

Scientific research behind IQoro[®] training

The following is a selected list of published scientific papers regarding the use of IQoro[®] in patient treatments. In most cases an abstract of the paper is shown. Readers are encouraged to follow the links on the www.iqoro.com website to read the entire studies, but it is hoped that the following will provide a useful overview of the research journey.

Thesis

Sensorimotor Brain Plasticity in Stroke Patients with Dysphagia

Abstract

Hagg, M. 2007. Sensorimotor Brain Plasticity in Stroke Patients with Dysphagia. A Methodological Study on Investigation and Treatment. Acta Universitatis Upsaliensis. Digital Comprehensive Summaries of Uppsala Dissertations from the Faculty of Medicine 299. 79 pp. Uppsala. ISBN 978-91-554-7042-5.

Aims

The aims of the thesis were to validate investigation instruments for stroke patients with dysphagia, and to improve oropharyngeal dysphagia therapies.

Methods/Results

A Lip Force Meter, LF 100, affirmed excellent intra- and inter-reliability, sensitivity and specificity. Controls had significantly stronger lip force (LF) and swallowing capacity (SC) than stroke patients. A normal lower limit of LF was set to 15 Newton. Dysphagia symptoms improved in 7 stroke patients after a 5-week sensorimotor stimulation therapy comprising manual body and facial regulation in combination with palatal plate application. Impaired LF and impaired SC were parallel phenomena in 22 acute stroke patients and did not differ regardless of presence or absence of facial palsy. LF and SC improved and were parallel phenomena in 30 stroke patients and did not differ regardless of presence or absence of facial palsy, time lag between stroke attack and start of treatment, or age. SC was normalized in 19 of 30 dysphagia patients after a 5-8-week daily lip muscle self-training with an oral screen.

Conclusions

LF100 is an appropriate and reliable instrument for measuring lip force. Dysphagia improvement, by body and facial sensorimotor stimulation in combination with palatal plate application, or by training with an oral screen is excellent examples of brain plasticity and cortical reorganisation. . Swallowing capacity and lip force in stroke patients are parallel phenomena. A sub clinical facial paresis seems to be present in most stroke patients. Training with an oral screen can improve LF and SC in stroke patients with oropharyngeal dysphagia.

1. Effects of Motor and Sensory Stimulation in Stroke Patients with Long-Lasting Dysphagia

Abstract

Dysphagia is a common post stroke symptom with negative effects on recovery and rehabilitation. However, the orofacial regulation therapy, developed by Castillo Morales, comprising body regulation and orofacial regulation in combination with a palatal plate

application has shown promising results in stroke patients. This therapy is based not only on muscle exercises but also on an improvement of the entire sensory-motor reflex arc involved in normal deglutition, and on the knowledge that the function of face and oropharynx at deglutition is closely interrelated with the entire body posture as well as with appropriate breathing.

The treatment concept is relatively unknown to caregivers, partly due to lack of scientific evaluation of treatment results. The present investigation aimed to assess the effect of motor and sensory stimulation in stroke patients with dysphagia persisting for more than six months.

Seven patients were evaluated with respect to orofacial and pharyngeal motility and sensory function before and two weeks after a five-week treatment period. The evaluation comprised a swallowing capacity test, a meal observation test, clinical examination of oral motor and sensory function, a velopharyngeal closure test, and videofluoroscopy. In addition, the symptoms were scored by the patients.

An overall single-blind estimation showed objective and self-assessed swallowing improvement in all seven patients. Kappa coefficients are calculated on all reliability data, both inter- and intrarater reliabilities. Sensory and motor stimulation seems to be a promising therapy in stroke patients with long-lasting and persistent oropharyngeal dysphagia.

2. Reliable Lip Force Measurement in Healthy Controls and in Patients with Stroke: A Methodologic Study

Abstract

A prefabricated oral screen has shown promising results as a muscle self-training device to improve the lip function of stroke patients affected by oropharyngeal dysphagia. However, a technique for the measurement of lip muscle force, whether in healthy individuals or in stroke patients, is lacking.

The present study was designed to (1) test the intra- and interreliability of lip force measurements by means of a newly devised Lip Force Meter, LF100, (2) determine a normal lower limit for lip force in newtons (N), and (3) ascertain the instrument's sensitivity and specificity.

LF100 is a modified strain gauge for recording the ability of lips to withstand pressure from a predentally placed oral screen.

Forty-two healthy controls and 22 stroke patients agreed to participate in the trial. The controls and patients were examined three times with the LF100, with 2-min rest intervals, twice by investigator MH and once by investigator MO.

Intrainvestigator reliability with the LF100 proved excellent in both controls and patients: ICC was 0.83 and 0.90, respectively.

Interinvestigator reliability was good or excellent in both groups: ICC was 0.71 and 0.91. There was a significant difference in lip force between controls and stroke patients (mean = 24.7 ± 6.3 N and 9.5 ± 5.5 N, $p < 0.001$). The sensitivity of LF100 was 91% and the specificity

95%. The cutoff level for normal lip force was 15 N. The LF100 showed itself to be a suitable and reliable instrument for measuring lip force.

3. Lip muscle training in stroke patients with dysphagia

Abstract

Conclusion. Training with an oral screen can improve lip force (LF) and swallowing capacity (SC) in stroke patients with oropharyngeal dysphagia, irrespective of the duration of pretreatment of dysphagia, and irrespective of the presence or absence of central facial paresis. It is more plausible that treatment results are attributable to sensory motor stimulation and the plasticity of the central nervous system than to the training of the lip muscles per se.

Objectives: A close relationship has been demonstrated between LF and SC in stroke patients whether or not they are affected by facial paresis. It is not known how training of lip function can improve swallowing capacity. The present study was therefore designed to ascertain: (i) if training with an oral screen can improve the LF and SC of stroke patients with oropharyngeal dysphagia; to establish (ii) if improvement in LF and SC is connected with the presence or absence of central facial palsy, (iii) on the interval between stroke onset and initiation of treatment, (iv) on age, or (v) on sex.

Subjects and methods: This was a retrospective study of 30 stroke patients, 4988 years old, who were investigated with a Lip Force Meter, LF100 (LF100) and a swallowing capacity test (SCT) before and after a period of self-training lasting at least 58 weeks, using an oral screen. Initial central facial paresis was present in 24 patients.

Results. The median LF was 7 Newtons (N) (range 027) before treatment and 18.5 N (range 744) after treatment ($p < 0.001$). The median SC was 0 ml/s (range 09.1) before treatment and 12.1 ml/s (range 036.7) at follow-up ($p < 0.001$). There was no significant difference in swallowing improvement between patients with versus those without facial paresis. The interval between stroke attack and start of treatment, ranging from a few days up to 10 years, had no significant influence on the treatment results, nor did age or sex. The facial paresis was improved or at least ameliorated in all patients after the lip training period.

4. Influence of lip force on swallowing capacity in stroke patients and in healthy subjects

Abstract

Conclusion: In spite of no clinical signs of facial paresis, a pathological lip force (LF) will strongly influence swallowing capacity (SC). Stroke patients with impaired SC suffer a subclinical facial paresis. The results support earlier findings that LF training can be used to treat dysphagia.

Objectives: Lip muscle training with an oral screen can improve both LF and SC in stroke patients, irrespective of the presence or absence of facial palsy. The aim was therefore to study the influence of LF on SC.

Methods: This prospective study included 22 stroke patients, aged 38–90 years, with dysphagia, 12 with initial unilateral facial paresis and 45 healthy subjects, aged 25–87 years. All were investigated with a Lip Force Meter (LF100), and with an SC test.

Results: A significant correlation was found between LF/SC ($p = 0.012$) in stroke patients but not in healthy subjects. LF/SC was not age-related in stroke patients. LF was not age-dependent in healthy subjects, but SC decreased with increasing age ($p < 0.0001$). However, SC did not reach a pathological value and a regression analysis showed that 73% of the variation in SC is attributable to LF and age.

5. Longstanding Effect and Outcome Differences of Palatal Plate and Oral Screen Training on Stroke-Related Dysphagia

Abstract

Aim: This study aimed at evaluating (1) if the oral training effect on stroke related dysphagia differs between two different oral appliances, a palatal plate (PP) and an oral screen (OS), and (2) if the training effect remains at a late follow-up.

Methods: We included patients with stroke-related dysphagia at two different time periods: the first group of 12 patients studied in 1997- 2 002 had to train with a PP, the other one of 14 patients studied in 2003-2008 had to train with an OS. All patients were evaluated by a swallowing capacity test (SCT), and by a self-assessed visual analogue scale (VAS) of water swallowing capacity at entry of the study, after 13 weeks of training, and at a late follow-up.

Results: At end of treatment the SCT had normalized in 33% of PP patients and in 71% of OS patients. There was a significant SCT improvement difference between the PP and OS groups in the period from baseline to late follow-up ($p < 0.002$) in favor of the OS group. VAS as tested at baseline and at end of treatment did not differ significantly between the two groups. Training with PP and with OS produced remaining improvement of SCT and of VAS as assessed at a late follow-up.

Conclusion: The outcome of OS training on SCT in patients with stroke-related dysphagia seems to be superior to PP training. The improvement as assessed with VAS did not differ between the two groups. Training with PP or OS gives a longstanding improvement of SCT and VAS.

6. Four-Quadrant Facial Function in Dysphagic Patients after Stroke and in Healthy Controls

Abstract

This study aims to examine any motility disturbance in any quadrant of the face other than the quadrant innervated by the lower facial nerve contralateral to the cortical lesion after stroke.

Thirty-one stroke-afflicted patients with subjective dysphagia, consecutively referred to a swallowing centre, were investigated with a facial activity test (FAT) in all four facial

quadrants and with a swallowing capacity test (SCT). Fifteen healthy adult participants served as FAT controls.

Sixteen patients were judged to have a central facial palsy (FP) according to the referring physician, but all 31 patients had a pathological FAT in the lower quadrant contralateral to the cortical lesion. Simultaneous pathology in all four quadrants was observed in 52% of stroke-afflicted patients with dysphagia; some pathology in the left or right upper quadrant was observed in 74%. Dysfunction in multiple facial quadrants was independent of the time interval between stroke and study inclusion. All patients except two had a pathological SCT. All the controls had normal activity in all facial quadrants.

In summary the majority of poststroke patients with dysphagia have subclinical orofacial motor dysfunction in three or four facial quadrants as assessed with a FAT. However, whether subclinical orofacial motor dysfunction can be present in stroke-afflicted patients without dysphagia is unknown.

7. Effects on facial dysfunction and swallowing capacity of intraoral stimulation early and late after stroke

Abstract.

Background: Most patients with post-stroke dysphagia are also affected by facial dysfunction in all four facial quadrants. Intraoral stimulation can successfully treat post-stroke dysphagia, but its effect on post-stroke facial dysfunction remains unknown.

Objective: This study aimed to investigate whether intraoral stimulation after stroke has simultaneous effects on facial dysfunction in the contralateral lower facial quadrant and in the other three facial quadrants, on lip force, and on dysphagia.

Methods: Thirty-one stroke patients were treated with intraoral stimulation and assessed with a facial activity test, lip force test, and swallowing capacity test at three time-points: before treatment, at the end of treatment, and at late follow-up (over one year after the end of treatment).

Results: Facial activity, lip force, and swallowing capacity scores were all improved between baseline and the end of treatment ($P < 0.001$ for each), with these improvements remaining at late follow-up. Baseline and treatment data did not significantly differ between patients treated short and late after stroke.

Conclusions: Treatment with intraoral stimulation significantly improved post-stroke dysfunction in all four facial quadrants, swallowing capacity, and lip force even in cases of long-standing post-stroke dysfunction. Furthermore, such improvement remained for over one year after the end of treatment.

8. Effect of oral IQoro[®] and palatal plate training in post-stroke, four-quadrant facial dysfunction and dysphagia: A comparison study

Abstract

Conclusion: Training with either a palatal plate (PP) or an oral IQoro[®] screen (IQS) in patients with longstanding facial dysfunction and dysphagia after stroke can significantly improve facial activity (FA) in all four facial quadrants as well as swallowing capacity (SC). Improvements remained at late follow-up. The training modalities did not significantly differ in ameliorating facial dysfunction and dysphagia in these patients. However, IQS training has practical and economic advantages over PP training.

Objectives: This study compared PP and oral IQS training in terms of (i) effect on four-quadrant facial dysfunction and dysphagia after a first-ever stroke, and (ii) whether the training effect persisted at late follow-up.

Methods: Patients were included during two periods; 13 patients in 2005–2008 trained with a PP, while 18 patients in 2009–2012 trained with an IQS. Four-quadrant facial dysfunction was assessed with an FA test and swallowing dysfunction with a SC test: before and after a 3-month training period and at late follow-up.

FA and SC significantly improved ($p < 0.001$) in both groups. FA test scores after training and at late follow-up did not differ significantly between the groups, irrespective of whether the interval between stroke incidence and the start of training was long or short.

9. Effect of IQoro[®] training in hiatal hernia patients with misdirected swallowing and esophageal retention symptoms

Abstract

Conclusion: Misdirected swallowing can be triggered by esophageal retention and hiatal incompetence. The results show that oral IQoro[®] screen (IQS) training improves misdirected swallowing, hoarseness, cough, esophageal retention, and globus symptoms in patients with hiatal hernia.

Objectives: The present study investigated whether muscle training with an IQS influences symptoms of misdirected swallowing and esophageal retention in patients with hiatal hernia.

Methods: A total of 28 adult patients with hiatal hernia suffering from misdirected swallowing and esophageal retention symptoms for more than 1 year before entry to the study were evaluated before and after training with an IQS. The patients had to fill out a questionnaire regarding symptoms of misdirected swallowing, hoarseness, cough, esophageal retention, and suprasternal globus, which were scored from 0–3, and a VAS on the ability to swallow food. The effect of IQS traction on diaphragmatic hiatus (DH) pressure was recorded in 12 patients with hiatal hernia using high resolution manometry (HRM).

Results: Upon entry into the study, misdirected swallowing, globus sensation, and esophageal retention symptoms were present in all 28 patients, hoarseness in 79%, and cough in 86%. Significant improvement was found for all symptoms after oral IQS training ($p < 0.001$). Traction with an IQS resulted in a 65 mmHg increase in the mean HRM pressure of the DH.

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11. Effect of IQoro® training on impaired postural control and oropharyngeal motor function in patients with dysphagia after stroke

Abstract

Introduction: An investigation of the coincidence of Impaired Postural Control (IPC) and Oropharyngeal Motor Dysfunction (OPMD) in patients with dysphagia after stroke, and the effect of IQoro® neuromuscular training on these two conditions.

Method: A prospective clinical study of 26 adult patients referred by clinicians with observed dysphagia after first stroke. Two groups were studied: 15 patients who had suffered stroke more than 6 months before, and 11 within the last month. The IQoro®

treatment period for all was 3 months of 1½ minutes' daily training. Postural control tests and oropharyngeal motor tests were performed at baseline, after the training period, and at a late follow-up (median 59 weeks after training).

Results: All patients showed pathological values for all IPC and OPMD measures at baseline. At completion of IQoro[®] training all IPC and OPMD parameters showed significant improvement ($p < 0.01$ to $p < 0.001$). No outcome measure was significantly different between the long-term and short-term intervention groups. Swallowing Capacity Tests showed an average improvement of 6.0ml/sec after training in both groups. 25 of 26 patients exhibited misdirected swallowing at baseline, but only two after training and at late follow-up: IPC was not improved in these two individuals either. Five patients were fed via PEG at baseline, all had their PEGs removed during or after the training period.

Discussion: All patients with dysphagia after stroke exhibited IPC as well. IQoro[®] training delivers significant and enduring improved patient outcomes in treatment of IPC and OPMD. Timing of intervention commencement after stroke was not significant.

12. Meal observation test for treatment assessment of stroke-related dysphagia.

13. Lip force in healthy children.

14. Oral Screen training in patients with dysphagia after stroke

A prospective randomized open-label study with blinded evaluators This study is conducted together with Hudiksvalls hospital and Norrlands University hospital in Sweden.

15. Oral neuromuscular training relieves hernia-related dysphagia and GERD symptoms as effectively in obese as in non-obese patients

Abstract

Background: Many physicians insist patients lose weight before their hiatal hernia (HH) condition and related symptoms including intermittent esophageal dysphagia (IED) and gastroesophageal reflux disease (GERD) can be treated, but it is not proven that body mass index (BMI) has an impact on exercise-based treatment of HH-related symptoms.

Aims/Objectives: To investigate whether BMI has significance on IQoro[®] neuromuscular training (IQNT) effectiveness in treating HH-related symptoms.

Material and Methods: Eighty-six patients with sliding HH and enduring IED and GERD symptoms, despite proton pump inhibitor medication, were consecutively referred for 6 months' IQNT comprising 1½ minutes daily. They were grouped by BMI which was recorded before and after IQNT, as were their symptoms of IED, reflux, heartburn, chest pain, globus sensation, non-productive cough, hoarseness, and misdirected swallowing. They were also assessed on food swallowing ability, water swallowing capacity and lip force both before and after treatment.

Results: After IQNT, all BMI groups showed significant improvement ($p < .001$) of all assessments' and symptoms; and heartburn, cough and misdirected swallowing were significantly more reduced in the severely obese.

Conclusions and significance: IQNT can treat HH-related IED and GERD symptoms as successfully in moderately or severely obese patients as in those with normal bodyweight.

16. Study protocol for the SOFIA project: Swallowing function, Oral health, and Food Intake in old Age

A descriptive study with a cluster randomized trial.

17. DESIRE – A two-centre intervention study with IQoro[®] of stroke survivors with dysphagia.

A collaboration between the Medical Clinic at Umeå University Hospital and Speech Therapy Unit at Danderyds hospital in Stockholm.

18. Post-market evaluation, in the United Kingdom and Sweden, of the IQoro[®] programme for remediation of dysphagia, hiatus hernia and reflux, sleep apnoea and snoring.

The present investigation evaluated whether the IQoro[®] training regime could provide benefits for patients as a home-based training regime. With 658 included participants this is the largest post-market investigation of the IQoro[®] training regime. Three indications were investigated, those with dysphagia following stroke, those with Hiatus hernia and GERD, and those people who reported challenges with snoring and/or sleep apnoea. The results clearly showed that IQoro[®] was easy to use, had high compliance in terms of training regime and the majority of participants indicated that IQoro[®] provided them with significant observable benefits in their daily quality of life.

Therefore, IQoro[®] can be recommended by health care providers as a suitable home-based training regime for the remediation of symptoms for dysphagia, central facial paralysis and other symptoms following stroke, Hiatus hernia and GERD, and snoring and sleep apnoea. The use of a home-based therapy solution promises potential benefits in terms of reduced cost to the healthcare system and ability for patients to use the treatment at home rather than thickened fluids or to seek more complex medical and surgical solutions.

19. Sleep Apnoea, Snoring and IQoro® Training.

In a scientific study, 10 patients at 10 different sleep speciality clinics in Sweden were recruited for a study. Each of the patients underwent a sleep registration evaluation at their clinics, and all but two patients were measured to have 'Severe' sleep apnoea, the others being 'Moderate' (median 36.6). All were long-term sleep apnoea sufferers and were using CPAP devices at night to relieve their symptoms.

Without the knowledge of their local sleep speciality clinics, all were treated for three months with IQoro® training comprising three daily sessions of 30 seconds each: totally 16 minutes per day. They were then re-tested by their local clinics after the three-month period without revealing what treatment they had had. The worst-affected, 'Severe' level, patient improved dramatically, but without changing his severity capacity (from 59.3 to 35.4). All others improved and moved to lower severity bands: either 'Mild' category (five patients), or 'Moderate' category (four patients). The median score for the whole group improved from 'Severe' (36.6), to 'Moderate' (17.7). It is interesting that the median BMI value for the group was almost unchanged during the test/re-test period.