

Differential Neuropsychological Outcomes Following Targeted Responsive Neurostimulation for Partial Onset Epilepsy

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SUMMARY

- Patients treated with the RNS® System showed no adverse cognitive effects.
- Patients with seizures of neocortical onset showed statistically significant improvements in naming.
- Patients with seizures of mesial temporal onset showed statistically significant improvements in verbal memory.

METHODS

Study Design: Data from the open label period of the randomized, controlled, double-blinded pivotal trial with follow up at 1 and 2 years

Population: 175 patients¹. Subset analyses in patients who had seizure onsets only in the mesial temporal lobe (MTL, n=86) or only in the neocortex (Neo, n=76)

Primary Outcomes: Naming (Boston Naming Test), Verbal Memory (AVLT Learning)

Secondary Outcomes: Executive Function, Visual Memory, and Motor Processing Speed

Reliable Change Indices (RCIs) were used to identify patients with improvements or declines that cannot be attributed to practice effects or measurement error in the test-retest setting

KEY RESULTS

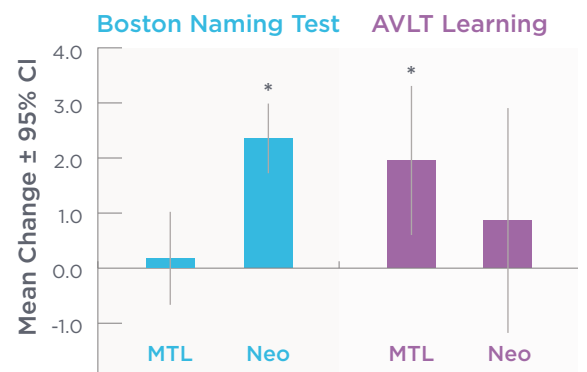
Primary Outcomes

No significant group decline on any primary or secondary neuropsychological outcome measure at 1 or 2 years².

Significant group improvements in **naming** ($p < 0.001$) and **verbal memory** ($p = 0.03$).

It is likely that these improvements were not due to practice effects because cognitive improvements in naming and memory varied as a function of the region from which seizures arose.³

Change in Cognitive Function by Seizure Onset Region



* $p < 0.05$



Secondary Outcomes

Significant improvements in

Visual Memory

- BVMT-R Total Recall (p=0.03)

Executive Function

- D-KEFS Design Fluency (p<0.001)
- Block Design (p<0.001)
- Information (p=0.009)

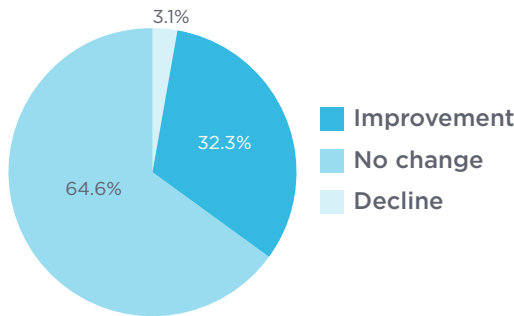
ANALYSES BY REGION OF SEIZURE ONSET

Neocortical Onset Patients (n=76)

Patients with neocortical onset seizures showed statistically significant improvements in naming (p<0.001).

At 2 years, 32% demonstrated RCI improvements in naming and 3% demonstrated declines.

Changes in Naming: Neocortical Patients

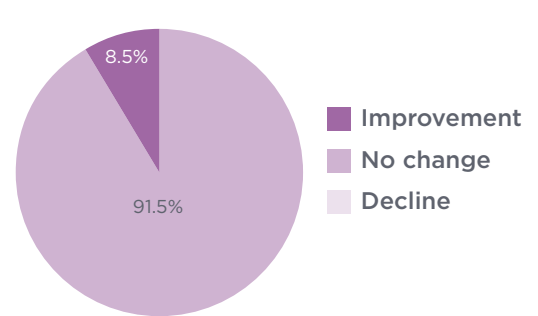


MTL Onset Patients (n=86)

Patients with MTL onset seizures showed statistically significant improvements in verbal memory (p=0.005).

At 2 years, 8.5% demonstrated RCI improvements in verbal memory and no patients demonstrated a decline.

Changes in Verbal Memory: MTL Patients



ADDITIONAL OBSERVATIONS

There was no statistically significant relationship between performance on cognitive tests and change in seizures or change in antiepileptic medications.

Footnotes

1. 18 yrs. or older, refractory to 2 or more AEDs and with no more than 2 foci localized by diagnostic testing
2. GEE (Generalized Estimating Equation)
3. If improvements were due to practice effects, one would expect to see the same improvement regardless of the brain region being stimulated.



See important prescribing and safety information in the RNS® System labeling. This is intended as supplementary information and should be used in conjunction with the labeling. Refer to the labeling for a description of the RNS® System and its components, indications for use, contraindications, warnings, cautions, adverse events and instructions for use. The manuals are available at www.NeuroPace.com.

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