Key Studies Supporting PES Treatment of Dysphagia

PUBLICATION	DESCRIPTION	OBJECTIVE(S)	PRIMARY OUTCOMES
Treating postextubation dysphagia after stroke with PES - insights from a randomized controlled pilot trial Suntrup-Krueger S, Labeit B, Marian T, et al. Neurotherapeutics. 2025 Jul;22(4):e00613. DOI:10.1016/J.NEUROT.2025.E00613 Suntrup-Krueger S, Labeit B, Marian T, et al.. Critical Care. 2023 Oct 3;27(1):383. DOI:10.1186/S13054-023-04665-6	Independent Single-center Prospective RCT N=60 Acute stroke + post extubation	Evaluate safety and effectiveness of PES to improve swallowing function and reduce complications shortly following extubation	Full Analysis, *PES vs. sham respectively* • FOIS: 4.1 vs 2.1, p<0.0005 • ICU days: 3.1 vs 8.5, p=0.008 • Acute-care days: 13.8 vs 21.9, p=0.004 Interim Analysis , *PES vs. sham respectively* • Pneumonia rate: 60% vs 83%, p=0.045 • Time to total oral nutrition: 4.3 vs 10.2 days, p=0.001 • Tube dependent at discharge: 27% vs 53%, p=0.035
PES for early decannulation in tracheotomised patients with neurogenic dysphagia after stroke (PHAST-TRAC): a prospective, single-blinded, randomized trial Dziewas R, Stellato R, van der Tweel I, et al. Lancet Neurol. 2018;17(10):849-859. DOI: 10.1016/S1474-4422(18)30255-2	International Multicenter Prospective RCT Crossover design N=69 Stroke + tracheostomized	Evaluate safety & efficacy of PES to improve swallowing function and accelerate readiness for decannulation	• After three PES treatments, 49% of patients improved swallowing function and were able to be decannulated vs 9% of patients in the sham group (p=0.00082) • After six PES treatments, an additional 27% of patients were able to be decannulated
The Outcome of Intraluminal Electrical Pharyngeal stimulation on Oropharyngeal Dysphagia in Acute Stroke Patients Youssef G, and El-Banna M. Al-Azhar Assiut Med Journal. 2015; 13(1):68-72.	Independent Prospective RCT N=18 Stroke	Evaluate role of early treatment with PES in improving swallowing function.	PES treatment significantly improved swallowing function, as compared to sham treatment • PAS: >2x greater improvement (59.6% vs. 29.8%, p=0.017) • FOIS: 25% greater improvement (85% vs. 67.8%, p=0.024) • Pharyngeal Secretions: >2x greater improvement (68.2% vs. 33.9%, , p=0.032)

Phagenyx

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Pharyngeal electrical stimulation for neurogenic dysphagia following stroke, traumatic brain injury or other causes: Main results from the PHADER cohort study
 	
Bath PM, Woodhouse LJ, Suntrup-Krueger S, et al. EClinicalMedicine. 2020;28:100608. Published 2020 Nov 10.
DOI: 10.1016/j.eclinm.2020.100608
	International
	Multicenter
	Single arm
	Prospective
	Observational study
	
	N=255
	Stroke, TBI, non-neuro + non-vent, post-extubation & tracheostomized
		Evaluate effectiveness of PES to improve swallowing function in a real-world cohort	• PES linked to positive swallow and diet intake outcomes including DSRS, PAS and FOIS scores
			  • DSRS: Significant improvement in all groups ($p<0.001$)
			  • Stroke w/o mechanical ventilation: 6.7-point reduction at 3 months
			  • Stroke w/ vent + tracheotomy: 6.5-point reduction at 3 months
			  • PAS: Improved with rates falling significantly across all groups (mean = 4.1 units, p=0.003)
			  • FOIS: Improved across the cohort (mean = 2.9 points, p=0.042)

Electrical pharyngeal stimulation for dysphagia treatment in tracheotomized stroke patients: a randomized controlled trial Suntrup S, Marian T, Schröder JB, et al. Intensive Care Med. 2015;41(9):1629-1637. DOI:10.1007/S00134-015-3897-8.	Independent Single-center Prospective RCT N=30 Stroke + tracheostomized	Evaluate PES for swallow recovery in severely dysphagic tracheotomized stroke patients and earlier decannulation compared to sham.	• After PES treatment, 75% of patients improved swallowing function and were able to be decannulated vs. 20% of patients in the sham group ($p<0.01$)
Increase of Substance P Concentration in Saliva after Pharyngeal Electrical Stimulation in Severely Dysphagic Stroke Patients - an Indicator of Decannulation Success? Muhle P, Suntrup-Krueger S, Bittner S, et al., Neurosignals. 2017;25(1):74-87. DOI: 10.1159/000482002	Independent Single-center Single-arm Prospective Observational study N=23 Stroke + tracheostomized	Evaluate efficacy of PES on decannulation of tracheotomized patients and potential link between treatment success and increase in Substance P.	• After PES treatment, 61% of patients were able to be decannulated • PES linked to increase in swallow-related neurotransmitter Substance P • 79% increase in responders vs. 11% increase in non-responders

PAS = Penetration Aspiration Scale, FOIS = Functional Oral Intake Scale, DSRS = Dysphagia Severity Rating Scale

The Phagenyx® system is available for sale in the United States, European Economic Area, UK and Switzerland.

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