Clinical Evaluation of a Novel Multipoint Radiofrequency Ablation Device to Treat Chronic Rhinitis

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OBJECTIVE

Evaluate the safety and efficacy of the NEUROMARK® system for treating chronic rhinitis.

METHODS

36 participants

4 centers

Severity of Chronic Rhinitis	Mild	0% (0/36)
	Moderate	25.0% (9/36)
	Severe	75.0% (27/36)
Previous sinus or nasal surgery		41.7% (15/36)

EVALUATION

1 month — Device-related SAEs

3 month — Change from baseline:

- VAS NSS for nasal congestion and rhinorrhea
- rTNSS
- mini RQLQ

SAE: Serious Adverse Event
VAS NSS: Visual analog scale nasal symptom scale
rTNSS: Reflective Total Nasal Symptom Score
mini RQLQ: Mini Rhinoconjunctivitis Quality of Life Questionnaire
MCID: Minimal clinically important differences

RESULTS

53% **53% improvement** in rhinorrhea VAS TNSS score

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55% **55% improvement** in nasal congestion VAS TNSS score

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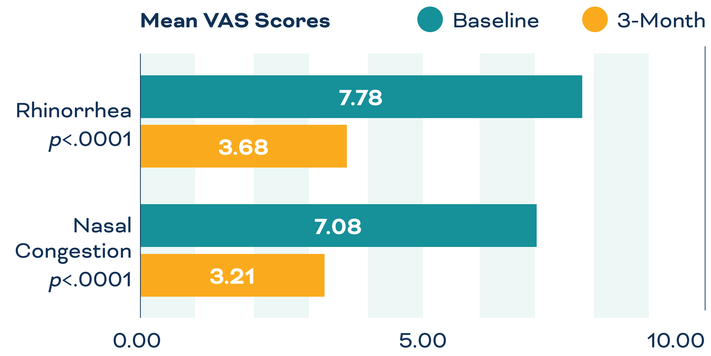
78% **78% responder rate** for rTNSS (≥30% reduction from baseline at 3 months)



55% Mean mini RQLQ **improved 55%**,...

89% ...with **89%** of participants achieving MCID (≥0.4 point reduction from baseline at 3 months)

0 **0** Serious Adverse Events

Mini RQLQ Domain	Baseline (N=36)	3-Month Follow-up (N=36)		
		Follow-up	Change	*P* value
Activities	3.58	1.51	-2.07	<.0001
Practical Problems	3.68	1.79	-1.89	<.0001
Nose Symptoms	3.68	1.73	-1.94	<.0001
Eye Symptoms	1.94	0.93	-1.02	<.0001
Other Symptoms	2.34	0.88	-1.46	<.0001
Total	**3.00**	**1.34**	**-1.66**	**<.0001**

Excellent safety profile

- No SAEs, no epistaxis, no "ice cream headaches" reported
- Safety results are more favorable than previously published data for other devices
- 12-24 hours post procedure, 72% of participants rate their discomfort as 0

CONCLUSION

- Safe and effective treatment
- Statistically significant and clinically meaningful improvements in symptoms and quality of life

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INDICATIONS FOR USE: The NEUROMARK System is indicated for use in otorhinolaryngology (ENT) surgery for creation of radiofrequency (RF) lesions to disrupt posterior nasal nerves in patients with chronic rhinitis. Most common side effects associated with the NEUROMARK device include infection, bleeding, and temporary pain or discomfort. Please see Instructions for Use (IFU) for a complete listing of warnings, precautions, and adverse events.
CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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