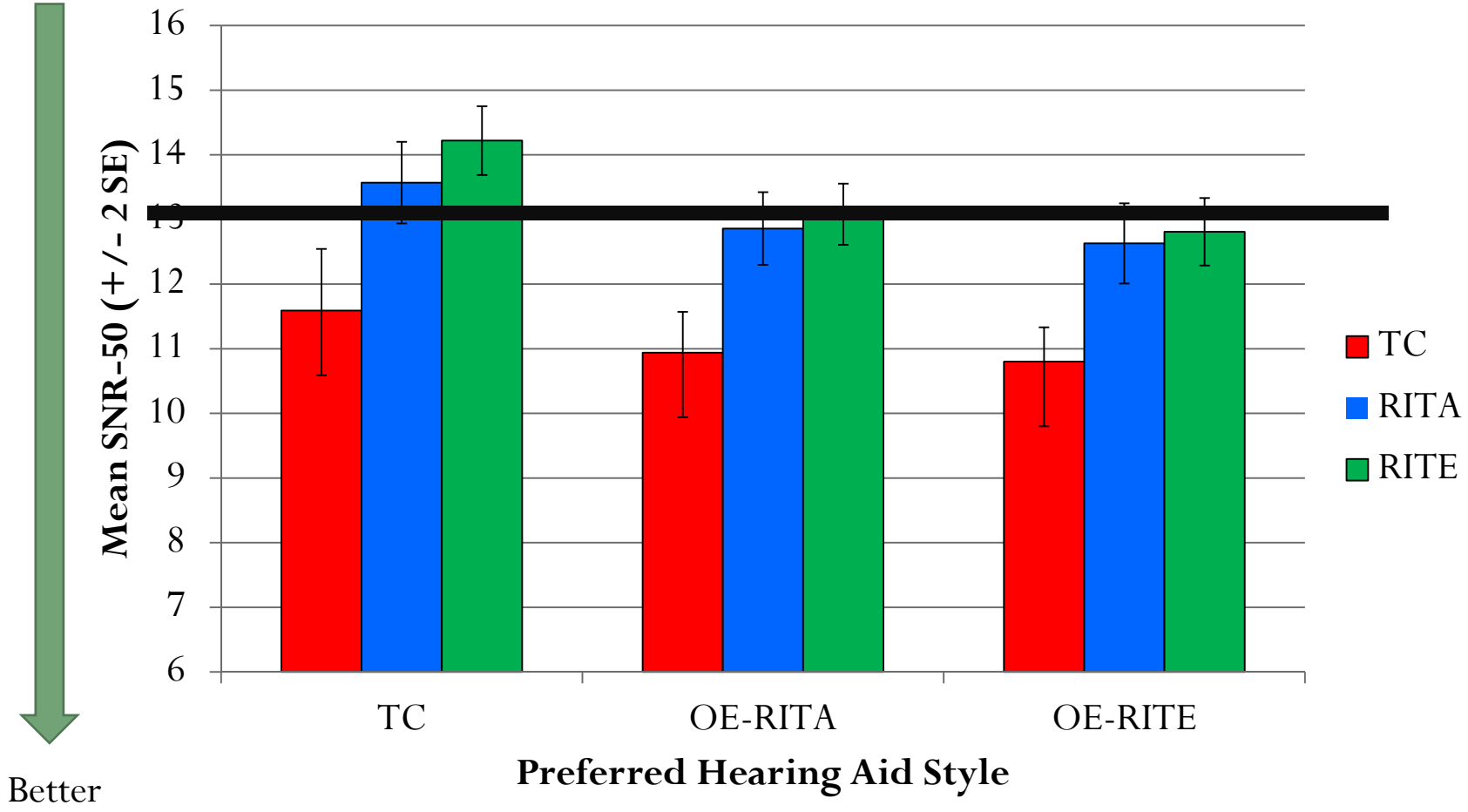

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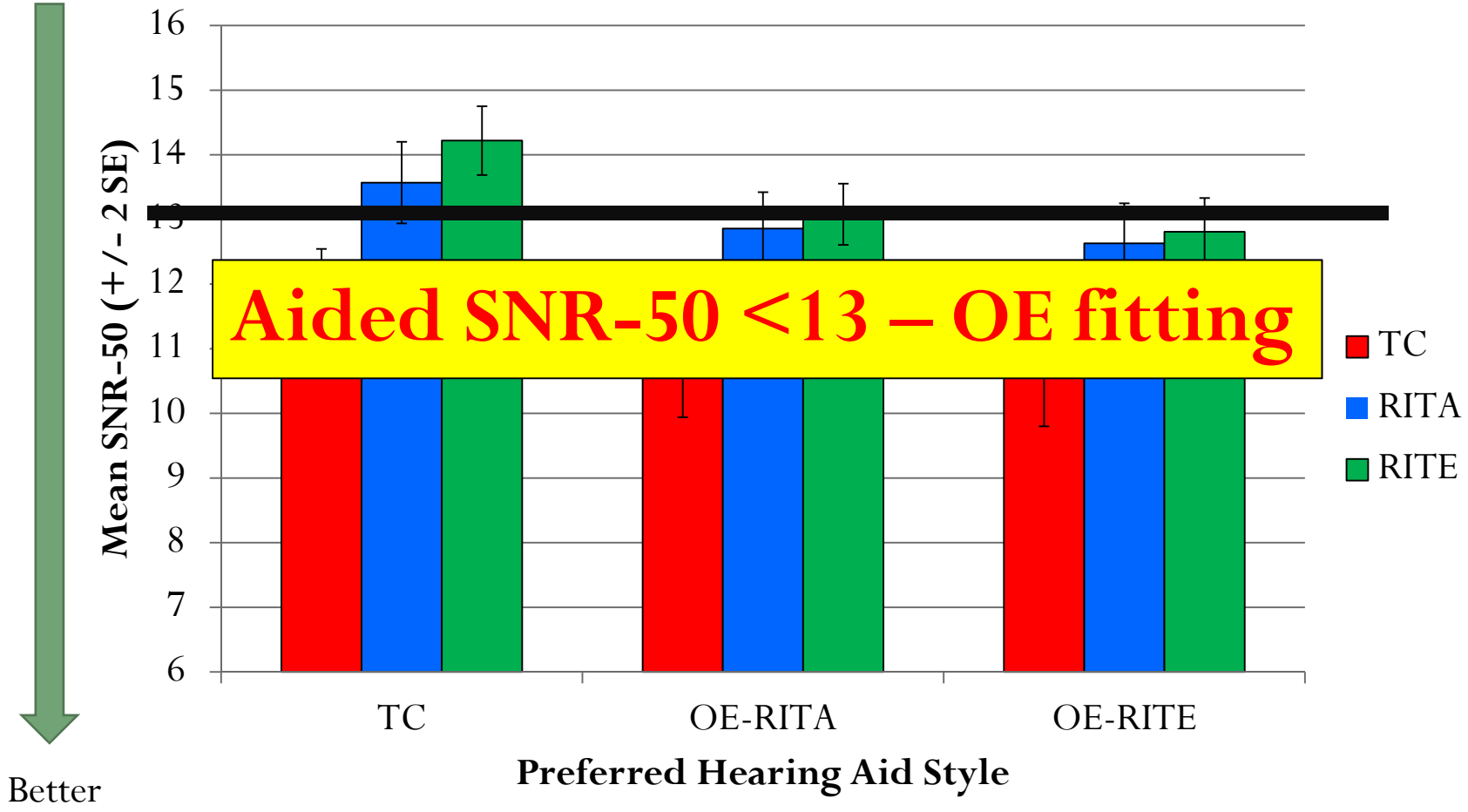
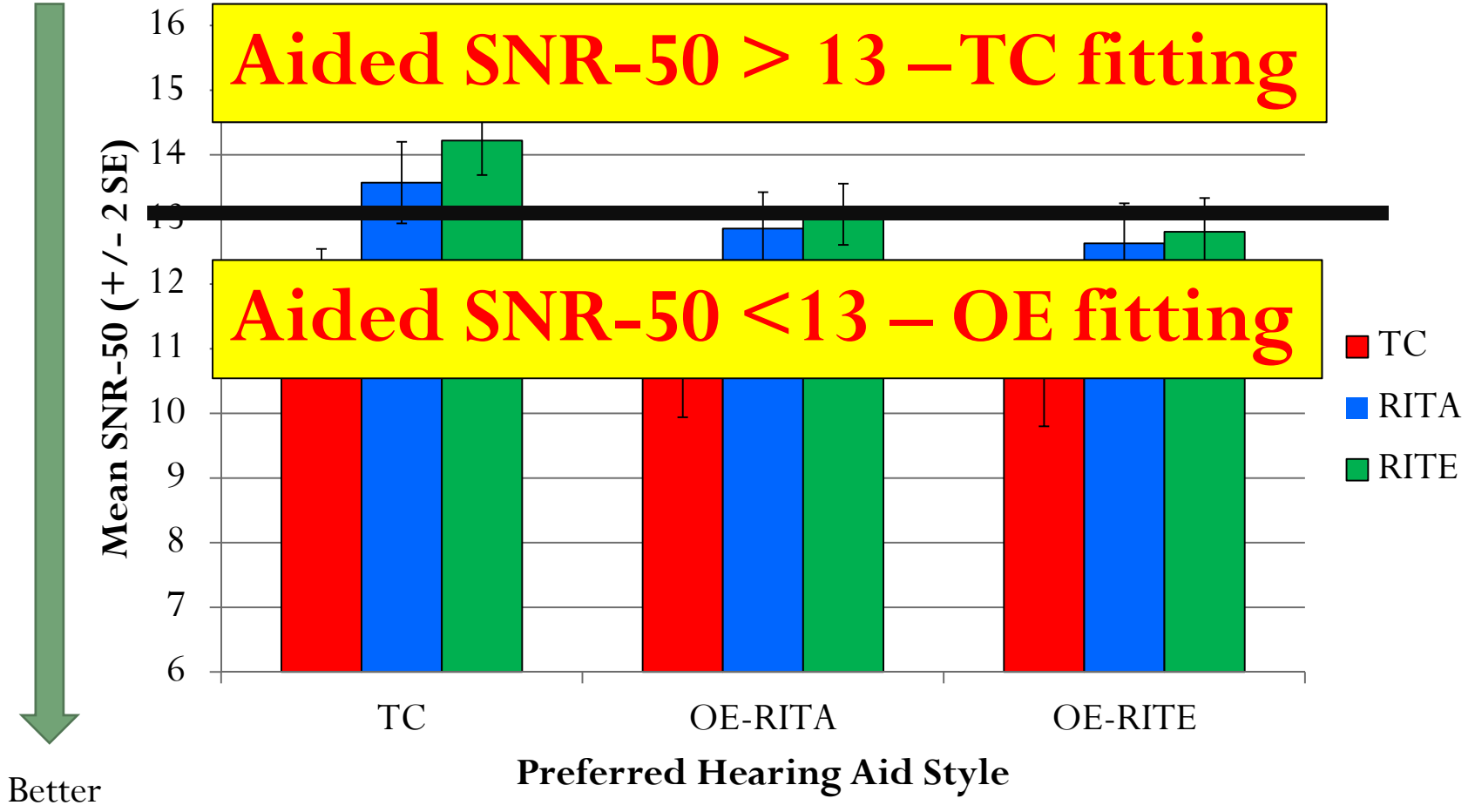


Aided WIN as a Function of Preferred Hearing Aid Style



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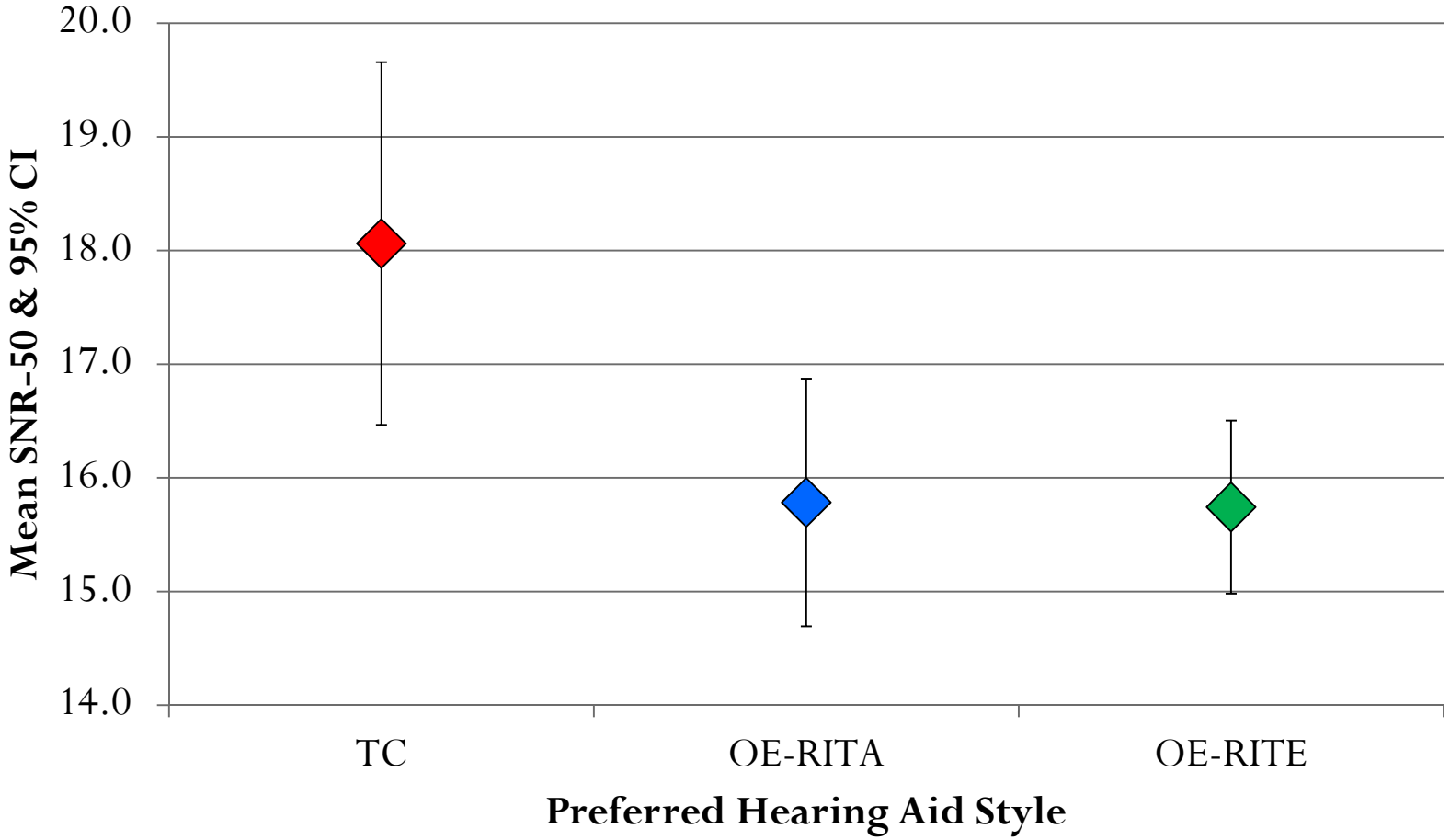

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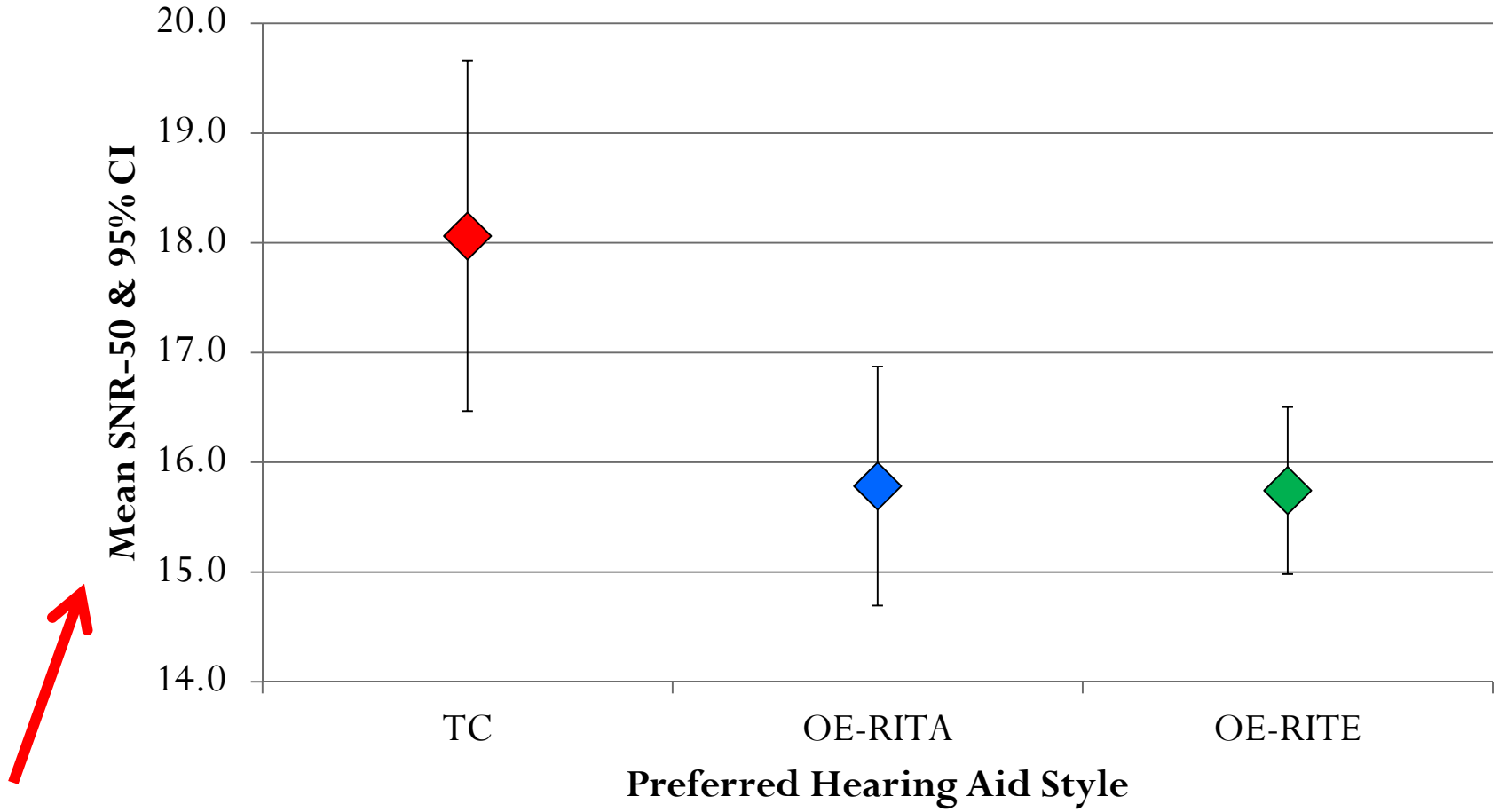

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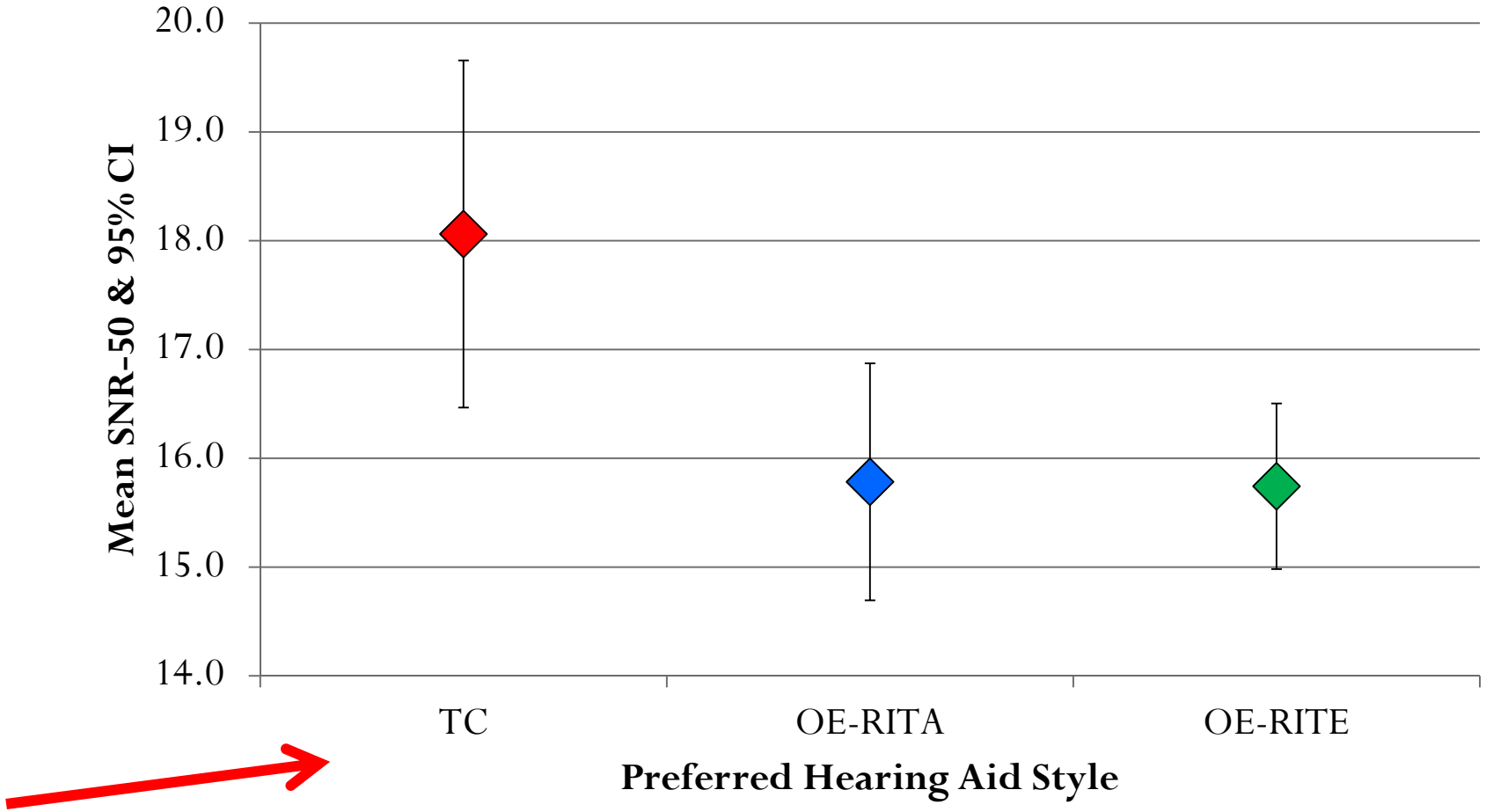

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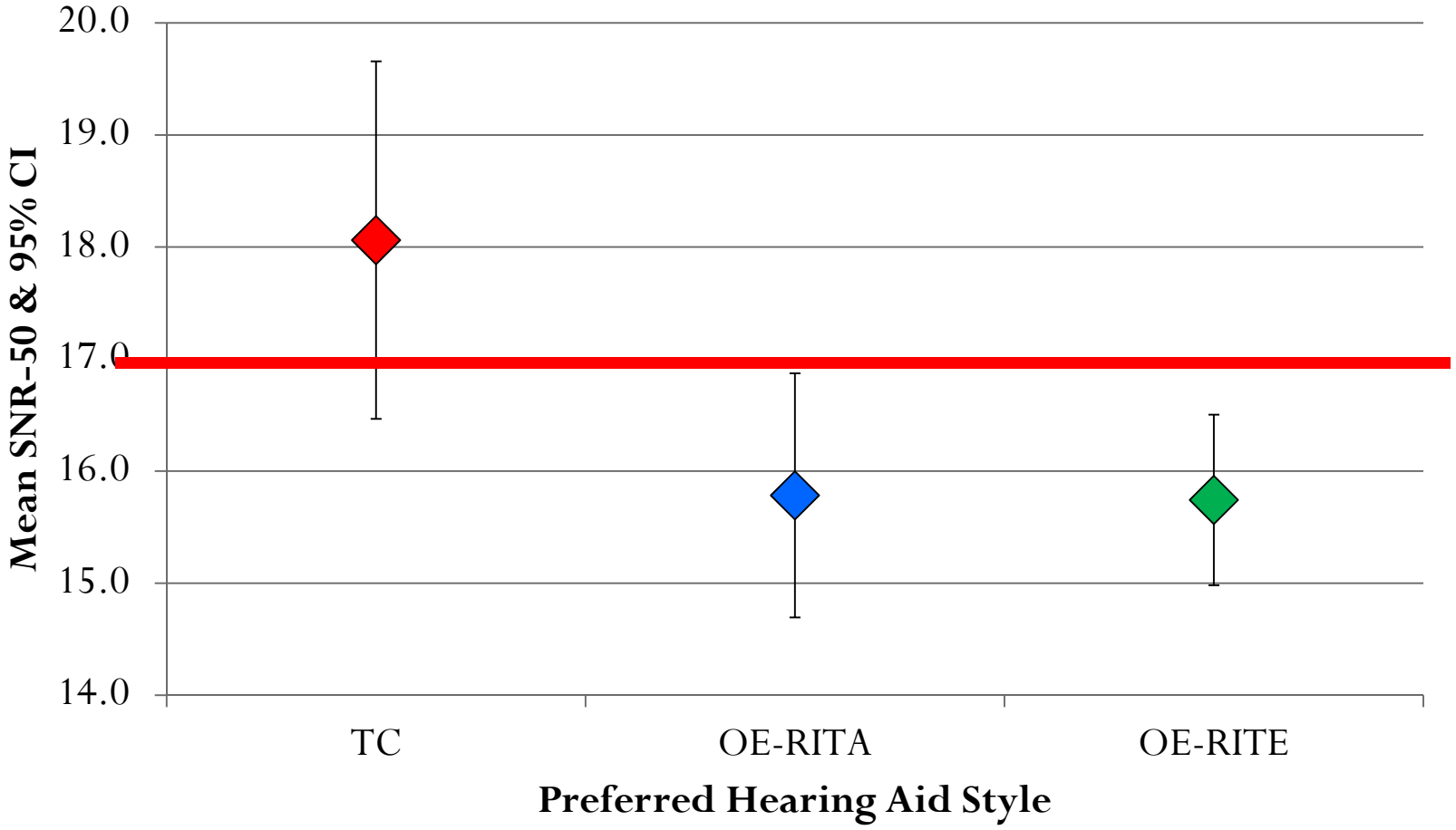

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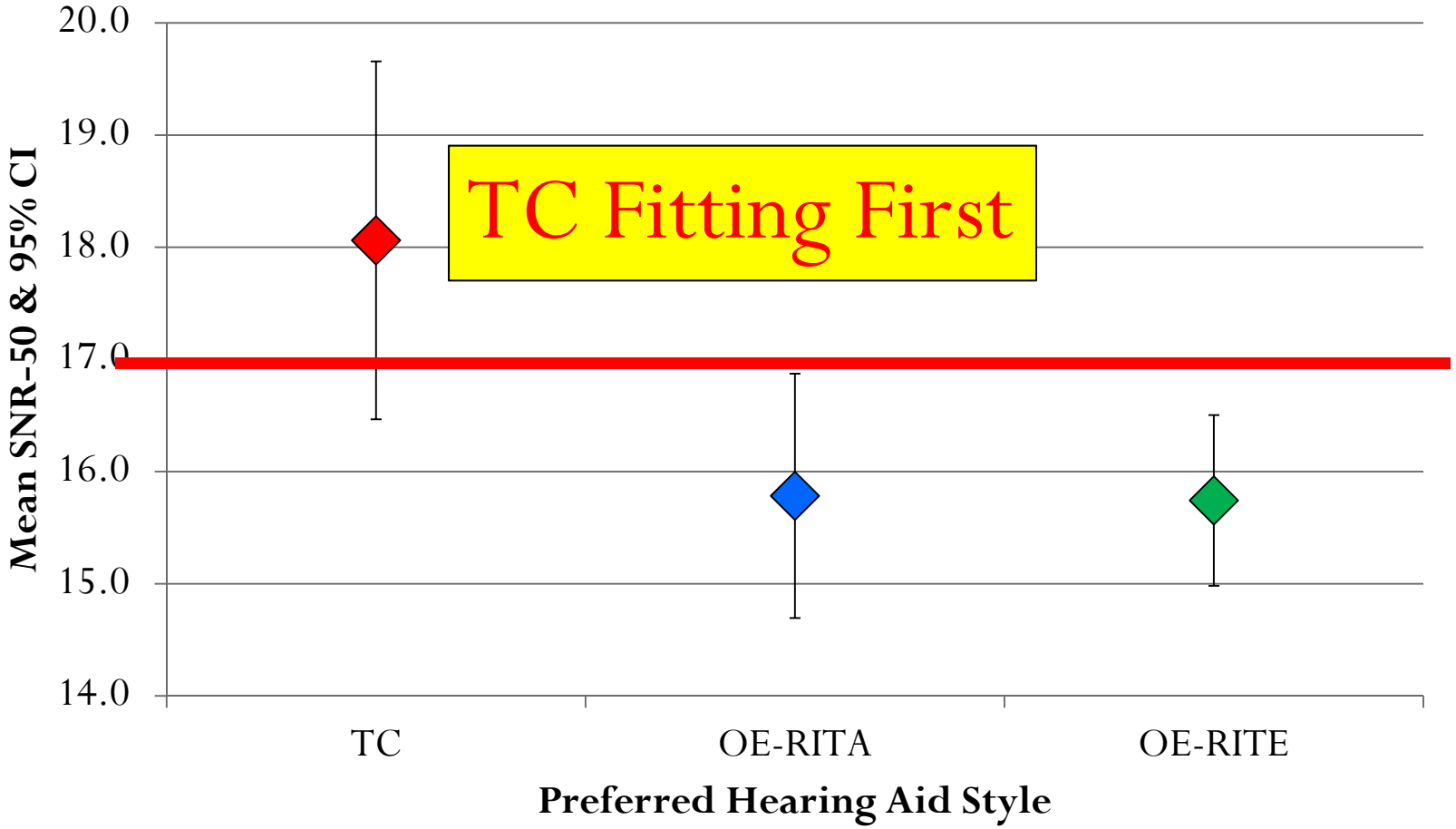

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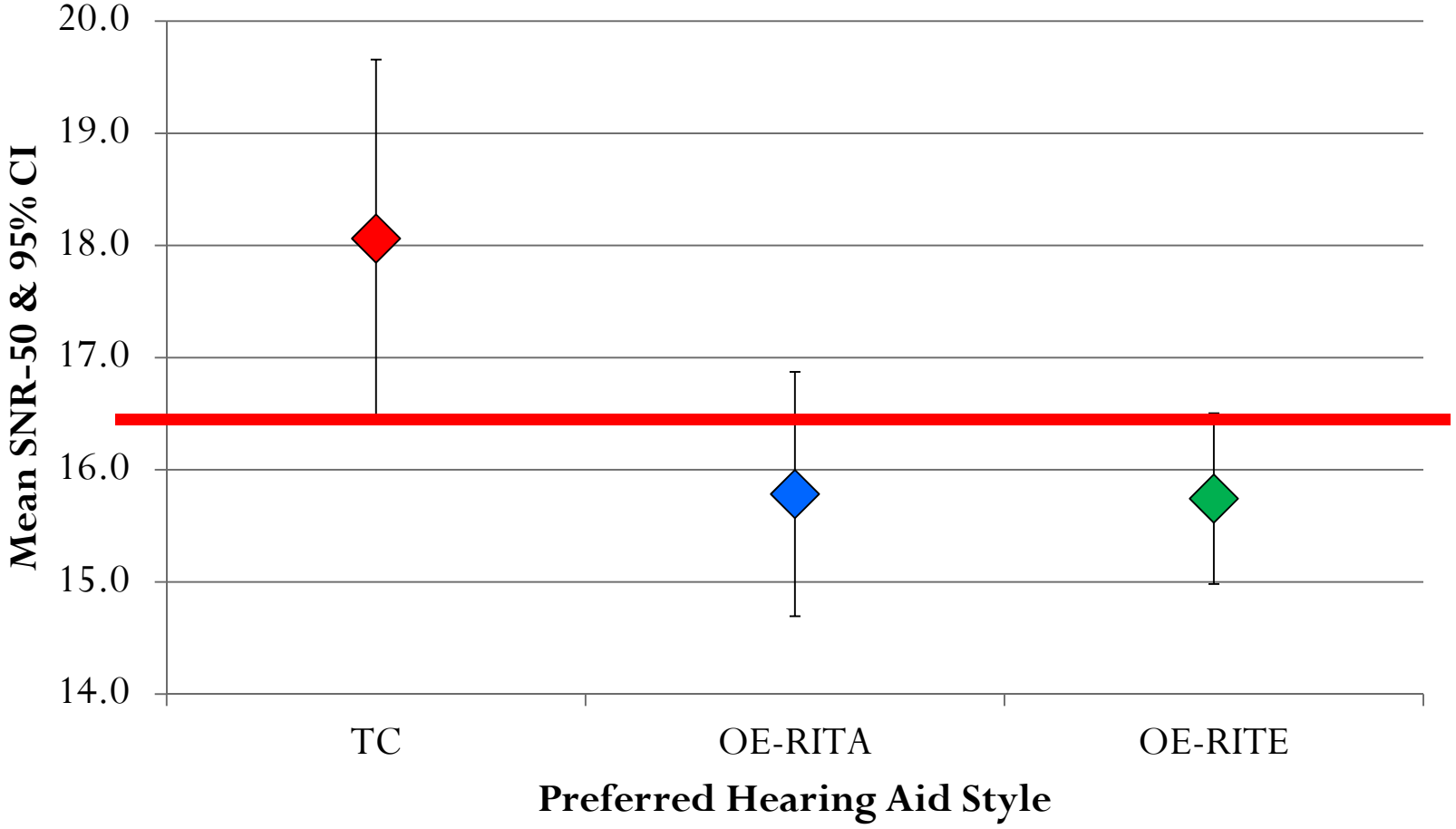

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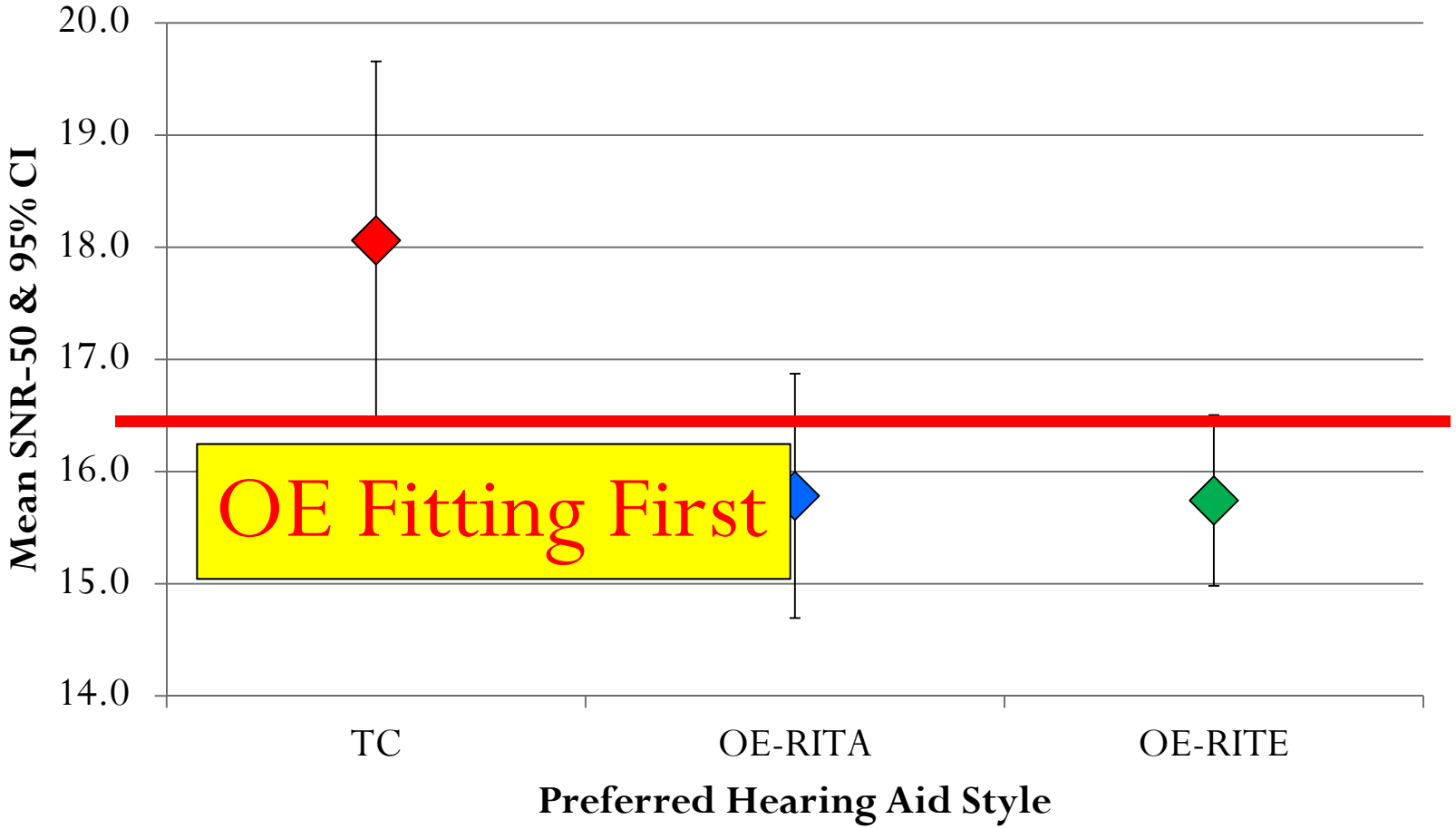

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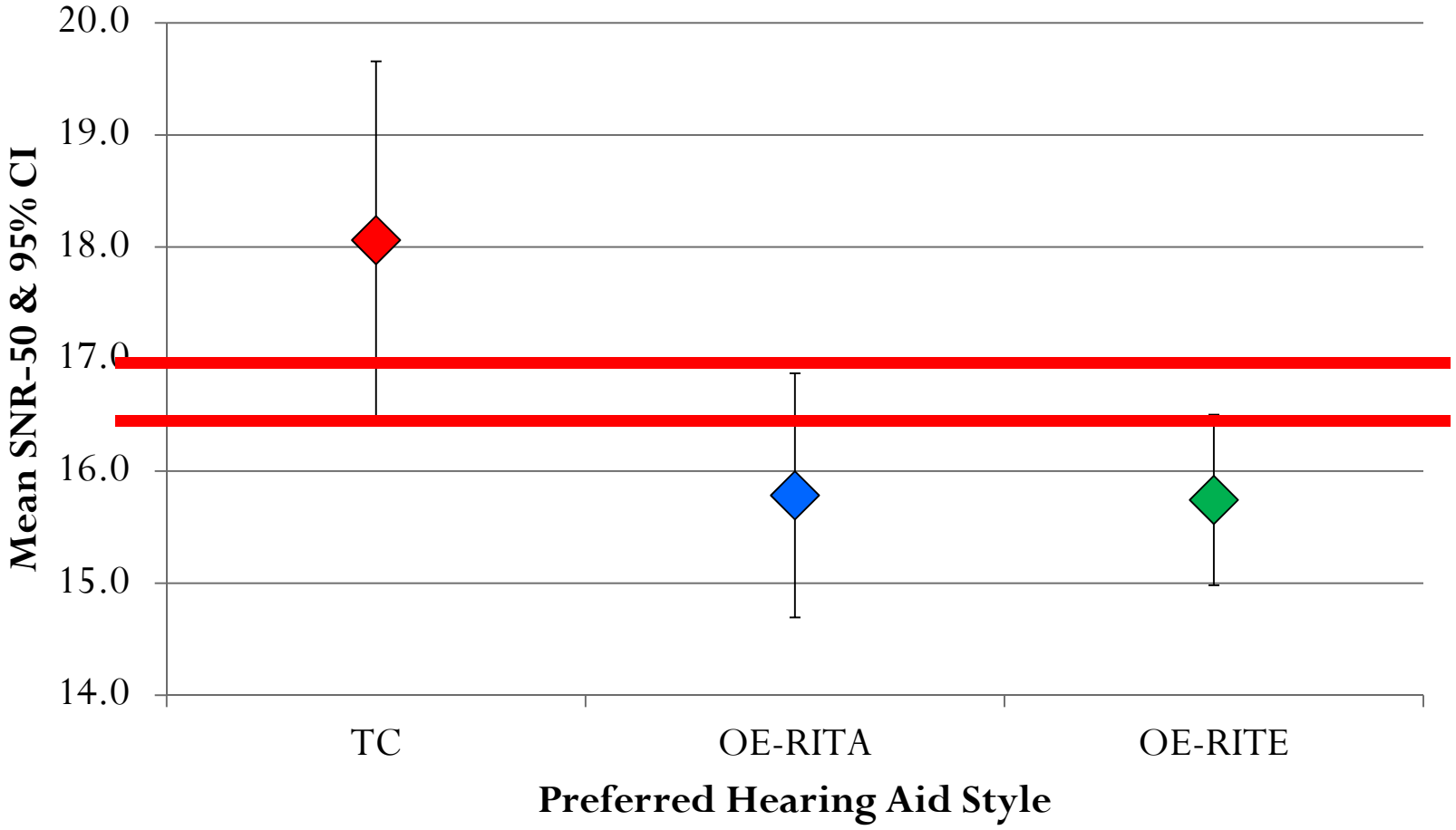
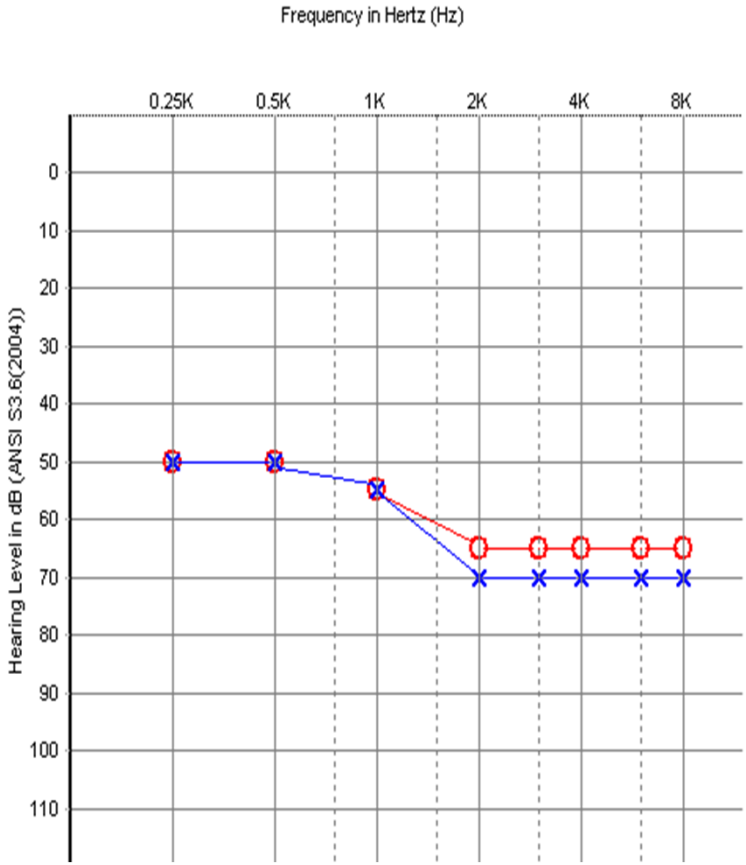


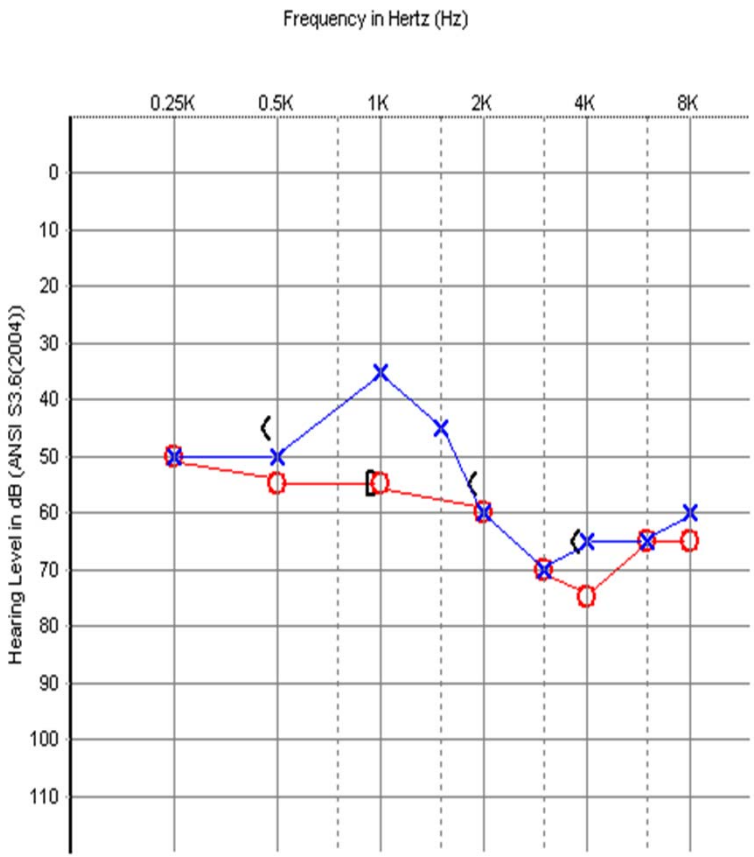
Preliminary Take Home Message

- Measuring Unaided Speech-in-Noise Performance
- Critical to Optimal Amplification Treatment Planning

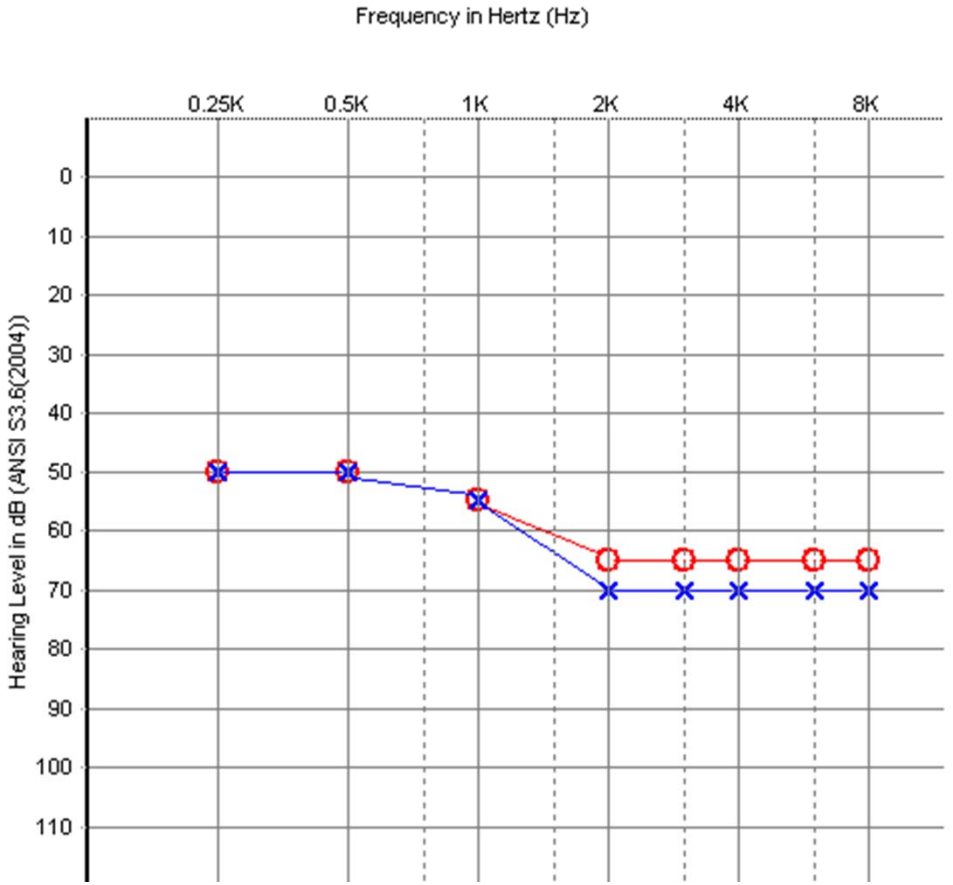
What would you fit?

Both long-term previous ITE users



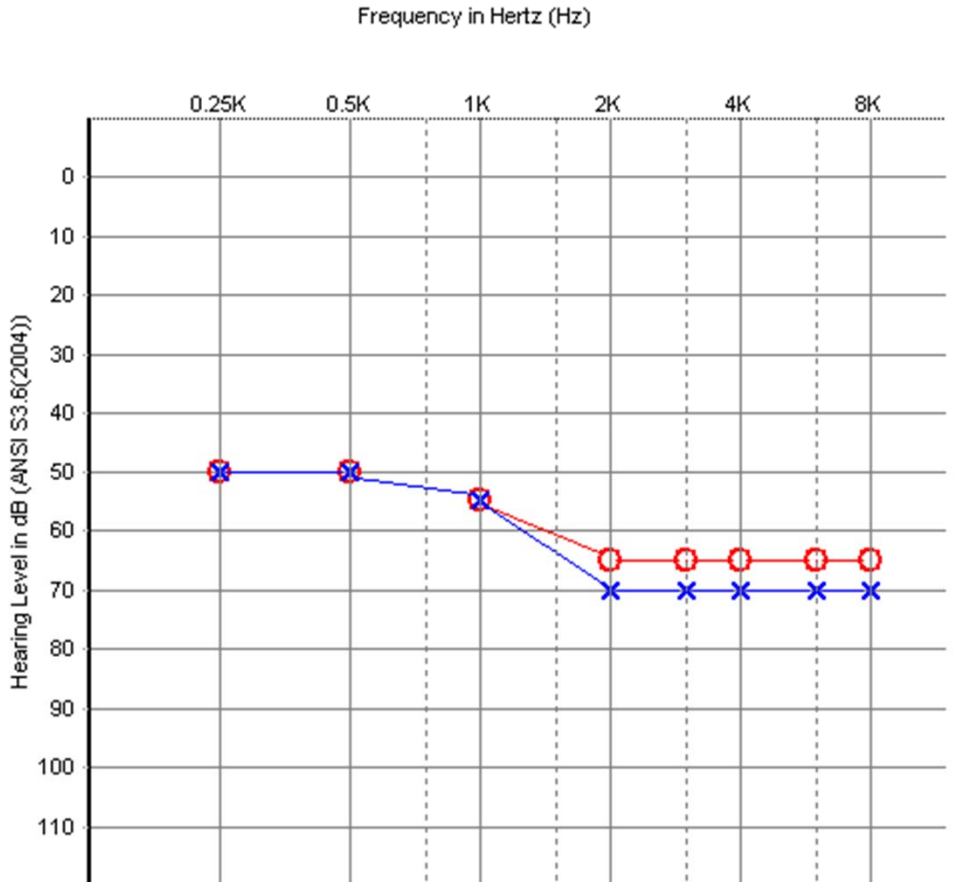


Patient 1, 66 years old



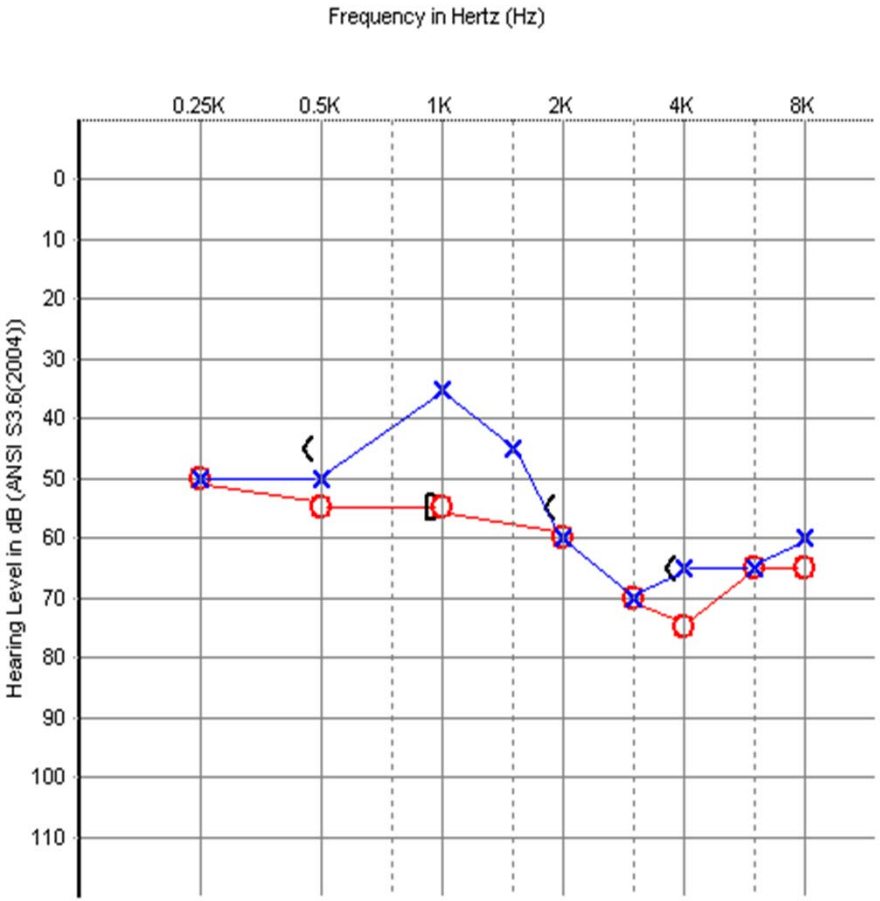
Unaided WIN = +15.2 dB

Rank order: 1-RITE, 2-RITA, 3-TC



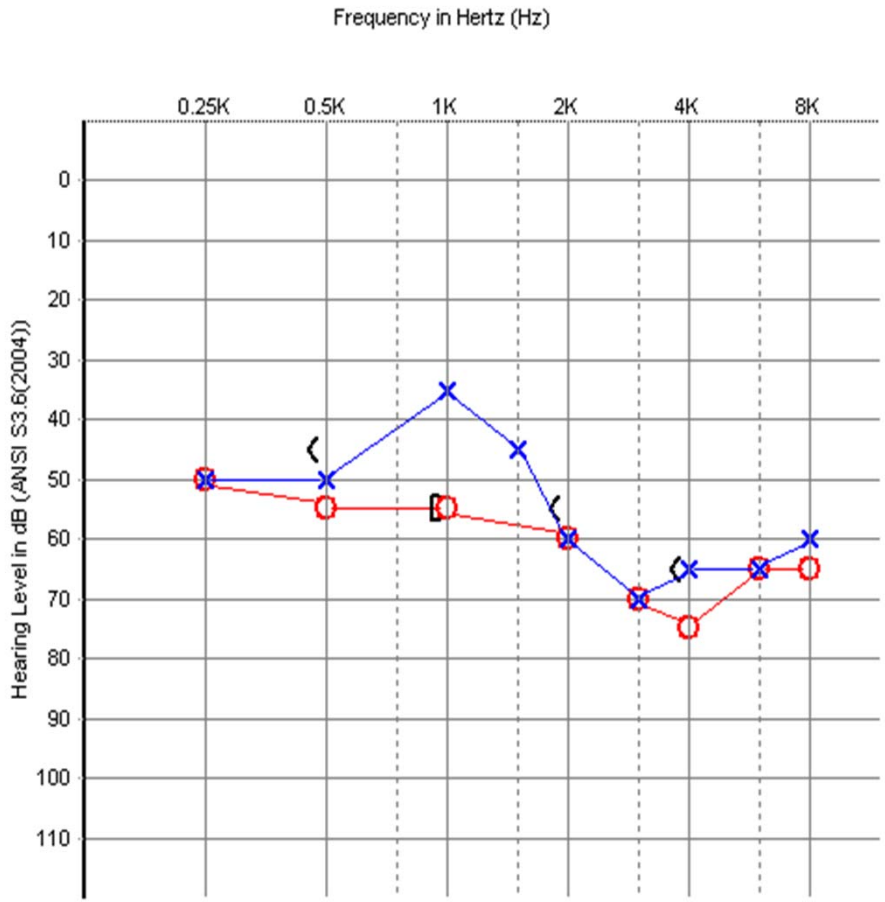
Unaided WIN = +15.2 dB

Patient 2, 77 years old



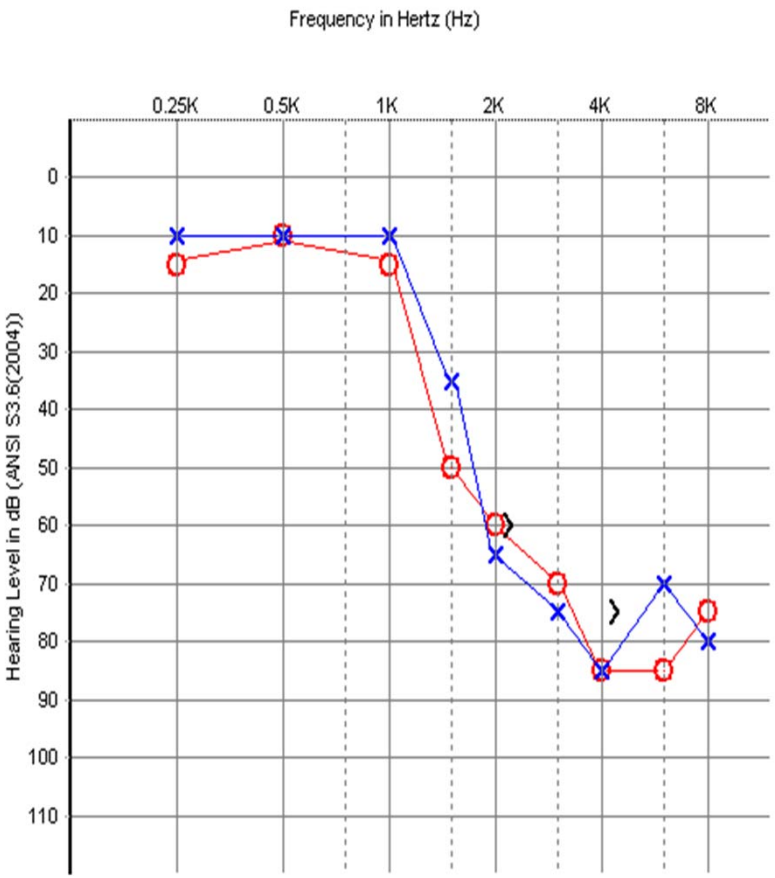
Unaided WIN =
=+24.0 dB

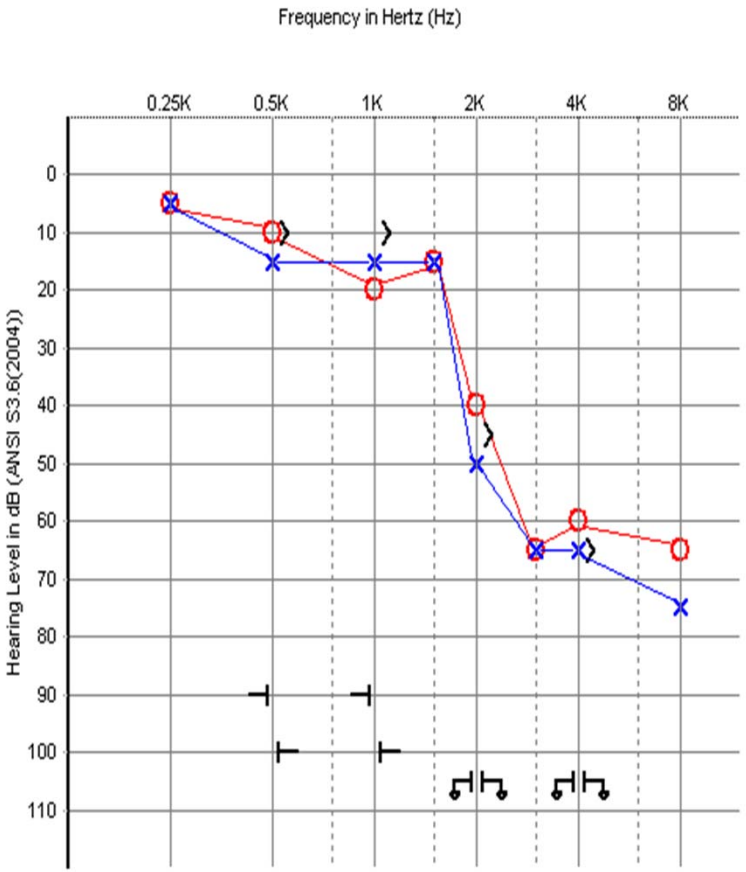
Rank order: 1-TC, 2-RITE, 3-RITA



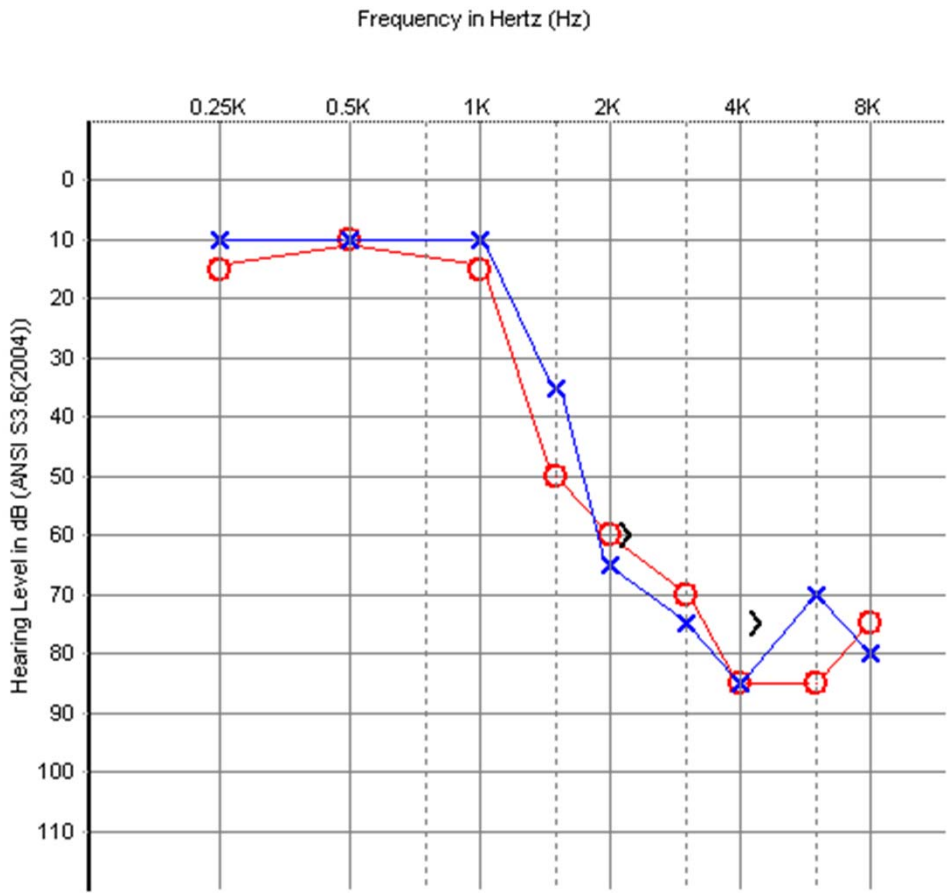
Unaided WIN =
=+24.0 dB

More traditional open-ear candidates



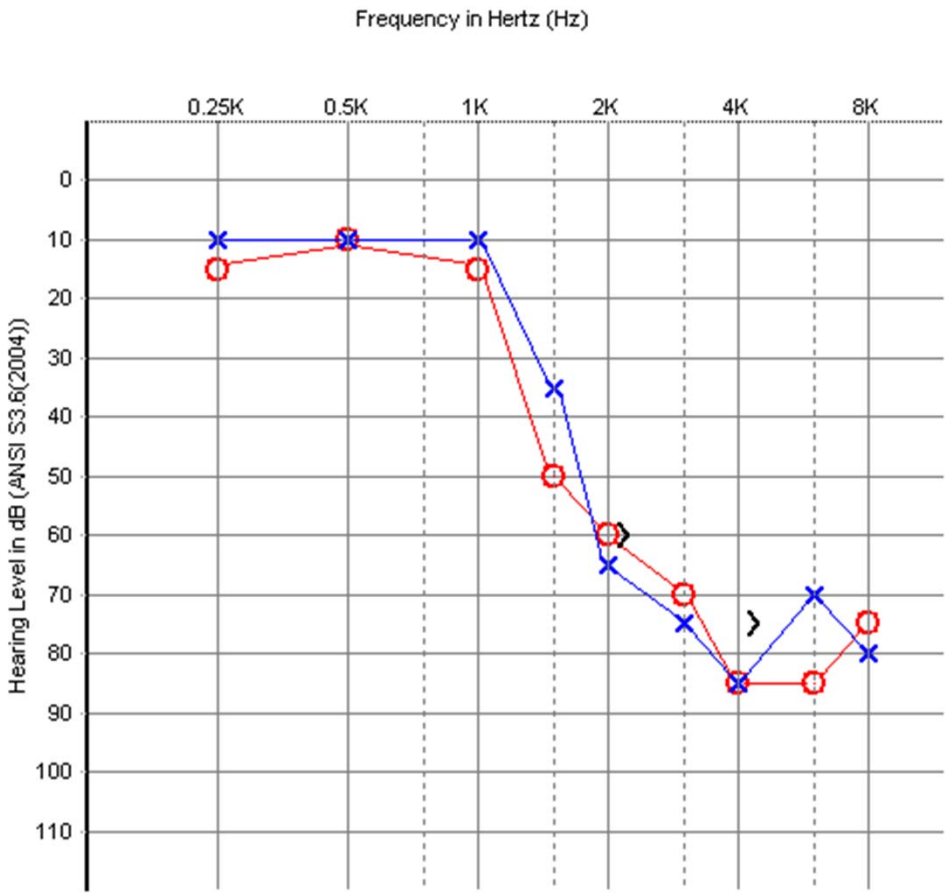


Patient 3
Previous ITE user, 67 years old



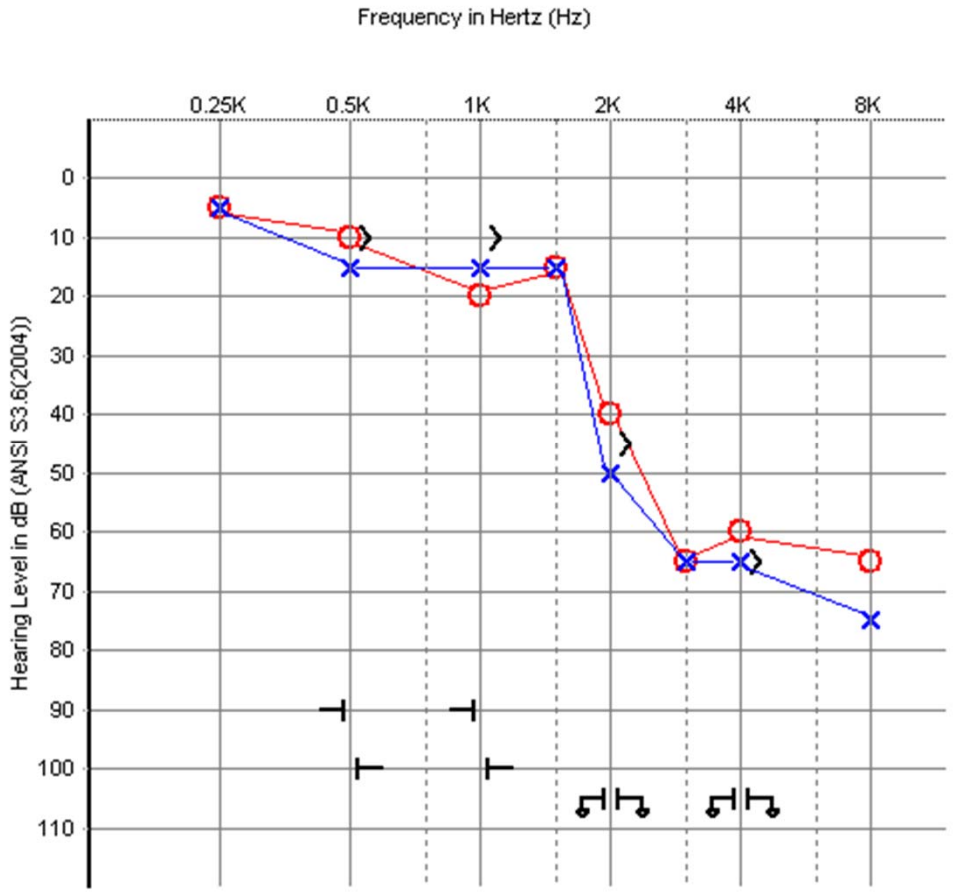
Unaided WIN = +15.2 dB

Final Ranking: 1-RITE, 2-TC, 3-RITA



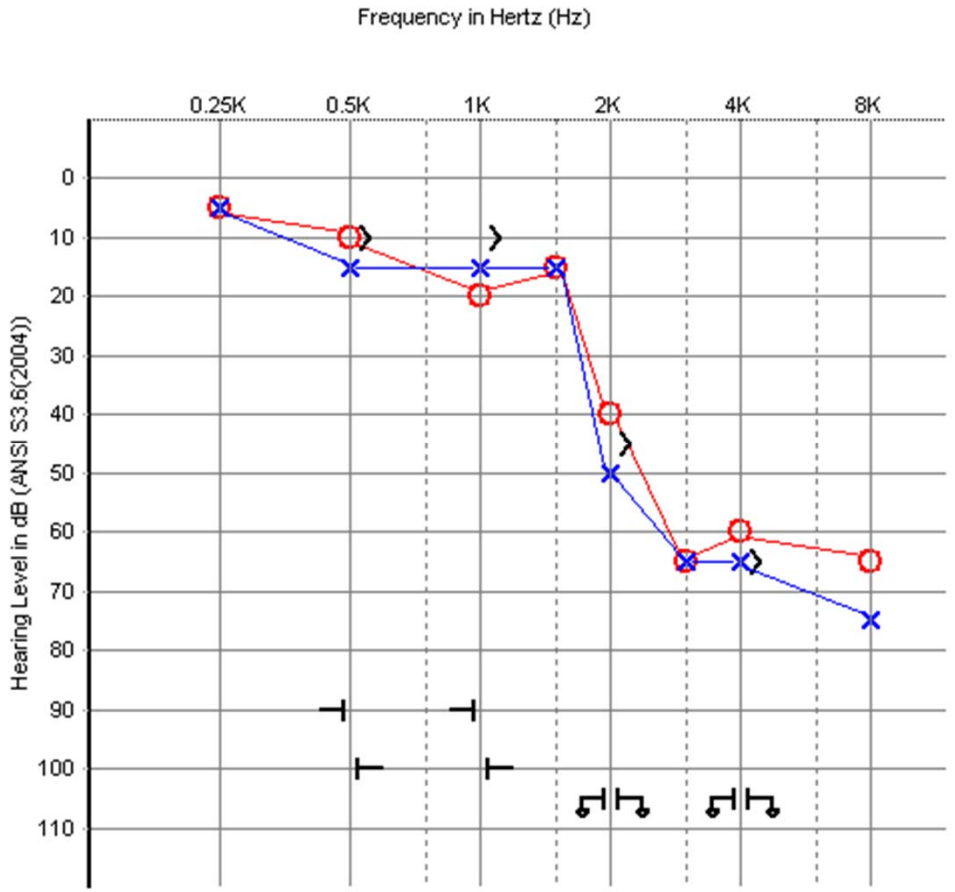
Unaided WIN = +15.2 dB

Patient 4
42 year old New Hearing Aid User



Unaided WIN
= +14.8 dB

Final ranking: 1-TC, 2-RITE, 3-RITA

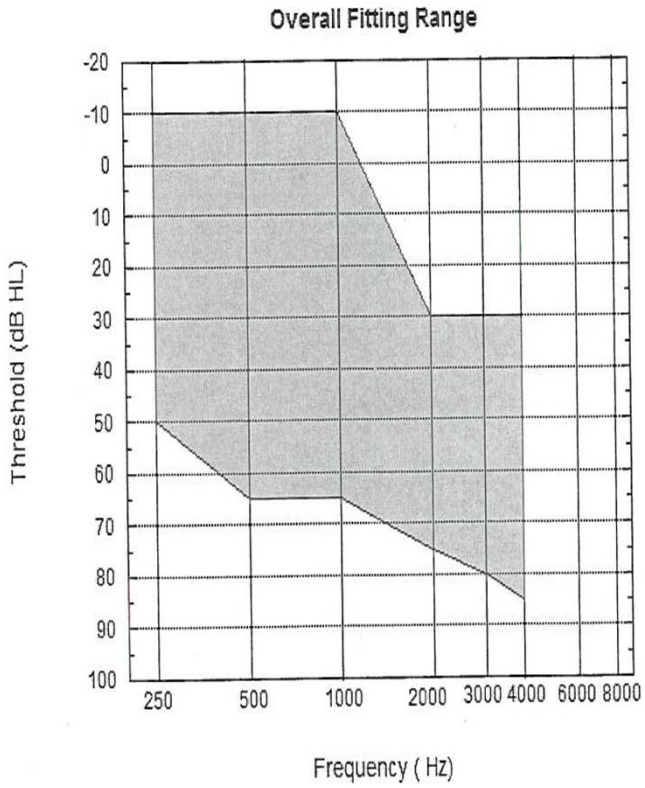


Unaided WIN
= +14.8 dB

Why did Patient 4 Chose a TC?

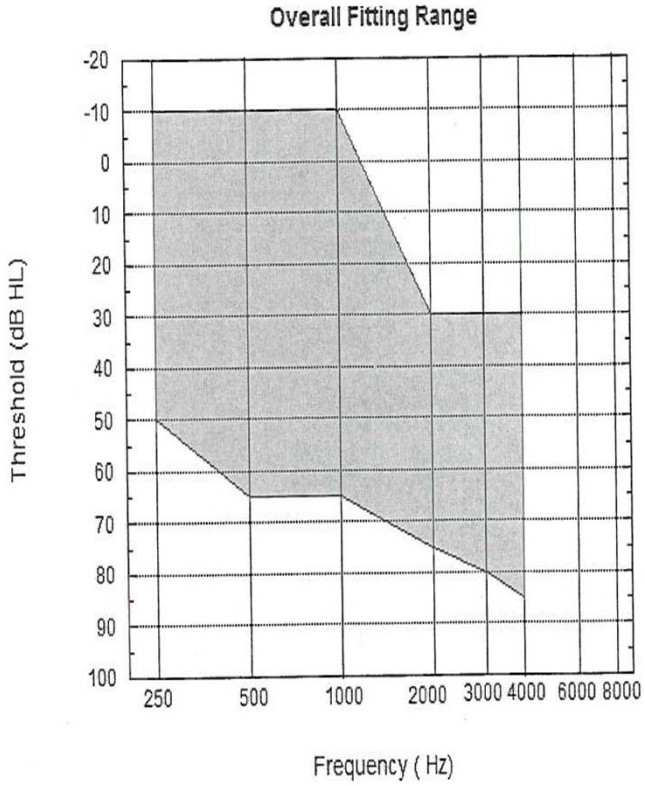
- Work situation
  - Electrician who could use TC better with safety glasses
- TC felt more secure in his ears – had to remove OE devices in certain work situations (e.g., duct work, maneuvering in tight spaces)

Final Take Home Message



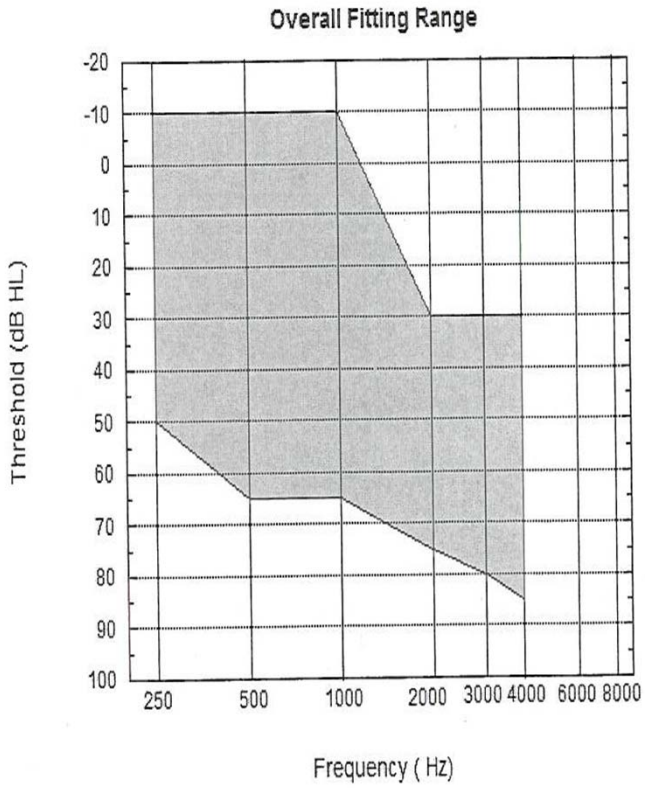
Final Take Home Message

- Open Ear is likely the best way to go for the majority of your patients



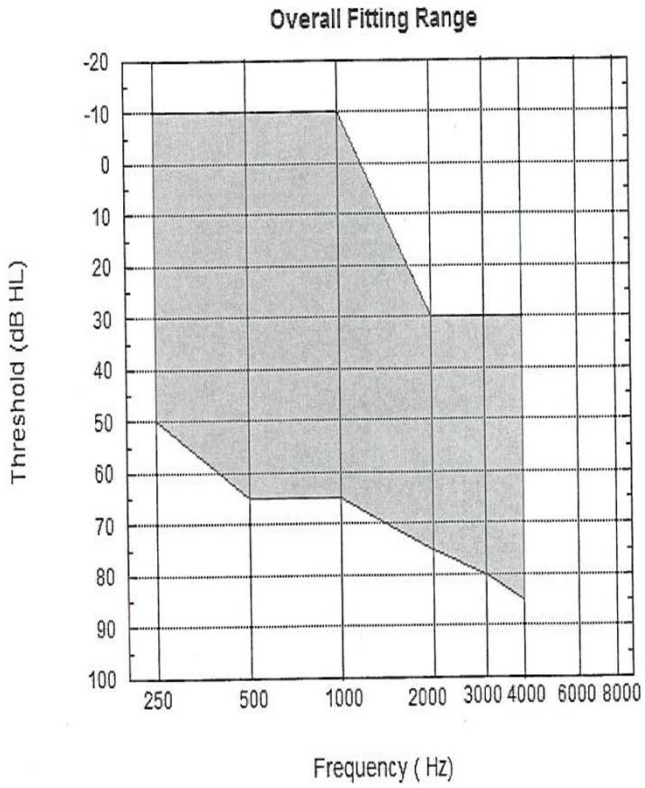
Final Take Home Message

- The audiogram alone is not enough for optimal patient management



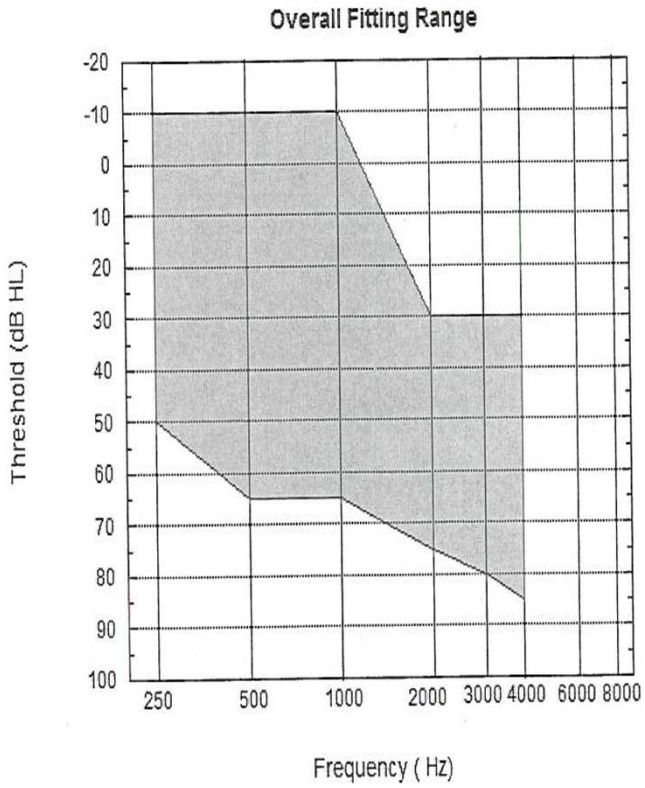
Final Take Home Message

- It is critical to measure speech-in-noise performance



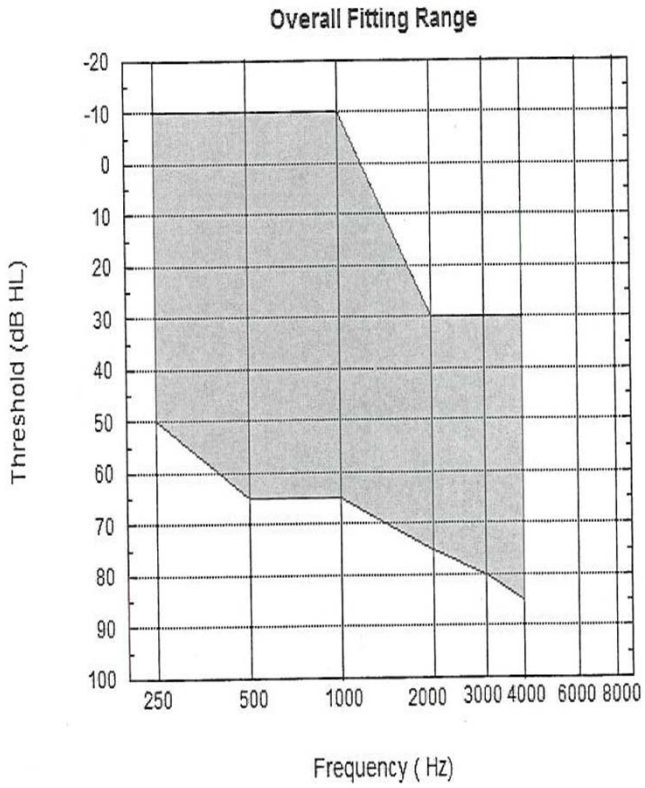
Final Take Home Message

- Measuring up-front can save you and your patients time!



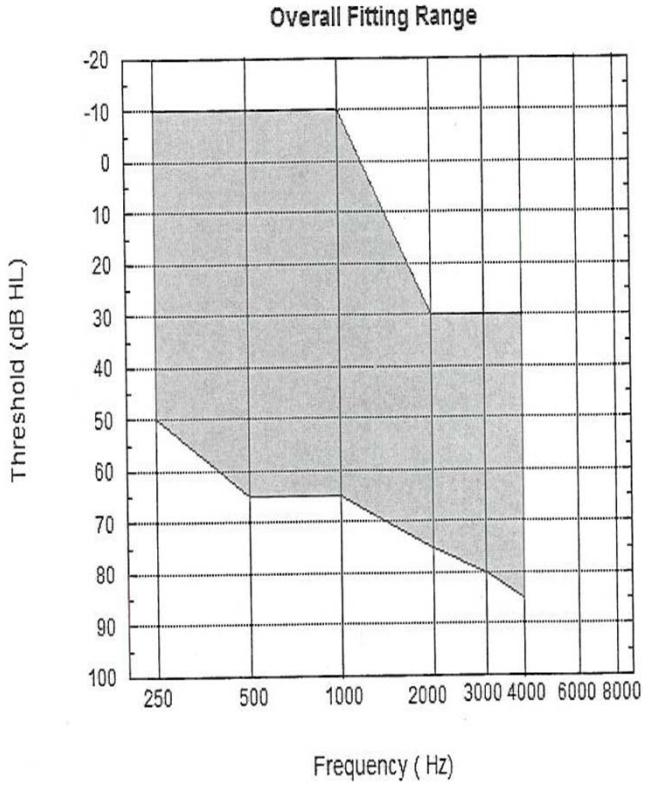
Final Take Home Message

- Practice Patient-Centered Care!



Final Take Home Message

- Practice Patient-Centered Care!
- Ask your patients about their communication goals and needs



Client Oriented Scale Of Improvement

Name : _____
Audiologist : _____
Date : 1. Needs Established _____
2. Outcome Assessed _____

SPECIFIC NEEDS

Category New _____
Return _____

Indicate Order of Significance

	Degree of Change						Final Ability Person can hear				
	Worse	No Difference	Slightly Better	Better	Much Better	CATEGORY	Hardly Ever 10%	Occasionally 25%	Half the Time 50%	Most of the Time 75%	Almost Always 95%
☐ Understanding while I work as an electrician		✓					✓				
☐ Hearing Sherri Smith during dinner			✓	✓					✓		
☐ Talking with Harvey Dillon in the pub					✓						✓
☐											
☐											

NATIONAL ACOUSTIC LABORATORIES

Categories
1. Conversation with 1 or 2 in quiet
2. Conversation with 1 or 2 in noise
3. Conversation with group in quiet
4. Conversation with group in noise
5. Television/Radio @ normal volume
6. Familiar speaker in phone
7. Unfamiliar speaker on phone
8. Hearing phone ring from another room
9. Hear front door bell or knock
10. Hear traffic
11. Increased social contact
12. Feel Embarrassed or stupid
13. Feeling left out
14. Feeling upset or angry
15. Church or meeting
16. Other

H. Dillon (NAL) et al

Increasing Hearing Aid Adoption & Use

Increasing Hearing Aid Adoption & Use

In all of those individuals with hearing loss who seek your help