

Our experience with Phagenyx (Pharyngeal Electrical Stimulation)

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Phagenesis



Guidelines

NATIONAL STROKE GUIDELINES (2023)

4.26 Swallowing

Patients with **tracheostomy and severe dysphagia after stroke may be considered for pharyngeal electrical stimulation to aid decannulation** where the device is available and it can be delivered by a trained healthcare professional. [2023]

EUROPEAN STROKE ORGANIZATION AND EUROPEAN SOCIETY FOR SWALLOWING DISORDERS GUIDELINE FOR THE DIAGNOSIS AND TREATMENT OF POST-STROKE DYSPHAGIA (2021)

In patients with post-stroke dysphagia, we recommend that treatment with neurostimulation techniques should preferably be conducted within a clinical trial setting.

In tracheotomized stroke patients with severe dysphagia, we suggest treatment with pharyngeal electrical stimulation to accelerate decannulation.

The Phagenyx System is easy to use

Consists of base station and single-use catheter

Optimised Stimulation

Individualised patient treatment



Smart Chip

Retains all patient and treatment information

Clear Guidance

This ensures the electrodes are in the correct position

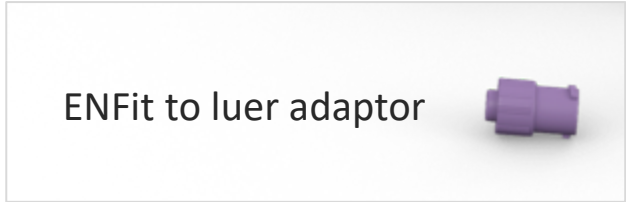
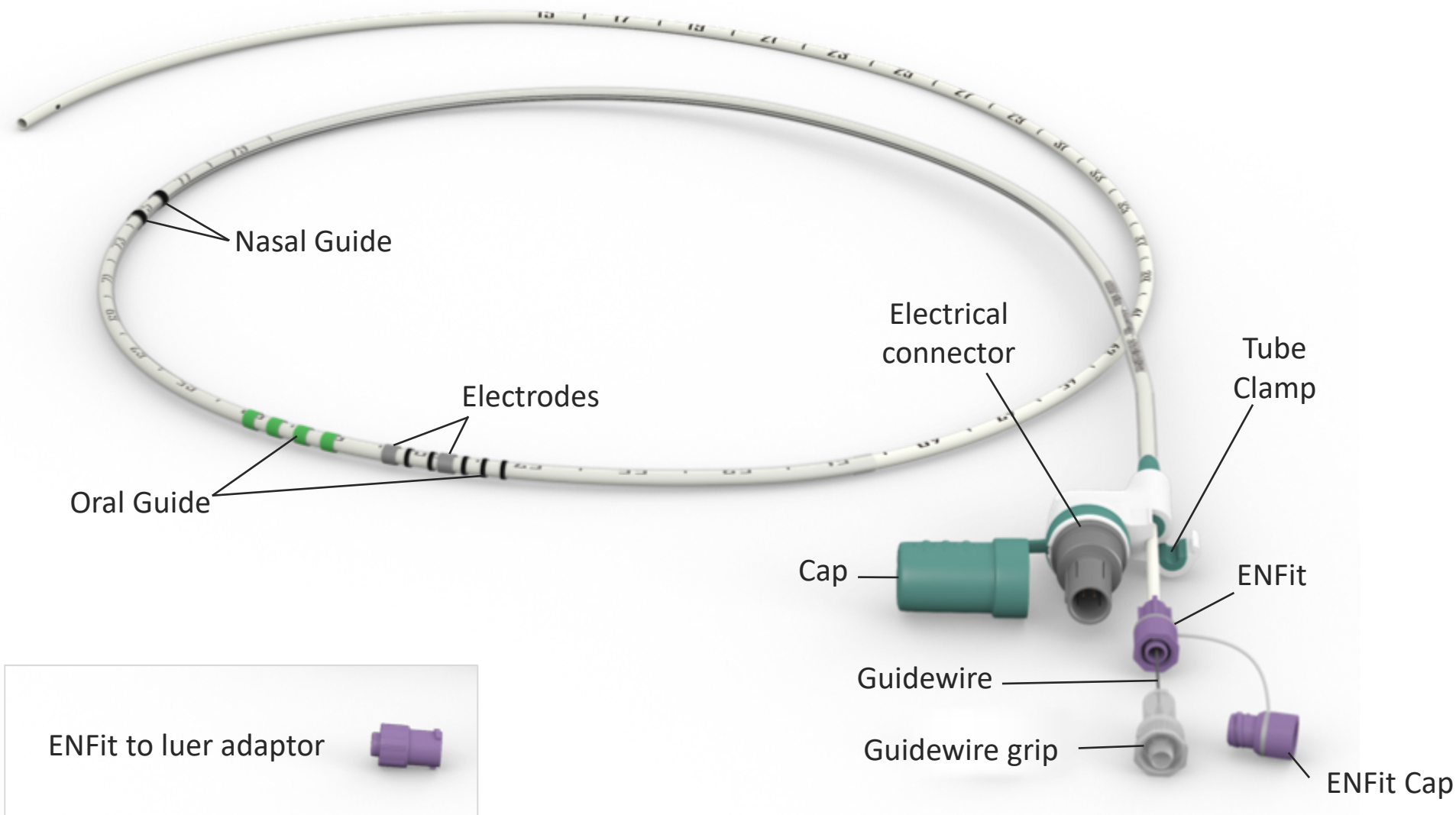
Touch Screen with Intuitive Software

Guides the user through the entire process

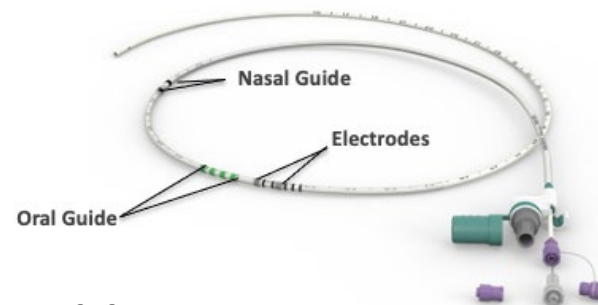
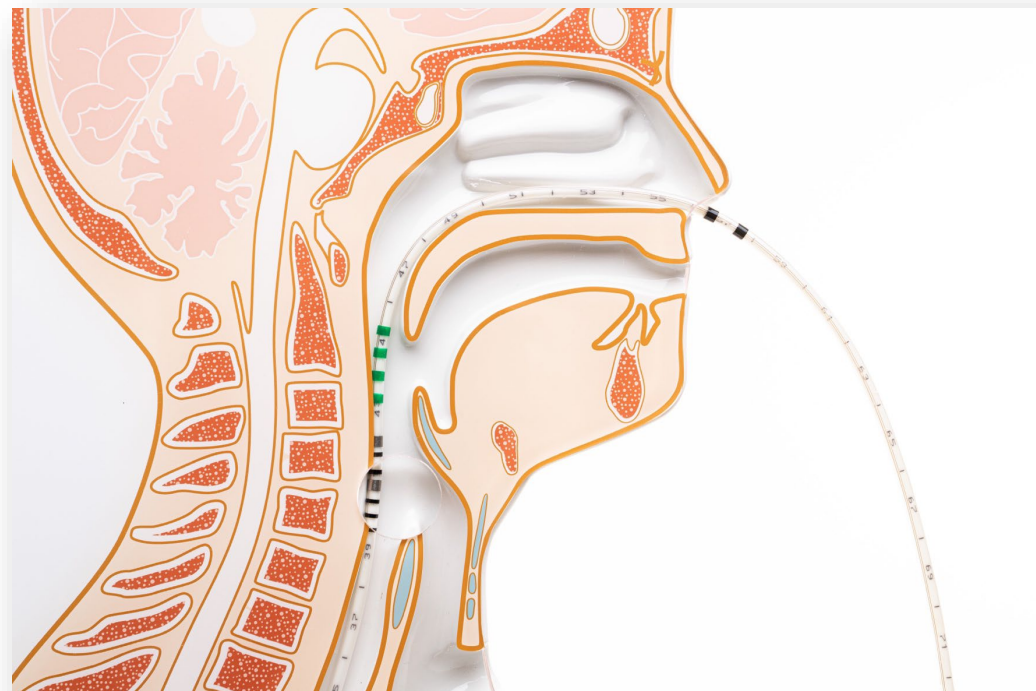
Feeding Tube

Incorporated for delivery of enteral feeds and fluids if required

Catheter – NG tube and Sleeve



Phagenyx PES Electrode Placement

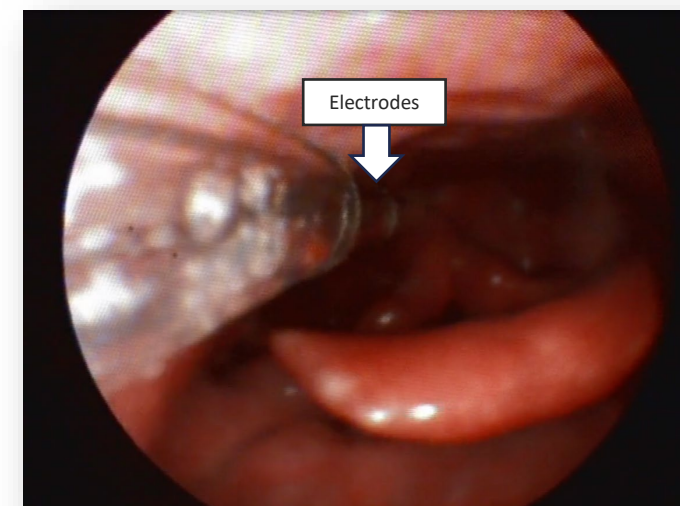


Catheter Position

- Opposite the C3 /C4 vertebral junction

Electrical Field:

- Safe "super bolus"
- Acts on pharyngeal and laryngeal mucosa
- Field extends in all directions
- No gender differences impacting outcomes



Sensory Nerves Targeted

- Pharynx - Pharyngeal plexus (branches of Glossopharyngeal (IX) and Vagus (X))
- Base of tongue - Glossopharyngeal (IX)
- Epiglottis - Superior laryngeal branch of Vagus (X) and lingual branch of Glossopharyngeal (IX)
- Larynx - Internal and external branches of the superior laryngeal nerve (branches of Vagus (X))

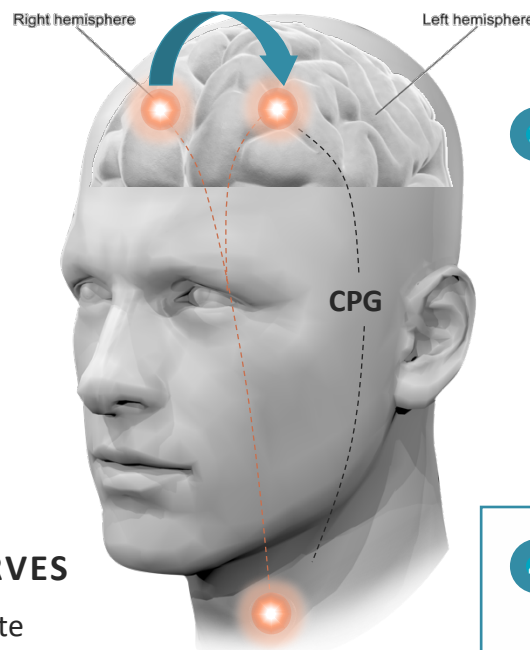
Phagenyx - How does Pharyngeal Electrical Stimulation (PES) work?

2 SIGNALS EXCITE MOTOR CORTEX

- » Powerful afferent signals excite both damaged and undamaged parts of the higher brain.

1 5HZ STIMULATION OF SENSORY NERVES

- » Patient-specific intensity delivered to discrete location in oropharynx.



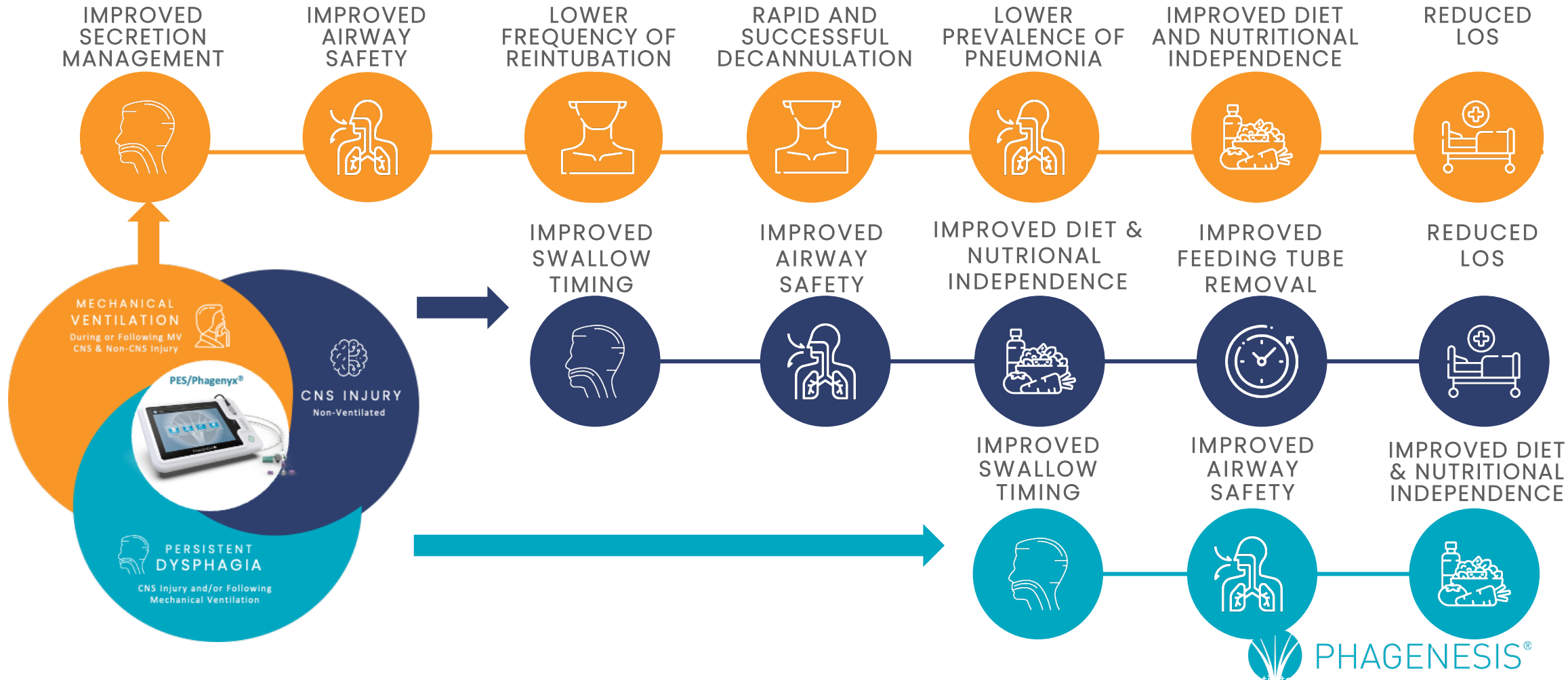
3 EXCITATION DRIVES NEUROPLASTIC FUNCTIONAL REORGANIZATION

- » Swallowing control is moved to undamaged area.

4 INTEGRITY OF NEUROLOGICAL SWALLOWING CONTROL IS RESTORED

- » Efferent output signals are restored from the higher brain to the brainstem to modulate swallow reflex.
- » Associated with an increase in neurotransmitter 'Substance P' in the pharyngeal mucosa.

Phagenyx demonstrates clinically significant improvements using a range of dysphagia and economic outcome measures.



PES Patient Selection Criteria

Adult patients with neurogenic dysphagia as a result of **central** (e.g., stroke, TBI) and/or **peripheral** (e.g., desensitization following prolonged mechanical ventilation) injury.

Clinical Presentation

Patient presents with **one or more** of the following:

- ✓ Reduced or no spontaneous swallowing
- ✓ Poor laryngeal sensation impacting swallow safety
 - *Airway invasion of material (saliva, liquid or solid) with no sensation (no response/reaction for clearance)*
- ✓ Poor pharyngeal sensation impacting swallow efficiency
 - *Pharyngeal pooling of material (saliva, liquid or solid) with no sensation (no response/reaction for clearance)*

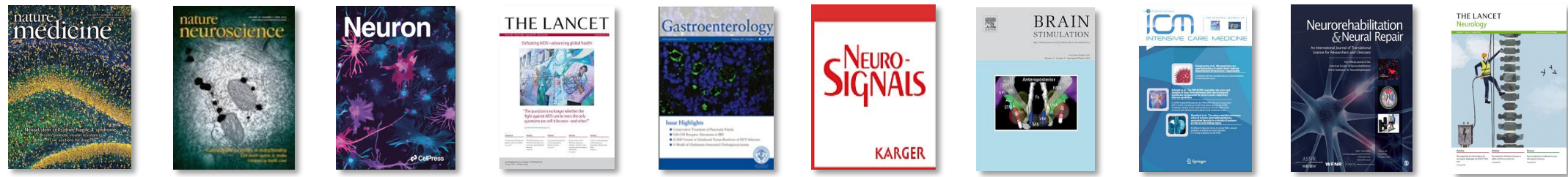
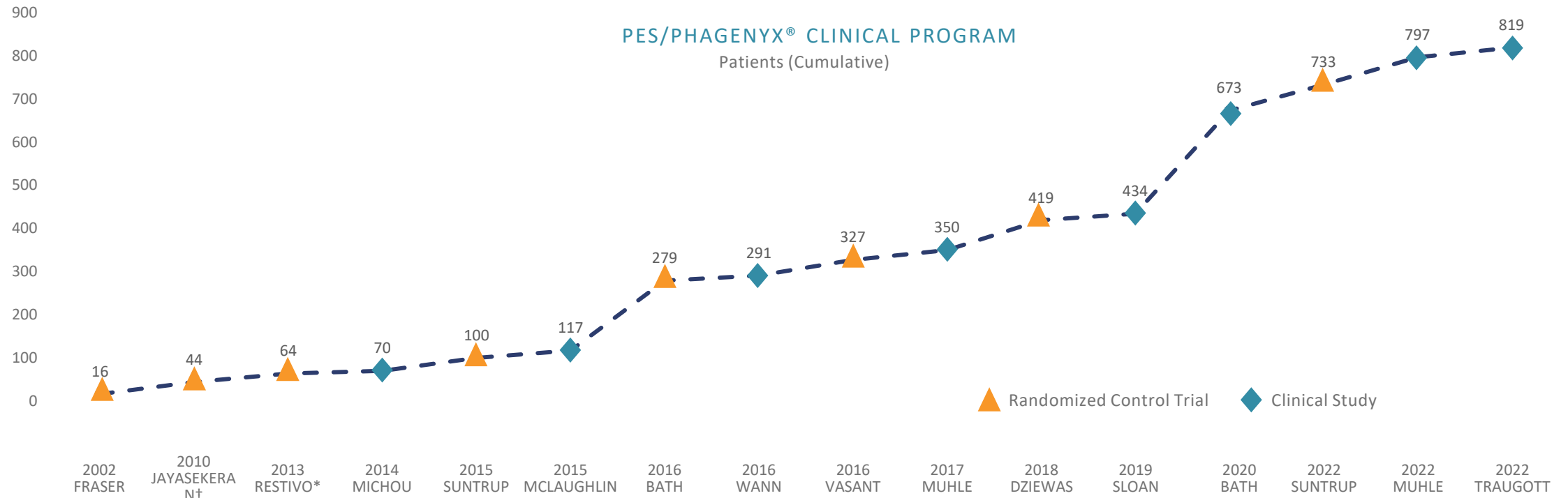


Catheter – Contraindications

- Do not attempt to insert in the presence of oral/pharyngeal anatomical abnormalities, oesophageal perforation, stricture or pouch or if the patient has a cardiac or respiratory condition that might render the insertion of a catheter into the throat unsafe
- Do not use in patients with third party permanently implanted electrical devices unless indicated as safe to do so by the manufacturers of those devices
- Do not use if patient is pregnant
- Do not use in children
- If the patient presents with an oropharyngeal infection this should be treated and resolved before the Phagenyx PNX-1000 catheter is inserted.

Extensive Clinical Evidence

No SAEs associated with stimulation



*Neurodegenerative disease

†Part 3 is an RCT

Note: graph does not include original (4) proof of concept studies

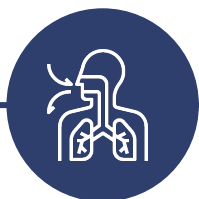
Patients Following CNS Injury

NON-VENTILATED (Stroke, TBI)

IMPROVED SWALLOW TIMING



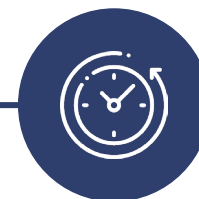
IMPROVED AIRWAY SAFETY



IMPROVED DIET & INDEPENDENCE



IMPROVED FEEDING TUBE REMOVAL



REDUCED LOS



MEASURES:

- | | | | | |
|----------------------------------|--------------------|----------------------------------|----------------------------------|---------------------------|
| » Pharyngeal transit time (VFSS) | » PAS (VFSS, FEES) | » Diet level (DSRS, FOIS) | » Timing of feeding tube removal | » Hospital length of stay |
| » Swallow response time (VFSS) | | » Meal supervision level (DSRS) | | |
| | | » Feeding tube dependency (FOIS) | | |

STUDIES/PUBLICATIONS:

- | | | | | |
|---------------|----------------------|----------------------|-------------------|--------------------|
| » Fraser 2002 | » Bath (PhADER) 2020 | » Bath (PhADER) 2020 | » McLaughlin 2015 | » Jayasekeran 2010 |
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| | » Jayasekeran 2010 | » Essa 2017 | | |
| | | » Wann 2016 | | |
| | | » McLaughlin 2015 | | |

KEY

- VFSS = Videofluoroscopic Swallowing Study, also known as Modified Barium Swallow Study (MBSS)
- FEES = Flexible Endoscopic Evaluation of Swallowing
- PAS = Penetration-Aspiration Scale
- DSRS = Dysphagia Severity Rating Scale
- FOIS = Functional Oral Intake Scale

Patients During or Following Prolonged Mechanical Ventilation

CNS (Stroke, TBI) OR NON-CNS INJURY (including COVID-19 patients)

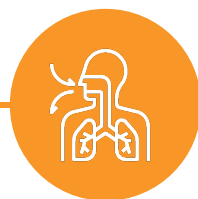
INCREASED
SUBSTANCE P
LEVELS



IMPROVED
SECRETION
MANAGEMENT



IMPROVED
AIRWAY SAFETY



LOWER
FREQUENCY OF
REINTUBATION



RAPID AND
SUCCESSFUL
DECANNULATION



LOWER
PREVALENCE OF
PNEUMONIA



IMPROVED DIET
AND NUTRITIONAL
INDEPENDENCE



REDUCED
LOS



MEASURES:

- | | | | | | | | |
|--|---|--------------------------------------|-----------------------------|--|---|--|------------------|
| » Substance P saliva levels post-treatment | » SESETD (FEES)
» Pre-swallowing observations (FEES) | » PAS (VFSS, FEES)
» FEDSS (FEES) | » Frequency of reintubation | » Successful decannulation with no recannulations
» Readiness for decannulation | » Pneumonia prevalence
» FEDSS (Warnecke 2009 links FEDSS to pneumonia prediction) | » Diet level (DSRS, FOIS, FIM+FAM, IDDSI)
» Meal supervision level (DSRS)
» Feeding tube dependency (FOIS) | » Length of stay |
|--|---|--------------------------------------|-----------------------------|--|---|--|------------------|

STUDIES AND PUBLICATIONS:

- | | | | | | | | |
|---------------------------|---|---|---|---|--|---|--|
| » Muhle 2017 [^] | » Dziewas (PHAST-TRAC) 2018 [^]
» Suntrup 2015 [^]
» Muhle 2017 [^]
» Traugott 2022 [^]
» Sloan 2019+
» Beirer 2020 [^] (GBS) | » McGrath 2022 [^]
» Suntrup 2022 [~]
» Muhle 2022*
» Bangert 2022 [^]
» Bath (PhADER) 2020+ ^{^~}
» Blakemore 2021 [~] (COVID)
» Lee 2022 [^] (COVID) | » Muhle 2022*
» Suntrup 2022 [~]
» Koestenberger 2020* | » Dziewas (PHAST-TRAC) 2018 [^]
» Suntrup 2015 [^]
» Bath (PhADER) 2020+ [^]
» Muhle 2017 [^]
» Traugott 2022 [^]
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» Beirer 2020 [^] (GBS) | » Suntrup 2022 [~]
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» McGrath 2022 [^]
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» Blakemore 2021 [^] (COVID)
» Traugott 2021 [~] (COVID)
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» Suntrup 2022 [~]
» Traugott 2022 [^]
» Dziewas (PHAST-TRAC) 2018 [^] |
|---------------------------|---|---|---|---|--|---|--|

Patients with Persistent Dysphagia

CNS INJURY (Stroke) AND/OR FOLLOWING MECHANICAL VENTILATION

IMPROVED SWALLOW TIMING



IMPROVED AIRWAY SAFETY



IMPROVED DIET & NUTRITIONAL INDEPENDENCE



MEASURES:

» Pharyngeal response time (VFSS)

» PAS (VFSS)

» Diet level (DSRS, FOIS)

» Meal supervision level (DSRS)

» Feeding tube dependency (FOIS)

PUBLICATIONS:

» Michou 2014

» Michou 2014

» Bath (PhADER) 2020

- VFSS = Videofluoroscopic Swallowing Study, also known as Modified Barium Swallow Study (MBSS)
- PAS = Penetration-Aspiration Scale
- DSRS = Dysphagia Severity Rating Scale
- FOIS = Functional Oral Intake Scale

Phagenyx case report

Presenting complaint

56 yr old, male

06.20 embolization of R vertebral artery. Followed by C1/2 laminectomy and craniotomy and debulking. Post op significant disability with VI/VII/IX/ & X paresis and right hemiparesis due to R PICA artery infarct post-op
PEG fed with NBM since op
08.20 developed hydrocephalus

Referred to our Voice service 01.21 with continuing SALT in Community for dysphagia, after intensive rehab in specialist Unit

Instrumental Assessment (FEES):

24/10/22 significant secretion build up, tipping into larynx, no reflexive cough until aspirated.



FEES 24/10/22

Treatment details

Commenced 08.06.23 – 2x 3cycles as continued overt 'wet' voice after the initial cycle of 3 stimulation episodes

DAY	THRESHOLD	TOLERANCE	STIMULATION
1	18mA	50mA	42mA
2	18mA	50mA	42mA
3	19mA	50mA	42mA
4	19mA	50mA	41mA
5	12mA	49mA	40mA
6	14mA	50mA	41mA

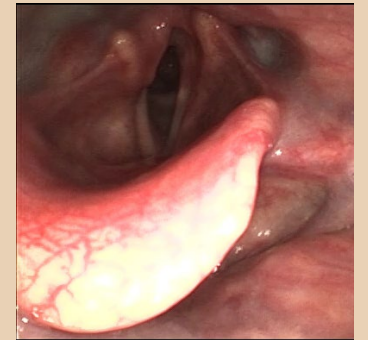
Initial Response: FEES 72 hrs post treat.
Impression of improved secretion management but FEES shows continued but less overspill into larynx post swallow with slow motor dysphagia



Patient outcomes

Main goal for patient is to be able to have some oral intake and reduced choking on saliva.

Repeat FEES 24.07.23 Improved sensation, stimulates more prompt swallow triggering prior to laryngeal penetration but swallow remains



FEES 24/07/23

2 weeks after treatment = voice less 'wet', reduced choking on secretions NBM
6 weeks after treatment = dry voice, minimal secretion build up, but continues NBM as reflux from UES as swallow occurs
Waiting ENT CP dilation, then MDTP swallow therapy to work on motor element of swallow now sensory element has improved.

Phagenyx case report

Presenting complaint

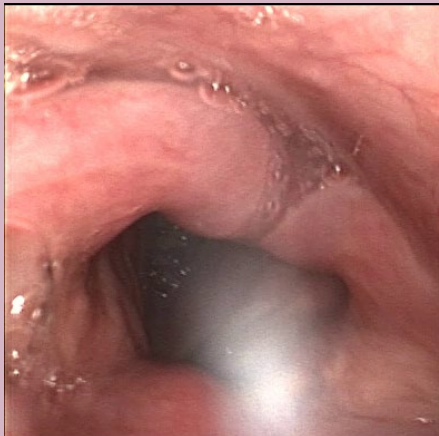
54, male Cardiac arrest with multi focal cerebral infarcts 08.01.23; seen by SLT 10.2.23 cuffed tracheostomy tube in situ with subglottic port due to high secretion load

Unable to be discharged from CCU due to inability to manage cuffed tube with subglottic post on Stroke Unit

Instrumental Assessment (FEES):

23 Feb 23 – Pooled secretions throughout, aspiration to these with no reflexive response. Able to trigger weak delayed swallow however neither safe nor efficient.

Severe motor and sensory dysphagia identified



FEES 23/02/23

Treatment details

Commenced 07.03.23 (eight weeks post-admission due to wait for equipment)

6 treatments (2 cycles) (incomplete data due to machine change)

DAY	THRESHOLD	TOLERANCE	STIMULATION
1	-	-	46mA
2	-	-	48mA
3	-	-	42mA
4	-	-	-
5	-	-	47mA*
6	15mA	40mA	-

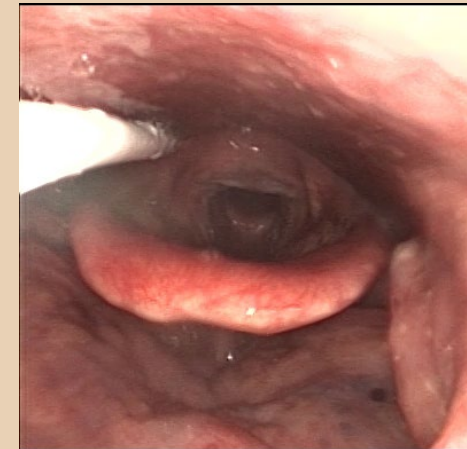
**treatment box was swapped and therefore data incomplete*

After three treatments he had improved swallow trigger and reduced post-swallow residue, but had continued penetration of secretions with delayed awareness. Trials of cuff deflation to increase laryngeal awareness of residue.

Further 3 treatments given, with improved pharyngeal sensation /awareness of secretions, resulting in more prompt swallowing triggering and commencement of oral intake. Patient tolerated cuff deflation. Transfer to Stroke Unit

Patient outcomes

Complex dysphagia with multifactorial issues, but sensation to secretions and penetration/aspiration improved. Decannulation occurred



FEES 20/03/23

Commenced Level 0 via tsp trials post Phagenyx , with gradual improvement in motor dysphagia following ongoing therapy.

Recommendations: Discharged to rehab ward on Level 1 and level 7 consistencies. PEG avoided

1

SLIGHTLY THICK

REGULAR

EASY TO CHEW

7

Phagenyx case report

Presenting complaint

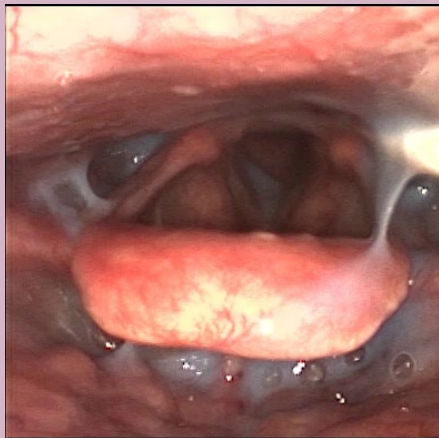
74, male

LMCA & LICA stenosis, left respiratory tract infection treated with antibiotics; placed on Level 2 Fluids and Level 5 diet initially but SLT referred for FEES due to variable bedside picture

Instrumental Assessment (FEES):

21 June 23 – Moderate pharyngeal motor and sensory dysphagia and silent/ overt aspiration across all trials. Patient Nil-by-mouth and aspirating secretions.

Low mood and anxious at remaining NBM. Poorly tolerant of NGT initially



FEES 21/06/23

Treatment details

Commenced 23 June 23 (day 6 post-admission)
6 consecutive treatments (2 cycles) Post cycle FEES

DAY	THRESHOLD	TOLERANCE	STIMULATION
1	9mA	28mA	23mA
2	15mA	21mA	20mA
3	12mA	24mA	21mA
4	16mA	24mA	22mA
5	18mA	26mA	24mA
6	20mA	36mA	32mA

Initial Response: Sensation/awareness of secretions improved but his secretion load remained high due to level of LPR (management included a triple pronged approach including lansoprazole, famotidine and Gaviscon advance).

Phagenyx improved pharyngeal sensation sufficiently for him to be aware of his secretions and allowed him to commence modified consistencies, removal of NGT and plan for discharge home

He required traditional dysphagia therapy alongside treatment to support his transition to oral intake.

Patient outcomes

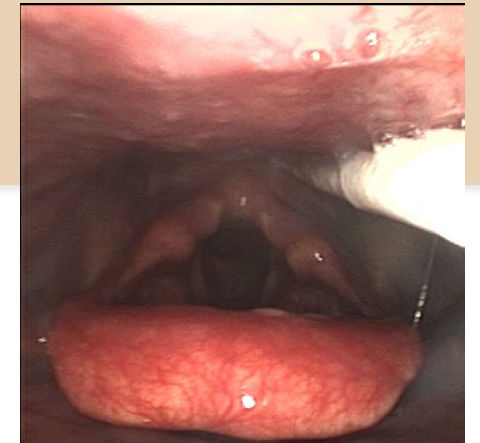
Main goal for patient was to be discharged home eating and drinking safely, without non-oral nutritional support.

Recommended:

Level 5 minced/ Moist Diet and Level 2 Mildly Thick fluids (05/07/23)



On-going Community SALT to further improve dysphagia following discharge



PEES treatment

FEES 05/07/23

Phagenyx case report

Presenting complaint

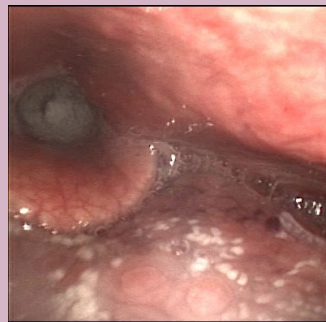
64, male Basilar artery thrombus 13.4.23 @ Royal London Hospital transferred to Basildon post IR mechanical thrombectomy 14.4.23 Multiple infarcts. Tracheostomised, cuff up, unable to discharge from CCU

Instrumental Assessment (FEES):

28 April 23 – Severe dysphagia. Severe, constant, silent aspiration of secretions; severe LPR. Desensate. NBM.

11 May 23 – Regurgitating feed, however, remains silently aspirating across trials, reduced awareness of residue. No response on LAR. NBM.

5 July 23 – LPR resolved, response to treatment seen on scope with nil signs laryngeal penetration +/- aspiration with thin fluids and modified diet



FEES 28/04/23



FEES 11/05/23

Treatment details

Commenced 02.05.23 (day 20 post-admission)
6 consecutive treatments (2 cycles) Post cycle FEES

DAY	THRESHOLD	TOLERANCE	STIMULATION
1	20mA	49mA	42mA
2	18mA	50mA	42mA
3	21mA	48mA	41mA
4	25mA	50mA	44mA
5	20mA	42mA	37mA
6	22mA	44mA	39mA

Well tolerated throughout, excessive secretions seen initially and significant oedema suggestive of unmanaged laryngopharyngeal reflux (LPR). Although sensation improved his secretion load remained high due to level of LPR, management included a triple pronged approach using lansoprazole, famotidine and Gaviscon advance.

Phagenyx gave enough sensation to be aware of his secretions. He required traditional dysphagia therapy alongside treatment to support his transition to oral intake.

Patient outcomes

Multiple repeat instrumental assessment (FEES). Subsequent FEES conducted two months after final treatment (in keeping with likely response to reflux management) and able to commence full oral intake.

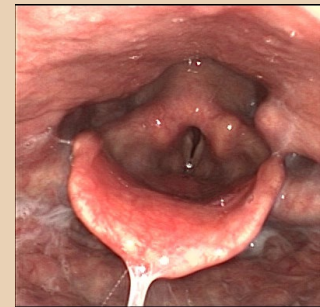
Recommended:

Level 5 minced/ moist diet and Level 0 thin fluids, moving eventually to Level 0 & level 7 (normal diet and fluids) prior to discharge.

Comments: the treatment allowed better secretion management, therefore decannulation and commencement on diet and fluids, and opened up discharge options including a potential to live at home.



FEES 05/06/23



FEES 05/07/23

Phagenyx case report

Presenting complaint

59 year old female Fall with subsequent long lie 16.1.23 Multiple vertebral fractures, (L3, T7 – impacting diaphragm) right para spinal abscess and epidural abscess – confirmed paraplegic. Admitted to ITU and intubated. 3x Failed extubations resulting in a tracheostomy on 09.03.2023. Difficult tracheostomy wean as presents with type 2 respiratory failure during longer periods of cuff down and PMV insitu and intermittently needing to be placed back on ventilation

Instrumental Assessment (FEES):

13.03.2023: severe dysphagia with inability to manage own secretions. Silent aspiration pre and post swallow observed on secretions and all consistencies trialed. Recommended NBM.



FEES
13.03.23

Treatment details

Commenced 22.03.23

DAY	THRESHOLD	TOLERANCE	STIMULATION
1	13	50	41
2	11	50	41
3	14	50	40
4	8	50	40
5	29	50	45
6	8	50	40

Complete swallows seen consistently during the treatment. Tolerated well, described sensation as 'odd, but not painful.'

04.04.2023: FEES

Repeat instrumental assessment (FEES) conducted 4 days after final treatment. Significant improvements from initial FEES seen with regards to swallow function and saliva management.

Recommendations: IDDSI level 4 pureed diet and level 0 thin fluids.

Patient outcomes

Due to respiratory complication she could not be weaned from tracheostomy, but Phagenyx improved sensation of secretions and boli, improved response and allowed commencement to full oral diet within a few weeks of treatment.

Patient has been interviewed by NICE regarding her experiences and is a firm advocate of the treatment "everyone should be offered this" she told them!!



POST TREAT FEES 04.04.23

Phagenyx case report

Presenting complaint

65 yr old, male

03.08.22 L lat medullary infarct= L VC palsy and severe dysphagia with poor secretion management, made NBM

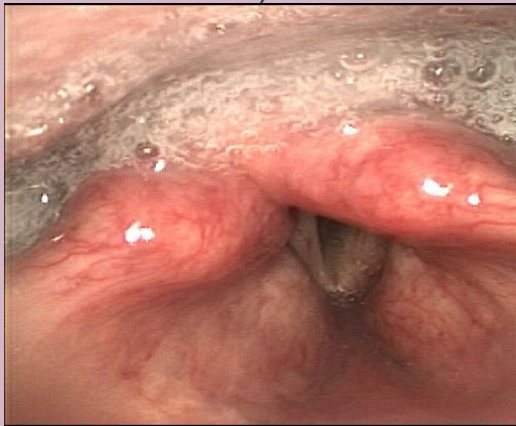
PEG 01/09/22

Instrumental Assessment (FEES):

Following in-patient swallow and voice rehab in both Stroke acute and rehab wards

Jan 23 – severe sensory and motor pharyngeal stage dysphagia, with L vc palsy

NB 6 admissions with aspiration pneumonia since CVA inc 2 which resulted in admission to CCU following Type 1 resp failure likely due to aspiration of secretions, swallow trials and/or vomit



FEES 22/12/22

Treatment details

Commenced 08.06.23 – 2x 3cycles as continued overt 'wet' voice after the initial cycle of 3 stimulation episodes

DAY	THRESHOLD	TOLERANCE	STIMULATION
1	29mA	50mA	45mA
2	29mA	46mA	42mA
3	32mA	50mA	46mA
4	28mA	50mA	45mA
5	24mA	50mA	44mA
6	21mA	50mA	43mA

Initial Response: FEES 72 hrs post treat.
Sensation/awareness of secretions improved
Phagenyx also improved pharyngeal and laryngeal awareness of residue (not within valleculae).
Commenced sips Level 0 + small amounts Level 6 diet with fluid chasers + 'dry' swallows.

Repeat FEES 24.07.23 Improved sensation, stimulates more prompt swallow triggering. Only poor awareness of residue is in valleculae, continue dry swallows

Patient outcomes

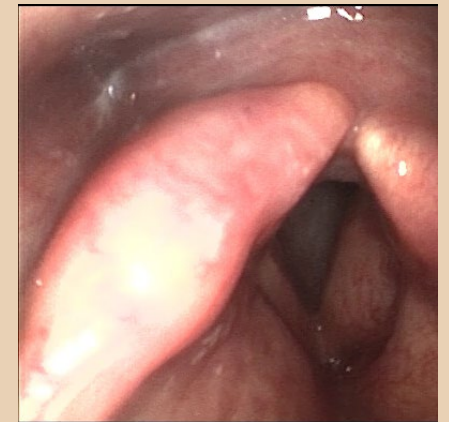
Main goal for patient was to have small amounts of oral intake to join in with family – and a "blue smartie".

BUT....

2 weeks after treatment = Level 0 sips and Level 6 diet, small amounts

6 weeks after treatment = Level 0 + Level 7 , with fluid chasers, full oral intake, rev for PEG removal

- After 11 months being NBM and 6 significant aspiration events, pt on full oral intake and no chest infections since treatment (now 3 months).



FEES 05/07/23