Chapter

Introducing IQoro: A Clinically Effective Oral Neuromuscular Treatment for Dysphagia

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Abstract

There is a clear need for new advances in treating dysphagia; healthcare professionals currently have a restricted range of options to treat swallowing problems and related conditions. Usual treatments for dysphagia are based on compensatory measures which allow patients to live within the limitations of their condition. These measures do not address the underlying cause of dysphagia: neurological and physiological dysfunction. A senior speech and language therapist working with young people with Cerebral Palsy bemoans the fact that official care pathway guidelines list only medication and surgical intervention as alternatives to treat drooling. Neither of which, she contends, is effective or desirable. Esophageal dysphagia causes reflux-based diseases, which are also poorly served by current treatment alternatives and are currently managed by medication, or remedied by surgical intervention. Medication reduces the symptoms of reflux but does nothing to address the underlying pathophysiology, muscular dysfunction, at the root of the problem. That now changes with IQoro: a simple, innovative treatment that is available to patients and healthcare professionals to address all of the above conditions. The chapter explains the physiological and neurological process of the functional swallow in detail, with illustrations and explanations. The efficacy of IQoro treatment is proven with evidence from internationally published scientific studies, case studies, an NHS service evaluation, and NICE briefings.

Keywords: oropharyngeal dysphagia, esophageal dysphagia, reflux, hiatal hernia, neuromuscular training, cerebral palsy, service evaluation in NHS, NICE briefing

1. Introduction

Dysphagia is a widely prevalent phenomenon that brings the risk of other conditions like malnutrition, pneumonia, and even the necessity for non-oral feeding solutions [1–3]. It always leads to reduced quality of life, and can even be fatal [4].

1.1 Few real solutions

The ways that patients with dysphagia are cared for fall into two broad categories, of which the first is by far the most common. Patients are often provided with compensatory care, [5, 6] which allows them to live with the disabilities that dysphagia brings. These therapies may include modified often puréed solid foods that are easier to swallow, and thickened drinks that can be swallowed more safely with less risk of aspiration. Instruction on posture, eating habits, oral hygiene and more, are also common.

The second category of care is rehabilitation treatment [7–11] to address the causes of the dysphagia. In general they focus on increasing muscle strength in the affected organs.

1.2 A new, innovative solution

This chapter introduces a simple neuromuscular treatment using an oral therapy - IQoro (**Figure 1**) - that can usually be self-administered by the patient. The treatment has clinical evidence and scientific proof of striking success in treating people of all ages with all forms of dysphagia: oral-, pharyngeal- and esophageal [12–14]. When used with stroke survivors, the research shows equally good outcomes regardless of whether treatment started immediately, or long after the onset of stroke [10]. In scientific studies, the observed improved outcomes were still present at long-term follow-ups performed up to 18 months after the end of treatment [11, 12, 15–17].

2. Two innovative clinicians

2.1 Mary's journey

Associate professor Mary Hägg started her professional life as a hospital dentist where she became fascinated with the swallowing problems that some of her patients presented with. In Sweden, the remit of the dentist is wider than in some other countries and can encompass more orofacial issues than just teeth and gums. The more she worked with patients with swallowing difficulties some after stroke the more fascinated she became. She worked with exercises to strengthen the delinquent muscles and became more and more renowned for her focus on dysphagia.

In 1990, Mary founded a specialist multi-disciplinary unit within the ENT department of a Swedish teaching hospital and has managed it since its inception. The purpose of this speech and the swallowing unit is to encourage and ensure cooperation across a range of clinical specialties to deliver improved patient outcomes.

In 1997 she was awarded a stipend to visit and study the subject more deeply with Dr. Castillo Morales, Cordoba, Argentina, and in 2001 with Professor Bronwyn Jones, Dept. of Radiology, The Johns Hopkins Hospital, medical center in Baltimore, Maryland, USA.

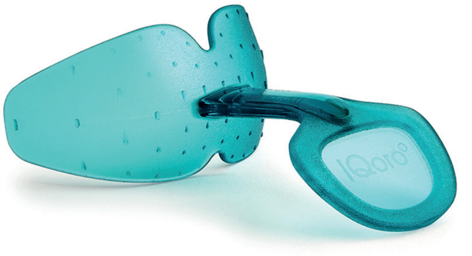


Figure 1.
The IQoro neuromuscular training device.

As she treated more and more patients that were referred to her, she came to two conclusions: firstly, those swallowing difficulties manifest themselves as a muscular deficiency, but usually have a neurological dysfunction at the root; and secondly, that there were few effective treatment options. In many cases, patients received only compensatory care which allowed them to function with their disability, but with no active plan to address the underlying problem.

To address the first issue Mary decided that she must study to be a doctor in order to understand the neurology that lies behind dysphagia. It is clear that the day before a patient has a stroke that his or her swallowing can be fine and that it is the neurological event that causes the immediate onset of dysphagia. Mary's Ph.D. thesis "Sensory-motor brain plasticity in stroke patients with dysphagia. A methodological study on investigation and treatment" 2007, used massage to restore muscular strength by stimulating brain activity. Mary invented and had manufactured a validated scientific instrument to measure the strength of certain components in the swallowing chain by measuring resistance in the pharyngeal sling or buccinator mechanism [18, 19]. She also developed and validated orofacial motor test methodologies [20].

The second problem, the lack of suitable treatments [21, 22] that could be easily and widely used even by the patients themselves was a harder task. Her journey took her through working with all types of dysphagia in people from premature babies through children, adults, and to end-of-life. The journey resulted in her inventing, developing, and patenting the revolutionary IQoro device that is now, July 2021, used by over 50,000 people in many countries.

2.2 Natalie's vision

Decades later Natalie Morris came across the IQoro device, and it set her wondering if it would help her patients too. Natalie is a Speech and Language Therapist working in the UK and is the founder and CEO of The Feeding Trust a not-for-profit multi-disciplinary feeding clinic in the Midlands. During her 20-year career as an SLT, Natalie has become specialist in the assessment and treatment of communication and swallowing difficulties in children and young people (CYP) with neuro-developmental disabilities and acquired brain injuries. She is the founder of Integrated Therapy Solutions Ltd. where she and her team help CYP with swallowing difficulties.

She looked at the scientific evidence supporting IQoro and was disappointed to find that there was none that was directly relevant to one of her main patient groups: CYP clients with Cerebral Palsy (CP). This was significant because NICE guidelines for the management of saliva control in CP [23] offer few options:

1. Assess contributory factors before starting drug therapy

2. Medication

3. Botulinum toxin injections

4. Surgery

In other words, the only treatment options after considering compensatory strategies such as positioning, are drug therapy or surgery. But the Cochrane review of interventions for drooling in children with CP according to Walshe M, Smith M, Pennington L 2012 [24] concludes: "*There is no clear consensus on which interventions are safe and effective in managing drooling in children with CP*." Her own clinical observations and experiences over the years have been that difficulties with saliva control are a persistent problem with no real effective treatment.

Natalie reasoned that if IQoro could help patients with neurological problems such as after a stroke, then it might help her patients with CP too. And if there was no evidence to prove that it worked, then she would have to investigate it herself.

This chapter will show the success of these two clinicians' work.

3. The physiology of the swallow

This is a brief description of the four different physiological phases of the swallowing process, the following section will look at the neurology of the swallow in detail [5, 25].

During a day, a normal person swallows approximately 600 times: 350 of these are during the day, 200 when eating or drinking, and 50 times when asleep. We use our voluntary muscles to transfer food to our mouths and chew it, after this our reflexive systems take over to complete the swallow unconsciously. When we swallow whilst asleep it is, of course, an entirely reflexive process.

3.1 The phases of the swallow

3.1.1 Pre-oral phase

Simply described, the swallowing process starts when we transfer food from the plate to the mouth. (**Figure 2**). This phase is negatively affected when postural control or arm and hand motility are reduced, possibly after stroke [17].

3.1.2 Oral phase

The oral phase (**Figure 2**) starts when we close our lips, chew, reduce the food to manageable pieces and mix it with saliva. As the food is formed into a bolus the tongue's backward and upwards movements propel it towards the pharynx, at the same time the floor of the mouth rises. And then immediately before the swallowing reflex is triggered we press our lips together creating a low pressure in the mouth. This activity normally takes up to 10 seconds [5]. The decrease in pressure in the mouth eases the transport of the food mixture from the mouth to the pharynx.

The phases employ a mixture of voluntary and involuntary commands.

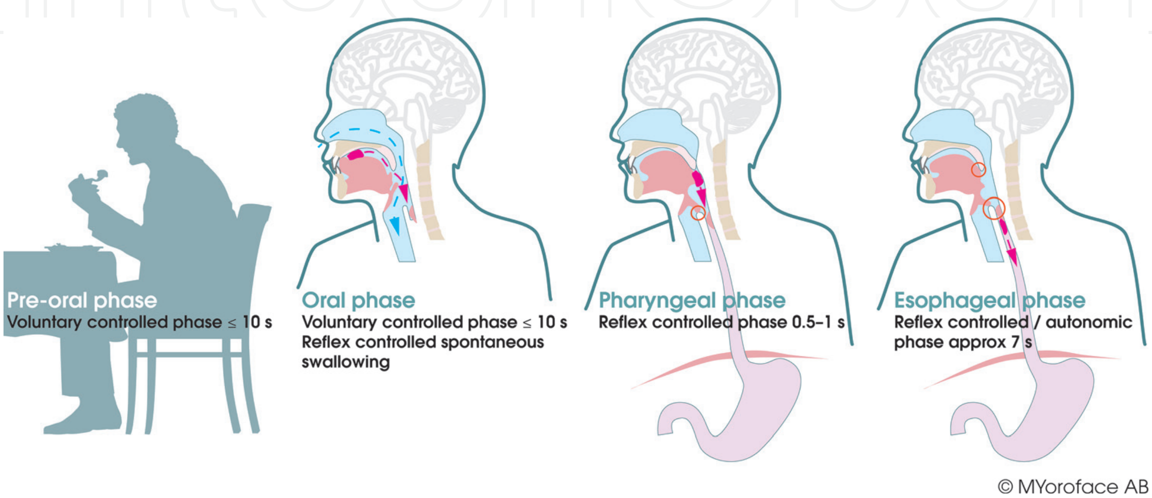


Figure 2.
The four phases of the swallowing process.

3.1.3 Pharyngeal phase

Once the bolus has passed the anterior palatal arch towards the pharynx, the swallow reflex takes over. This is controlled by the brain stem no longer consciously controlled as the pre-oral and oral phases were. The interplay between the voluntary and involuntary processes is described in the following section on the neurology of the swallow.

A normal swallow requires a balance between the infrahyoid and suprahyoid muscles to stimulate the swallowing reflex [20, 26].

In a later section "The neurology of the swallow" we will see that these muscles are triggered by the following nerves - Infrahyoidal muscles: CN XII hypoglossus.

– Suprahyoidal muscles: CN VII facialis, CN V trigeminus, CN XII hypoglossus.

Middle illustration: A Functional swallow is prepared when the hyoid bone is pulled backward and upwards (red arrow) by the styloid muscles (CN VII) and the posterior part of the digastric muscles (CN VII), at the same moment as the tongue base retracts.

The swallow reflex is then triggered when the hyoid bone is pulled forwards and upwards (blue arrow) by the digastricus anterior abdomen (CN V), m. mylohyoideus (CN V), and m. geniohyoideus (CN XII). At the same moment, a breathing suspension is caused as the epiglottis closes the laryngeal air pathway, and tongue forward movement is initiated. The chewing muscles are active throughout the swallow.

Left illustration: A dysfunctional swallow. If the chewing muscles are weak, the patient cannot lift his lower jaw and close his lips fully, which hinders swallowing. At the same time, the lower muscle groups of the tongue pull the hyoid bone downwards, which further degrades swallowing ability. The same thing happens when grinding the teeth.

Right illustration: A dysfunctional swallow. When the head falls backward, because of impaired head control, the mouth opens spontaneously and the equilibrium of the hyoid bone is completely upset, resulting in swallowing difficulties.

The pharyngeal phase (**Figures 2–4**) is a critical part of the swallow controlled purely reflexively and takes between 0.5 and 1 second. It requires a precise interplay between breathing and swallowing functions [5, 13]. When the bolus is to be swallowed, the tongue moves it back towards the anterior palatal arch and the

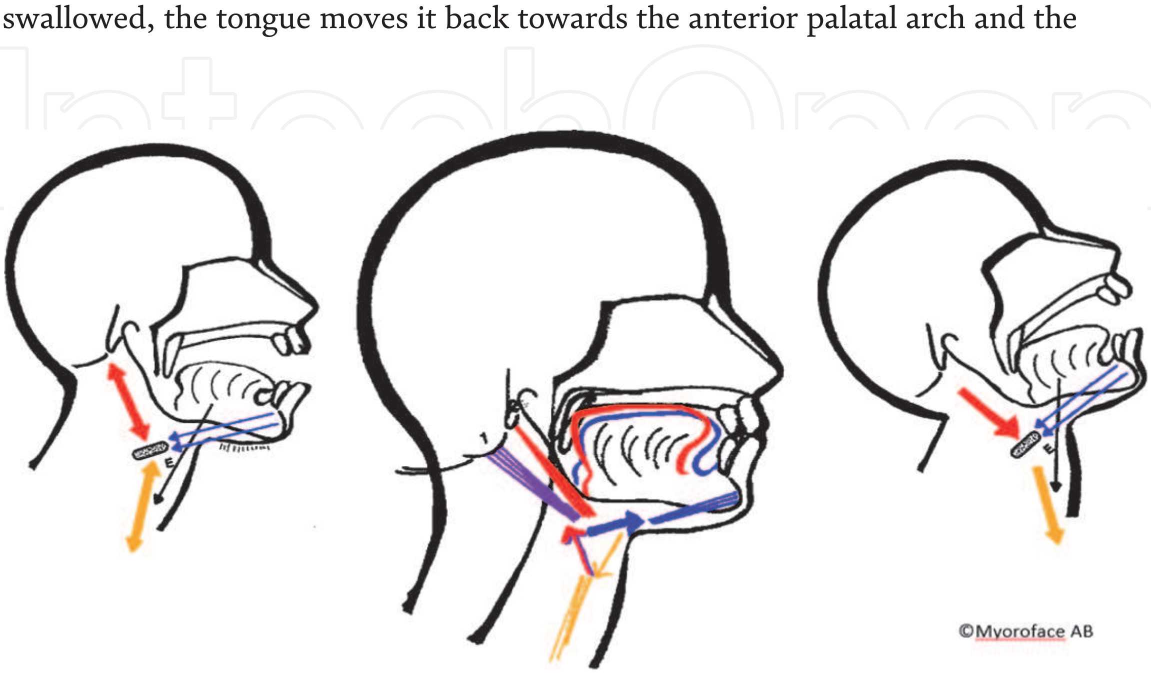


Figure 3.
Functional and dysfunctional swallow.

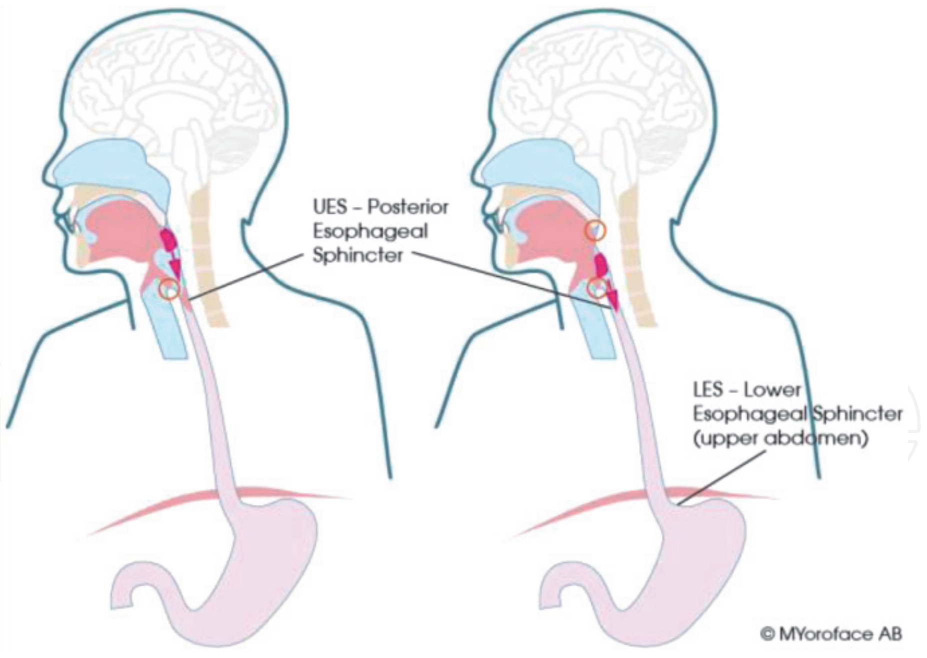


Figure 4.
The pharyngeal phase - a critical phase requiring coordination of swallowing and breathing.

smooth palate which seals against the nasal passages. The larynx raises reflexively, and the tongue starts its forward movement.

The first of four security levels to prevent aspiration of food or drink is now activated. The constrictor muscles: *Constrictor pharyngeus superior*, *Constrictor pharyngeus middle*, *Constrictor pharyngeus inferior* contract [27]. The last of these is also known as the UES [28]. The second level is achieved when the epiglottis closes over the trachea or air pathway. The third and fourth levels are executed as first the false vocal cords close, and then the true vocal cords themselves.

There is perhaps more crossover in dysfunction in the different phases than is often thought. Misdiagnosis is a risk when healthcare professionals concentrate too much on their own specialities without considering a more holistic approach.

For example:

- Mis-directed swallowing, post-nasal drip, aspiration, hoarse or gurgly voice, persistent non-productive cough, something stuck in the throat, and blockage are all symptoms often thought of as being caused by a brain injury. Causes of such brain damage can be a stroke, trauma, progressive neurological diseases, or other. In fact, all the symptoms described could equally well be caused by a Hiatal hernia [14].

- Patients exhibiting voice changes are often referred in firsthand to a speech and language therapist. If the SLT is not aware that the cause of the problem may be dysfunction in the esophageal phase - like a Hiatal hernia - then optimal outcomes may not be achieved. This problem is aggravated by the fact that SLTs in some countries are not routinely concerned with esophageal dysfunction.

- Patients with symptoms of Hiatal hernia are often referred to a medical consultant to rule out the possibility of stroke. When this has been done, then the finger may be pointed at a brain tumor, ALS, or some other neurological condition. Examination for these conditions is both alarming for the patient whilst waiting for examination and results, and expensive. Around 20% of the world's population suffers from a reflux-based condition, and it is thus logical in many cases to start treating for a Hiatal hernia as soon as stroke has been ruled out.

3.1.4 Esophageal phase

The esophageal phase (**Figure 2**) concerns the movement of food and drink from the esophagus down to the stomach. The esophagus' longitudinal musculature is activated, forming a stiff pipe and allowing the entrance to the Upper Esophageal Sphincter (UES) to relax and open to allow the passage of the bolus into the esophagus. At the same time, the Lower Esophageal Sphincter (LES) opens to allow the entrance of the bolus to the stomach. [5, 29] This phase takes around 7 seconds to complete.

As well as the outer longitudinal layer of muscles, the esophagus also has an inner layer of circular muscles. To transport the food down to the stomach, these circular muscles produce coordinated peristaltic wave motions - this explains why we can swallow even if we were hanging upside down.

4. The neurology of the swallow

4.1 The phases of the swallow

The four phases of the swallowing process described above involve 148 muscles and six cranial nerves. Of course, the muscular activities described are not separate from the nerve and brain activity that control them, the entire neurophysiology [25] of the swallowing process must work correctly. Understanding how is fundamental to appreciating how a dysfunctional swallow can be treated.

Figure 5 illustrates four important areas of the brain [25].

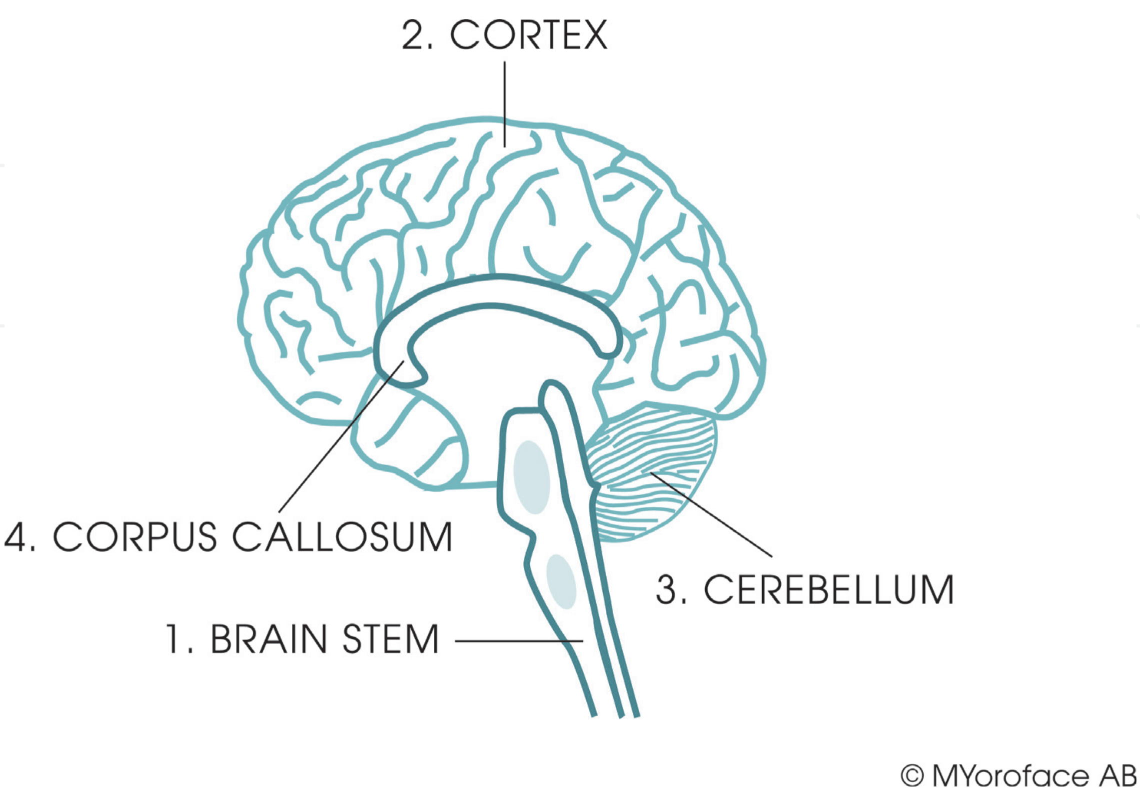


Figure 5.
The brain.

1. Brain stem: It controls non-voluntary "unconscious" automatic functions such as breathing, blood pressure, heart rhythm, the reflex swallowing phases; and also functions as a communication node between the cerebrum, the cerebellum, the spinal cord, and the peripheral nervous system.

2. Cortex: It controls our voluntary "conscious" most advanced functions such as language, thinking, fine-motor skills, and the voluntary swallowing phases.

3. Cerebellum: It co-ordinates our movements, our balance, and our ability to act in response to our immediate surroundings.

4. Corpus callosum: It connects the two brain hemispheres' cortex areas with each other. It consists of some 200 to 800 million nerves that coordinate the activities of the brain's two hemispheres.

4.2 Brain functions in swallowing

The sensory nerves report perceptions of pressure, texture, taste, and temperature, and these are transmitted by these afferent nerves to the brain. The primary source of these stimuli is from the nerves in the lips and then, in turn, the tongue, soft palate, and pharynx (**Figure 6)** [5, 29]. The (CN V) Trigeminus is the thickest and fastest of the efferent nerves, and thus the signals from the lips are the first to reach the brain stem. It is therefore a mistake to concentrate on therapies for the tongue, soft palate, and pharynx that omit the importance of the lips.

The five cranial motor nerves that are important for swallowing are CN V Trigeminus, CN VII Facialis, CN IX Glossopharyngeus, CN X, Vagus, and CN XII Hypoglossus. The first four are both sensory (afferent), and motor (efferent) nerve pathways; which send information both to and from the brain - the sensory-motoric reflex arc.

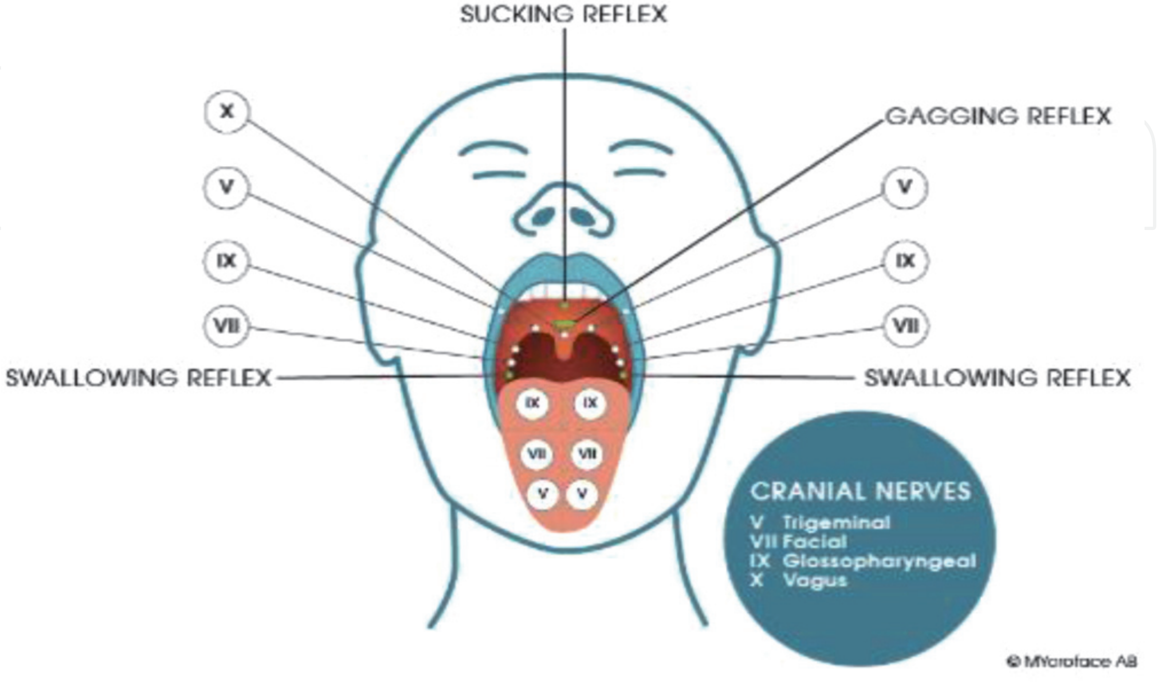


Figure 6.
The cranial nerves and reflex points of the oral cavity.

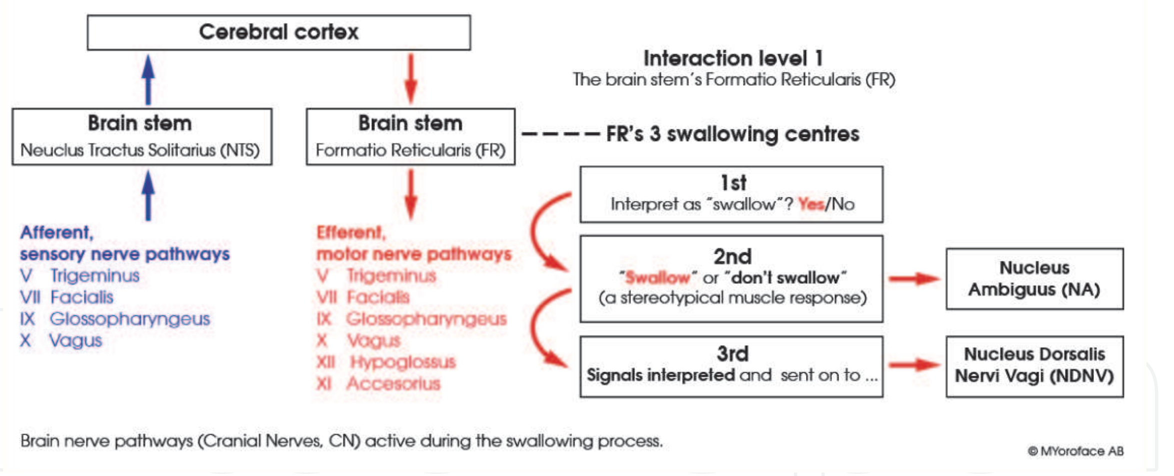


Figure 7.
The sensory-motor reflex arc (level 1).

In the brain stem (**Figure 7**) we find the Nucleus Tractus Solitarius (NTS): the afferent nucleus. The NTS is the core that gathers all incoming sensory signals via the afferent nerve pathways as described (**Figure 7**). The NTS then transmits the signals onwards either to the brain's cortex or directly to the network-like system in the brainstem called the Formatio Reticularis (FR). These efferent motor signals are transmitted to the musculature of the face, mouth, esophagus, diaphragm, down to the stomach, the intestines, and the rectum. The process by which the incoming sensory signals trigger afferent commands is known as the sensory-motoric reflex arc (**Figure 7**) [5, 25, 26, 29].

The three swallowing centers' interactions - from the brain stem to muscles.

In the FR, the afferent signals from the NTS and the cortex (**Figure 7**) are first interpreted and then passed through various distribution nodes to the efferent nuclei: the Nucleus Ambiguus (NA), and the Nucleus Dorsalis Nervi Vagi (NDNV).

The NA (**Figure 7**) sends impulses to the skeletally striated musculature in the oral and pharyngeal regions; and the NDNV (**Figure 7**) to the smooth musculature of the esophagus and beyond. How these function during swallowing we will explain in more detail below.

In the FR there are three distribution nodes (swallowing centers) that are key to the swallowing process; as well as a number of other centers that control breathing, speech, chewing, coughing, vomiting, evacuation of the bowels and bladder, and those muscles that control the body's posture (**Figure 8**). [5, 25, 26, 29].

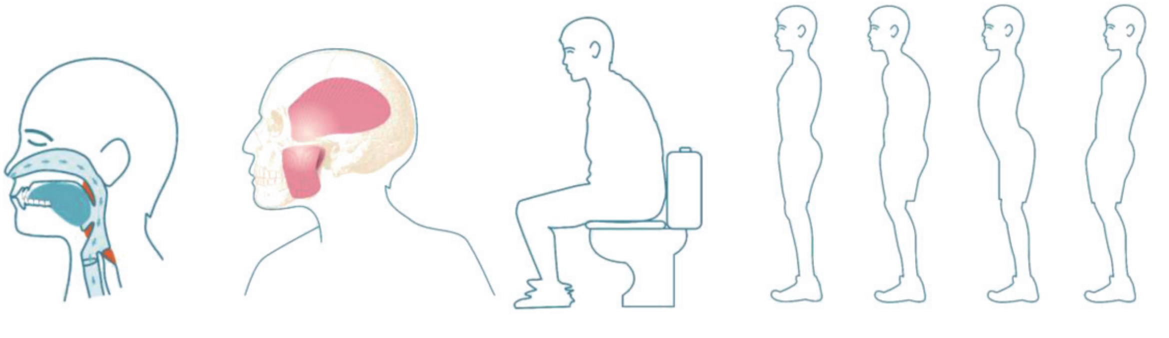


Figure 8.
The Formatio Reticularis (FR) is the control centre for a variety of vital functions.

The Formatio Reticularis is the control centre for several vital functions including breathing, speech, chewing, coughing, vomiting, evacuation of the bowels and bladder, and those muscles that control the body's posture.

The incoming information is routed by the Nucleus Tractus Solitarius (NTS) in two pathways: some directly to the first of the three swallowing centers in the brain stem, whilst the remainder of the information continues upwards to the cortex to be processed before being also directed to the first swallowing center (**Figure** 7).

4.3 The swallowing centers

4.3.1 First swallowing center

If the combination of information received by the first swallowing center (**Figure 9**) from the NTS and from the cortex is interpreted as that something is to be swallowed, this instruction is sent to the second swallowing center.

4.3.2 Second swallowing center

The second swallowing center (**Figure 9**) transmits signals to the muscles via the motor nerves – the downward-transmitting efferent nerve pathways. Here, there is a pre-programmed "swallow / don't swallow" stereotypical muscle response.

If the food is to be swallowed, a command is sent to the NA, which in its turn sends the instruction via the efferent nerve pathways to the striated musculature in the oral and pharyngeal regions of the swallowing chain. Concurrently, impulses are also sent to the third swallowing center.

4.3.3 Third swallowing center

The third swallowing center (**Figure 9**) transmits information to the NDNV - an efferent nucleus and then onwards to the esophagus' smooth musculature to complete the swallowing action and to transport the bolus downwards to the stomach.

The three swallowing centers´ interactions from the 2nd center to the striated muscles, and the 3rd center to the smooth muscles is illustrated here.

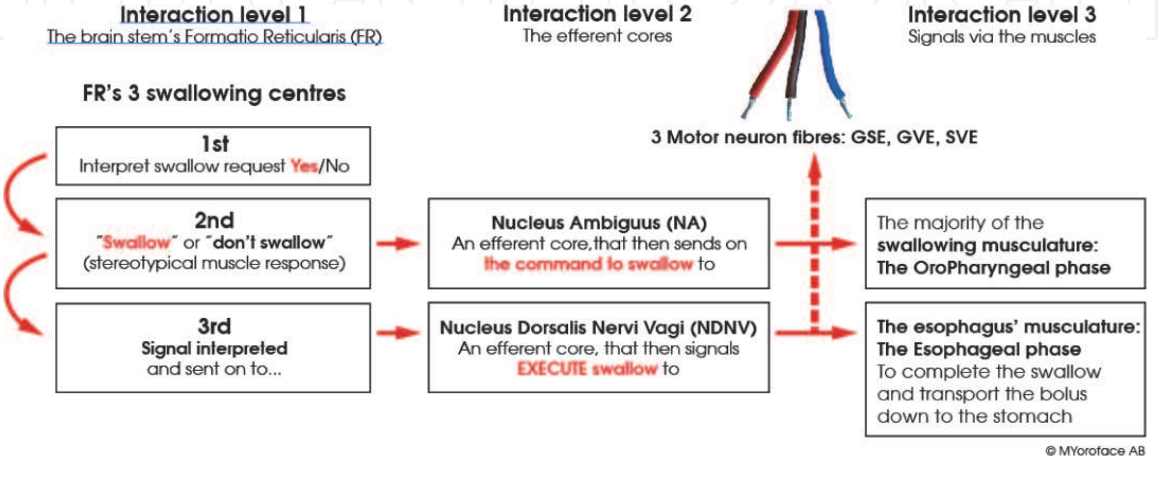


Figure 9.
The sensory-motoric reflex arc (level 1–3).

The 3rd swallowing center transmits information to the Nucleus Dorsalis Nervi Vagi (NDNV), and then onwards to the smooth muscles including those in the esophagus (**Figures 9** and **10**).

4.4 The motor neurons

The motor signals are transmitted via efferent nerves that can be thought of as cables containing various fibers and motor neurons to the muscles and glands. There are three different kinds of motor neurons that are important in the swallowing process (**Figure 10**) [5, 25, 29].

- The General Somatic Efferent (GSE) motor neurons are present in the CN Hypoglossus (XII) and CN Oculomotorius (III) which transmit signals onwards to the tongue's and the inner eyes' voluntary skeletal striated musculature.
- The Special Visceral Efferent (SVE) motor neurons act through the CN Trigeminus (V), CN Facialis (VII), CN Glossopharyngeus (IX), CN Vagus (X) and CN Accessorius (XI) which transmit signals to the voluntary musculature in the mouth, chewing muscles, facial musculature, pharynx, larynx, esophagus, and diaphragm.
- The General Visceral Efferent (GVE) motor neurons act via CN Facialis (VII) and CN Glossopharyngeus (IX) which transmit signals to the glands, blood vessels, and smooth muscles in the pharynx, stomach, and rectum.

The sum of all the above signals executes pre-programmed cooperation between the 148 muscles that are involved in the transport of each food bite from the mouth down to the stomach.

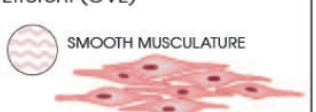
Motor neuron fibres	Cranial nerves	Muscles and glands
General Somatic Efferent (GSE) STRIATED MUSCULATURE 	XII Hypoglossus III Oculomotorius	Tongue Eyes´ inner muscles
Special Visceral Efferent (SVE) STRIATED MUSCULATURE 	V Trigeminus m. tensor tympani VII Facialis m. stapedius IX Glossopharyngeus X Vagus XI Accessorius	Face Oral cavity Chewing muscles Eyes´ outer muscles Pharynx Larynx Esophagus Diaphragm
General Visceral Efferent (GVE) SMOOTH MUSCULATURE 	VII Facialis IX Glossopharyngeus	Glands Blood vessels Smooth musculature

Figure 10.
Three types of motor neurons.

The efferent nerves send signals via the three different motor neuron fiber types to the muscles and glands.

4.5 Understanding the three neurological phases

4.5.1 Oral phase

As we have said earlier, the oral phase is consciously controlled (voluntary) and is managed by the brain's cortex region [5, 25]. But when the bolus has passed the anterior palatal arch towards the pharynx, the swallow reflex takes over and this is controlled by the brain stem – no longer consciously or voluntarily controlled.

4.5.2 Pharyngeal phase

The tongue's movement backward and upwards transports the food towards the pharynx. When the bolus reaches the anterior palatal arch and the smooth palate, the reflexive phase of the swallow starts [5, 6] causing the larynx to rise, As the tongue begins its return movement forward, the epiglottis seals the airway and the food passes into the pharynx. The pharyngeal phase takes between 0.5 and 1 second.

In this phase, the coordination between breathing and swallowing is crucial to avoid food 'going down the wrong way' [5, 25, 30, 31]. Breathing and swallowing are guided by different centers in the brain stem, however, all the muscles that are active in these two functions are controlled from the same concentrated grouping of specialized nerves nucleus in the brain stem. This allows the swallowing center to take control of breathing during a crucial phase in the act of swallowing. When the 1st and 2nd Swallowing Centers signal that swallowing is underway, the body breathes in. During the subsequent exhalation, the food portion is driven to the back of the tongue and the exhalation stops as the bolus crosses the airway. Breathing ceases for 2 seconds about twice as long as it takes for the bolus to pass the pharynx then breathing is resumed with a continued exhalation.

4.5.3 Esophageal phase

The esophagus' longitudinal musculature forms a stiff pipe, the UES relaxes and opens to allow the passage of the bolus into the esophagus. The sphincter to the stomach – LES - opens to enable the entrance of the food.

The muscle function and the downwards transport of the bolus are controlled by the Vagus CN X and a branch of the Glossopharyngeal CN IX. Together these nerve pathways build a local network in the esophagus' *Plexus Pharyngeus* [25].

Both types of muscle: voluntary skeletal striated muscles and involuntary smooth muscles are present in the esophagus. The voluntary musculature is the same type as we have, for example, in our arms and legs: so-called skeletal striated muscles which are attached to the skeleton or tissue, and that are voluntarily controlled. The smooth musculature cannot be controlled voluntarily but is instead controlled by the autonomic nervous system: functioning unconsciously and involuntarily. These muscles are stimulated via the GVE motor neurons (**Figure 10**) in the brain stem which sends signals to the involuntary musculature.

The esophagus' upper third consists of skeletal striated muscles, the middle third is a mixture of skeletal striated muscles and smooth musculature, and the bottom third is solely smooth muscle.

5. Dysphagia and reflux diseases are related

5.1 What are reflux-based diseases?

This chapter has so far focussed mostly on the swallowing process of conveying food and drink to the stomach successfully, Hiatus hernia has been mentioned only in passing. Here we explain more about this condition. IQoro treats all dysfunctions in the process of swallowing food and drinks safely and successfully, and in retaining it in the stomach without reflux [14, 32]. A distinction between these two areas although often regarded as separate from a healthcare perspective is artificial. The same neuro-physiological processes are common to both dysfunctional swallowing and reflux.

5.1.1 Prevalence and symptoms

Reflux-based diseases are thought to affect around 20% of the world's population [33, 34]. Reflux is a condition in which stomach acids sometimes bubble up from the stomach, through the esophagus, and into the throat, larynx, and pharynx. The effect of these acids is to cause the symptoms of [35]:

- Heartburn
- Burning sensation in the chest
- Acidic reflux
- Swallowing difficulties
- Feeling of a lump in the throat
- Feeling of a blockage in the chest when eating
- Chest pains
- Pain under the breastbone (sternum)
- Stomach pains before eating
- Stomach pains after eating
- Reduced appetite
- Early "Full up" feeling
- Feeling sick
- Constipated, gassy
- Vomiting
- Persistent dry or phlegmy cough
- Food or drink 'goes down the wrong way'

- Hoarseness
- Breathing difficulties

It should be noted that if some of the above symptoms are chronic, and especially if they do not respond to medication, they could be caused by cancer or other diseases [36], and this should be considered before diagnosing reflux as the sole cause.

Refluxing stomach acids is the underlying cause of several conditions: LPR, GERD (or GORD), Silent Reflux, IED, Dyspepsia, etc. These conditions are sometimes known by their full names: Laryngopharyngeal Reflux, Gastroesophageal Reflux Disease, and Intermittent Esophageal Dysphagia. These various conditions exhibit some or all of the symptoms listed above, they vary slightly but are all caused by the corrosive effect of the refluxed stomach acids.

5.1.2 Cause of reflux

These symptoms occur when stomach acids reflux into the esophagus. The normal position of the stomach and the LES - the valve at the mouth of the stomach - is below the diaphragm. The esophagus passes through the diaphragm muscle through an aperture called the hiatus canal. In functional anatomy the muscle grips tightly around the esophagus and holds the stomach down in its correct position. The LES behaves like a trapdoor in this position, swinging downwards to let food and drink into the stomach before closing again. The LES cannot open upwards to allow reflux. An exception to this is if we need to belch or vomit; then the LES intrudes through the diaphragm slightly into the chest cavity and can flap open upwards and allow stomach gases, liquids or solids to reflux.

A Hiatal hernia is a weakening in the muscle that grips around the esophagus where it passes through the diaphragm. When this occurs the mouth of the stomach and the LES can intrude in an unwanted and uncontrolled fashion and allow reflux to occur.

5.1.3 Existing treatments for reflux-based diseases

The treatment options for reflux-based diseases fall into two broad camps: reducing the symptoms, or addressing the underlying cause.

In the former category, symptom reduction can be achieved by lifestyle changes or medication. Changing poor living, smoking, drinking, eating and diet habits can improve the impact of reflux, but lifestyle changes have an inconclusive effect [37].

Many Over the Counter (OTC) medications have a base pH and address the problem of reflux by reducing the acidity of the stomach acids which are being refluxed. Although the unpleasant sensations of reflux are reduced, the harmful effects on the vulnerable esophagus and other organs continue. Long-term use of OTC medication is generally regarded to be free from harmful side effects.

Prescribed PPI medications act by inhibiting the amount and strength of the acids produced in the stomach. PPI medications have significant known side effects and hence long-term PPI usage is generally discouraged and several countries insist that clinicians perform a medication review before renewing PPI prescriptions. At least once per year is recommended in the UK [38]. PPI medication is usually not expensive in itself, but the costs of repeat Healthcare Professional (HCP) interventions build to a considerable amount when prescribed for rest-of-life.

PPI drugs belong to one of the safest medication groups, but some research suggests a list of unwanted side effects [39, 40] include increased risk of cardiovascular disease, osteoporosis, dementia, male infertility, diabetes, and increased vulnerability to severe covid19 infection.

In addition, harmful bacteria in the stomach like Helicobacter pylori (HP) that would not survive in normal circumstances, can thrive in the weakened acids after PPI treatment. These germs can enter the body and live in the digestive tract. After many years, they can cause sores, called ulcers, in the lining of the stomach or the upper part of the small intestine. For some people, an infection can lead to stomach cancer.

In the case of all medications, there is no expectation that the underlying cause of the reflux – the weakened diaphragm musculature [34, 41]– will be addressed, merely the severity of the reflux symptoms.

The muscular deficiency at the root of the problem can sometimes be remedied by a surgical operation [42] that re-wraps muscles in the hiatal canal around the esophagus, or a similar procedure. Clearly, addressing the underlying cause is preferable in many ways to long-term medication and IQoro, as presented here, offers a simple non-invasive alternative to a surgical operation.

5.1.4 Existing treatments for dysphagia

As discussed, patients with a dysfunctional swallow sometimes after stroke are often treated with compensatory treatments [5, 6]. These care pathways allow patients to live within the limitations of their conditions. Direct and successful treatment of the dysfunctional swallowing chain is to be preferred and is presented in this chapter.

5.1.5 Treating the muscles

If the cause of both dysphagia and reflux is known to be neuromuscular, why are the most common treatments medication or surgical intervention? It is easy to grasp the idea that rebuilding muscle strength will improve swallowing, and allow the muscles in the Hiatal canal to regain their ability to grip around the esophagus.

If a patient presented with an arm that had atrophied because it had been in a plaster cast for some weeks, we might expect a rehab program based on weights and exercises. However, the atrophied-arm parallel has an important disconnect. As we have explained earlier, there are key differences between the arm muscles and many of the muscles that are needed to ensure an effective swallow and to prevent LES intrusion through the diaphragm allowing reflux. The arm is made up of skeletally striated muscles that can be commanded by the individual to flex, and can therefore be consciously exercised; whereas most of the muscles in the swallowing chain cannot, they are controlled and commanded through other nerve types and command systems. The paradox then is how to exercise muscles that cannot be commanded to flex.

6. IQoro

6.1 What is IQoro?

IQoro (**Figure 1**) is a simple hand-held plastic device that is inserted predentally (inside the lips and in front of the teeth) by a patient and pulled forward against lip pressure to exercise the swallow. At the time of writing, July 2021, it has been used by more than 50,000 individuals and is used by healthcare professionals to treat patients in hospitals and other settings across several countries. It is a CE-marked Class 1 Medical device, internationally patented and costing around USD 150.

6.2 How to train

The patient inserts the device pre-dentally and seals the lips against the handle, then pulls forward firmly displacing the lips forward slightly. This position is held for 10 seconds, followed by a short pause to relax, and then the action is repeated twice more. This 30-second training session should be carried out three times per day, preferably before mealtimes (**Figures 11–13**).

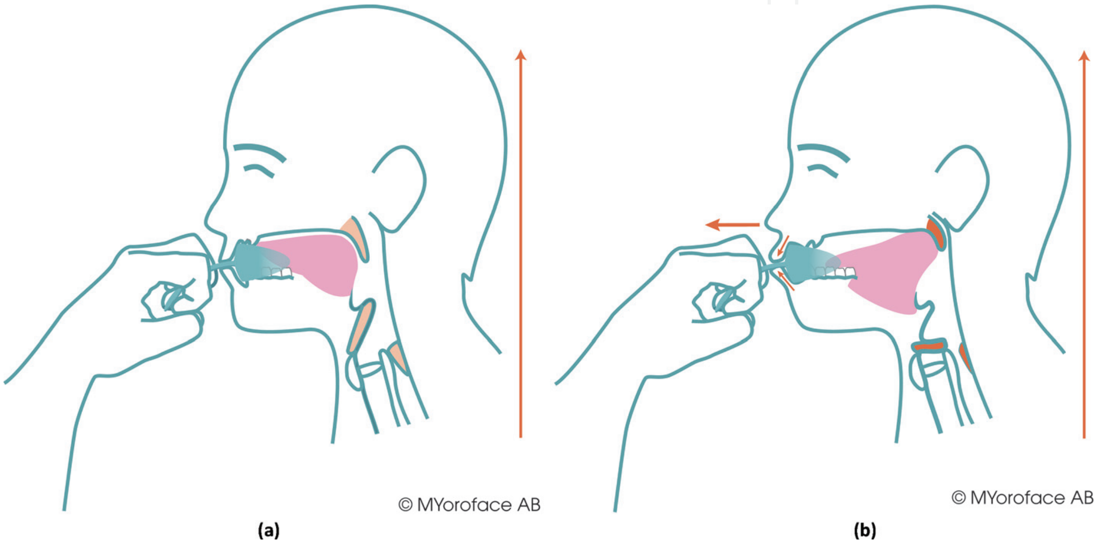


Figure 11.
(a, b): IQoro training action. (a) the IQoro is inserted pre-dentally, behind closed lips. (b) the patient presses his lips firmly together whilst pulling straight forward strongly for 5–10 seconds, and does this 3 times with 3 seconds rest between each pull. These sessions are performed three times per day, preferably before mealtimes. ***Video 1.***

Figure 12.
Video 1. [43].

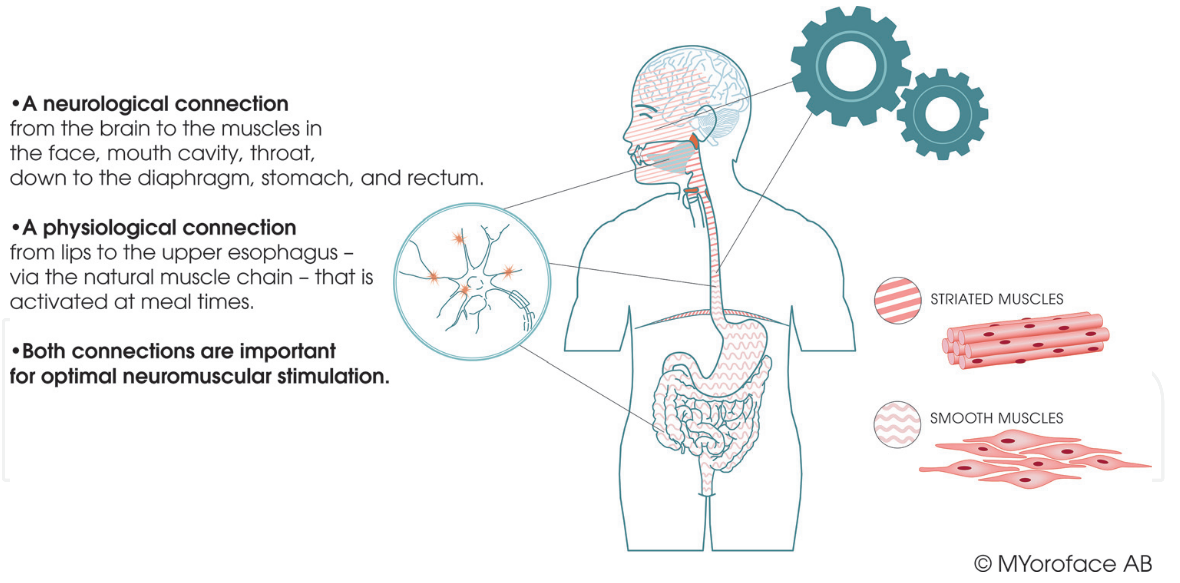


Figure 13.
Neurological and physiological considerations in muscle stimulation when eating or during neuromuscular training with IQoro.

Where a patient initially lacks lip strength or has diminished hand or arm function – perhaps after stroke - an assistant can help with this procedure. The vast majority of IQoro users self-treat without assistance.

6.3 How it works

IQoro causes all the muscles in the swallowing chain to be flexed and thus retrained and strengthened.

Training with IQoro triggers the sensory-motor reflex arc.

The muscles in the chain from the lips through to the upper third of the esophagus are mostly skeletally striated and are voluntarily activated [5, 29] when eating normally. Smooth musculature is present in the lower part of the esophagus, and down through the hiatus canal, LES, stomach, intestines, and rectum, and these muscles can only be activated by signals from the autonomic system [5, 29]. It is thus the case that striated musculature is activated by voluntary neurological and physiological commands, but the smooth muscle can only be activated and exercised via commands from the autonomic system.

Studies show that rehabilitation of the smooth musculature traditionally takes longer [14, 32, 44] and requires ongoing maintenance training after treatment.

When you close your lips tightly against the handle and pull the device forward, a low pressure is created in the mouth, making the tongue retract and seal against the anterior palatal arch and the soft palate. The effect of this is to strongly stimulate the sensory nerves in the oral cavity which send afferent signals to the brainstem as described in the neurology section above. Here they provoke a so-called sensory-motor reflex arc which causes intense efferent motor signals to exercise the muscles in the swallowing chain. In this way, IQoro training reaches and strengthens even the smooth musculature that cannot be voluntarily commanded by the patient.

Training with IQoro activates all the muscles in the swallowing chain, including the outer longitudinal muscles that run along the sides of the esophagus and fasten under the diaphragm. As they are activated by IQoro training they exercise the muscles at the site of the rupture, strengthening the weakened muscles back into a functional condition.

In other words, the training action and regime used to treat dysphagia [10] are equally appropriate for Hiatal hernia and reflux-based conditions [14, 32, 44].

7. Evidence of IQoro's efficacy

This section presents the scientific support for the efficacy of IQoro in treating the two closely related conditions of dysphagia and reflux-based diseases caused by a hiatal hernia. For reasons of space and readability, most studies have been reduced to short summaries of their purpose and conclusions and a link to the full article. Exceptions to this are 8.1.4 and 8.1.5 which are presented in more detail, having not been published in a scientific journal previously.

7.1 Dysphagia

7.1.1 Dysphagia studies

The evidence behind the efficacy of IQoro as a treatment for dysphagia includes more than a dozen peer-reviewed and internationally published scientific research papers.

7.1.1.1 Study: Effects on facial dysfunction and swallowing capacity of intraoral stimulation early and late after stroke

Study type

Peer-reviewed, prospective, cohort pre and post-study designed according to Good Clinical Practice (GCP) [15].

This study showed that IQoro is effective in improving swallowing ability, facial activity in all four facial quadrants in patients, and pharyngeal sling force after stroke, irrespective of time from stroke debut to start of treatment. Improvements were still present at late follow-up (>1 year after the end of treatment).

The 31 patients were grouped according to having had a stroke with recent onset, or a long time before. By implication, the similarly successful results in the two groups rule out spontaneous recovery as a likely cause of the improvements seen.

Conclusion

IQoro is effective in improving swallowing ability, facial activity in all four facial quadrants, and pharyngeal sling force after stroke, irrespective of time from stroke debut to start of treatment.

7.1.1.2 Study: Effect of IQoro training on impaired postural control and oropharyngeal motor function in patients with dysphagia after stroke

Study type

Peer-reviewed, prospective, cohort pre and post-study [17].

The study used IQoro as a treatment for 12 weeks in a patient group that had pathological levels for both Impaired Postural Control (IPC) and Oropharyngeal Motor Dysfunction (OPMD).

The 26 adults recruited to the study were divided between those with recent stroke, and those who had stroke onset a long time before. Results were equally positive in both groups showing the efficacy of IQoro in immediate intervention or in chronic sufferers. Once again, the similar results in the two groups rule out spontaneous recovery as a likely cause of the improvements seen.

At end of training significant improvement ($p < 0.001$) in tongue and velum function, velopharyngeal closure, and swallowing ability were recorded in the late intervention group. Almost all other outcome improvements in this group showed a ($p < 0.01$) statistical significance, as did all measures in the early intervention group.

Improvements were maintained at late follow-up (median 59 weeks after the end of training).

Two patients showed no improvement in either IPC or OPMD, all others regained normal abilities in both functions. Five patients presented with Percutaneous Endoscopic Gastrostomy (PEG) feeds at recruitment; all five PEGs were removed by/at end-of-training and all recovered the ability to eat and drink unmodified foods and liquids.

Conclusion

- IQoro successfully treats impaired postural control and oropharyngeal motor function in patients with dysphagia after stroke.
- PEGs can be removed after several years of use, after 3 months' IQoro treatment.
- Velum function is significantly improved by IQoro training.
- Improvements made are still present at long-term follow-up.
- The similarity of results in the two intervention groups further supports the contention that improvement is not due to spontaneous remission.
- The effectiveness of IQoro treatment is not affected by the time from stroke to the start of treatment, nor the age or gender of the patient.

The positive effect on muscle groups not directly accessed by IQoro neuromuscular training supports the contention that the improvements are triggered by neurological rehabilitation.

7.1.1.3 Study: Effects of oral neuromuscular training on swallowing dysfunction among older people in intermediate care: A cluster randomized, controlled trial

Study type

Peer-reviewed, prospective, cohort pre and post-study, Randomized Controlled Trial (RCT) [12].

385 elderly participants in intermediate care units were screened, and 116 with impaired swallowing were randomly assigned to IQoro neuromuscular training or usual care. Standard IQoro training was employed: 3 x 10 seconds, three times per day for 5 weeks and patients, were measured at three-time points: before training, at end of training, and at late follow up (6 months post-treatment).

- At end of treatment, the geometric mean of the swallowing rate in the intervention group had significantly improved 60% more than that of controls ($p = 0.007$).
- Signs of aspiration were significantly reduced in the intervention group compared with controls ($p = 0.01$).

- At 6 months post-treatment, the swallowing rate of the intervention group remained significantly better (p = 0.031).
- No significant between-group differences were found for swallowing-related quality of life.

Conclusion

Treatment ended at discharge from the residential facility in order that a long-term follow-up could determine that the improvements seen at end-of-treatment were sustained. Oral neuromuscular training is a new promising swallowing rehabilitation method for older people in intermediate care. Better clinical results would likely have been achieved if IQoro treatment had continued for longer than 5 weeks.

7.1.1.4 Study: Measuring the effectiveness of IQoro® treatment of saliva control dysfunction in children and young people with cerebral palsy using practice-based evidence outcome measures

This study is that performed by Natalie Morris and her team and referred to at the beginning of this chapter.

Saliva control difficulties.

Difficulty in controlling saliva is a common problem for people with Cerebral Palsy (CP). Drooling is not normally a result of overproduction but inefficient control of salivary secretions due to:

- Inadequate lip closure / habitual open mouth posture
- Reduced or impaired sensory feedback
- Atypical muscle tone
- Underlying swallowing difficulties
- Dental problems
- Side effects from other medications
- Impaired postural control

Existing and recommended treatments

Natalie's own clinical observations and experiences of working with children and young people (CYP) with CP were that difficulty with saliva control is a persistent problem with no real effective treatment. The Cochrane review of interventions for drooling in children with cerebral palsy concludes, "*There is no clear consensus on which interventions are safe and effective in managing drooling in children with CP. There is insufficient evidence to inform clinical practice on interventions for drooling in children with CP*" [24].

The UK's National Institute for Health and Care Excellence (NICE) guidance [23] on the assessment and management of CP in under 25 s recommends clinicians assess factors that may affect drooling in children and young people with cerebral palsy, these include:

- Compensatory strategies and management of contributory factors such as positioning - Multi-Disciplinary Teams (MDT) working with Occupational Therapists (OT) and Physiotherapists to promote head control.

- Increasing awareness of saliva - behavioral approaches to prompt children to swallow more often and wipe their faces. However, many people with CP have reduced sensory feedback and are often unaware that their chin is wet. Furthermore, the physical action of wiping their own chin can be difficult.

- Oral-motor therapy - aims to target musculature that can be voluntarily trained to improve muscle strength, tonicity, and coordination. However, from a neurological point of view, it is important to consider that although some of our swallows are initiated during the conscious process of eating, drinking, and specific exercises, the majority are reflexive: swallowing away our saliva without conscious involvement. The autonomic nervous system is responsible for the overall control of salivation: these nerves are not under conscious control.

- Improving oral health - reducing reflux and maintaining good oral hygiene will reduce the bacterial load of saliva and reduce the risk of infection.

- Eliminating mouthing behaviors - some tools that are provided to improve oral skills e.g., chewy tubes for jaw stability, can precipitate difficulties with saliva control if used incorrectly and not as part of a structured program.

Most CYP with CP is given some form of medication to help with saliva control.

NICE produced guidelines in 2017 [23] on the treatment of drooling in children with CP.

The most common medications prescribed are:

- Oral Glycopyrronium Bromide

  NICE concludes there is moderate evidence for the effectiveness of this treatment and no evidence for the long-term safety. Side effects include dry mouth, vomiting, constipation, and thickening of secretions, which may increase the risk of respiratory infection and pneumonia. Many children are kept on this medication for years, at great cost to the NHS (NICE gives an average of GBP 320 per bottle, around GBP 430 for 28 days' treatment, approx. GBP 5160 per year).

- Hyocine patches + Trihexyphenidyl Hydrochloride

  Although commonly prescribed, at the time of publication (January 2017), neither medication had a UK marketing authorization for use in CYP under 18 for treatment of hypersalivation.

- Finally, if other treatment methods have been investigated, Botulinum Toxin injections into the salivary glands or surgery to remove the glands may be considered. Although these would obviously be highly aversive experiences and considered only as a last resort.

IQoro as a possible treatment

In 2018, Natalie attended the Association of Speech and Language Therapists in Independent Practice (ASLTIP) conference in London and came across IQoro neuromuscular training device that exercises and strengthens the muscles needed for feeding and swallowing by activating the nervous system to and from the brain. The manufacturers suggest that while traditional oral-motor therapy can target.

The musculature that can be voluntarily trained to improve muscle strength, tonicity, and coordination, it does not target the two-thirds of the swallowing

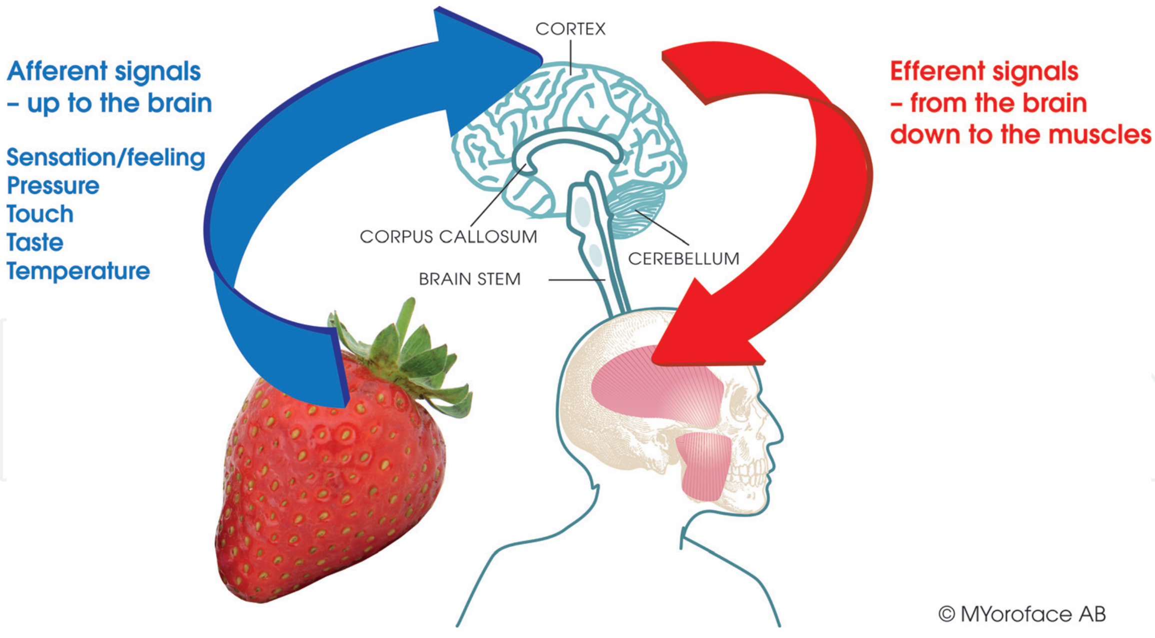


Figure 14.
The sensory-motoric reflex arc.

process that is controlled by the autonomic nervous system. IQoro claimed to trigger the sensory-motoric reflex arc which enables messages to be sent to musculature beyond the reach of voluntary control. The sensory-motoric reflex arc [5, 25], (**Figure 14**) effectively has a "leveraging" effect on direct muscular training and can improve the entire swallowing process.

IQoro could point to an impressive amount of research that had been conducted on adults with acquired swallowing difficulties, but no evidence to support its use with children. The question that interested Natalie was: "*Does IQoro improve saliva control in CYP with CP*?" Over a 20-week period, she collected ground-breaking practice-based evidence to answer this question.

Study method and design

The programme used a case series design: 10 participants aged between 6 and 22 years old all had a primary diagnosis of CP. A single case study design was applied to each individual and in addition to individual outcomes, inferences were drawn from the collective data.

Several measures were taken to establish baselines, and these were compared to the measurements taken after the treatment phase.

She and her team used a mixed-method strategy, producing quantitative data regarding oral motor and swallowing ability as well as collecting qualitative data about how the patients/carers / MDT members perceived the value of the tool.

Data collection & interventions

Natalie chose to use a Goal Attainment Scaling in Rehabilitation (GAS) method; GAS statistically scores the extent to which each patient's individual goals are achieved in the course of intervention. There is substantial literature that demonstrates its usefulness, both as part of the communication and decision-making process and as a person-centered outcome measure for rehabilitation [45]. Original: [46].

- Baseline assessments were taken of swallowing ability, oral motor function, and speech.

- Rating scales were used that allowed for skill breakdown and functional description of each area.

- The baseline assessment scores were used to set for intervention.
- An individual program for using the IQoro was designed for each patient and then carried out 3 x per day (by parents/carers) for 20 weeks.

Results

The composite GAS is transformed into a standardized measure with a mean of 50. If goals are set in an unbiased fashion, one would expect a normal distribution of scores, and the GAS thus performs at the interval level. If goals have been fully achieved, we would expect to see a score of 50 (**Table 1**).

Results indicated that IQoro does improve saliva control in children with CP, with improvements also demonstrated with oral motor skills. Using the measures of articulation, there was no change to speech. However, changes to voice were observed in the qualitative analysis (**Table 2**).

GAS Score	Swallowing	Oral Motor	Speech
Baseline	35.1	34.5	32.2
Range	34.9–35.8	31.3–36.3	26.5–35.2
Achieved	53.7	48.1	32.2
Range	44.3–60.3	45.8–51.6	26.5–35.2
Change	18.8	13.6	0
Range	8.5–25.3	10.6–20.3	0

Table 1.
Results showing GAS scores pre and post-treatment.

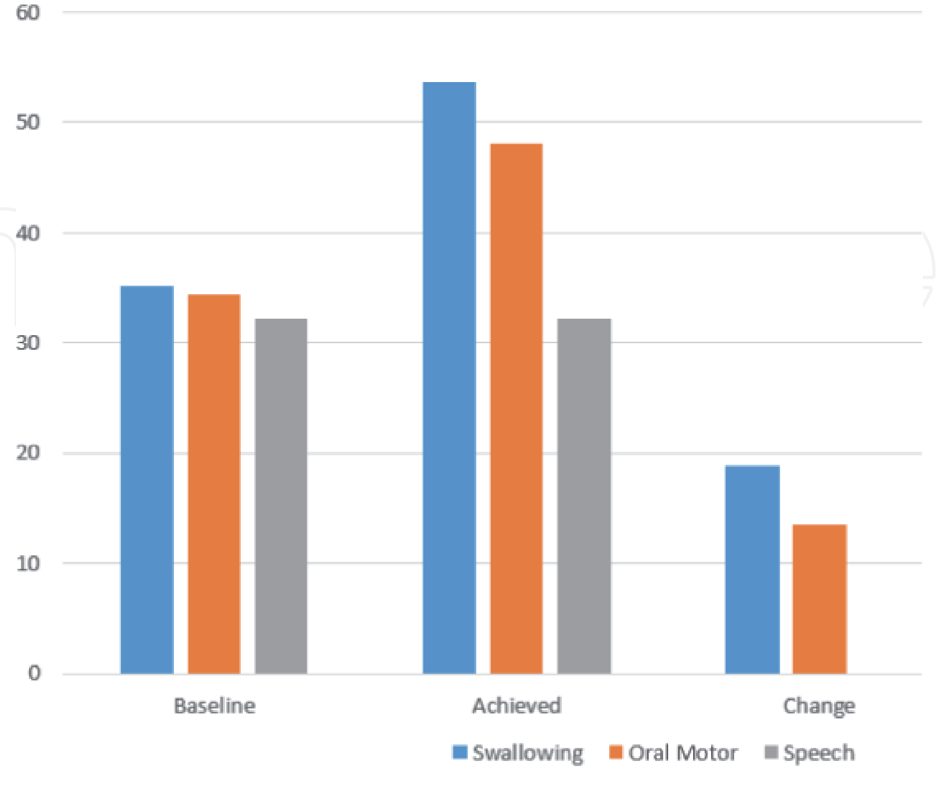


Table 2.
Improved outcomes in swallowing and oral motor skills, but not speech.

Discussion, quantitative and qualitative analysis

In this study, it has been possible to demonstrate an improvement with saliva control resulting from treatment using IQoro. On average, ratings reduced from 4 ("unable to control", saliva loss 75–100% of the time) to 2 ("moderate difficulty", saliva loss 25–50% of the time). However, at least half of the participants improved further to a score of 1 ("mild difficulty", saliva loss 10–25% of the time).

Qualitative data reported (but not measured) saw improvements with: teeth brushing; nasal breathing; breath control for speech; reduction in chest infections; sensory feedback (perception of saliva on chin) and tongue retraction. Positive feedback has been received from schools (less damage from saliva to IT equipment and worksheets) and physio colleagues (able to work in supine for longer periods due to an increase in swallowing of secretions).

Future plans include creating an assessment protocol and running a training program. Further research is indicated to see if this would be a cost-effective treatment that could be made available on the NHS.

Conclusion

It has been the case that there is a severe lack of options in treating children and young people with Cerebral Palsy with dysfunction that leads to drooling. Existing medication and surgical intervention alternatives are often ineffective, invasive, and even not strictly approved for patients in these age groups. Many medication alternatives are expensive when compared with IQoro treatment.

IQoro has been proved to be a suitable treatment for the group studied, including those at the higher end of the scale of motoric and other difficulties. In the case of some of the latter, two assistants were required to perform the training.

Swallowing and oral motor competence improved significantly to a level around the 50-point target of the GAS goals, although the measured speech ability did not. Other functions and abilities important in daily life also improved as reported above.

Much-improved drooling and saliva control had great influence in improving the patients' quality of life, not least where it allowed the use of laptops, books, and other educational material in schools.

7.1.1.5 Study: IQoro dysphagia therapy in an NHS setting: A service evaluation

Roseanne, Exell 1; Hayley McBain 2; Sam Turvey 2; Gill Hardy 1

1. Royal Devon and Exeter NHS Foundation Trust

2. South West Academic Health Science Network

A service evaluation was carried out in southern England in 2020 resulting in the following abstract.

Background

This evaluation explored the introduction of IQoro into a National Health Service (NHS) setting.

Method

Patients with chronic dysphagia were recruited from acute and community settings and completed a 12-week program using IQoro. Clinical and well-being measures were taken pre and post-training. Feedback was gained from the Speech and Language Therapists delivering this program.

Results

25 patients were recruited into the evaluation, 21 completed the program. There were significant improvements in self-reported quality of life scores, including the

overall scores and burden of dysphagia and mental health subscales. There was a significant improvement in functional measures of dysphagia, including the consistencies of food and drink that patients could safely manage. There was also a significant improvement in the facial movement and symmetry of the lower half of the face. Feedback from SLTs indicated that IQoro improved the range of therapy options available and many planned to use it again. Qualitative feedback suggested that the use of IQoro may change SLTs clinical thinking, including in relation to intervention or compensation for dysphagia.

Conclusion

IQoro can be successfully introduced into an NHS team and can be effective in supporting patients with chronic dysphagia. However, factors such as the ability to follow patients across different settings and the individual risk of further decline need to be considered.

7.1.1.6 Customer survey

In an email survey in June 2021 of all IQoro users that had purchased within the previous 1–15 months, users were canvassed on the effectiveness of IQoro treatment for dysphagia. Totally 4440 responses were received, 983 were specifically treating symptoms associated with dysphagia after stroke. Patients had trained for 1 month or more (**Table 3**).

Conclusion

This survey of a large population of people using IQoro to treat various types of dysphagia and facial weakness is that their outcome experience is positive. This survey differs from the studies quoted elsewhere in this chapter in that the results shown are not at end-of-training in all cases. Many had not trained long enough at the time of the survey to experience the full effect in symptom reductions: some having only trained for as little as 1 month. Nevertheless, 79% - 86% reported symptom improvements since starting training.

7.1.1.7 Medtech Innovation Briefings

The UK's National Institution for Health and Care Excellence (NICE)), was commissioned by the UK government and advises and supports National Health Service and social care commissioners and have made a review of IQoro and its claims and effectiveness. They have issued a Medtech Innovation Briefing [47] that recognized "*IQoro is an innovative treatment, with no similar technologies currently recommended, and that the intended place in therapy would be in addition to standard speech and language therapy in people with stroke-related dysphagia*".

	Symptom free	Big improvement	Small improvement	No improvement yet	
Difficulty in swallowing liquids safely	11%	42%	33%	14%	100%
Difficulty in swallowing solid foods	7%	35%	38%	21%	100%
Drooling	9%	24%	44%	23%	100%
Facial or speech weakness	4%	28%	47%	21%	100%

Table 3.
Improved outcomes in swallowing and facial abilities.

7.1.2 Hiatus hernia and reflux-based conditions

Reflux occurs when the neck of the stomach and the Lower Esophageal Sphincter (LES) intrude through the diaphragm into the chest cavity. In this position, the LES can open upwards and allow stomach contents to reflux, in its correct position it can only allow one-way traffic downwards. This intrusion or hernia is made possible when the musculature of the diaphragm around the hiatal canal is weakened (**Figure 15**).

IQoro is an effective treatment for reflux-based diseases and their various symptoms: heartburn, pain behind the sternum, persistent unproductive cough, blockage in the throat, and more. Training with IQoro provokes stimuli from the brainstem to flex and strengthen all the muscles in the swallowing chain including those allowing a Hiatal hernia.

The evidence behind the efficacy of IQoro as a treatment for Hiatus hernia includes the following three peer-reviewed and internationally published scientific research papers which are briefly summarized here.

7.1.2.1 Study: Esophageal dysphagia and reflux symptoms before and after oral IQoro training

Study type

Peerreviewed, Prpospective, cohort pre and post-study [14].

43 patients who had esophageal dysphagia for a median of 3 years (range: 1–15 years) were recruited to this study. All displayed the symptoms of a Hiatal hernia, but only 21 had had their condition confirmed by examination. All had been prescribed Proton Pump Inhibitor (PPI) medication for more than 1 year without any effect, all medication ceased at the start of IQoro treatment.

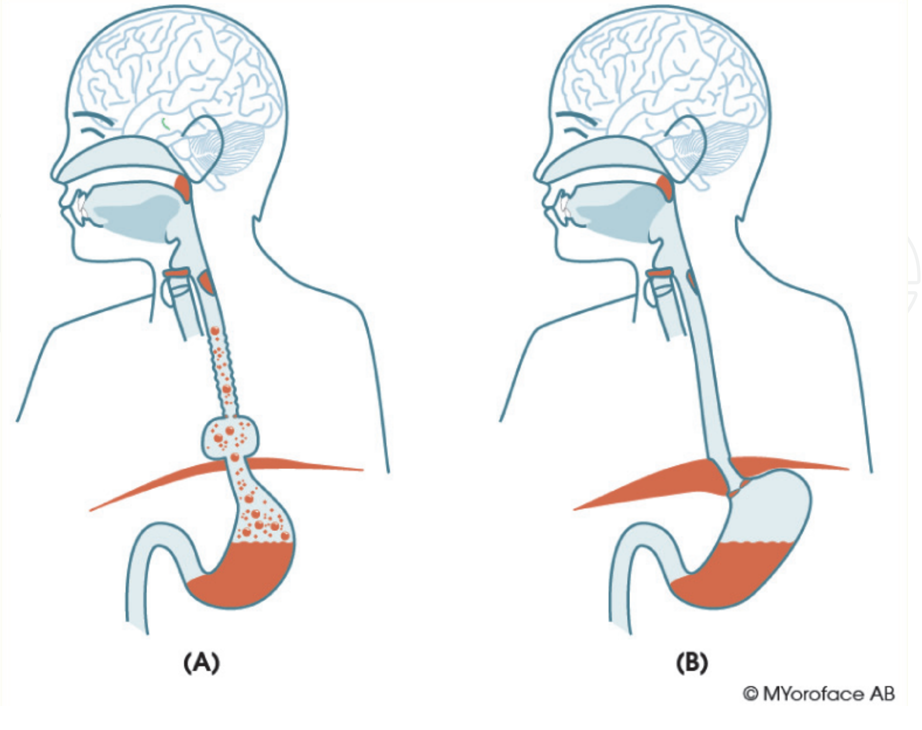


Figure 15.
(A) Sliding hiatal hernia. The upper part of the stomach and the LES has slid up through the hiatal canal. This allows gastroesophageal reflux and also causes difficulties with opening the PES at the top of the esophagus. (B) Normal anatomy. The neck of the stomach is correctly held below the diaphragm promoting normal LES function and preventing reflux.

Outcome measurements

A validated test battery was employed at baseline and at end of training including questionnaires and tests for all patients. In addition to these measures 12 patients with confirmed hiatal hernia were measured using High Resolution Manometry (HRM) [48] to measure pressure at resting and during IQoro traction.

Results

- No statistical difference (p = NS) between symptoms or outcomes between those with or without confirmed Hiatal hernia diagnosis – both before and after treatment.

- Esophageal dysphagia was present in all 43 patients at start of treatment, and 98% of patients showed improvement after IQoro neuromuscular training ($p < 0.001$).

- Reflux symptoms were reported before training in 86% of the patients, 100% of these showed improvement at end of training, ($p < 0.001$) and 58% were entirely symptom free. All patients ceased PPI medication at recruitment to the study.

- VAS scores were classified as pathologic in all 43 patients, and 100% showed improvement after IQoro neuromuscular training ($p < 0.001$).

- Pharyngeal sling force and velum closure test values were both significantly higher ($p < 0.001$) after IQoro neuromuscular training.

Those tested with HRM showed the following results:

- During IQoro traction there was an increase in mean pressure in the diaphragmatic hiatus region and in the Upper Esophageal Sphincter (UES) (**Table 4**).

Conclusion

IQoro neuromuscular training can relieve/improve esophageal dysphagia and reflux symptoms in adults, likely due to improved hiatal competence. The similarity of the results in the two groups suggests that many people suffer from Hiatus hernia despite this not having been confirmed by diagnosis.

7.1.2.2 Study: Effect of IQoro training in hiatal hernia patients with misdirected swallowing and esophageal retention symptoms

Study type

Peer-reviewed, prospective, cohort pre and post-study [17].

Items Pressures in mmHg	UES *n* = 12	Hiatus *n* = 12
Normal pressure	>30	10–35
Resting pressure	68 (40–110)	0 (0–0)
During IQoro traction	95 (80–130)	65 (20–100)

Data are mean (range) mmHg.

Table 4.
High-resolution manometry (HRM) results in UES and hiatus both at rest and during IQoro traction.

The study investigated whether 28 patients with hiatal hernia and misdirected swallowing and esophageal retention symptoms could be successfully treated with a 6-month regime of standard IQoro training: 30 seconds three times per day. Patients had had their condition for median of 4 years (range 1–28).

Results

- Reflux symptoms were reported before training in all patients,

  100% of these showed improvement ($p < 0.001$) at end of the training, and 61% were entirely symptom-free despite ceasing PPI medication at the start of training.

- All hiatal hernia patients were improved after training with IQoro and showed significant improvements ($p < 0.001$) in
  - misdirected swallowing,
  - cough,
  - hoarseness,
  - esophageal retention,
  - globus sensation,
  - scores for VAS, pharyngeal sling force, VCT, and TWST.

- Traction during the training action with IQoro resulted in a 65 mmHg increase in the mean pressure of the diaphragmatic hiatus as measured by high-resolution manometry (**Table 4**).

Conclusion

IQoro training significantly improves all the symptoms of hiatus hernia, likely through improved hiatal competence.

7.1.2.3 Study: Oral neuromuscular training relieves hernia-related dysphagia and GERD symptoms as effectively in obese as in non-obese patients

Study type

Peer reviewed, prospective, clinical study, cohort pre and post-study [32].

It has been thought that treatment of Hiatus hernia in overweight patients can be unproductive and that weight loss should be a prior step to interventions.

In this study 86 adult patients with verified hiatal hernias and long-standing Intermittent Esophageal Disease (IED) and other Gastro-Esophageal Reflux Disease (GERD) symptoms were grouped according to their Body Mass Index (BMI), before entry into the study (**Table 5**): Group A: normal weight, Group B: moderately obese, Group C: severely obese.

Results

At entry into the study there were no significant differences between the three BMI groups in baseline testing for swallowing ability, or for IED and GERD symptom severity, except that:

- Heartburn and cough were significantly more common in Groups B (moderately obese) and C (severely obese).

Items	Group A; *n* = 37	Group B; *n* = 28	Group C; *n* = 21
Median age	69 yrs. (20–85)	57 yrs. (22–85)	62 yrs. (44–87)
Gender	19 women, 18 men	16 women, 12 men	11 women, 10 men
GERD symptom duration	5 yrs. (1–75)	6 yrs. (1–15)	3 yrs. (1–29)
BMI before/after IQNT	23 (17–24) /23 (20–25)	28 (26–29) / 27 (24–29)	33 (30–37) / 31 (27–38)

Ranges in parentheses. BMI and GERD: median values; IQNT: Neuromuscular training with an oral IQoro.

Table 5.
Analysis of subjects by BMI grouping - age, gender, and GERD symptom duration.

- Misdirected swallowing was significantly more common in Group C.

After IQoro neuromuscular training, the following was observed in all three BMI groups:

- All IED and GERD symptom scores were significantly improved or reduced ($p < 0.001$).
- Median BMI was not significantly changed.
- Self-assessed GERD symptom improvement showed no significant difference across the groups, except for heartburn, cough, and misdirected swallowing which were significantly ($p < 0.01$) more reduced in obese patients than in normal bodyweight patients.
- The swallowing tests showed significant improvement ($p < 0.001$) in median values, with no significant difference between the BMI groups except for:
    - Timed Water Swallow Test (TWST) values, which were significantly ($p < 0.01$) more improved in Group C (severely obese) than in Group A (normal weight).
    - pharyngeal sling force, which was significantly ($p < 0.05$) more improved in Group B (moderately obese) than in Group A.

Conclusion

IQoro neuromuscular training (IQNT), a non-surgical treatment for IED and other GERD symptoms in hiatal hernia patients, is equally successful in treating moderately or severely obese patients as in treating sufferers of normal weight. Obesity in itself does not, therefore, seem to be a handicap in treating IED and other GERD symptoms by IQNT.

7.1.2.4 Customer survey

In an email survey in June 2021 of all IQoro users that had purchased within the previous 15 months, users were canvassed on the effectiveness of IQoro treatment for dysphagia. Totally 4440 responses were received of which 3436 were specifically treating classic reflux symptoms caused by Hiatus hernia, the rest of the responses were from people treating symptoms associated with dysphagia after stroke or snoring and sleep apnoea. Patients had trained for 1 month or more.

	Symptom free	Big improvement	Small improvement	No improvement yet	
Reflux / acid reflux	6%	40%	37%	17%	100%
Heartburn	9%	42%	34%	15%	100%
A sensation of something stuck in your throat	12%	38%	34%	17%	100%
Excessive or thick phlegm	4%	30%	42%	24%	100%
Dry, persistent cough	8%	34%	36%	22%	100%
Gassy, burping often	4%	35%	39%	22%	100%
Pain in your chest or esophagus	11%	39%	33%	17%	100%
Food that you have swallowed comes up again	15%	38%	31%	16%	100%
Hoarseness	8%	29%	39%	24%	100%

Table 6.
Improved outcomes in hiatal hernia related symptoms.

76%–84% of respondents reported symptom improvement, it can be assumed that some of those not yet reporting improvements had only trained for a short while (**Table 6**).

Conclusion

A large population, 3436 people, using IQoro to treat reflux symptoms showed positive outcome experiences. This survey differs from the studies quoted elsewhere in this chapter in that the results shown are not at end-of-training in all cases. Many had not trained long enough at the time of the survey to experience the full effect in symptom reductions: some having only trained for as little as 1 month. Nevertheless, 76% - 85% reported symptom improvements since starting training.

7.1.3 NICE Medtech innovation briefing

In March 2019 the UK's National Institute for Health and Care Excellence (NICE) developed a Medtech Innovation Briefing (MIB) [49] regarding the use of IQoro to treat Hiatus hernia, it points out the innovative nature of the device and its potential to save the NHS money.

> *"The NICE MIB highlights the innovative nature of IQoro as being its uniqueness in treating Hiatus Hernia through an exercise regime with an oral device. It also highlights that the resource impact of using IQoro could be to reduce costs for the NHS in the long term, one of the main points of our analysis of possible cost savings in this briefing is the device's potential to be resource releasing when compared to long term PPI maintenance."*

8. Conclusions

All versions of dysphagia have an unsatisfactory range of treatment options. Swallowing difficulties, reflux, and other manifestations are often met with compensatory strategies instead of the treatment of the underlying causes. IQoro is simple, inexpensive, non-invasive, and takes just 90 seconds per day.

IQoro is proven both in clinical practice and in research studies to be highly effective in treating the underlying causes of the conditions and symptoms described in this book. The evidence base for its efficacy is strong.

This innovative device and treatment are shown to be effective in treating all types of dysphagia in the pre-oral, oral, pharyngeal, and esophageal phases. Similarly, Hiatus hernia and its resulting reflux symptoms can be addressed successfully. In all of these conditions, it is shown that time from onset of the condition stroke or Hiatus hernia for example, to the time when IQoro treatment starts, does not affect the positive outcome results of the treatment. The stroke studies show that improvements achieved at end-of-treatment persist at long-term follow-up. Several studies and evaluations show that patients with PEG feeding tubes have had them removed after IQoro therapy.

All healthcare professionals working with dysphagia and its related conditions should want to know more about IQoro and how it improves patient outcomes and gives clinicians an important and powerful new treatment option.

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Conflict of interest

IQoro is patented in Sweden - SE 1350314-9, 2014 July 14 - and widely internationally. It is CE-marked as a Class 1 Medical Device for therapeutic use by the manufacturer MYoroface AB. Mary Hägg is the inventor.

The authors, Mary Hägg and Natalie Morris declare that they have no conflict of interest.

Notes/thanks/other declarations

All studies were performed according to the Helsinki Declaration. Informed written and verbal consent was obtained from all the participants in the studies. All images are kindly provided by MYoroface AB.

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