



## **PhD thesis**

# Difficulties in swallowing and eating following acquired brain injury

- From a professional and a patient perspective



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## Preface

*"Eating, apparently a biological matter is actually profoundly social. What we eat, where we get it, how it is prepared, when we eat and with whom, what it means to us – all these depend on social arrangements" (DeVault 1991) (page 35)*

First of all, I would like to take you on a little, but for me long journey leading up to this thesis. I have, since I graduated as an occupational therapist (OT) in 1989, worked within rehabilitation of persons with severe acquired brain injury (ABI). First, I worked as a leading OT at the "Genoptræningscentret Lunden" in Varde. In 1990, I met a young man who had been involved in a motorbike accident. He was diagnosed as in a persistent vegetative state three months after his accident and was admitted from the neurological ward to a nursing home, where I met him nine month after his injury. He still had a nasal feeding tube and had just got to taste a little yoghurt. His parents wanted him to live in another place, and they visited "Lunden". During the conversation with his parents, he was sitting in his wheelchair beside us. I had placed a piece of chocolate in front of him. Suddenly, without our notice, he had, with his uncoordinated movements, put a piece of chocolate in his mouth and we could hear his cheerful sounds and see his excited facial expressions.

Why is this story so important to me? Because it became very obvious that eating is very important to both the person and the relatives, and I realised that I did not know how to systematically assess and treat him. At that time I did not realise that there was a close relation between eating and drinking and all the infections and pneumonias that the residents at "Lunden" had. I could not find anyone in Denmark, who was able to supervise and teach me, so I just did my best!

On my further professional journey, searching for knowledge and skills about assessment and treatment of difficulties in swallowing and eating, I met a lot of very important and inspiring persons. I will especially name two. Karen Nielsen, the leading therapist at "Therapiezentrum Burgau" (TZB), Germany, who gave me the opportunity to work at an early rehabilitation unit at TZB, where I was introduced to both the rehabilitation approaches of "Gespürter Interaktionstherapie" by Fèlicie Affolter and Facial-Oral Tract Therapy (F.O.T.T.) by Kay Coombes. Later I met and got to know the speech and language therapist Kay Coombes, United Kingdom. In 2002, I became the first Nordic F.O.T.T. instructor. In 2005 I wrote the book "Ansigt, mund og svælg – Undersøgelse og behandling efter Coombes konceptet" ("Face, mouth and oral tract – assessment and treat-

ment by the Coombes approach”). This book is based on a holistic approach to assessment and treatment of the face, mouth and oral tract and the enclosed charts are now systematically used in Danish clinical neurorehabilitation practice and at the OT basic education programmes.

Since 2000, I have worked at Hammel Neurocenter, where I started as a project OT responsible for a development project “Undersøgelse af synkeproblemer hos senhjerneskadde patienter” (“Assessment of swallowing problems in brain injured patients”). The increased need for evidence-based medicine became more apparent and at that time, I got the opportunity to upgrade my clinical skills with academic skills. In 2006, I graduated as a Master of Science in Occupational Therapy (MScOT) at the University of Lund, Sweden, and as part of my master thesis I searched for evidence of the assessment and treatment charts from my book.

I began my PhD journey in 2008. As you can see I have had many years of clinical OT experience with the assessment and treatment of difficulties in swallowing and eating following ABI, so my position as a researcher is not neutral. On the other hand, my clinical skills and knowledge have aided me in formulating hypotheses and collecting and understanding my research data.

## Financial and other conflicts of interest

This study was supported financially by the University of Southern Denmark (Health, Man and Society, The Research Initiative for Activity Studies and Occupational Therapy and the Faculty of Health Science), The Danish Association of Occupational Therapy (FF 1/10-9 and FF1/11-2) and The Region Hospital Hammel Neurocenter. The author is a certified F.O.T.T.™ instructor and is regularly conducting G/F.O.T.T. courses. The author has no personal financial interest in any commercial company or institution directly or indirectly related to this thesis.

## List of abbreviations

ABI	Acquired Brain Injury
BDI	Berliner Dysphagia Index
BMI	Body Mass Index
CPG	Central Pattern Generator
FEES	Fiberoptic Endoscopic Evaluation of Swallowing
FEESST	Fiberoptic Endoscopic Evaluation of Swallowing with Sensory Testing
FIM	Functional Independence Measure ( $\Delta$ FIM = FIM change from admission to discharge from IRP)
FOIS	Functional-Oral Intake Scale
F.O.T.T.	Facial-Oral Tract Therapy
GCS	Glasgow Coma Scale
HR	Hazard Ration
ICF	International Classification of Functioning
IRP	Inpatient Rehabilitation Programme
LOS	Length Of Stay
MBS	Modified Barium Swallow
OT	Occupational Therapist or therapy
PAS	Penetration-Aspiration Scale
PEG	Percutaneous Endoscopic Gastrostomy
RCT	Randomized Controlled Trial
RLAS	Rancho Los Amigos Scale ( $\Delta$ RLAS= RLAS change from admission to discharge from IRP)
SWAL-CARE	Swallowing Quality of Care Questionnaire
SWAL-QOL	Swallowing Quality of Life Questionnaire
TBI	Traumatic Brain Injury
UES	Upper Esophageal Sphincter
UTI	Urinary Tract Infections
VFS	Video Fluoroscopy Swallowing
VSE	Videofluorographic Swallowing Evaluation
WHO	World Health Organization

## Definitions

### **Acquired brain injury**

Acquired brain injury is defined as damage to the brain that occurs after birth, and which is not related to congenital disorders, developmental disabilities, or processes that progressively damage the brain (Toronto Acquired Brain Injury Network 2011).

### **Adaptation**

Adaptation is defined as the process by which a person maintains a useful relationship to the environment (Coelho and others 1974).

### **Dysphagia**

Dysphagia is understood as oropharyngeal dysphagia, which is defined as difficulties in ingestion, swallowing, eating and drinking using subcategories in the International Classification of Functioning, Disability and Health (ICF) (WHO 2001).

### **Inpatient rehabilitation programme**

The inpatient rehabilitation programme is an intensive, hospital-based, interdisciplinary rehabilitation unit, here at a national neurorehabilitation centre. Interventions were based on 24-hour assessment and treatment approaches (Graham and others 2009; Affolter and others 2009; Hansen and Jakobsen 2010).

## Summary in English

Stroke and traumatic brain injury (TBI) are the main causes of acquired brain injury (ABI). In 2009, there were an estimated 12,500 cases of hospitalisations from stroke and an estimated 9,500 cases of hospitalisations from TBI in Denmark. Many of these patients need rehabilitation. Neurorehabilitation in Denmark is undergoing development and specialisation. In this process, difficulties in swallowing, eating and drinking (dysphagia) in patients with ABI have increasingly come to our attention. In foreign studies the incidence of dysphagia is given as 27 to 61% among brain-injured patients in neurorehabilitation. Dysphagia may result in lack of oral intake and consequently in malnutrition, dehydration and complications like aspiration, pneumonia and choking at worst. Dysphagia may result in prolonged rehabilitation and inappropriate transfers between intensive care and rehabilitation units.

The overall objective of this thesis is to evaluate difficulties in swallowing and eating following ABI in relation to rehabilitation from both a professional and a patient perspective. The thesis consists of two sub studies described in three papers. **Study I** is a randomized controlled trial reported in two papers, and **Study II** is a qualitative case study with multiple-cases described in **Paper III**.

**Study I (Paper I)** evaluates whether patients assessed for initiation of oral intake by clinical assessment (Facial-Oral Tract Therapy (F.O.T.T.) had a greater risk of developing aspiration pneumonia during neurorehabilitation than patients assessed by instrumental assessment (Fiberoptic Endoscopic Evaluation of Swallowing (FEES)). 679 patients with acquired brain injury were screened for possible participation in the trial, and 138 patients were randomized between June 2009 and April 2011. No significant diagnosis-related or demographic differences between the groups were found. 119 patients (62 F.O.T.T./57 FEES) were included in the analysis of the primary outcome. Four patients assessed by F.O.T.T. and 12 by FEES were diagnosed with pneumonia ( $p=0.03$ ). Excluding six patients with pneumonia before initiating oral intake and three patients, who did not fulfil the primary outcome criteria for aspiration pneumonia, left seven patients for analysis. Four of them developed aspiration pneumonia within 10 days after initiating oral intake; one patient evaluated by F.O.T.T. and three patients by FEES.

**Study I (Paper II)** investigates whether there is a difference in time for initiation of oral intake and time to total oral intake when initiation of oral intake is based on F.O.T.T. or on FEES, and how other factors may influence the time to initiation. **Paper II** includes a calculation of the inci-



dence of dysphagia in this study. The incidence of dysphagia in neurorehabilitation was 47 %. There was no difference in time for initiation or recovery of total oral intake during inpatient rehabilitation whether using F.O.T.T. or FEES. For 42% of the patients oral intake had been initiated on admission and 92% at discharge. 2.5% of the patients recovered total oral intake within the first 24 hours of admission, and 37% had recovered total oral intake before discharge. Within 62 days (F.O.T.T.) and 54 days (FEES) 25 % of the patients recovered total oral intake. The possibility of achieving this depends on a low level of consciousness and physical function, age, length of stay and number of dysphagia interventions.

**Study II (Paper III)** explores and interprets the patient perspective two to 18 months after discharge from neurorehabilitation. It explores how reduced functions of swallowing and oral intake influence the experience of food and meals as well as everyday life after the injury, and how the patients experience the neurorehabilitation approach to dysphagia. In this study six of the 119 patients from **Study I** were interviewed. A comparative analysis was used to analyse data. Five main themes resulted from the analysis: Individual psychological characteristics, swallowing and digestion, eating and drinking, communication and meals as well as rehabilitation during hospitalisation and after discharge. Processes of change were interpreted as adaptation processes. Three important subthemes emerged: 1) Tube feeding; 2) Difficulties in swallowing associated with meals involving social gathering and; 3) Neurorehabilitation approach to swallowing and eating.

It can be concluded that dysphagia occurs in nearly half the patients admitted to neurorehabilitation in Denmark. It has been demonstrated that a non-instrumental approach like F.O.T.T. to assess swallowing disorders in patients with ABI may be as effective in predicting safe swallowing (safe in terms of no or minimal aspiration) as an instrumental approach like FEES. The qualitative study shows that the patients' ability to adapt to the difficulties in swallowing and eating depends on the phases of their illness trajectory. The (even temporarily) reduced or lost swallowing and/or eating function is unexpected and difficult for the patient and causes strong emotional reactions even 18 months after the injury. The findings also show new knowledge of clinical interest; it is e.g. demonstrated that it is possible to adapt and develop new structures for valuable activities associated with swallowing and eating.

Keywords: Dysphagia, Neurorehabilitation, Facial-Oral Tract Therapy

## Sammenfatning på dansk

Apopleksi og traumatisk hjerneskade er de største årsager til erhvervet hjerneskade. Der var i 2009 ca. 12.500 indlæggelsesforløb pga. apopleksi og ca. 9.500 indlæggelsesforløb pga. traumatisk hjerneskade i Danmark. Mange af disse patienter har behov for rehabilitering. I Danmark udvikles og specialiseres neurorehabilitering. Herunder er man i stigende grad blevet opmærksom på problemer med at synke, spise og drikke (dysfagi) hos personer med erhvervet hjerneskade. Hyppigheden af dysfagi angives i udenlandske studier fra 27 til 61 % blandt hjerneskadede personer, som indgår i neurorehabilitering. Dysfagi kan resultere i, at man spiser og drikker for lidt og dermed kommer til at lide af under- eller fejlnæring, væskemangel samt komplikationer som fejl-synkning, udvikling af lungebetændelse og i værste fald kvælning. Dysfagi kan medføre en forlængelse af rehabiliteringen og u hensigtsmæssige overflytninger mellem intensivt- og rehabiliterings-afsnit.

Det overordnede formål med denne afhandling er at undersøge problemer med at synke og spise i forbindelse med neurorehabilitering, både i et professionelt og et patientperspektiv.

Afhandlingen består af to delstudier beskrevet i tre artikler. **Studie I** er et randomiseret kontrolleret studie, som rapporteres i to artikler. **Studie II** er et kvalitativt casestudie med seks cases, som er beskrevet i **artikel III**.

**Studie I (artikel I)** undersøger, om patienter, der vurderes at kunne initiere oralt indtag ved hjælp af klinisk undersøgelse (Facial-Oral Tract Therapy (F.O.T.T.)), har større risiko for udvikling af lungebetændelse på grund af fejlsynkning i forbindelse med neurorehabilitering end for patienter, der vurderes ved hjælp af instrumentel undersøgelse (Fiberoptic Endoscopic Evaluation of Swallowing (FEES)). I undersøgelsen er 679 patienter med erhvervet hjerneskade screenet for mulig deltagelse, og 138 patienter blev randomiseret i tiden fra juni 2009 til april 2011. Der var ingen signifikante diagnoserelaterede eller demografiske forskelle mellem grupperne. I analysen indgik 119 patienter (62 F.O.T.T./ 57 FEES). Fire patienter undersøgt ved hjælp af F.O.T.T. og 12 ved hjælp af FEES blev diagnosticeret med lungebetændelse ( $p=0.03$ ). Seks af disse patienter blev ekskluderet, da de udviklede lungebetændelse før initiering af oralt indtag, og tre patienter blev ekskluderet, da de ikke opfyldte det primære outcome kriterium for lungebetændelse på grund af fejlsynkning, hvilket efterlod syv patienter til analysen. Fire af disse udviklede lungebetændelse inden for 10 dage efter initiering af oralt indtag; en patient evalueret ved hjælp af F.O.T.T. og tre patienter ved hjælp af FEES.

**Studie I (artikel II)** afdækker, om der er forskel i tidspunkt for initiering af oralt indtag og tiden til totalt oralt indtag, når initiering af oralt indtag sker ved hjælp af F.O.T.T. eller FEES, og hvordan andre faktorer kan indvirke på dette. Desuden indeholder **artikel 2** en beregning af hyppigheden af dysfagi i dette studie. Hyppigheden af dysfagi i forbindelse med neurorehabilitering var 47 %. Der var ingen forskel i tid til initiering eller generhvervelse af total oralt indtag under indlæggelsen, uanset om der blev anvendt F.O.T.T. eller FEES. Oralt indtag var initieret for 42 % af patienterne ved indlæggelsen og for 92 % ved udskrivelsen. Totalt oralt indtag var opnået for 2,5 % af patienterne inden for det første døgn efter indlæggelsen, og 37 % var på totalt oralt indtag inden udskrivelse. Inden for 62 dage (F.O.T.T.) og 54 dage (FEES) opnåede 25 % total oralt indtag. Muligheden for at opnå dette var bl.a. afhængig af lavt bevidsthedsniveau og fysisk funktionsniveau, alder, indlæggelsestid og antal behandlinger for dysfagi.

**Studie II (artikel III)** udforsker og fortolker patientperspektivet to til 18 måneder efter udskrivelse fra neurorehabilitering. Her undersøges, hvordan funktionsnedsættelser omkring synkning og oralt indtag af mad og drikke påvirker oplevelsen af mad og måltider og hverdagslivet efter skaden, samt hvordan neurorehabiliteringsindsatsen i relation til dette opleves. I studiet interviewes seks af de 119 patienter fra **Studie I**. En komparativ indholdsanalyse blev anvendt til at analysere data. Fem hovedtemaer fremkom i analysen: Individuelle psykologiske egenskaber, synkning og fordøjelse, spise og drikke, kommunikation og måltider samt rehabilitering under indlæggelse og efter udskrivelse. Forandringsprocesser blev fortolket som adaptationsprocesser. Tre betydningsfulde undertemaer fremkom: 1) Mad og drikke ved hjælp af sonde; 2) Synkeproblemer i relation til måltider med socialt samvær samt; 3) Neurorehabiliteringstilgangen vedrørende synkning og spisning.

Det kan konkluderes, at dysfagi forekommer hos næsten halvdelen af de patienter, der indlægges til neurorehabilitering i Danmark. Det er blevet påvist, at en ikke-instrumentel tilgang som F.O.T.T. til undersøgelse af synkeproblemer hos patienter med erhvervede hjerneskader kan være lige så effektiv til at forudsige sikker synkefunktion (sikker hvad angår ingen eller minimal fejlsynkning) som en instrumentel tilgang som FEES. Det kvalitative studie viser, at det at leve med synke- og spiseproblemer afhænger af, i hvilken fase af sygdomsforløbet patienterne befinder sig. Den (selv midlertidigt) nedsatte eller tabte synke- og/eller spisefunktion er uventet, svær og fremkalder stærke følelsesmæssige reaktioner selv 18 måneder efter skaden. I resultaterne fremkommer således ny viden af klinisk interesse, hvor det bl.a. påvises, at det er muligt at adaptere og udvikle nye strukturer for værdifulde aktiviteter relateret til synkning og spisning.

Nøgleord: Dysfagi, Neurorehabilitering, Facial-Oral Tract Therapy

## List of publications

The thesis is based on two linked studies (**Study I and II**) with results reported in the following three papers. In the text they will be referred to as **Paper I, Paper II and Paper III**. The papers are attached to the thesis as **Paper I, II and III**.

- Paper I** Kjaersgaard A, Nielsen LH, Sjolund BH: Randomized trial of two swallowing assessment approaches: Facial-Oral Tract Therapy vs. Fiberoptic Endoscopic Evaluation of Swallowing.  
*Submitted*
- Paper II** Kjaersgaard A, Nielsen LH, Sjolund BH: When does oral intake take place in inpatient rehabilitation following acquired brain injury? A randomized study of two assessment approaches (Facial-Oral Tract Therapy vs. Fiberoptic Endoscopic Evaluation of Swallowing).  
*Submitted*
- Paper III** Kjaersgaard A, Kristensen HK, Borg T: Clinical implications of lived experience and adaptation to reduced abilities to swallowing and eating following acquired brain injury.  
*Submitted*

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# 1. INTRODUCTION

The main purpose of this thesis is to explore and evaluate the difficulties in swallowing and eating following acquired brain injury (ABI) during an inpatient rehabilitation programme (IRP), from a professional and a patient perspective.

ABI typically produces a potentially wide range of impairments affecting the physical, neuro-cognitive and/or psychological functioning (Teasell and others 2007).

Dysphagia may result in lack of oral intake, in malnutrition and dehydration, and in frequent/prolonged periods with infections that are responsible for a deteriorated and prolonged rehabilitation process (Perry and Love 2001; Westergren 2006). The condition is often caused by unrecognised aspiration of e.g. saliva or food (Langmore and others 1998). The incidence of clinically diagnosed dysphagia is stated to be from 27% to 93% among ABI patients in IRP (Winstein 1983; Hansen and others 2008a; Falsetti and others 2009).

Pneumonia is a major aspiration-related pulmonary complication in patients with ABI (Pilitsis and Rengachary 2001). Aspiration pneumonia is a main cause of early death in stroke, if the patients are not screened and treated for dysphagia (Smithard and others 1996; Perry and Love 2001; Ramsey and others 2003; Westergren 2006). Minimising the risks and episodes of aspiration, maximising nutritional intake, and providing the patient with the most appropriate alternative to oral feeding will help to facilitate the maximal recovery potential for these individuals (Mackay and others 1999b).

Ideally it should be possible to assess the difficulties in swallowing and eating using a three-tiered assessment cascade: screening, bedside evaluation (clinical assessment) and objective measurement (instrumental assessments) (Farrell and O'Neill 1999). This thesis will focus on the clinical assessment Facial-Oral Tract Therapy (F.O.T.T.) and the instrumental assessment Fiberoptic Endoscopic Evaluation of Swallowing (FEES). There is a wide range of multidisciplinary rehabilitation interventions, but the majority of the interventions are only supported by limited evidence (Cullen and others 2007). In Denmark neurorehabilitation is still developing and specialising (National Board of Health 2011), and there is increased attention to difficulties in swallowing and eating (dysphagia) and to the intervention approaches like F.O.T.T. and FEES.



Oropharyngeal dysphagia is typically managed by a multidisciplinary team with speech-language pathologists being primarily responsible for management (Cichero 2006); however, in Denmark this role is upheld by occupational therapists (OT) (Kjaersgaard and Langhorn 2007).

Takahata et al (Takahata and others 2011) conclude that early initiation of oral feeding after sufficient preparation may safely improve the clinical outcomes of intracerebral hemorrhage patients, in terms of survival, the incidence of chest infection, the LOS and swallowing function. Formisano et al (Formisano and others 2004) conclude that oral feeding appears to be an accurate prognostic index of the final outcome in severe traumatic brain injury (TBI). However, despite the significance of dysphagia following ABI, limited data are available regarding the natural history of swallowing disorders or on the prognosis and outcomes in this population.

This thesis aims to provide new knowledge of both scientific and clinical relevance about inpatient neurorehabilitation, specifically of the difficulties in swallowing and eating following ABI during inpatient neurorehabilitation described from both a professional and a patient perspective.

## 2. BACKGROUND

### 2.1 Difficulties in ingestion, swallowing, eating and drinking

#### 2.1.1 Difficulties in ingestion and swallowing

Dysphagia in this thesis is understood as oropharyngeal dysphagia, which is defined as difficulties in ingestion, swallowing, eating and drinking using subcategories in ICF (WHO 2001).

"Dysphagia" is derived from the Greek, *dys*—meaning disordered, and *phagein*—meaning to eat (Winstein 1983; Groher and Crary 2010). Dysphagia is often defined as the medical term for the symptom of difficulty in swallowing (Wikipedia 2012). Dysphagia affects the most cardinal of human functions, the ability to eat and drink (McHorney and others 2000). Dysphagia is common in patients with neurological disorders (Bakheit 2001). Neurogenic dysphagia may cause dehydration, malnutrition, aspiration and long periods with fever, can contribute to a less optimal and increased duration of rehabilitation and lead to feelings of shame, dependency and other negative experiences (Jacobsson and others 2000; Bakheit 2001; Carlsson and others 2004).

Dysphagia is not a primary medical diagnosis but rather a dysfunction or symptom of underlying disease and is therefore described more often by its clinical characteristics (signs) (Groher and Crary 2010). The risk of developing aspiration pneumonia cannot be accurately predicted from any single clinical sign or symptom. Dysphagia, when defined broadly, can include the perceptual and cognitive awareness of the eating situation and the physiological responses to the smell of food (Leopold and Kagel 1996). Dysphagia can also interrupt the eating pleasure (Buchholz 1996). Tanner (Tanner 2003) purposes this definition of dysphagia: "Impairment of emotional, cognitive, sensory, and/or motor acts involved with transferring a substance from the mouth to the stomach, resulting in failure to maintain hydration and nutrition, and posing a risk of choking and aspiration" (page 70).

Groher (Groher and Crary 2010) suggests that a swallowing disorder should be distinguished from a feeding disorder. A feeding disorder is the impairment in the process of food transport outside the alimentary system. A feeding disorder is usually the result of weakness or incoordination in the hand or arm used to move the food from the plate to the mouth.

Salassa (Salassa 1999) said that swallowing should not be confused with eating. Eating or oral nutrition requires three components: volition, preparation, and swallowing. Volition is the conscious mental ability or will to perform the act. Preparation is the physical ability to prepare nourishment and then take it into the mouth.

“When dysphagia is examined broadly, it is clearly /..... / one that has potential activity/participation limitations and psychosocial consequences for the person” (Threats 2007). There is a clear-cut need to optimise a brief initial examination that employs several key signs and symptoms to accurately detect patients with possible unsafe swallows and who therefore need more extensive testing (AHRQ 1999). There is a consensus that an interdisciplinary team approach is essential for the optimal management of patients with neurogenic dysphagia (White and others 2008; Karkos and others 2009). The treatment of difficulties in swallowing and eating often takes two parallel courses: compensations to allow the patients to eat at least some food orally without aspirating and rehabilitative exercises to build strength and coordination so that the patients no longer need the compensations and can return to full oral intake (Logemann 2008; Gonzalez-Fernandez and Daniels 2008).

Evaluation of the effect of therapy in oropharyngeal dysphagia fits into this growing interest. In a systematic review (Speyer and others 2010) Speyer et al conclude that in general, statistically significant positive therapy effects are found. However, the number of papers is rather small and many of these effect studies have diverse methodological problems. Furthermore, the conclusions of most studies cannot be generalised easily or compared to one another because of the diversity in subject characteristics, therapies, and assessment instruments. Therefore, when trying to determine whether swallowing therapy in general is effective, one may conclude that no single answer can be given. Speyer et al also conclude that many questions about the effects of therapy in oropharyngeal dysphagia remain unanswered. Although some positive significant outcome studies have been published, there is a need for further research using RCTs.

### **2.1.2 Difficulties in eating and drinking**

The ability to swallow and eat without difficulty provides satiety and pleasure and is one of the most important aspects of social life (Gustafsson and Tibbling 1991). People, who have difficulties in swallowing and eating, are experiencing major limitations in their daily lives. Beyond physical difficulties they can also experience cognitive and/or social problems. Their striving for control are based on strategies as being careful when eating (Medin and others 2010b). They avoid getting out among others and isolate themselves and lose one of the most important things in human context: Sharing meals with relatives and others, which reduces a person's quality of life significantly (Grahn 1996; Elferich 2001; Ekberg and others 2002). Eating and related activities were

clearly important aspects of life for stroke survivors, socially and psychologically, as well as functionally (Perry and McLaren 2003). It is important for the treating clinicians to be aware of psychological issues, to address them according to the patients' clinical recovery, and to consider the interplay between psychological and biomedical consequences (Martino and others 2010).

## 2.2 The meaning of eating, food and meals

Swallowing and eating are necessities of life and are often taken for granted. They are complicated processes based on physical and cognitive skills (Kumlien and Axelsson 2002; Johansson and Johansson 2009). Eating is not just nutrient supply but also entails socialising and pleasurable experiences for healthy people, and meals are often the focus for celebrations with family members and friends (Stringer 1999; Johansson and Johansson 2009). Those who eat and drink together are by this very act tied to one another by a bond of friendship and mutual obligation (Smith 1894). "Eating, apparently a biological matter is actually profoundly social. What we eat, where we get it, how it is prepared, when we eat and with whom, what it means to us – all these depend on social arrangements" (DeVault 1991) (page 35). "This (the transformation of the meal into a sociological issue) gives birth to the rules regulating eating and drinking, rules that do not, however, concern food as a substance, but the *form* of its consumption" (Simmel 1984).

### 2.2.1 Theories about the mouth and eating

The sociologist Pasi Falk (Falk 1994) describes that the mouth is central in the process of eating. "The mouth is the central character in the story outlining the corporeality of (modern) consumption, not only due to its role as the primal organ of consumption but also due to its expressive functions, as an organ of speech" (page 7). "The mouth is the most controlled opening of the body, with regard to the influx (eating) but also concerning the "sublimated" outflux of speech" (page 14). In other words, the mouth is the place where the expression and experience meet. Angelella (Angelella 2009) describes in her PhD thesis about "Alimentary modernism" that there have been a few theorists who have posited the interpenetration of body and world in acts of eating (page 8). She postulates that according to Merleau-Ponty (Merleau-Ponty 1962), and opposed to Bakhtin (Bakhtin 1984), "we cannot say that a person eats and, in eating incorporates the world into himself; it is rather through eating that he comes into being" (page 10). Bakhtin is one theorist, who has posited the interpenetration of body and world in acts of eating, and he describes that "eating and drinking is one of the most significant manifestations of the grotesque body" (page 281).

### **2.2.2 Food and meals**

“Food and drink are essential to human life, not just as nourishment, but also as carriers of meaning and significance” (Jenkins 1999). One of the culinary most important functions is to demonstrate the community and the distance between social groups within a society. “Food is also part of our identity that we carry with us, without necessarily being aware of it” (Bourdieu 1992). The food is surrounded by rules of what is good and evil, what is healthy and unhealthy, right and reasonably as right and wrong. The food has symbolic meanings and conceptual content, it refers to something more e.g. to sex, sexuality and family (Holm 1998). Jenkins (Jenkins 1999) found that Danes are more concerned about eating and drinking as a social event than about what we eat and drink, and how food and drink are produced.

The meal is an important mean to maintain, establish and develop social contacts (Buchholz 1996). Meals unite people, and it is a recurring, regular and daily activity of living, which emphasises everyday communities in families and among colleagues. In many cultures meals are a framework for the indication of special occasions or selected communities in social life (Holm 2003). Meals are also social events which bring family members together and which give the individual the opportunity to experience himself as linked to others. The meal symbolises the family as a social unit, and the food served during the meal is thus a material carrier of the community (Holm 2003). Participation in meals and meals are part of everyday life, an ordinary and familiar thing we do every day. It is an activity in which people participate throughout their lives. Other activities are encapsulated in such meals e.g. shopping, cooking, serving and cleaning up (Bundgaard 2005).

## **2.3 Swallowing**

Effective swallowing is an essential part of life and is performed thousands of times per day, often without conscious consideration (Barritt and Smithard 2009). For most people, swallowing or deglutition is a normal and effortless task, but despite its ease, it is a complex and dynamic sensorimotor event involving volitional and involuntary movements of the lips, tongue, and floor of the mouth, soft palate, pharynx, larynx, oesophagus and respiratory muscles. 26 pairs of muscles and five cranial nerves are involved (Ertekin 2002; Mistry and Hamdy 2008; Matsuo and Palmer 2008). Swallowing describes a complex function in which food and liquid are transported from the oral region to the stomach in what appears as a well-coordinated function (Miller 2008). Understanding the normal physiology and pathophysiology of eating and swallowing is fundamental to evaluate and treat disorders of eating and swallowing, and to develop dysphagia rehabilitation programmes (Matsuo and Palmer 2008).

### **2.3.1 Neural control of the tongue and swallowing**

The tongue in mammals has important motor and sensory functions. Besides exploratory and manipulating functions it is essential for suckling, swallowing and vocalisation. Bilateral supranuclear innervation of the hypoglossal nucleus and other bulbar nuclei may have afforded an evolutionary survival value to animals. It had been long believed that the cortical representation of tongue motor control is symmetrical in the two hemispheres (Umapathi and others 2000).

Swallowing is a complex motor and sensory activity that depends on a hierarchical interaction between the cerebral cortex, the brain stem swallowing centre, and cranial nerves (Mistry and Hamdy 2008). Coordination of swallowing depends on the integrity of sensory pathways from the tongue, mouth, pharynx and larynx (cranial nerves V, VII, IX, X) and coordinated voluntary and reflex contractions involving cranial nerves V, VII, and X-XII (Wiles 1991). The main centre for swallowing control is located in the brain stem – called the Central Pattern Generator (CPG) - and has two main functions: 1) the triggering and timing of the swallowing pattern and 2) the control of the motor neurons involved in swallowing (Gonzalez-Fernandez and Daniels 2008). The CPG is located in the upper medullary and pontine areas of the brain and is bilaterally distributed within the reticular formation. The CPG represents the first level of swallowing control.

The second level is the sub-cortical structures, such as the basal ganglia, hypothalamus, amygdala, and tegmental area of the midbrain. Evidence shows that the swallowing musculature is bilaterally controlled (Ertekin and Aydogdu 2003). Hamdy et al (Hamdy and others 1996) showed that muscles involved in human swallowing appear to be represented bilaterally on the pre-central cortex, in discrete topographic areas, which display interhemispheric asymmetry, independent of handedness. Lateralisation to the right hemisphere tends to be greater than that in the left hemisphere. Insular cortex is found to lateralise to the right hemisphere in right-handed subjects for voluntary saliva swallows. It has also been reported that reflexive or automatic swallows are represented in the primary sensorimotor cortex and in several other common cortical regions (Ertekin and Aydogdu 2003).

Stroke affecting the hemisphere with the dominant swallowing projection results in dysphagia and clinical recovery has been correlated with compensatory changes in the previous non-dominant unaffected hemisphere. This asymmetric bilaterality may explain why up to half of stroke patients are dysphagic and why many will regain a safe swallow over a comparatively short period (Singh and Hamdy 2006).

### 2.3.2 Normal physiology of swallowing

Over the past 20 years, research on the physiology of swallowing has confirmed that the oropharyngeal swallowing process can be modulated, both volitionally and in response to different sensory stimuli.

The swallowing function can be defined with regard to either its clinical or neurophysiological basis. From the clinical point of view, voluntary swallow occurs when a human has a desire to eat or drink such as during mealtime and while awake and aware. Spontaneous swallow is the result of accumulated saliva and/or food remnants in the mouth. It occurs mostly without the person being aware, such as between meals and during sleep. Voluntary swallow is part of eating behaviour, while spontaneous swallow is a type of protective reflex action. It is important to emphasise that although the initiation of voluntary swallow is planned, its pharyngeal phase is a reflex (Ertekin 2011).

Understanding the normal physiology and pathophysiology of eating and swallowing is fundamental for evaluating and treating the difficulties in swallowing and eating (Matsuo and Palmer 2008). Functional swallowing occurs as a result of a series of purposeful movements that allow transport of food and liquid from the mouth into the oesophagus. Since the airway and the “foodway” effectively share a common path in the mouth and pharynx, an elaborate mechanism exists to separate the two during swallowing thus preventing airway penetration by swallowed material: at the same time breathing and speech are necessarily arrested (Wiles 1991).

The normal swallow in humans is generally conceptualised as occurring in different phases (Daniels and Huckabee 2008). Normal swallowing is often divided (artificial construct) into three phases: 1) *oral phase* divided into a *preparatory part*, with preparation of food for propulsion to the pharynx, and an *oral propulsive part*, where the food is pushed by the tongue through the pharynx, (2) *pharyngeal phase*, with specific movements to transport the bolus to the upper oesophageal sphincter (UES), and (3) *oesophageal phase*, where the bolus is propelled through the oesophagus and lower oesophageal sphincter to the stomach (Logemann 1998; Matsuo and Palmer 2008). The *oral phase* (oral preparatory and oral propulsive part) is mostly under voluntary control (Palmer and others 2007; Ertekin 2011). Once oral propulsion occurs, the following processes are a series of spontaneous movements designed to transport the food and protect the airway (Gonzalez-Fernandez and Daniels 2008).

The traditional definition of swallowing includes all events once nutrition is placed in the mouth, the oral preparation, and the transfer of nutrition from mouth to stomach. Defined as such, swallowing consists of one voluntary phases (oral phase (oral preparatory and oral propulsive)) and two involuntary phases (pharyngeal and oesophageal) (Salassa 1999).

### 2.3.3 Pre-oral phase

A model of ingestion considering both pre-swallowing and swallowing functions has been described by Leopold & Kagel (Leopold and Kagel 1997), while the traditional definition of normal swallowing does not consider external factors as attention, eating behaviour, and feeding method, which may also have an impact on swallowing efficiency and safety (Daniels and Huckabee 2008). The F.O.T.T. approach also adds an additional phase to the described three phases of the normal swallow in humans, which is the *pre-oral phase*, including factors influencing swallowing, before the food gets into the mouth (Hansen and Jakobsen 2010). Since 1976 Coombes (Coombes 2008a; Coombes 2011) has emphasised the significance of the pre-oral phase in normal eating. It is a state of readiness for eating.

It is important to promote this state of readiness in those with eating difficulties before they begin to eat. For example, they should be seated in an appropriate way, with an opportunity to prepare for the presentation of food by seeing it, smelling it and by tactile contact with the table (spontaneous or guided touching), the cutlery and handling the food or holding a cup with assistance as required. Leopold & Kagel (Leopold and Kagel 1983; Leopold and Kagel 1997) support this paradigm and they call it the Pre-oral (Anticipatory) Stage: Interstage Relationships and describe it as a useful paradigm, particularly in neurogenic populations, to modify the next stage of ingestion, the oral-preparatory stage. During the pre-oral stage of ingestion, the visual and olfactory qualities of food excite salivation which mechanically assists bolus preparation, transfer, and transport.

The normal pre-oral phase is essentially the state of sensori-motor “readiness”. It involves preparation and transport of food to the mouth, anticipatory saliva production and possibly swallowing, in response to smelling the food, or seeing it. Preparation includes anticipation of the meal, coordination of the movements of the eyes, arms, and hands together with the movements of the trunk, head, and jaw. The spontaneous “postural background” allows for an optimal relation of head, shoulders and trunk, promoting a stable foundation for manual dexterity, eye-hand co-ordination, arm movement and co-ordinated jaw opening (Coombes 2001; Hansen and Jakobsen 2010).

These important operations “set the scene” for the oral phase which comprises bolus formation and transport, lubricated with saliva, to the back of the mouth so that it can be delivered into the pharynx (throat). Each phase influences the subsequent phases of normal swallowing. Thus, the incoordination of the oral phase affects the timing and co-ordination of the pharyngeal phase, even when the pharyngeal reflex remains intact (Coombes 2008b). The pre-oral phase includes a



lot of therapeutic possibilities of involving the person in the daily activity of eating and drinking (Gratz 2002; Kjærsgaard 2005a).

## 2.4 Rehabilitation of persons with acquired brain injury (ABI)

Stroke and traumatic brain injury (TBI) are the main causes of ABI. According to the Danish National Patient Registry, Denmark had about 12,500 cases of hospitalisation from stroke in 2009 and about 9,500 cases of hospitalisation from TBI and other forms of ABI. Many of these people need rehabilitation (National Board of Health 2011). Rehabilitation of patients with severe ABI is a sub-speciality within neurorehabilitation (Chua and others 2007). ABI is an umbrella term, encompassing a wide spectrum of brain injuries that generally include traumatic and non-traumatic aetiologies such as cerebral concussion, brain contusions, subarachnoid haemorrhages or other “acquired” problems such as hypoxia. The definition of ABI in this study is employed by the Toronto Acquired Brain Injury Network (Toronto Acquired Brain Injury Network 2011), in which ABI is defined as “damage to the brain that occurs after birth and which is not related to congenital disorders, developmental disabilities, or processes that progressively damage the brain”. Causes of ABI include (but are not limited to) such as hypoxia, illness, infection, stroke, substance abuse, toxic exposure, trauma, and tumour. ABI may cause temporary or permanent impairment in such areas as cognitive, emotional, metabolic, motor, perceptual motor and/or sensory brain functions (Turner-Stokes and others 2005; Wiseman-Hakes and others 2010).

A severe brain injury is considered if the initial Glasgow Coma Score (GCS) is 8 or lower (Rimel and others 1979; Rimel and others 1982). GCS is a neurological scale that aims to give a reliable, objective way of recording the conscious state of a person for initial as well as subsequent assessment. A patient is assessed against the criteria of the scale after six hours following head trauma, the lowest possible GCS (the sum) is 3 (deep coma or death), while the highest is 15 (fully awake person) (Teasdale and Jennett 1974; Jennett and Teasdale 1977). In Denmark, GCS is a standard score in all patients with TBI and other severe ABIs, but is not a standard score within the stroke population.

In a Cochrane review from 2003 of multi-disciplinary rehabilitation of ABI the authors concluded that problems following ABI vary; different services are required to suit the needs of patients with different problems. Patients admitted acutely to hospital with moderate to severe ABI should be routinely followed up to assess their need for rehabilitation. Intensive intervention appears to lead to earlier gains. The balance between intensity and cost-effectiveness has yet to be determined. Patients discharged from IRP should have access to outpatient or community-based

services appropriate to their needs. Even those with milder ABI benefit from follow-up, and appropriate information and advice.

Another systematic review of rehabilitation of ABI from 2007 (Teasell and others 2007) found that only 28% of the interventional studies were RCTs. Over half of the 275 interventional studies were single group interventions, pointing to the need for studies of improved methodological quality into ABI rehabilitation. In a review of the efficacy of ABI rehabilitation from 2007 (Cullen and others 2007) the findings show that the majority of interventions were only supported by limited evidence, and the conclusion was that there is a need for studies of improved methodological quality into ABI rehabilitation. The growing evidence suggests that ABI rehabilitation and research should be guided by a philosophy that focuses on: restoration, compensation, function and participation in all aspects of daily life (Wiseman-Hakes and others 2010).

## 3. AIM AND OBJECTIVES

### 3.1 General aim

Based on the described background, the overall aim of this thesis was to explore and evaluate the difficulties in swallowing and eating during inpatient neurorehabilitation – from a professional and a patient perspective.

The overall aim was achieved by addressing three specific aims:

#### 3.1.1 Specific aims

The specific aims for each of the included papers were:

- To examine whether patients assessed for initiation of oral intake by F.O.T.T. had a greater risk of developing pneumonia during neurorehabilitation than patients assessed by FEES (**Paper I**).
- To investigate if there is a difference in time to recovery of functional oral intake before discharge from an inpatient neurorehabilitation programme for patients with ABI assessed using F.O.T.T. and for patients evaluated by FEES,
  - if other factors than the assessment approaches, measurable in the clinical setting, influenced the time to recovery,
  - and to calculate the incidence of dysphagia (**Paper II**).
- To explore and interpret how persons with ABI experience and adapt to reduced abilities to swallowing and eating - and clinical implications (**Paper III**).

## 4. CONCEPTUAL FRAMES

### 4.1 Scientific frames and methodological considerations

The different aims guided the scientific frames and methods for each study. The research methods included in this thesis are both quantitative and qualitative. **Study I** was performed within the natural science tradition focusing on testing objective theories by examining the relationship among variables (Creswell 2009b). **Study II** was performed within a phenomenological (Merleau-Ponty 1962)-hermeneutic (Gadamer 2004) science tradition focusing on exploring, understanding and interpreting the meaning that individuals or groups ascribe to a social or human problem (Creswell 2009b). The explorative approach to development of this knowledge was used, because existing knowledge in this field is very limited, and because learning about the impact of biomedical and psychological consequences of dysphagia, from a patient perspective provides a deeper understanding of what is important to the patient (Olson 2001; Martino and others 2010)

### 4.2 Rehabilitation and the International Classification of Functioning, Disability and Health (ICF)

Rehabilitation is a complex health intervention undertaken in a complex environment (Shiell and others 2008). "Rehabilitation" is taken to be a *process* and not a treatment or specific action (Wade 2005). Rehabilitation aims to alter activities and participation; it does not necessarily aim to return a person to some pre-existing or socially "normal" state (Wade and others 2010). Rehabilitation is set in a complex system, so the relationship between any particular action or change and change in other domains is nonlinear (Shiell and others 2008). Rehabilitation is a multidisciplinary health care activity (Wade 2005). According to the World Report on Disability, rehabilitation is "a set of measures that assist individuals who experience, or are likely to experience, disability to achieve and maintain optimal functioning in interaction with their environments" (World Health Organization 2011). The Convention of the Rights of Persons with Disabilities, in its article 26 calls for "appropriate measures /-/- to enable persons with disabilities to attain and maintain their maximum independence, full physical, mental, social and vocational ability, and full inclusion and participation in all aspects of life" (United Nation 2006).

To me, the ICF is not a theoretical model and I agree with Whyte (Whyte 2008) describing that “ICF contains seeds of a unified theory, but is not a theoretical model. ICF is fundamentally a taxonomic system of human functioning with hints of theory of the enablement and disablement process”. In this thesis ICF was used as framework for understanding the meaning and the complexity of having difficulties in swallowing and eating following ABI. The ICF is based on a bio-psychosocial model of functioning and disability, a model which integrates components of health into a unified and coherent view. The model sets out and maps out the relationships between six components of health (Appendix 1): the Health Condition, Body Functions and Structures, Activity, Participation, Environmental Factors and Personal Factors (WHO 2001; Geyh and others 2011).

*Dysphagia was in this thesis defined as difficulties in ingestion, swallowing, eating and drinking.*

In **Paper I** focus was on difficulties in ingestion and swallowing (impairments), in **Paper II** on eating and drinking (activity limitations) and in **Paper III** on ingestion, swallowing, eating and drinking (activity limitations and participation restrictions) and personal factors as individual psychological assets.

The keywords (underscored) are defined from the World Health Organization’s The International Classification of Functioning, Disability and Health (ICF) (WHO 2001).

- **b510 Ingestion functions** are related to taking in and manipulating solids or liquids through the mouth into the body. Inclusions: functions of sucking, chewing and biting, manipulating food in the mouth, salivation, swallowing, burping, regurgitation, spitting and vomiting; impairments such as dysphagia, aspiration of food, aerophagia, excessive salivation, drooling and insufficient salivation.
- **b5105 Swallowing** is clearing the food and drink through the oral cavity, pharynx and oesophagus into the stomach at an appropriate rate and speed.
- **d550 Eating** is carrying out the coordinated tasks and actions of eating food that has been served, bringing it to the mouth and consuming it in culturally acceptable ways, cutting or breaking food into pieces, opening bottles and cans, using eating implements, having meals, feasting or dining.
- **d560 Drinking** is taking hold of a drink, bringing it to the mouth, and consuming the drink in culturally acceptable ways, mixing, stirring and pouring liquids for drinking, opening bottles

and cans, drinking through a straw or drinking running water such as from a tap or a spring; feeding from the breast.

ICF does not contain a classification of Personal Factors, but characterises it as follows: “Personal Factors are the particular background of an individual’s life and living, and comprise features of the individual that are not part of a health condition or health state. These factors may include gender, race, age, other health conditions, fitness, lifestyle, habits, upbringing, coping styles, social background, education, profession, past and current experience (past life events and concurrent events), overall behaviour pattern and character style, individual psychological assets and other characteristics, all or any of which may play a role in disability at any level” (Geyh and others 2011).

The traditional medical definition of dysphagia as difficulty of swallowing (Wikipedia 2012), is included in the ICF dimension of body functions and anatomy with ingestion and swallowing functions (difficulty in oral, pharyngeal and oesophageal phase), which contains definitions of oral intake of food and swallowing function. In this study the understanding of dysphagia was expanded with the ICF definitions of eating and drinking (pre-oral phase), which is included in the ICF dimension of activity and participation. In this thesis oesophageal dysphagia was excluded.

### 4.3 Rehabilitation as a process related to adaptation

Adaptation at an interpersonal level, with the influence of both personal (individual adaptation) and environmental (environmental adaptation) and human behaviour exerts an influence on each other over time. In **Study II** the patients’ processes of changes over time were understood theoretically as adaptation.

Adaptation is an essential concept in rehabilitation and has various definitions (Van Dijk 2004; Eriksson and others 2006). Adaptation is defined as the process by which a person maintains a useful relationship to the environment (Coelho and others 1974). The process of adaptation is not seen as linear, but as back and forth endeavours that will entail periods of regression and subsequent progression.

A theoretical framework might help the practice of rehabilitation to select relevant variables for measurement, and subsequently make interpretations of the measurement outcomes that are relevant for this practice (Van Dijk 2004). Van Dijk defines the aims of rehabilitation as a process related to adaptation, or, framed differently, maintaining or regaining meaningfulness. Rehabilitation is considered both as a process of adaptation and as assistance in that process. The aim of rehabilitation as assistance could then be considered as reinforcing the person’s resources and

enriching his or her environment in order to maintain or regain meaningfulness (Van Dijk 2000). Fugel-Meyer (Fugel-Meyer and Fugl-Meyer 1988) describe that the primary task of rehabilitation after brain injury is to restore function and to turn residual disability to ability as much as possible, and he based this paradigm on the concept that health means ability to experience satisfaction of life. Understanding the aim of rehabilitation is to mobilise the resources of individuals with impairment(s) so that, by having realistic goals, they may achieve optimal life satisfaction (Van Dijk 2004).

The Spencer et al. (Spencer and others 1996) in his concept of adaptation focuses on changes in life narratives and provides insight into what happens when chapters end and begin in a person's life story. Two aspects of this concept are particularly relevant to the examination of major life changes. First, adaptation is an interactive process that occurs between an organism and its environment. Second, adaptation is an inherently cumulative process in which the past shapes the future. Spencer et al. describe three premises for the adaptive repertoire, which includes: the environment, the person, and the processes of change.

Moreover, King (King 1978) describes four basic characteristics of the individual adaptive process: 1) Dependent upon the individual having a positive and active role 2) Occurs only when it is evoked by the specific environmental demands of needs, tasks and goals 3) Is most efficiently organised below the level of consciousness, with conscious attention being directed to objects or tasks 4) It is self-reinforcing, with each successful adaptation serving as a stimulus for tackling the next more complex environmental challenge.

The aim of using theories of adaptation in this thesis was to explore, understand and interpret the person's level of adaptation or acceptance of lost functional skills related to swallowing and eating, right after the injury and at the time of interview. Central elements were the patient's experiences of interdisciplinary neurorehabilitation approaches concerning the assessment and treatment of difficulties in swallowing, eating and drinking following ABI and the adaptation to daily living with social relationships involving food and liquid.

## 5. METHODS

Different quantitative instruments were used to evaluate the difficulties in swallowing and eating following ABI. Moreover, the persons' individual experience of difficulties in swallowing and eating was explored by using semi-structured, qualitative interviews.

### 5.1 Study design

The thesis was designed as two separate studies described in three papers.

**Study I** was a randomized controlled trial, consisting of two papers (**Paper I and II**). The study was designed as a prospective randomized controlled trial. The basis of the power calculation was the estimated risk of aspirations during neurorehabilitation, since it was not possible to find any specific data regarding aspiration pneumonia. It was assumed that there is a 20% higher risk of aspiration in the group assessed using F.O.T.T. than in the group using FEES (Lim and others 2001; Leder and Espinosa 2002). With a significance level of 5% and a strength of 80%, the sample size was calculated by a power calculus, showing that each group had to include 59 subjects for rejection of the null hypothesis. The study was therefore designed to include 118 subjects.

**Study II** was a multiple-case study described in one paper (**Paper III**). See Figure 1 on the following page.



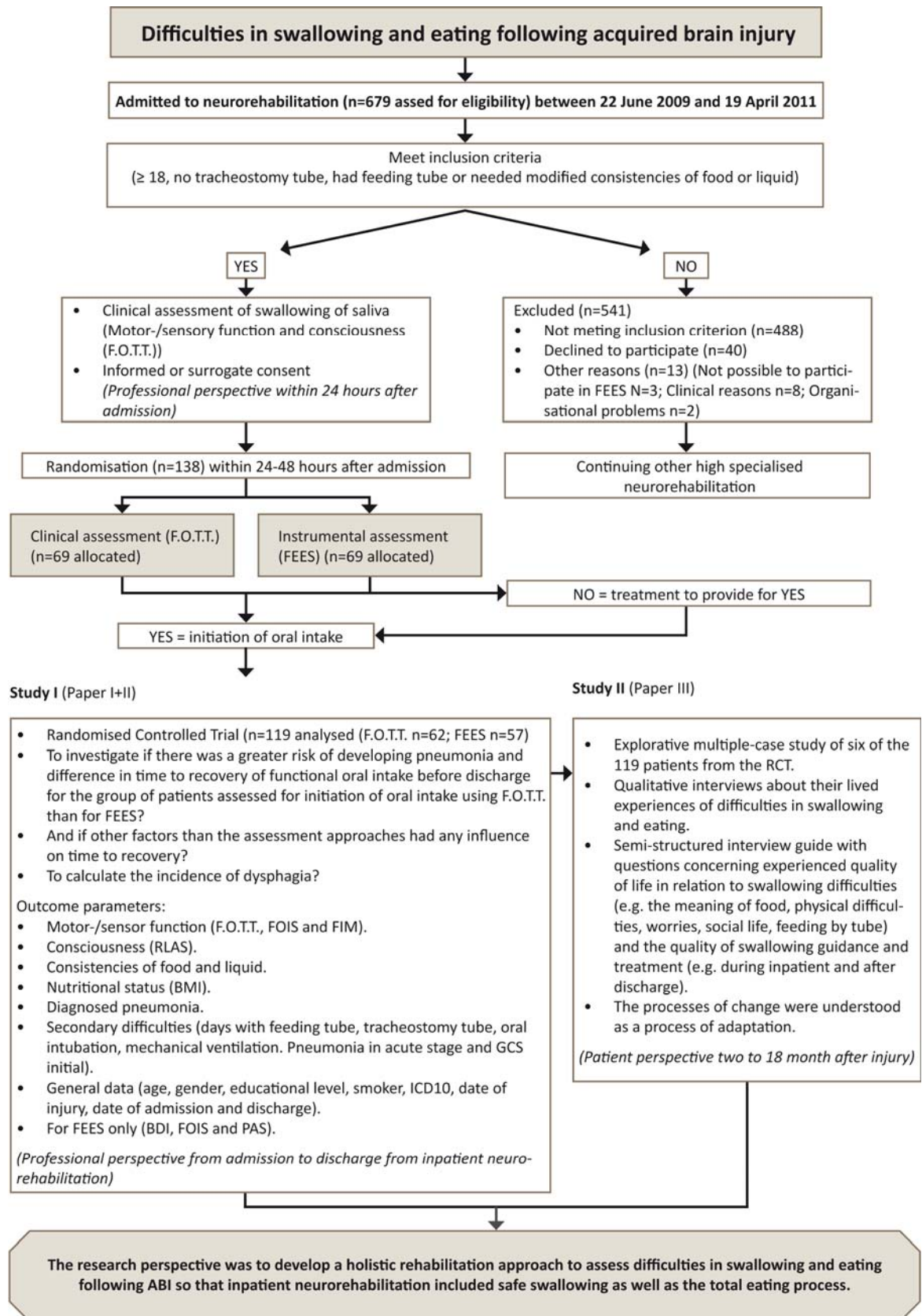


Figure 1: Thesis process map

## 5.2 Participants

Patients with ABI, defined as stroke, subarachnoid haemorrhage, TBI, anoxia and other acute neurological disorders were enrolled consecutively in **Study I**. The enrolment was performed between June 2009 and April 2011.

The inclusion criteria in **Study I** included anamnestic information on swallowing difficulties from the acute hospital (need for a feeding tube or modified consistencies of food or liquid), stable vital functions and personal or surrogate consent. The exclusion criteria included full oral intake present on admission without the need for feeding tube or modified texture of food and liquids, previously known dysphagia, cancer diagnosis, pneumonia present on admission, tracheostomy tube present on admission, or under 18 years of age.

In **Study II**, six persons with ABI were purposefully selected from the larger **Study I**. The inclusion criteria were: 1) Person with ABI enrolled in the study mentioned above 2) has or has had a feeding tube 3) was able to understand the interview question and express/describe their experience in Danish (Functional Independence Measure (FIM) score 5-7 at item: Expression and Memory present on admission or at discharge from neurorehabilitation). The participants were selected, with help from the local, clinical dysphagia expert, working in each unit at Hammel Neurocenter, using purposeful sampling (Creswell 2009a) to make sure that the persons included in the study showed variation according to age, gender and severity in swallowing and eating difficulties. The participants gave their verbal and written informed consent to participate and were guaranteed confidentiality. Participation was voluntary, and participants could withdraw from the study at any time.

## 5.3 Randomization

An administrator not involved in the study, produced blocks of opaque sequentially numbered sealed envelopes containing the randomization information (F.O.T.T or FEES) from an independently computer-generated randomization list, produced by a hospital pharmacy. The randomization was performed in blocks of 20. The patients were asked to participate in the study via the nurse in charge of admitting patients to the centre.

The patients or their relatives and the patients' general practitioner or medical public health officer received the oral and written information about the study from the treating occupational therapist (OT) within 24-48 hours. After having obtained the consent, either informed or surrogate, two leading staff members were responsible for the allocation of patients by opening the next sealed envelope and using the information therein. The OTs did not participate in the in-

strumental assessment. Similarly, the co-authors and the data analyst took no part in the data collection or assignment of patients.

## 5.4 Inpatient neurorehabilitation setting

The Region Hospital Hammel Neurocenter is an intensive, hospital-based, interdisciplinary national neurorehabilitation centre. Interventions are based on 24/7 assessment and treatment approaches, which emphasises early sensory-motor stimulation to facilitate the activities of daily living (Graham and others 2009; Affolter and others 2009; Hansen and Jakobsen 2010).

At Hammel Neurocenter, dysphagia treatment is based on the treatment of the whole individual (Hansen and Jakobsen 2010). If the patient could not initiate oral intake at the first clinical or instrumental assessment, it was repeated continuously as part of the dysphagia treatment sessions. The objectives of the treatment were that the patients would be able to fulfil the criteria for initiation of oral intake (see below). The number of treatments for dysphagia was determined by the patient's overall condition, the severity of impairments, and the patient's responses to the interventions. After initiation of oral intake the treatment was individually planned and performed based on the F.O.T.T. approach.

## 5.5 Intervention approaches

This section contains a presentation of the two main intervention approaches (F.O.T.T. and FEES) used in this thesis.

### 5.5.1 Facial-Oral Tract Therapy (F.O.T.T.)

The clinical assessment F.O.T.T. was used to both to assess and to treat difficulties in swallowing and eating in the **Studies I-III**.

F.O.T.T.<sup>™</sup> (Coombes 2008a; Hansen and Jakobsen 2010) was developed by the speech and language therapist Kay Coombes, UK and is used in many different countries and neurorehabilitation settings. Several courses are held in most parts of Europe every year (Coombes 2011).

F.O.T.T. is a neurorehabilitation approach widely used in Denmark (Kjærsgaard 2004), despite the low number of studies addressing its effectiveness or efficacy (Seidl and others 2007).

F.O.T.T. provides a comprehensive interdisciplinary approach and a structured way of both assessment and treatment of persons with swallowing and eating difficulties, oral hygiene, non-verbal communication, and speech movements caused by neurological conditions (Kjærsgaard 2005a; Hansen and Jakobsen 2010). The focus in this thesis was on the assessment part of the

F.O.T.T. approach. F.O.T.T. is a practical hands-on approach originally founded on the work of Bobath (Graham and others 2009) and aims for reintegration and reorganization of the facial-oral functions in the context of daily living. Single impairments are not treated in isolation, but are analysed and treated in combination with all impairments, activities and participation (Seidl and others 2007).

### **Aims of therapy:**

- To facilitate long-term functioning.
- To prevent deformity and pain due to deterioration over time even in non-progressive conditions (Coombes 2008b).

### **Principles of therapy :**

- Eating and drinking problems respond to treatment of the whole individual. Swallowing is influenced by a number of factors that must be taken into account and modified as necessary in treatment to produce improvement. Influential factors include: muscle tone and body posture; balance and dynamic stability; the position of the carer and the way in which the food is presented; food texture; cutlery size and material; the mealtime environment e.g. noise and visual distractions; comfort and the time available for eating.
- Emphasises the role of sensation i.e. *feeling* or “feedback” from the body’s position and movement. This is more effective than *telling* someone how to move or eat, or rely on use of vision.
- Does not require understanding of the spoken language, and the individual is not guided by verbal direction but by physical touch and handling. Therefore the approach is very helpful when assessing and treating ABI patients in vegetative and minimal consciousness state.
- Handling facilitates the normal muscle tone and gradually increases the tolerance of touch in the patients where hypersensitivity makes feeding and teeth cleaning difficult.
- Seeks to prevent unhelpful learning experiences, for example swallowing with the head falling or tilted backwards. This is unsafe because it opens the airway, increasing the risk of choking and aspiration. Moreover, the person will become accustomed to the abnormal head position and they will find it increasingly difficult to adapt to a safer way of eating.
- Importantly, F.O.T.T. avoids “forced” experience in attempts to provide nutrition and maintain oral hygiene. Force-feeding and physical restraint during teeth cleaning are symptoms of

desperation and are counterproductive. They are liable to result in gagging or vomiting which can be difficult to reverse.

- Careful attention is paid to the *entire sequence of an activity* and this includes taking into account the way in which it is initiated. Therefore, since 1976 Coombes has emphasised the significance of the *pre-oral* phase in normal eating.
- The face, mouth and hands are rich in sensation and afford enormous possibilities for sensori-motor learning, given appropriate input. Helpful sensory feedback from the body is the most reliable route to improving the experience of mealtimes and promoting verbal and non-verbal communication (Coombes 2008a; Coombes 2008b).

### **F.O.T.T. in contrast to other treatment approaches**

In F.O.T.T. postural control is recognised as fundamental to selective normal movement patterns for all activities, including movements of the face and oral tract. Therefore, positioning the patient to promote postural control is an integral part of the treatment. F.O.T.T. differs from other swallowing therapies or approaches in being an integrated treatment and assessment for swallowing, speech, breathing and facial expressions united in one approach. Moreover, in contrast to other treatments, F.O.T.T. uses functional activities and objects from everyday life where the therapist provides the patient with tactile information to facilitate movements which are as normal as possible instead of using verbal instructions mainly for exercises (Kjærsgaard 2005a; Hansen and Jakobsen 2010; Nusser-Müller-Busch 2011). In other behavioural therapeutic approaches, the patient must have sufficient perceptive, cognitive, and sensory motor prerequisites to perform strategies or manoeuvres. These strategies are designed to place specific aspects of pharyngeal swallow physiology under voluntary control e.g. the Mendelssohn manoeuvre is designed to increase the extent and duration and width of cricopharyngeal opening, the supraglottic swallow is designed to close the airway at the level of the true vocal folds before and during swallow and the Chin-Down Posture widens valleculae to prevent bolus from entering airway; narrows airway entrance; pushes epiglottis posteriorly and pushes tongue base backward toward pharyngeal wall (Logemann 1998; Logemann 1999). These strategies are focusing on airway protection, strengthening of muscles, and compensation manoeuvres, whereas in F.O.T.T. the therapist will strive for the patient to perform a movement or a movement pattern (e.g., chewing, drinking from a cup) as normal as possible and involve the patient as much as possible, but still focusing on airway protection (Kjærsgaard 2005a; Coombes 2008a; Hansen and Jakobsen 2010; Nusser-Müller-Busch 2011).

## **Clinical assessment of the mouth and oral tract**

Clinical assessment of oral functions (Kjærsgaard 2005b; Kjærsgaard 2008; Hansen and Jakobsen 2010), where individual items of the F.O.T.T. approach were selected (in close cooperation with other F.O.T.T. experts), was performed by the treating OT within 24 hours of admission. The aim was to perform the visual and tactile assessment and to assess the prerequisites for swallowing saliva and initiation of oral intake (Kjærsgaard 2005b; Hansen and Jakobsen 2010). The visual assessment of the oral cavity was made with a flashlight and a spatula to inspect the oral structures: teeth, gums, lips, tongue, cheeks and soft palate, both at rest and in movement and an observation of structures, movements, range and quality of movements. In the tactile assessment the OT applies, via a gloved, wet small finger, a structured stimulation with tactile, rhythmic strokes of the gums and cheeks with jaw control grip. It is repeated three times at each quarter of the mouth. Then a three-step touch along the tongue and lastly a firm touch at the alveolar ridge. After each part the patient is given the opportunity to swallow (Seidl and others 2007). In the tactile assessment focus is on the responses to oral sensation and tone. In the visual and tactile assessment it is observed whether the patient swallows saliva spontaneously, frequency of swallowing and the ability to protect the airway. As a conclusion the OT evaluates the following seven criteria: Is the patient: 1) Awake and conscious and/or can he respond to verbal communication? 2) Able to sit in an upright position with some head control? Does he: 3) have some oral transport of saliva? 4) Have spontaneous or facilitated swallowing of saliva? 5) Cough after swallowing of saliva? 6) Have gurgling breath sounds after swallowing of saliva? 7) Experience difficulties in breathing after swallowing of saliva? To initiate oral intake the patient needs functional abilities, so that the therapist can put a YES in the four first criteria and a NO in the following three criteria. The conclusion of the evaluation was documented in a special study chart and the clinical assessment lasted 30-60 min on average.

## **Treatment**

The aim of the F.O.T.T. treatment is the reintegration and reorganization of the facial-oral functions in the context of daily living. Impairments are not treated in isolation, but are analysed and treated in combination with all impairments (Seidl and others 2007). The treatment methods include slow, organised touch of the patient's hands, facilitating hand-to-hand and hand-to-face contact, together with specific oral stimulation, therapeutic oral hygiene routines, and facilitation of swallowing. F.O.T.T. does not require that the patients are capable of following instructions. Therefore, patients with a very low level of consciousness also receive F.O.T.T. e.g. to begin with,

they will be given treatment with oral stimulation and therapeutic eating (small amounts of food given in the treatment session).

### **Therapeutic eating**

The initiation of oral intake (therapeutic eating) is performed safely and controlled with food and liquids of different textures and the OT prevents inappropriate patterns and enhances normal movements (Kjærsgaard 2005a; Hansen and Jakobsen 2010). It is used to graduate food and liquid textures in the attempt to achieve total oral intake. Modified consistencies are described later in the section of methods. If the patient could not initiate oral intake at the first clinical or instrumental assessment, it was repeated continuously as part of the dysphagia treatment sessions. The treatment goals were that the patients would be able to meet the criteria for initiation of oral intake, described in the clinical assessment. All OTs at the centre are all continuously trained in F.O.T.T., and there is an OT specialist in F.O.T.T. at every ward to support colleagues in the assessment and treatment of swallowing and eating. The number of treatments for dysphagia was determined by the patient's overall condition, the severity of impairments, the patient's responses to the interventions. After initiation of oral intake treatment was individually planned and performed based on the F.O.T.T. approach.

### **5.5.2 Fiberoptic Endoscopic Evaluation of Swallowing (FEES)**

The instrumental assessment FEES was used, by the examining team within 24-48 hours of admission, to assess the prerequisites for swallowing saliva and initiation of oral intake, for the evaluation of the swallowing function and the ability to protect the airways. FEES was performed by an interdisciplinary team consisting of a physician and an OT with formal special training or two specially trained OTs with competency in performing FEES. Furthermore, it was possible to try out therapeutic interventions to decide whether oral intake was safe and to make recommendations and implement strategies allowing safe oral intake. FEES is easy to perform and repeat, and it can be performed at the bedside and it involves few risks for the patient (Langmore 2003; Leder and Murray 2008).

Before the process of FEES the patient was positioned with in upright, straight position of the spine, the pelvis forward and the neck in a flexed position. The patient's nose and mouth were cleared of saliva, and the nasogastric feeding tubes were removed. The endoscope was passed through the patient's nostril and moved forward along the floor of the nose through the velopharyngeal port. The tip of the endoscope was advanced into the hypopharynx (Leder 1999). The examining team observed via colour video monitor changes in the anatomy structures of the lar-

ynx and pharynx at rest and in motion, timing and eliciting physiologic movements of the bolus through the pharynx, the ability to protect the airways, identifying the presence and management of oropharyngeal secretions (by light source to enhance visibility), spontaneous swallows, the capability to clear the bolus during deglutition, residue of material in the hypopharynx, and timing of bolus flow and laryngeal closure. If dysphagia was identified, implication of various therapeutic interventions was performed (with the endoscope in place) to determine if postural (e.g. head position), dietary (e.g. bolus volume and consistency), and behavioural changes (e.g. effortful swallow or two swallows per bolus) were successful in promoting a safer and more efficient oral intake (Leder and Murray 2008). All examinations were visualised, recorded and stored on hard disc. The examination lasted 30 min on average.

Documentation was carried out using: the Berliner Dysphagia Index (BDI) (Seidl and others 2002), the Penetration Aspiration Scale (PAS) (Rosenbek and others 1996) and the Functional Oral Intake Scale (FOIS) (Crary and others 2005) to document the functional level of oral intake of food and liquid which was recommended after the FEES. The scales are described in the following section of methods. The findings were documented, immediately after each FEES assessment. In case the patient could not co-operate and/or saliva was pooling with penetration or aspiration (PAS 8), no oral intake was initiated (FOIS 1). The treatment goal was then to increase the patient's consciousness and/or ability to swallow saliva and a re-FEES was always performed before initiating oral intake. The patients were also referred for a re-FEES, when the treating OT clinically evaluated that it was possible to increase the level oral of intake.



## 5.6 Data collection and outcome measures

In the two studies and three papers a number of approaches, scales and interviews (Table 1) were used for assessing and collecting data concerning impairments and functioning. Thus, aspiration pneumonia was diagnosed following specific criteria, swallowing impairments were assessed with the FOIS (overall functional level of oral intake), the PAS (level of aspiration and/or penetration), the BDI (anatomy and physiology) and the modified consistencies of food and liquid (specification of level of oral intake). Cognitive impairment was assessed using the RLAS. On the activity level FIM was used as an overall functional measure. On the participation level semi-structured interviews were used for assessment. Conversely, in the present clinical setting, radiological techniques were not available, which excluded videofluoroscopy as well as direct measurements of brain function or structure.

Table 1: An overview of the approaches, scales and interviews used as data collection methods in the two studies

Approaches/scales/interview	Study I	Paper I	Paper II	Study II	Paper III
Aspiration Pneumonia	X	X			
Functional Oral Intake Scale	X		X		
Penetration Aspiration Scale	X	X			
Berliner Dysphagia Index	X	X			
Level of modified consistencies of food and liquid	X			X	X
Functional Independence Measure	X	X	X	X	X
Rancho Los Amigos Scale	X	X	X	X	X
Semi-structured interviews				X	X

### 5.6.1 Aspiration pneumonia

Since it was not possible for resource reasons to send all patients for a videofluoroscopy evaluation of swallowing (with the radiology department 28 km away), we decided to use aspiration pneumonia occurring during the time of neurorehabilitation as the primary outcome measure. Aspiration pneumonia was diagnosed according to the definition described in the British Thoracic Societies Guideline for Management of Community Acquired Pneumonia in Adults (Lim and others 2009) as: 1) fever ( $>38^{\circ}\text{C}$ ), 2) leukocytosis with neutrophilia or leucopenia or increase in C-Reactive Protein and 3) appearance of new infiltrative changes on chest radiograph plus detection of at

least one of the following clinical findings: cough; expectoration; dyspnea and pain, synchronous to respiration; tachypnoea; attenuation and/or crepitation at lung auscultation. This diagnosis was based on records made by the treating physicians on a special study chart and in the patients' medical record. After the inclusion of all patients and before breaking the code, the first and second author double-checked all medical records for patients receiving antibiotics and results of the chest radiographs.

### 5.6.2 Functional Oral Intake Scale (FOIS)

The functional swallowing ability of each patient was estimated using the FOIS (Crary and others 2005), which is a simple 7-level ordinal scale (Table 2) with a high intra-rater agreement and sensitivity (McMicken and others 2010). FOIS is applicable to patients with impaired consciousness, and can, therefore, potentially be used to objectively quantify the swallowing in patients with ABI (Takahata and others 2011). FOIS was scored prospectively by the treating OT following the assessment and treatment of the patient's functional level of food and liquid safely ingested. Levels 1 through 3 relate to varying degrees of non-oral feeding; levels 4 through 7 relate to varying degrees of oral feeding without non-oral supplementation. A Danish version of the scale was used, which was formally forward-backward translated, but not validated in a Danish context (Hansen and others 2008a). FOIS was rated on the day of admission and when there was a change in the patient's functional level of oral intake. Here, the FOIS level 7 of oral intake was used as a sign of successful functioning of the swallowing process. The exact date for initiating oral intake was registered in the study chart for the clinical assessment, but the time for total oral intake was not directly registered as a date of total oral intake in that study chart, but it was systematically registered in a separate study chart for FOIS.

Table 2: Functional Oral Intake Scale (FOIS)

Level	
1	Nothing by mouth
2	Tube dependent with minimal attempts of food or liquid
3	Tube dependent with consistent oral intake of food or liquid
4	Total oral diet of a single consistency
5	Total oral diet with multiple consistencies, but requiring special preparation or compensations
6	Total oral diet with multiple consistencies without special preparation, but with specific food limitations
7	Total oral diet with no restrictions

### 5.6.3 Penetration Aspiration Scale (PAS)

The Penetration Aspiration Scale (PAS) (Rosenbek and others 1996; Robbins and others 1999), illustrated in table 3 on the following page, was used as documentation following every FEES examination to guide safe initiation and level of oral intake of food and liquid. A Danish version of the scale, which was not formally forward-backward translated and validated in a Danish context, was used. The PAS is an 8-point scale to quantitative selected aspects of penetration and aspiration. Scores on the scale are determined primarily by the depth to which material passes in the airway and by whether or not material entering the airway is expelled. In case the patient could not co-operate and/or saliva was pooling with penetration or aspiration (PAS 8), no oral intake was initiated.

Table 3: The Penetration Aspiration Scale (PAS) (Multidimensional depth of airway invasion and residue)

Category	Score	Description
No penetration or aspiration	1	Contrast does not enter the airway
P E N E T R A T I O N	2	Contrast enters the airway, remains above vocal folds, no residue
	3	Contrast remains above vocal folds, visible residue remains
	4	Contrast contacts vocal folds, no residue
	5	Contrast contacts vocal folds, visible residue remains
A S P I R A T I O N	7	Contrast passes glottis, visible sub-glottic residue despite patient's response
	8	Contrast passes glottis, visible sub-glottic residue, absent patient response

#### **5.6.4 Berliner Dysphagia Index (BDI)**

During the FEES examination the patient's anatomical structures and functions in nose, pharynx and larynx, different consistencies of food and liquid, protection of the airways and consciousness related to oral functions and swallowing were evaluated using a Danish modified version of this protocol (Appendix 1), which is not back-translated and validated. The BDI (Seidl and others 2002) is a standardised protocol to document the FEES examination and it has been examined for inter- and intra-rater reliability, which indicated that the BDI can be used to document FEES (Seidl and others 2002). Findings from the BDI were transferred to a rating scale in order to assess the severity of the swallowing function. In study I the BDI provided a classification of the severity of swallowing and eating and served as a documentation of FEES and made it possible to compare the different FEES examinations during IRP. Together with the F.O.T.T. assessment, the BDI provided the treatment recommendation for the treating OT.

#### **5.6.5 Level of modified consistencies of food and liquid**

The level of modified consistencies of food and liquid was assessed by the OT using the F.O.T.T. approach: therapeutic eating and registered with a date in a special study chart every time there were changes in the level of food or liquid during IRP. The date registered was the date when the patient was able to eat or drink, the consistency in question together with different professionals and their relatives. The levels of modified food and liquid were given according to the Complete Danish Diet Handbook (National Board of Health and others 2012) with four levels of liquid (jelly, honey, natural thick e.g. chocolate milk, normal thin liquid) and three levels of food (puree, souf-flé, soft and solid food).

#### **5.6.6 Functional Independence Measure (FIM™)**

During IRP admission, every four weeks and at the discharge scores of the patients' functional levels of independence were rated, as a standard procedure, by the interdisciplinary team by observing the patients' functions.

The FIM™ is an 18-item ordinal scale (Granger and others 1993), used in relation to all diagnoses within a rehabilitation population. It is viewed as most useful for assessment of progress during inpatient rehabilitation. FIM™ scores range from one to seven: a FIM™ item score of seven is categorised as "complete independence" while a score of one is "total assist" (performs less than 25% of task). Scores falling below six require another person for supervision or assistance.

The FIM™ measures independent performance in self-care, sphincter control, transfers, locomotion, communication, and social cognition. By adding the points for each item, the possible total score ranges from 18 (lowest) to 126 (highest) level of independence (Wright 2000).

### **5.6.7 Ranchos Los Amigos Scale (RLAS)**

The patients' cognitive level of functioning in the study was rated by the interdisciplinary team using RLAS. This is a standard procedure on admission to IRP, every four weeks during IRP and at discharge.

RLAS is also called The Rancho Level of Cognitive Functioning Scale (LCFS) (Sander 2002) and is one of the earlier developed scales used to assess cognitive functioning in post-coma patients (Hagen and others 1972). It was developed for use in the planning of treatment, tracking of recovery, and classification of outcome levels. Use of the scale generates a classification of the patient in one of eight levels, with level I (No response) and level VIII (Purposeful-appropriate).

RLAS is tested as a reliable and valid scale (Gouvier and others 1987). For patients with severe ABI, oral intake is related to their cognitive function and consciousness. Mackay et al. (Mackay and others 1999b) recommend that RLAS Level IV was needed for initiation of oral intake; Level VI was needed for total oral intake.

### **5.6.8 Other quantitative, functional outcome measures**

Patient characteristics such as age, gender, ICD10 diagnosis, GCS in the acute stage (initial), date of injury to calculate the time since injury, Body Mass Index (BMI) present on admission and discharge, LOS in IRP (days), duration: of oral intubation, of mechanical ventilation, of tracheostomy tube and of feeding tube and the amount of coded dysphagia interventions (number of interventions concerning stimulation of the oral cavity, oral tract, and face in the Danish intervention documentation system (National Board of Health 2012)) were all documented from the medical records by the treating OT.

### **5.6.9 Semi-structured interviews**

Semi-structured interviews (Kvale 2007; Kvale and Brinkmann 2009; Tanggaard and Brinkmann 2010) were carried out in the qualitative **Study II** in order to capture the participants' perspectives and priorities of their experiences of difficulties in swallowing and eating following ABI .

A semi-structured interview attempts to understand themes of the lived everyday world from the subjects' own perspective. It comes close to an everyday conversation, but as a professional interview it has a purpose and involves a specific approach and technique; it is semi-structured – it is neither an open everyday conversation nor a closed questionnaire (Kvale 2007; Kvale and

Brinkmann 2009). The semi-structured interview was chosen because the pre-defined research questions guided the interview, and the semi-structured open interview questions also made it possible to depart from them and at the same time open to the participants' own reflections and perspectives.

Kvale's and Brinkmann's (Kvale 2007; Kvale and Brinkmann 2009) seven stages (thematizing, designing, interviewing, transcribing, analyzing, verifying and report) of an interview inquiry was used for systematic planning of **Study II**. The key questions when planning an interview investigation concern the *why* (clarifying the purpose of the study), the *what* (obtaining pre-knowledge of the subject matter to be investigated) and the *how of the interview* (becoming familiar with different techniques of interviewing and analyzing, and deciding, which to apply in order to obtain the intended knowledge (Kvale 2007; Kvale and Brinkmann 2009). The thematization of "the *what*" requires preliminary and detailed literature studies (Tanggaard and Brinkmann 2010). In **Study II** the stage of thematizing consisted of both a detailed literature search and my pre-understanding. As hermeneutics (Gadamer 2004) has demonstrated it is only possible to understand the world through a pre-understanding (Tanggaard and Brinkmann 2010) and familiarity with the content of an investigation is not only obtained through literature and theoretical studies (Kvale and Brinkmann 2009). In **Study II**, many years of experience as a clinician, treating patients with difficulties in swallowing and eating provided me, as the interviewer, with extensive knowledge and pre-understanding of the local language, the daily routines, and the power structures during neurorehabilitation.

The literature search showed that in the past two decades, noteworthy advances have been made in measuring the physiologic outcomes of dysphagia, including measurement of duration of structure and bolus movements, stasis, and penetration–aspiration. However, there was a paucity of data on health outcomes from the *patients' perspective*, such as quality of life and patient satisfaction. In a study of McHorney et al (McHorney and others 2000) they found that a patient-based, dysphagia specific outcomes tool was needed to enhance information on treatment variations and treatment effectiveness. The conceptual foundation and the item generation process for the SWAL-QOL and SWAL-CARE were obtained by qualitative data on dysphagia quality-of-life and quality-of-care health outcomes from dysphagic patients and their caregivers participating in focus groups. Using the focus group data, they wrote a large number of questionnaire items and constructed a standardized, disease-specific questionnaire (the SWAL-QOL) that measures dysphagia patients' experiences of health outcomes).

### **Preparation for interview**

Two months before the interview, as preparation for the interview, the participants received an information letter with the informed consent form and a questionnaire. The questionnaire was used as preparation to help the participants to focus on their difficulties in swallowing and eating (and not the whole process of rehabilitation) during the interview. The questionnaire was a Danish translation and modification of the SWAL-QOL (McHorney and others 2000) and the SWAL-CARE (McHorney and others 2002) (Appendix 3). The two patient-centred outcome tools were developed by well-known researchers within dysphagia e.g. McHorney A.C., Rosenbek J.C., Robbins J, Logemann J.A. for dysphagia researchers and clinicians. The questionnaire was used as preparation for the interview and as inspiration for themes in the semi-structured interview guide (Appendix 4), but it was also stressed that the coming interview should focus on the reflections and perspectives of the participant. The modification process of the questionnaire was supervised by a senior researcher, and the questionnaire was translated by a professional. However, the Danish version of the questionnaire (Appendix 3) is not back-translated and validated.

### **The interview guide**

The semi-structured interviews were conducted according to an interview guide (Appendix 4). The semi-structured interview guide was inspired by topics from the SWAL-QOL and SWAL-CARE (McHorney and others 2002) (Table 4 on the following page) with suggested questions, but not constructed as a questionnaire with closed questions. The semi-structured interview guide was developed with brief and simple types of interview questions that intended to open the reflections and perspectives of the participant.

Table 4: Domains in the semi-structured interview guide

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Introduction
PART I. Questions concerning experienced quality of life in relation to swallowing difficulties

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1. General questions in relation to eating and drinking
2. The meaning of food and liquid before the injury
3. The meaning of food and liquid at the time of interview and right after the injury
4. Do you experience any physical difficulties today, which may influence eating and drinking? How was it right after the injury?
5. Do you experience worries today and do they influence your mood in relation to eating and drinking? How was it right after the injury?
6. Your social life (meals with the family, work, leisure activities, parties, vacations, etc.) – how is it today? How was it right after the injury?
7. Your experiences of getting food and drink via feeding tube

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PART II. Questions concerning the quality of swallowing guidance and treatment
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1. Your experience during inpatient neurorehabilitation
2. Your experience after discharge

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Closing interview (debriefing)
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### **The process of interviews**

The interviews included both introductory, follow-up, probing, specifying, direct, indirect, structuring, silence and interpreting questions (Kvale 2007; Kvale and Brinkmann 2009) to get as rich descriptions of the participants' subjective experiences as possible. The interviews were designed to gather rich descriptions of the participants' actual, lived experiences and management of their eating and drinking difficulties to capture the participants' present and previous experiences and management of swallowing and eating difficulties. Through open questions the interviews focused on the topic of research and it was then up to the participants to bring forth their reflections and the perspectives they found important by the themes of inquiry. My concern as the interviewer was to lead the participant to reflect and to express his/her own perspectives towards certain themes, but not to specific opinions about these themes (Kvale 2007).

In **Study II**, the aim was to explore the participants' subjective perspective on their lived experiences concerning quality of life and quality of guiding and treatment in relation to difficulties in swallowing and eating in the everyday situations and spheres of life in the various contexts (Borg 2002) (During inpatient neurorehabilitation and after discharge) and the participants' different illness phases following ABI (Kirkevold 2002). Therefore, four participants were interviewed once in their own homes from nine to 18 months after the injury, in the semi-stable phase after onset of ABI, where they were beginning to realise that life would not return to what it was be-



fore (Kirkevold 2002). The last two participants were interviewed twice, and got the same questions twice, in the continued rehabilitation phase after onset of ABI, which is a phase of constant change, although as time passes, changes occur more slowly and gradually (Kirkevold 2002). The interviews took place in their rooms in the ward (two months after injury) and about one month after discharge in their own home/room at a nursing home (four months after injury).

The interviews, which lasted between 30-60 minutes, were tape-recorded and fully transcribed verbatim. The transcribed data were then de-identified and fictive names were created for each participant to maintain and respect their confidentiality. Reflective notes (Creswell JW 2009) were taken after the interview to enhance the understanding of the participants' described lived experiences during the analysis of the interviews. The reflective notes and the results from the Danish translated and modified SWAL-QOL and SWAL-CARE questionnaire were not further analysed.

## 5.7 Data analysis

Several data analyses were conducted in the two studies included in this thesis.

### 5.7.1 Data analysis paper I

The patients were grouped into five main categories according to their ICD10 diagnosis: stroke (Cerebral infarction, brain stem infarction and haemorrhage); subarachnoid haemorrhage; traumatic brain injury; anoxia and other. All data were analyzed using STATA/SE 11 for Windows. The analysis was undertaken by the authors who were blinded to the randomization, and all data were analyzed before dividing the list into two groups. Patient demographic variables were summarised by median, minimum and maximum values for continuous variables, and by count and percentage for categorical variables. The Student's t-test was used to compare normally distributed data and the Wilcoxon signed-rank test was used to compare non-normally distributed variables.

### 5.7.2 Data analysis paper II

Data were analysed using STATA/SE 11 and SAS 9.1. A statistical consultant assisted in the analysis. Patient demographic variables were summarised by median, minimum and maximum values for continuous variables, and by count and percentage for categorical variables. We compared FOIS scores present on admission and discharge by the Wilcoxon signed-rank test. Within the intervention groups, the probability distributions of time from admission to initiation and full oral intake were estimated by Kaplan-Meier curves and compared by the log-rank test. Moreover, the

comparisons were adjusted for the influence of predictor variables using the multiple Cox proportional hazards model (31), where the effects of predictor variables were expressed by hazard ratios and their 95%-confidence intervals (CI). The chance of reaching total oral intake during IRP was compared between the intervention groups and assessed for the influence of predictor variables by logistic regression. As general statistical rules of thumb dictate a limit to the number of predictor variables (Vittinghoff and McCulloch 2007) to ensure valid results, several sets of predictor variables was considered. The Hosmer-Lemeshow test (Hosmer and Lemeshow 2000) was used to assess the goodness of fit of the logistic regression model for each set of predictor variables.

### **5.7.3 Data analysis paper III**

An ongoing process involving continuous reflection (Creswell 2009a) was used for data analysis. The eight interviews were read separately and as a whole, and thoroughly several times by the first author to obtain an overall understanding of each person and the data. The words and phrases dealing with different aspects of experiences related to the domains in the semi-structured interview guide were coded by the author of this thesis. The coding process was performed using a freeware computer program "Open Code" (Dahlgren and others 2004). The codes in each interview were then compared to identify similarities and differences, and subsequently codes that reflected similar aspects were generated into main and sub-themes. The ICF (WHO 2001) domains were afterwards used as a conceptual framework to organise the themes. ICF made it possible to structure the perspective of the body, the individual and society to describe the bio-psycho-social complexity of swallowing, eating, communication and meals.

## 6. ETHICAL CONSIDERATIONS

**Study I** was approved by the Regional Committee on Biomedical Research Ethics in Denmark (Reg. No.: 20090013) and the Danish Data Protection Agency (Reg. No: 2007-58-0010). The patients or their relatives or peers received the oral and written information about the study from the treating OT within 24-48 hours of admission. Information was given that participation in the study was voluntary and that participants had the right to end their participation at any time. All participants or relatives or peers as well as the patient's general practitioner or medical public health officer gave surrogate consent before randomization and enrolment in the study.

In **Study II** the treating OT took the first contact and introduced the study. The next contact was made by the author of this thesis, two months before and repeated the week before the interview. Two months before the interview the participants received an information letter with an informed consent form and a questionnaire (Appendix 3). The participants gave their verbal and written informed consent to participate and were guaranteed confidentiality. Participation was voluntary, and participants could withdraw from the study at any time. Data were considered confidential in line with the legislation of The Act on Processing of Personal Data (Act No. 429 of 31 May 2000) issued by Danish Data Protection Agency, who also gave their permission to the study (Jr. nr. 1-16-02-5-09). The Central Denmark Region Committees on Biomedical Research Ethics wrote on 27 September 2010 (Reg. nr. 20395) that "The interview study is not directly related to the first study and should be regarded as an independent study. It follows the guideline of the Law Committee of the interview studies equated with surveys. This means that interviews only have to be notified to the Committee, if they include human biological material, which is not the case from your description, and you can therefore conduct this study without further feedback from the Committee (Act No. 402 of 28. May 2003)".

## 7. RESULTS

Between June 2009 and April 2011, 679 potentially eligible patients were screened for inclusion in **Study I**. The flowchart (Figure 2) below illustrates the included and excluded patients in **Study I**.

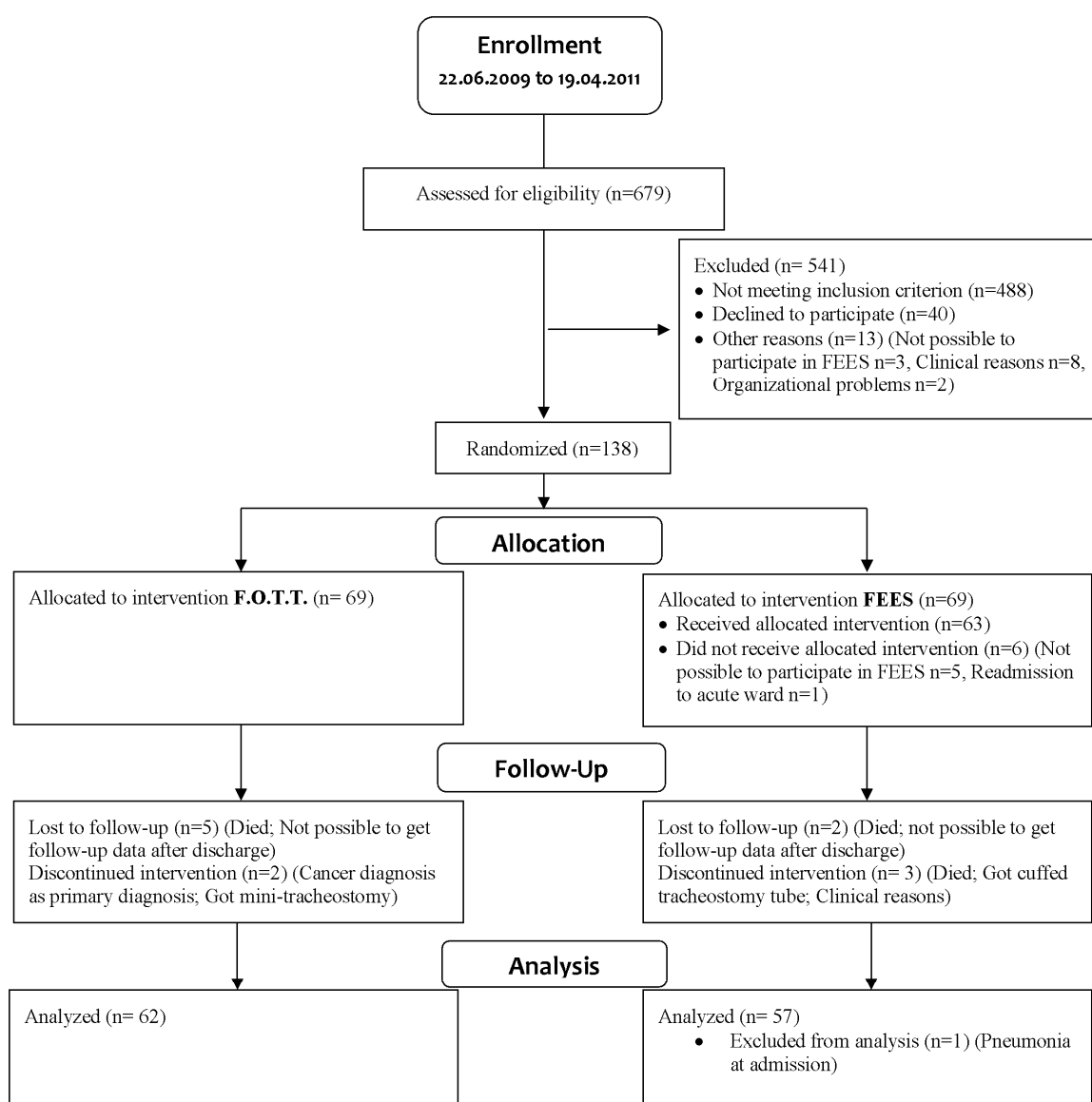


Figure 2: Flowchart for **Study I**

541 patients were excluded before randomization, mainly because of full oral intake or tracheostomy. 138 patients with ABI were randomly assigned and received either F.O.T.T. (n=69) or FEES (n=69). 57 patients gave informed consent and for 81 patients surrogate consent was given by relatives or peers as well as by a general practitioner or medical public health officer. Six patients from the FEES group did not receive the allocated intervention (five patients could not participate in the FEES assessment because of cognitive difficulties); seven patients were lost to follow up (five from F.O.T.T. and two from FEES); five patients discontinued the intervention (four from F.O.T.T. and one from FEES) and were excluded from the analysis. The main reasons for dropouts in both groups were 'being lost to follow-up' or 'discontinued intervention'. Other reasons for dropouts are detailed in Figure 2. Before data analysis we realized that one patient from the FEES group had a diagnosis of pneumonia present on admission and was therefore excluded from the analysis.

Finally, 119 patients could be included in the analysis of the primary outcome (62 F.O.T.T./ 57 FEES). 112 patients were included within 90 days after the injury, two patients within 180 days and five patients more than 360 days after injury.

The patient characteristics were similar in the groups at baseline. There were no significant differences in the demographic, injury-related, respiratory-related, functionally or cognitively related parameters. The mean age in the study population was 60 years and the gender index men/women was two to one.

	<b>Study I (Paper I &amp; II)</b>		<b>Study II (Paper III)</b>	
	Randomized Controlled Trial		Explorative, multiple-case study	
	F.O.T.T. (n=62)	FEES (n=57)	F.O.T.T. (n=3)	FEES (n=3)
Age, median (range)	61 (30-78)	59 (18-76)	53 (30-60)	27 (18-62)
Men (n)	38	41	3	1

Most patients had stroke and, importantly, about as many patients with brainstem infarctions were allocated to either group. The mean days (range) in mechanical ventilation were 8 (0-38) for F.O.T.T. and 9 (0-64) for FEES. Median days from injury to admission to IRP were for F.O.T.T. 36 (range, 10-447d) and for FEES 35 (range, 10-2845d). 2845 days in FEES was a single extreme value, and the maximum without this extreme value was 447 days. The median BMI for F.O.T.T. present on admission was 24 (range, 17-40) and at discharge 24 (range, 18-39) and for FEES present on admission 23 (range, 16-39) and at discharge 24 (range, 16-38). The overall number of infections during neurorehabilitation (excluding pneumonia) was 93 (65 urinary tract infections (UTI)) with no significant differences between the groups. The centre is one of two national, highly special-

ized neurorehabilitation centres in Denmark. In this study 42% of the patients were transferred to further IRP in regional neurorehabilitation units. Twenty-six percent were discharged to nursing homes or sheltered accommodation with municipal rehabilitation service, 20% were discharged to their own home for further municipal outpatient rehabilitation, and the remaining 12% were discharged to other hospital departments for further medical treatment.

In **Study II**, six persons with ABI were recruited from **Study I**. There were no dropouts in **Study II**.

## 7.1 Paper I

*The aim of **Paper I** was to test the hypothesis that patients with ABI (stroke, subarachnoid hemorrhage, TBI, anoxia etc.), who are evaluated for initiation of oral intake using only the assessment component of F.O.T.T., have a greater risk of developing of pneumonia during neurorehabilitation than those who are evaluated using FEES.*

The results will be described in brief. Please refer to **Paper I** for additional details e.g. tables and figures to support the results.

### 7.1.1 Incidence of pneumonia

The overall incidence of pneumonia was 13.5% (16/119 patients) during the study period. Four of the 62 patients in the F.O.T.T. group and 12 of 57 in the FEES group were diagnosed with pneumonia difference significant at  $p=0.03$  by Fishers exact test. The number of days from admission to neurorehabilitation to pneumonia ranged from 0 to 60. Six patients in the FEES group but none in the F.O.T.T. group developed pneumonia before initiation of oral intake and had to be excluded from further analysis. Three of these six patients were unable to initiate oral intake during the period of neurorehabilitation.

The remaining 10 patients (4 F.O.T.T./ 6 FEES) developed aspiration pneumonia three to 49 days after initiation of oral intake. Of these 10 patients, five developed aspiration pneumonia three to 10 days (1 F.O.T.T./ 4 FEES) after initiation of oral intake and five patients after 32 to 49 days (3 F.O.T.T./ 2 FEES). Moreover, the diagnosis of pneumonia in three of these patients was not in accordance with our the primary outcome definition of aspiration pneumonia (Lim and others 2009) two FEES patients did not have new infiltrative changes on chest radiography and one patient assessed by F.O.T.T. was not evaluated by chest radiography. Thus, seven patients remained for analysis. Of these three of the 62 patients were assessed by F.O.T.T. and four of the 57 patients were assessed by FEES.

There was no significant difference in the number of dysphagia interventions between the two groups, or between patients with pneumonia before or after oral initiation.

## 7.2 Paper II

*The aim of **Paper II** was to investigate if there was a difference in time to recovery of functional oral intake in inpatient neurorehabilitation of patients with ABI assessed using F.O.T.T. and FEES, respectively, and if other factors influenced the time to recovery, and the calculation of incidence of dysphagia.*

The results will be described in brief. Please refer to **Paper II** for additional details e.g. tables and figures to support the results.

### 7.2.1 Incidence of dysphagia

Between June 2009 and April 2011, 679 ABI patients were admitted to inpatient neurorehabilitation and 320 of 679 patients (47%) had clinically diagnosed swallowing difficulties (dysphagia) according to the clinical criteria used at the centre, where dysphagia is defined as difficulties in the pre-oral, oral, pharyngeal and/or oesophageal phase of normal swallowing.

### 7.2.2 Initiation of oral intake

A total of 50 of 119 patients (42%) (29 F.O.T.T./ 21 FEES;  $p=0.35$ ) patients were initiated for oral intake on admission, while 109 of 119 patients (92%) ( 59 F.O.T.T./ 50 FEES;  $p=0.35$ ) were initiated before discharge. All patients who were initiated on admission maintained their status during IRP. For the 59 of 119 patients initiated during IRP, the median number of days after injury until initiation was 39 (range, 10-447) and from admission until initiation 1 day (range, 0-65). Comparison of the Kaplan-Meier curves between groups (log-rank test) showed no significant difference in the time to initiation of oral intake. The median time until initiation in IRP was 8 days (F.O.T.T.) and 7 days (FEES), respectively. For patients on total oral intake at discharge, the median number of days post injury onset until initiation was 32.5 (range: 10-88), and the median number of days from admission until initiation was 0.5 days (range: 0-20). Adjusting the comparison of the groups for the confounding effect of other factors did not show any significant difference in the time to initiation of oral intake between the groups ( $p=0.120$ ). The likelihood to be initiated during IRP tended to be dependent on cognitive functioning as assessed by the RLAS score (Hazard Ratio (HR) 1.266;  $p=0.056$ ). The instantaneous probability increased by 27% for each step to a higher level of RLAS. While TBI and stroke tended to be more critical diagnoses regarding initiation com-

pared to the reference group “other”, there was no statistically significant difference between the diagnostic groups. 10 out of 69 patients` time to initiation of oral intake were right-censored, because they were not initiated at discharge.

### **7.2.3 Reaching total oral intake**

Three of 119 patients (2.5%) (0 F.O.T.T./ 3 FEES;  $p=0.11$ ) achieved total oral intake within 24 hours of admission to IRP, while a total 44 of 119 patients (37%) (19 F.O.T.T./ 25 FEES;  $p=0.18$ ) were on total oral intake at discharge. Three patients who achieved total oral intake within 24 hours of admission remained so at discharge; 41 patients went from FOIS <7 to FOIS=7 during IRP. A survival analysis showed that the estimated mean time from injury until total oral intake was 56.0 days (range: 22-179) and from admission until total oral intake 29.5 days (range: 0-151). In the Kaplan-Meier curves, 75 out of 116 patients were right-censored, because they were not at total oral intake at discharge. During IRP many of the patients moved from FOIS levels 1 and 2 to FOIS levels 5 or 6. A comparison between the groups showed no difference in the time to total oral intake.

### **7.2.4 Factors of importance for reaching total oral intake**

Using a Cox-regression analysis to compare the groups adjusted for the potential influence of confounding factors for the time to total oral intake did not show a statistical significant difference between the groups ( $p=0.120$ ). The time to total oral intake was, however, shown to decrease significantly with age ( $HR=0.965$ ;  $p=0.003$ ); an estimated 35% decrease of probability for each 10 years of age. Also here, TBI and stroke seemed to be more critical diagnoses regarding oral intake compared to the reference group “other”, but there was no statistically significant difference between the diagnostic groups. Three patients achieved total oral intake within 24 hours of admission so 116 of 119 patients could be included in the logistic regression analyses of the chance of achieving total oral intake during IRP. Ultimately, 44 patients were on total oral intake at discharge from IRP. Three sets of predictor variables were chosen for the analysis. Set 1 data included group, age and diagnostic groups (basic variables), degree of independence (FIM-change) and cognitive functioning (RLAS-change). The findings showed that the probability of reaching total oral intake decreased significantly with age ( $p=0.0200$ ) and increased significantly with FIM - change ( $p<0.0001$ ). Set 2 data included group, age and diagnostic groups (basic variables), number of coded dysphagia interventions and LOS (treatment variables). The findings showed that the probability of reaching total oral intake decreased significantly with age ( $p=0.0031$ ) and number of coded dysphagia interventions ( $p<0.0001$ ), but increased by LOS ( $p=0.0013$ ). Set 3 was made from a combination of set 1 and 2 and data included diagnostic groups, degree of independence



(FIM-admission), cognitive functioning (RLAS-admission), number of coded dysphagia interventions and LOS ( $p=0.0013$ ). The findings showed that the probability of reaching total oral intake decreased significantly with number of coded dysphagia interventions ( $p=0.0049$ ), but increased with LOS ( $p=0.0251$ ). These different analyses contain 18 statistical tests, i.e. the expected number of false significances was 0.9.

## 7.3 Paper III

*The aim of Paper III was to explore and interpret how persons with ABI experienced and adapted to reduced abilities to swallowing and eating - and clinical implications.*

The findings from the semi-structured interviews will be described in brief under the five main themes that emerged from the analysis: individual psychological assets, swallowing and ingestion, eating and drinking, communication and meals, and rehabilitation of swallowing and eating. Please refer to **Paper III** for additional details and quotations to support the findings.

### 7.3.1 Individual psychological assets

Three sub-themes were identified. The first was *general health status*. Most of the participants described that they were healthy and seldom ill. They could do anything now, activities had become more time consuming, and they got tired very fast. The second theme was *functional level of swallowing and eating*. Three of them could swallow and eat as before the injury, there were no problems and no need for further rehabilitation after discharge. One participant felt that the swallowing difficulties came on top of other difficulties, like he was “twice affected” right after the injury. One of the participants with swallowing difficulties after discharge said that eating did not take up more energy, but progress was very slow and this was very annoying. But he expected that swallowing would get better, even that he was still coughing. One participant had got a feeding tube again after discharge, and started to doubt whether it would ever be better. The final theme was *participants’ treatment goals*. Their treatment goals were expressed very differently. Some did not feel that they had ever had any swallowing and eating difficulties after the injury. One expressed getting to walk was first priority and getting to eat was a side issue. Others said that the main treatment goal during neurorehabilitation was to regain normal oral intake and in company with others.

### 7.3.2 Swallowing and ingestion

Four sub-themes were identified. The first theme was *symptoms choking, coughing, voice clearing and saliva*. Some did not remember any of these symptoms. Others had a lot of saliva, right after

the injury and was both clearing the voice and coughing a lot, and sometimes had to leave the dining room at the ward. The second theme was *worries about swallowing, choking and pneumonia*. Most of the participants had not been afraid of aspiration and worried about pneumonia. Others were worried right after the injury. But one was, at the last interview, still thinking a lot about pneumonia, and that it was the swallowing difficulty that caused all his pneumonias. The third theme was *hunger*. The participants did not feel hungry right after the injury. The last thing they were thinking about was food and the taste was lacking. The last theme was *mood and fatigue*. Right after the injury they were all tired and needed a lot of sleep. Some expressed not being able to eat was just a side issue. Others said that the difficulties in swallowing and eating affected their mood and took up much energy during neurorehabilitation, but at the time of the interview, it did not affect most of them any more.

### **7.3.3 Eating and drinking**

Four sub-themes were identified. The first theme was *meaning of food*. Most of the participants described themselves as lovers of food both before the injury and at the time of the interview. Some said that right after the injury food did not mean anything to them and others said that the importance of food gets very clear when you cannot eat by mouth and need feeding by tube. The second theme was *feeding by tube*. Half of the participants had a nasal tube and the rest had had both a nasal and a PEG tube. About the nasal tube, one of the participants said that it was really annoying having a tube in one's nose, and it affected one's mood. She was happy the day it could be removed, although it was uncomfortable when it was pulled out. One of the participants having had PEG for four months said, that he did not really think much about it. It was a necessary evil, but it did not hurt and to him it had not had any negative impact. Others described it as terrible, horrible, hated it and it was a tough time getting formula and they would rather not remember it.

The third theme was *first oral intake*. The participants were yearning to get something in the mouth after a long period of tube feeding, to get normal food and even yoghurt tasted like a grand Christmas dinner. The final theme was *modification of taste*. Their taste buds had changed since the injury. Some had also stopped smoking and they said that food tasted much better now.

### **7.3.4 Communication and meals**

Two sub-themes were identified. The first theme was *communication*. The participants just experienced minor communication problems. One said that sometimes he had trouble to speak out loudly, and it was more difficult getting the words out. After discharge he had the feeling that he had lost his voice completely. The second theme was *swallowing difficulties and meals with social*

*interactions*. Most of the participants did not feel that their previous swallowing difficulties had caused changes in their social lives after discharges. But they gave a lot of examples during rehabilitation e.g. that his parents never ate in his presence, because they felt sorry for him. Others said that it had affected them that they could not eat with the others on the ward. After discharge most of them had again joined gatherings with family and friends. But one said that he did not eat as much as at home, because he needed extra time and also tried to avoid coughing too much.

### **7.3.5 Rehabilitation of swallowing and eating**

Two sub-themes were identified. The first theme was *inpatient neurorehabilitation approach concerning swallowing and eating*. The participants expressed both positive and negative experiences concerning: guidance from the OT, oral stimulation, mobilisation of the tongue, chewing in gauze, modified consistencies and the FEES. The second theme was *rehabilitation of swallowing and eating after discharge*. Two participants needed further rehabilitation. One said that he was still coughing and had asked the community rehabilitation centre for OT treatment of the swallowing function. The other had been in several places since discharge. First, in a nursing home for six days, and then at an intensive care unit for more than one month treated for severe aspiration pneumonia. At the time of interview he had been at a new nursing home for six days, just lying in his bed and had not had any therapy at all. He had a new appointment for FEES at the inpatient rehabilitation centre one month after the last interview.

The three predominating sub-themes that emerged in the five main themes were: feeding by tube (in swallowing and ingestion), difficulties in swallowing and meals with social interactions (in communication and meals), and inpatient rehabilitation approach concerning swallowing and eating (in rehabilitation of swallowing). The predominant experiences are presented in the conceptual model of **Study II** (Figure 3, next page), which illustrates the dynamic and reciprocal interaction between the findings.

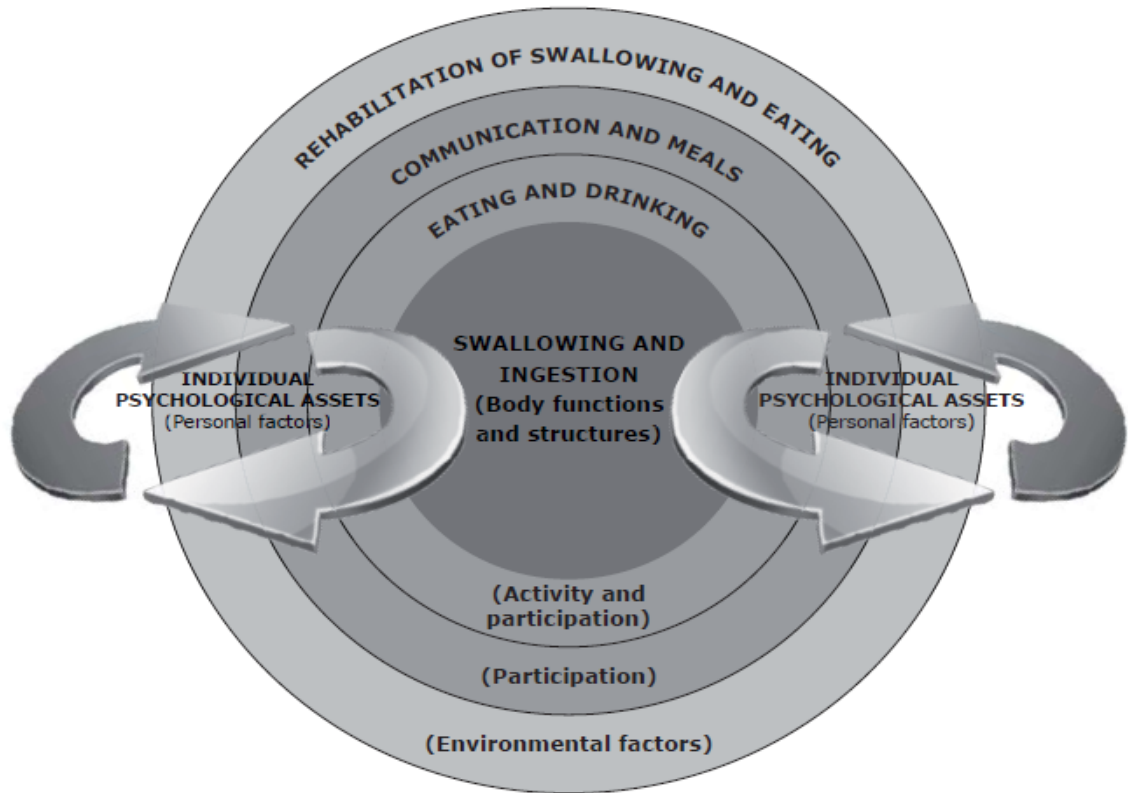


Figure 3: Conceptual model of **Study II**

## 8. DISCUSSION

The two studies included in this thesis have explored and evaluated different aspects of difficulties in swallowing and eating following ABI. Both quantitative and qualitative methods have been used in the evaluation and exploration.

To understand the complexity of the assessment of difficulties in swallowing and eating and the following discussion this section begins with a brief introduction to the different approaches used.

The majority of research on dysphagia and aspiration deals with acute settings (Barquist and others 2001; Brown and others 2011), where dysphagia is likely to be temporary (White and others 2008). Dysphagia and aspiration are important difficulties in many patients with ABI in inpatient settings. Early detection is crucial in a postacute stroke population and there is a need for reassessment on admission to IRP (Heckert and others 2009). There seems to be consensus (Farrell and O'Neill 1999; Hammond and Godstein 2006; Singh and Hamdy 2006) on the assessment of dysphagia as a three-tiered assessment cascade of screening, bedside evaluation, and objective measurement. This cascade has been described as the best clinical practice in the rehabilitation of patients with TBI in Denmark (Langhorn and others 2008). The disadvantage is that it is difficult to refer patients to objective measurements due to lack of availability.

Bedside screening is the first step to assess whether the patients have an impairment of swallowing. The next step is an in-depth bedside clinical assessment. However, the accuracy of a clinical assessment has shown to be a poor predictor of pharyngeal dysphagia (Splaingard and others 1988; Linden and others 1993; O'Donoghue and Bagnall 1999). A clinical assessment may be augmented by objective measurement (instrumental assessment), such as FEES, the Video Fluoroscopy Swallowing (VFS) also referred to as Modified Barium Swallow (MBS), or even VSE (Videofluorographic Swallowing Evaluation).

VFS allows the clinician to see where the swallowed material actually goes, e.g. if food or fluid is entering the respiratory tract, and if so, how much and whether the pharyngeal or oesophageal muscles are functioning properly (White and others 2008). For this reason VSE is regarded as being more sensitive than clinical assessment in the diagnosis of dysphagia (Lim and others 2001; Mayer 2004).

FEES is a new, but well established assessment tool in otorhinolaryngology. Scintigraphy, manometry, and acoustic assessment are much less commonly used (White and others 2008). An RCT demonstrated that if dysphagic outpatients have their dietary and behavioural management guided by the results of VFS or Fiberoptic Endoscopic Evaluation of Swallowing with Sensory Testing (FEESST), their outcomes with respect to pneumonia incidence and pneumonia-free interval are essentially the same (Aviv 2000). A multitude of studies have shown a high level of agreement between the two instrumental assessments, and the use of VFS as gold standard is no longer appropriate. It is likely that both assessments will continue to be used and will be seen as complementary tools rather than competitive ones (Langmore 2003).

The following discussion consists of three interrelated parts: the most important results from my two studies and their relation to existing knowledge; the different conceptual frameworks in the studies and the methodological considerations and limitations. Finally, the discussion has a section with implications for clinical practice.

## 8.1 Main results and insights across the two studies

### 8.1.1 Does dysphagia matter?

The incidence of dysphagia in the **Study I** population was 47%. Dysphagia is an important issue which needs attention within IRP. The incidence in this study is nearly 50% larger than that identified by the TBI study by Winstein (Winstein 1983), but almost 50% less than identified in a TBI study by Hansen (Hansen and others 2008a), and nearly identical to that reported in a stroke study by Fasetti (Falsetti and others 2009). Although these studies were conducted in multidisciplinary IRP settings and dysphagia was diagnosed clinically, it was not possible to directly compare our findings, because our study population included both patients with TBI and stroke and other studies had either or.

### 8.1.2 Are both F.O.T.T. and FEES necessary?

The findings in this thesis show that a non-instrumental approach like F.O.T.T. to assess the swallowing disorders in patients with ABI may be as effective in predicting safe swallowing and suitable time for the initiation of oral intake as an instrumental approach like FEES. Thereby it may be possible to avoid costly and time-consuming instrumental examinations. The findings show that there is no need (in terms of predicting safe swallowing) for FEES to guide the level of oral intake until recovery of total oral intake during inpatient neurorehabilitation.

This was an unexpected finding as the application of an instrumental and invasive approach like FEES in previous studies had been considered to be more reliable than a clinical approach (Splaingard and others 1988; Leder and Espinosa 2002). Leder et al (Leder and Espinosa 2002) concluded that the clinical examination, when compared with FEES, underestimated the aspiration risk in patients with aspiration risk and overestimated the aspiration risk in patients who did not exhibit aspiration risk. Their clinical swallowing examination consisted of six clinical identifiers of aspiration risk e.g. dysphonia, dysarthria, abnormal gag reflex, abnormal volitional cough, cough after swallow, and voice change after swallow. Leder also concluded that careful consideration of the limitations of clinical testing leads us to believe that a reliable, timely, and cost-effective instrumental swallow evaluation should be available for the majority of patients following acute stroke.

Interestingly, the findings from **Study I** are different from the findings in the above studies. Despite the fact that F.O.T.T. evaluates the pre-oral and oral phase of swallowing and FEES evaluates the pharyngeal phase of swallowing, both techniques produce the same outcome in respect to aspiration pneumonia and resuming oral intake. The difference in our findings could be due to our different choices of clinical identifiers. Leder's (Leder and Espinosa 2002) six clinical identifiers of aspiration are specific swallowing items (Daniels and others 2012). The assessment part of the F.O.T.T. approach, used in this thesis as the clinical criterion for initiation of oral intake (see methods), includes both swallowing and non-swallowing items (e.g. in the pre-oral phase with cognition and head and body posture). Difficulties in swallowing and eating respond to the treatment of the whole individual. Swallowing is influenced by a number of factors that must be taken into account and modified as necessary in treatment. Trapl et al (Trapl and others 2007) examined 50 consecutive patients with acute stroke and suspected dysphagia, admitted to an acute stroke unit. They found the non-invasive, non-instrumental, standardised bedside screening to be the most reliable compared to FEES to assess the risk and severity of aspiration. Similarly, in studies in acute settings, the addition of a FEES examination did not change the incidence of aspiration or post-extubation pneumonia (Barquist and others 2001; Brown and others 2011).

The findings in this thesis underline that a thorough clinical assessment like F.O.T.T. should precede any instrumental procedure. The instrumental assessment of swallowing is only part of the cascade of assessments of swallowing (Groher and Crary 2010). Our findings may implicate that a clinical assessment like F.O.T.T. should be the primary assessment, while it contains both an assessment and a treatment part and is easy to perform, and FEES may be performed in addition to F.O.T.T., to guide the planning of treatment. The advantage of FEES is the visualization of the pharyngeal phase of swallowing (before and after swallow), which is a very difficult phase to as-

sess using a clinical assessment like F.O.T.T. But clinicians must be aware that FEES is just a snapshot of the difficulties in swallowing and eating and not a whole picture.

### **8.1.3 The best swallowing protocol?**

Daniels et al (Daniels and others 2012) conclude in their systematic review of valid items for screening dysphagia risk in stroke patients that the best combination of non-swallowing and swallowing items as well as the best swallowing protocol remain unclear. With reference to the conclusion from Daniels et al, the findings from this thesis provide important new knowledge for the development of a future valid swallowing protocol with the best combination of swallowing and non-swallowing items.

Our findings imply that a non-instrumental based approach like F.O.T.T. in the assessment part consists of both swallowing and non-swallowing items, which may be as effective in predicting safe swallowing (safe in terms of no or minimal aspiration) as an instrumental approach like FEES. Furthermore, our findings emphasise that a swallowing protocol has to deal with the whole process of eating and not just the difficulties in swallowing, as supported in a systematic review by Westergren (Westergren 2006). Westergren concludes that the best nursing practice for detecting eating difficulties includes as the first step the Standardized Bedside Swallowing Assessment (SSA) to detect dysphagia (strong evidence). As the second step an observation should be made of eating including ingestion, deglutition and energy (moderate evidence).

### **8.1.4 Reduced consciousness in relation to swallowing and eating**

In F.O.T.T. the patient does not need to understand verbal communication but he/she needs a cognitive and conscious functioning corresponding to RLAS level IV (confused, agitated response) for initiation of oral intake (Mackay and others 1999a). On the other hand, Leder et al (Leder and others 2009) reported if the patient is able to answer orientation questions and follow single-step verbal commands, this is an indication that he/she could eat without aspiration. An interpretation of their findings would be that the patients should not initiate any oral intake before they are able to understand verbal communication and this is far from the F.O.T.T. practice used in a Danish neurorehabilitation context (Kjærsgaard 2005b) and evaluated in **Study I**. This part of the assessment is based on results from a previous study by Mackay et al (Mackay and others 1999b) which stated that the initiation of oral feeding required RLAS level IV. A study by Brady et al (Brady and others 2006) indicated that it is safe to provide therapeutic oral feedings to patients functioning at RLAS III if the patient: 1) does not demonstrate aspiration or aspiration is eliminated with volume or consistency modification by a baseline instrumental swallowing examination, and 2) is



given close supervision during oral feeding. So perhaps it is possible to initiate therapeutic oral feeding a little earlier than is our current practice.

Our findings in **Study I** showed that a lower frequency of patients with a higher level of cognitive skills recovered to total oral intake during IRP compared to the study of Brady et al (Brady and others 2009). Our findings may be caused by the fact that many of the patients in **Study I** were discharged to regional rehabilitation centres without reaching total oral intake, but if follow-up had been performed after regional IRP, our results might have been different.

Some of the patients in **Study I** randomized for FEES were excluded because they could not co-operate. For some of the patients with reduced consciousness it was very provoking to get the endoscope into the nose and some of them were fighting, and they were therefore excluded. In fact, Brady et al (Brady and others 2006) found that only a VSE or FEES could provide the necessary information to determine if oral feeding is safe for a patient with disordered consciousness. Brady et al (Brady and others 2009) have maintained that individuals with disordered consciousness can participate in an instrumental assessment of swallowing, which is contrary to our experience.

### **8.1.5 Other factors influencing initiation of oral intake and reaching total oral intake**

In the present study care was taken to assess those functional factors that are possible to collect from many patients in a clinical setting like Hammel Neurocenter. Hence, videofluoroscopy or direct measurements of brain function or structure were neither possible nor included here. However, it was possible to make a coarse characterization of the central nervous system lesions from patient record data (Paper I, Table 1B) that shows a fairly even distribution between the assessment groups (F.O.T.T./FEES) of brainstem injuries, being especially prone to cause dysphagia. Nevertheless, the location of brain injury may be a confounding factor when attempts were made to analyse for the importance of external factors (Paper II).

Our findings showed that the likelihood to be initiated during IRP tended to be dependent on the cognitive functioning as assessed by the RLAS score. The probability increased by 27% for each step to a higher level of RLAS. The findings in Study I were similar to the findings by Terre & Mearin (Terre and Mearin 2007) showing that the cognitive function evaluated by RLAS is the best prognostic factor of oro-pharyngeal dysphagia. The time to reaching total oral intake was shown as a minor decrease significantly with age.

Factors such as intervention group (F.O.T.T. or FEES) did not influence the probability of reaching total oral intake during IRP. Adjustment for more functional-related variables like changes in the functional independence (FIM-change) had a significant influence. A high FIM change score is an expression of good overall functional progress and increases the likelihood of

reaching total oral intake during IRP. The fact that one of 18 items in the FIM score is the item “Eating and drinking” may of course influence this to some degree. Adjustment for age revealed that an increase in age was a negative predictor of reaching oral intake during IRP. This finding is in accordance with other studies (Mann and others 1999; Ickenstein and others 2003; Hamidon and others 2006; Oto and others 2009) which found an increase in age to be the most powerful predictive factor of dysphagia outcome.

Another analysis adjusting treatment-related variables also shows that the probability of reaching total oral intake decreases significantly with an increase in age. The statistically significant effect of the number of dysphagia interventions is paradoxical in that the probability of reaching total oral intake decreased with the number of interventions received. However, this number may be a substitute for the patient’s condition i.e. many coded dysphagia interventions may reflect that the patient has a low level of functioning, required a lot of support and had a poor prognosis in terms of reaching total oral intake.

That therapy is indeed meaningful may be behind the significance of the LOS, where longer stays in IRP increased the patients’ probability of reaching total oral intake, which is similar to the results of Krieger et al (Krieger and others 2010), who showed that individuals with longer LOS were more likely to advance to three meals daily and have their feeding tube removed.

The last analysis combining the functional and treatment-related variables showed similar results to the first, which could obviously be due to the fact that the patients who received the least interventions were the patients’ with the highest functional abilities, even though the last analysis taking the patients low level of functioning into account by adjusting the treatment-related (FIM-admission and RLAS-admission) variables present on admission, does not change the strength (predictive significance) of coded dysphagia interventions and LOS.

### **8.1.6 Feeding by tube and first oral intake**

Our findings in **Study II** showed that even though feeding by tube seems to solve the participants’ swallowing and ingestion difficulties at the level of body functions and structure, it seems to have had a great impact on the participants’ level of activity and participation and their personal factors. Our findings specified feeding by tube as an important psychological impairment to be aware of as a clinician. If the participants had a nasal tube and a period of inpatient rehabilitation < 3 months, they could be classified as having had acute dysphagia (Martino and others 2010). At the time of the interview they did not experience any consequences of having had dysphagia, even though they had had a low initial GCS, long time in the intensive ward with 2-3 weeks in a mechanical ventilator, but with no episodes of acute pneumonia.

The picture was different if the participants had had both nasal and PEG tube and a period of inpatient rehabilitation for > 3 months including episodes of acute pneumonia, they could then be classified as having or having had chronic dysphagia (Martino and others 2010).

Our findings were similar to Martino et al (Martino and others 2010), where they found disparities in how acute (dysphagia < 3 months) and chronic (dysphagia > 3 months) persons prioritised the psychological impairment consequences of having dysphagia.

Our findings also corresponded with a study of Rogers et al (Rogers and others 2007) where persons with PEGs reported poor quality of life with significant deficits in all quality of life domains e.g. family life, intimate relationships, social activities, and hobbies, compared with persons not using PEG. In our study, the need for having a feeding tube seemed to leave negative experiences, and for some participants it has had a negative impact on the person's participation in social gatherings and quality of life. Especially for participants with chronic dysphagia and a long time with a PEG, the experiences were something they wanted to forget. Some of them thought that the tube delayed the initiation of oral intake. Even participants needing a nasal feeding tube for a short time expressed negative experiences about it.

During the time with tube feeding the participants in **Study II** were yearning for normal food and most of them remembered their first oral intake. Doolittle (Doolittle 1992) finds the first occasions when resuming activities to be important events: the participants speak of the first time they accomplish e.g. the first cup of tea without thickener. The participants in **Study II** had similar experiences e.g. getting the first taste of yoghurt after the ABI was like having a grand Christmas dinner.

Our findings showed that the time with tube feeding had a negative but not persistent impact on the person's quality of life. After withdrawal of the feeding tube, things often seemed to normalise, and the person used different strategies to be able to participate in social gatherings including food and drink as before the injury, did for example not take liquid together with solid food and did not go to a restaurant. Although they did not get a social life as before the injury, they got an acceptable and meaningful new life, and the time with tube feeding seemed like "a closed chapter".

### **8.1.7 Swallowing difficulties and meals with social interactions**

Some of the participants in **Study II** described that they were asked to eat in their room together with a helper and that they felt being "kept under surveillance" and kept outside the community of the patients. They were longing to be able to eat together with the other patients in the ward. They knew that it was because they had to concentrate on swallowing and eating and that they

would be distracted by the other patients, but still it was difficult for them to accept, because they wanted to be part of the social activity that the meal makes up in the ward.

Medin et al. (Medin and others 2010b) highlight the complexity of having eating difficulties after stroke. Aspects related to the participants' striving for control are based on strategies of being careful when eating, avoiding social activities, needing the help of others and analysing the consequences of eating different foods to eat safely and properly. The participants in this study were aware of eating properly, when they attended for example a dinner. So if something got stuck in the throat, they started coughing and had to leave the table, because other people should not be bothered by their coughing.

Like in our study Medin et al (Medin and others 2010b) find that in striving for control to eat safely and properly, some persons avoid activities which they used to perform when eating or in which they participated before their stroke. In our study three participants avoided drinking liquid together with food, when visiting family and did not talk and eat at the same time, so they did not eat as much as when they were eating at home. The reason for not eating that much with unfamiliar people could be fear of coughing and sense of shame for not eating properly.

### **8.1.8 Inpatient rehabilitation approach concerning swallowing and eating**

The participants in **Study II** spoke positively about the guidance they had received during inpatient rehabilitation. They expressed confidence in and satisfaction with the treatment, though sometimes they did not understand the goal of the treatment and why the treatment was needed. The predominant experiences concerning the treatment of swallowing and eating were oral stimulation and mobilisation of the tongue. It is important to emphasise that the mouth was a very intimate area to many participants and that oral stimulation with the direct contact of the therapist's finger at the participants' for example gums and tongue went beyond some of the participants usual limits. The mouth is central in the process of eating. Falk (Falk 1994) described the mouth is the most controlled opening of the body with regard to the influx (eating) but also concerning the "sublimated" outflux of speech. The mouth is the place where expression and experience meet.

All participants talked about the various ways of handling their situation, which could be understood as adaptation. Therefore the theories of adaptation were applied in the discussion of the individual losses of function as the theories provide ways of enhancing the knowledge of inside perspectives of what happens when disabilities change the conditions of everyday life.

## 8.2 Conceptual framework

### 8.2.1 The International Classification of Functioning, Disability and Health

Rehabilitation is a complex multidisciplinary, health care intervention undertaken in a complex environment (Turner-Stokes and others 2005; Shiell and others 2008). Using the ICF framework in this thesis made it possible to understand and interpret the meaning and the complexity of having difficulties in swallowing and eating following ABI. The ICF made it easier to evaluate and explore the whole process of eating. The use of the ICF framework made it possible to look at the person's difficulties in ingestion, swallowing, eating and drinking in relation to the six components of health: health condition, body functions and structure, activity, participation, environmental and personal factors.

When you deal with dysphagia, both as a patient and as a professional, you have to be aware of the importance of the whole process of eating and not just safe swallowing. So if I should argue against other authors' (Groher and Puntil-Sheltman 2010) description of difficulties in swallowing and eating, I will argue that a swallowing disorder should always be looked at both as a swallowing and a feeding disorder. As a clinician you have to look at the whole person in relation to his or her complex environment (Martino and others 2010; Medin and others 2010a).

The use of ICF as a conceptual framework in this thesis made it possible to justify and strengthen the whole rehabilitation process of the difficulties in swallowing and eating from an OT perspective and emphasise the rehabilitation focus on the level of activity and participation and not just on the level of body functions and structures. Of all the disorders that OTs evaluate and treat, the difficulties in swallowing and eating are the most medical in a traditional sense of a medical disorder being one that could potentially result in death, but it is also a very important issue related to the patient's quality of life, the ability to eat safely together with others (DeVault 1991; Jenkins 1999; Johansson and Johansson 2009).

### 8.2.2 Theories about adaptation

The ICF, if fully elaborated into a theoretical model, will tell us what will happen to a person's ambulation *if* we change his/her level of strength, but it will not tell us *how* to change the person's level of change (Whyte 2008). Whyte (Whyte 2008) asked: "Can we hope for a unified theory of rehabilitation?" The answer is: "Do not think so". In this thesis theories of adaptation were used to complement the ICF. The focus on adaptation was at the intrapersonal level (King 1978; Spencer and others 1996; Schultz and Schkade 1997) at which the adaptation to an ever-changing

environment with challenges of loss of abilities is complex and can be a long process, particularly when coping with major changes in a person's life (Jonsson and others 1999).

This process of adaptation for the participants in **Study II** is illustrated in the conceptual model of the main themes in this thesis, see Figure 3, which corresponds with Spencer's (Spencer and others 1996) concept of adaptation and the domains in the ICF framework.

The findings in thesis stressed that an ABI is a major, dramatic change and a process where the chapters in the participant's life story end and begin, and that the rehabilitation following ABI was an inherent, cumulative and prolonged process, which required a positive approach of the person with ABI. Brands et al (Brands and others 2012) describe in their clinical messages that adaptation to brain injury is an interactive and iterative process and that a serial model does not illustrate the complex process of adaptation in brain injury well. The aim of **Study II** was not to develop a model to illustrate the complex process of adaptation to the difficulties in swallowing and eating following ABI, but just to explore, understand and interpret the difficulties as processes of change. Our findings could be explicit using Spencer's description of the interactive process of adaptation that occurred between an organism and its environment.

Most of the participants experienced during time a difficult, but successful adaptation to a daily life with eating and drinking together with other people. The participants had or tried to get a positive and active role in their own lives even though not all of them could participate physically. Some of them did what "was expected from them" and others tried out themselves, not waiting for professional guidance. The participants were interacting with the specific environmental demands, and after discharge they found their way back to meals with social interaction with family and friends, even with some swallowing difficulties. Most of the participants experienced a process where they ensured individual control of swallowing saliva, initiated oral intake, had their feeding tube discontinued and became able to eat and drink all consistencies together with others. If there were still swallowing difficulties the conscious attention was not on the difficulty, but directed to the meal and to avoid coughing.

The adaptation strategies all served as stimuli for tackling the next more complex environmental challenge. This could be clarified and confirmed by using King's description of the individual adaptation as a behavioural adjustment made to ensure individual survival and self-actualisation. It was possible to identify King's (King 1978) four basic characteristics in the participants' individual adaptive process (see background section). Our findings provided knowledge about the person's ability to adapt to different conditions or environments involving eating with others, even though there had been severe difficulties right after the injury, which could be understood theoretically by using the understandings of adaptation described by both Spencer

(Spencer and others 1996) and King (King 1978) in the interpretation and discussion of the findings.

The findings emphasise that the persons with swallowing difficulties were satisfied with the guidance, even though they did not always understand the purpose of the treatment they took part in during IRP. Using the F.O.T.T. approach, the focus of attention was on meaningful activities and not exercises (Hansen and Jakobsen 2010), and according to King (King 1978) it was possible for the person to leave the organization of the sensory input and motor output to the subcortical centres (not conscious actions) where it was handled most efficiently and adaptively. The characteristic of F.O.T.T. is similar to King's (King 1978) description of the characteristic of OT and adaptation that there is always a double motivation: first, the motivation of the activity itself, and then the second motivation, recovering from illness, maintaining health, preventing disability.

The process of adaptation contained a relearning-to-eat process, a process of dealing with several losses and a process of adapting to different aspects of dependency. Our findings are similar to the finding by Hoogerdijk et al in a TBI population (Hoogerdijk and others 2011), where they found that the adaptation process is a long-term learning process that continues after IRP. At the time of the interviews the participants were in different phases of their adaptation to a daily life with swallowing and eating following ABI, some were still in IRP and others were living at home. Our findings indicate that severe difficulties in swallowing present on admission relate to a prolonging need for rehabilitation and time of recovery compared to the time frame in the illness trajectory.

Using Kirkeveld's model of stroke illness trajectory (Kirkeveld 2002) to interpret and discuss the time frame for the adaptation process provided new knowledge about the prolonging time frame of recovery and points out the participant's experiences in the different phases of the illness trajectory following ABI. The illness trajectory (Kirkeveld 2002) divides the first year after stroke into four phases, trajectory onset, initial rehabilitation, continued rehabilitation and semi-stable phase. The participant's experiences of living with difficulties in swallowing and eating were depending on the phase of the person's illness trajectory. The participants interviewed in the initial rehabilitation phase experienced a good deal of discomfort, including fear of aspiration and pneumonia and uncertainty in relation to eating although they were fairly independent in daily living. The time frame of recovery was prolonging as the participants discovered that the symptoms took longer to disappear regardless of intense work on their part. They were still hoping for continued rehabilitation of swallowing in order to continue the recovery process. The participants interviewed in the semi-stable phase of rehabilitation six to 18 months after injury, experienced that they had "normalised" eating, the meaning of food was the same as before the injury, they

had reached a point in their illness trajectory, where they did not worry about their possible swallowing and eating difficulties.

Perry and McLaren (Perry and McLaren 2003) find that eating-related activities are both an integral component of the rehabilitation process and markers of the relative “normality” of life six months after stroke, but in our findings the process of adaptation was prolonged compared to their study, the participants in our study were going on with life while adapting to the long-term effects of ABI and resuming valued activities, which is the ultimate goal of OT (King 1978) as well as in rehabilitation (Fugel-Meyer and Fugl-Meyer 1988) in general.

## 8.3 Methodological considerations and limitations

### 8.3.1 Methodological considerations

#### Study I

The most powerful experimental technique for assessing the effectiveness of an intervention (Robbins and others 2004; Whyte 2007) was chosen for **Study I**. The advantage in **Study I** was its prospective study design, which asks a question and looks forward. The study was designed before any information was collected. Its outcome was assessed relative to the intervention (F.O.T.T. or FEES). The RCT has long been held up to the “golden standard” of research evidence and is by some regarded as the only golden standard in research related to interventions (Kersten and others 2010); on the other hand, such designs are perhaps the most ethically challenging approach to research and with research subjects who cannot provide their own informed consent, the ethical complexities mount (Whyte 2007). The complexity of the rehabilitation intervention makes it difficult to describe an intervention and to identify the specific features being studied or those being effective, which in turn leads to difficulties in controlling for bias arising from expectations in the patient or treating team. In this thesis it was possible to define more than one “primary outcome”; the proximate goal in biomedical research is often pathophysiological which was possible in **Paper I** with aspiration pneumonia during IRP. Whereas in **Paper II** it became more complicated to measure the time to recovery of total oral intake during IRP, because IRP is usually at the levels of whole body function, activities, and social participation; follow-up periods are much longer; and relationships between other influencing factors are non-linear (Wade and others 2010).

One of the disadvantages of the prospective RCT design in **Study I** was the time used to carry out the study and the data collection period was nearly two years. Although we achieved the numbers of the power calculation there was still a potential failure of a Type II error (Kirkwood



and Sterne 2003) e.g. there was a risk of a documentation in the patients medical record concluding that an aspiration pneumonia was not present when it was.

Furthermore, it was difficult to monitor people for a long time and our goal was 90 days after admission to IRP, but this was not possible, so we chose the time window from admission to discharge from IRP. A lot of the studies (Winstein 1983; Hansen and others 2008a; Hansen and others 2008b; Krieger and others 2010), with which we compare our data, are retrospective studies, pose a question and look back. They use information that has usually been collected for reasons other than research, such as administrative data and medical records with a lower data quality.

Another methodological consideration was about the difficulty in describing the F.O.T.T. assessment part in **Study I**, where individual items of the F.O.T.T. approach were selected (in close cooperation with other F.O.T.T. experts). The assessment part of F.O.T.T. has not earlier been validated and published, and a validation process was not part of this PhD thesis. It was not easy to describe the different clinical F.O.T.T. interventions and to separate assessment from treatment. Usually the F.O.T.T. approach is described, taught and practiced as a process of evaluation and treatment, which starts with an analysis of the patient's problems and then continues to the next steps to set goals, select tasks, initiate treatment, evaluate treatment and then a new analysis etc. The intervention implies a circular rather than a linear process. So measuring treatment effects in rehabilitation research differs from biomedical research in several ways.

## **Study II**

Questions about credibility, applicability, consistency and neutrality (Ohman 2005; Curtin and Fossey 2007; Creswell 2009a; Brinkmann and Tanggaard 2010) were in focus when evaluating the scientific rigour in **Study II**. To contribute to the credibility of the study (Curtin and Fossey 2007) a triangulation with data from **Study I** (data from medical files) and interviews was performed together with a peer debriefing with two skilled researchers involved in the analysis and interpretation of the data and a member checking the transcripts of the interviews.

Applicability relates to the concept of transferability (Ohman 2005). Given the qualitative design of **Study II**, our findings were not intended to be generalized globally (Kvale and Brinkmann 2009; Creswell 2009a), but analytical generalization (Kvale 2007; Kvale and Brinkmann 2009) may be drawn from the interviews regardless of sampling and mode of analysis. Analytical generalization rests upon rich contextual descriptions and includes the researcher's argumentation for the transferability of the interview findings to other subjects and situations, as well as the readers' generalizations from the paper. However, with regard to transferability (Malterud 2009; Brinkmann and Tanggaard 2010) there are reasons to believe that the variety of experiences of difficulties in swallowing and eating in different phases of recovery following ABI is not unique to the

participants of this study. Thus, it is possible that similar results could be found in other persons with ABI. The transparency in a rich description of the setting, the steps in the data recording and findings were in view when writing the study (Curtin and Fossey 2007) and may increase the transferability of the study.

Consistency or dependability relates to the ability of the researcher in being flexible and able to change the perspective in accordance with the emerging process (Ohman 2005). The interviewer developed different strategies to mitigate the challenges of interviewing persons with ABI e.g. preparation, tolerance of extraneous stimuli and patterns of fatigue, selection of interview questions, debriefing to facilitate the participants' description of their experiences and to obtain their full and active participation (Paterson and Scott-Findlay 2002). Readers of this thesis should from the rich, thick description of the participants and setting provided, be able to determine if the findings can be transferred to their own contexts. The aim was to interview the person with ABI and not any proxy, as other studies conclude that proxy responses should be used with caution for questions about social activities and degree of satisfaction with participation (Dawson and others 2005; Hart and others 2010). It is important to emphasise that they were all able to verbally articulate their experiences in a reflective and meaningful manner (Carlsson and others 2007).

Neutrality is viewed slightly differently in qualitative methodology than in quantitative research. We are all coloured by previous knowledge, experiences and hypotheses, and it is important that we, as researchers, reflect upon our previous understanding (Ohman 2005). During the whole study period, I was very aware of my role as the researcher/practitioner and that I was the instrument through which data were gathered, analysed and interpreted. I have earlier worked as a developmental OT at the centre (not as a practitioner), and during the PhD period I was not part of the clinical rehabilitation. Nevertheless, the influence of my professional status might have influenced the research process both positively and negatively (Conneeley 2002). The participants had knowledge of my position as a PhD student at the centre and of my professional identity as former practitioner as an OT. My pre-understanding and experiences provided a common understanding between the participants and me as the researcher and they assumed my familiarity with the rehabilitation context which had been a significant part of their recent experience.

During some of the interviews direct questions were asked and advice and directions were requested. Obviously, in this situation I was regarded as the "expert", having professional knowledge (Cotterill and Letherby 1994). These issues at times caused conflict for me in my role as a researcher. This was sometimes resolved by advising the participants to contact the relevant professional in the community, or if I could be helpful, we took the questions after the interview. I

was aware that my role was not that of a counsellor (Cotterill and Letherby 1994; Conneeley 2002).

### **Study I and II**

The use of both quantitative and qualitative methods in a single research project has been a subject of considerable controversy and still remains a relatively uncommon practice in the study of health and illness (Clarke 2009). The combination of both a quantitative (**Study I**) and a qualitative (**Study II**) method in this thesis was found to be very useful and a major strength. Although the thesis was not designed within the mixed methods terminology, the use of different research techniques in parallel or sequential studies to inform and complement each other could be referred to this method (Creswell 2009b). For the mixed methods researcher, the study will take extra time because of the need to collect and analyse both quantitative and qualitative data (Creswell 2009b). These designs imply that researchers have a wide range of methodological skills and being an “expert” in both quantitative and qualitative methods may be unrealistic (Rauscher and Greenfield 2009). A triangulation of quantitative and qualitative methods may strengthen the credibility (Creswell 2009a) and has been suggested as an appropriate approach to be able to capture a more comprehensive understanding of subjective well-being following stroke (Clarke 2003; Clarke 2009). Mixed methods are especially well suited to study the complex processes of disablement in the WHO’s ICF (WHO 2001), namely the dynamic relationships between physical and psychosocial contextual factors that influence recovery (Jette 2006). In other words, the combination of methods in this thesis has hopefully increased the understanding of the difficulties in swallowing and eating following ABI.

As final methodological considerations, it had, for me as a PhD student, been a great benefit that I had worked at Hammel Neurocenter for eight years ahead of the PhD. I had longstanding clinical knowledge of the difficulties described in this thesis and exhaustive knowledge of the organization and the large group of OTs in clinical practice, which made this thesis possible. On the other hand, my neutrality could be considered, because of my longstanding clinical knowledge and my certification as a F.O.T.T.<sup>TM</sup> Instructor, where I am conducting approximately four (one week) G/F.O.T.T. courses yearly. But as I declare in the section of the financial and other conflicts of interest, I do not have any personal financial interest other than conducting courses in F.O.T.T.. With the RCT design, it was not possible to influence the results, because as the person handling outcome data, I was not aware of a patient’s allocation until the code of the randomization was broken.

### 8.3.2 Limitations

#### Study I

This study has some limitations. In spite of our power analysis, the incidence of aspiration pneumonia was low, which may cause a type II error, i.e. give too little sensitivity. Furthermore, the inhomogeneity of the neurological diagnoses among the present patients may influence the incidence of dysphagia, making interpretation difficult. However, as is evident from Table 1B in **Paper I**, the diagnoses have a reasonably symmetrical distribution between the two groups.

It should also be noted that the efficacy or effectiveness of F.O.T.T. as a treatment intervention is unknown and not scientifically evaluated. However, F.O.T.T. is already an accepted standard intervention in Danish neurorehabilitation. The fact that FEES is an instrumental procedure may indicate a higher threshold for its use in everyday clinical practice. If so, not using it may raise the possibility that undetected aspiration pneumonias could become more common.

Furthermore, there is a remaining uncertainty whether the frequency of silent aspiration was different between the two groups, since the relation between aspiration and pneumonia is not absolute. This is a consequence of the selection of a chest radiograph verified aspiration pneumonia as the primary outcome, rather than aspiration detected by videofluoroscopy, which was not available for economic and organizational reasons.

Five of the 119 patients were included more than 12 months after injury, with a more chronic dysphagia problem and these patients could have been excluded from the study. The intervals between some cases of pneumonia and oral intake were considerable, which called for alternative interpretations. We investigated the co-morbidity factor smoking, which did not influence the development of pneumonia. The relation between other co-morbidity factors as e.g. history of stroke, Chronic Obstructive Pulmonary Disease needs to be addressed in future prospective studies of patients with ABI. In **Paper II** there were many censored cases in the analyses of time to total oral intake, which leaves a rather small material to be analysed, with the risk of a type II error.

It has also been difficult to perform research in this study population because of the difficulties in getting an approval of **Study I** from the Ethical Committee, because I also wanted to include patients who were not able to sign an informed consent, but in Denmark we need surrogate consent from both relatives and the patient's general practitioner or the medical public health officer before inclusion and randomization. Another factor that made inclusion difficult was that many of the patients did not have any relatives to sign the surrogate consent form, resulting in exclusion of some patients, which could have interfered with the external validity.

The aim of **Study I** was to investigate the highly complex IRP of difficulties in swallowing and eating during daily, clinical, inpatient neurorehabilitation practice. I was concerned to carry out an RCT in IRP, because of the above-mentioned ethical challenge that 50% of the patients could not get a FEES examination. Hammel Neurocenter got the possibility for FEES already in 2002. In the beginning of **Study I** it was difficult for the clinicians to rely on their clinical assessment, if the patient was randomized to F.O.T.T. Sasaki & Leder (Sasaki and Leder 2009) have commented on the Danish retrospective study by Hansen et al (Hansen and others 2008a) “that no statement can be made about the benefit of F.O.T.T. to recovery of oral or swallowing function because there was no control group. Future research using a prospective, randomized design with both an experimental and a control group needs to investigate the impact of rehabilitation of swallowing”. The majority of the interventions with ABI rehabilitation are supported by limited evidence (Cullen and others 2007), and there are very few RCT studies including OT-related interventions (Gillen 2010). Two RCT studies with relatively small numbers of patients were found with dysphagia intervention related to ABI (Hamdy and others 2003; Terre and Mearin 2012). However, we succeeded in carrying out an RCT in a clinical setting including 119 patients with a lot of effort from the OTs in clinical practice and found evidence and were able to state that the patients with ABI could benefit from the dysphagia-related OT interventions in the F.O.T.T. approach.

Another limitation in **Study I** was the use of some not validated instruments. The Danish version of the BDI (Appendix 2), A Danish version of PAS are not forward-backward translated and validated in a Danish context and the Danish version of FOIS (Hansen and others 2008a) has not been validated in a Danish context.

In **Study I** it could be considered as an intervention bias that it was not the same OT, with the same knowledge and skills who had been assessing and treating all the patients, but that was impossible when collecting data in a daily clinical practice. There might have been a difference in how F.O.T.T. and FEES were carried out among the two groups. Another bias might have been that there was no blinding of the participants and interventions. It was, however, an advantage that the author and co-authors, as the data analysts assessing the primary outcome, were blinded to the treatment allocation (Lewis and Warlow 2004).

## **Study II**

A limitation in **Study II** was that the participants were selected from the same rehabilitation facility and a larger RCT **Study I**, so they represent a selected group of people with ABI during or after neurorehabilitation rather than the ABI population in general. In transferring the results, it is also important to consider the limitation that the participants had a moderate or severe ABI, and they were all able to articulate their experiences in a reflective and meaningful manner. Only three of

them had physical impairments at the time of the interview, but all of them have had severe difficulties in swallowing, eating and drinking during the time of IRP. Hopefully, they can be the voices of people with ABI with e.g. cognitive and communication difficulties in addition to their ABI (Carlsson and others 2007).

Nevertheless, it is important to consider that inclusion of only six participants might be a limitation of the study. Inclusion of new participants until a point of saturation, where further interviews yield little new information (Kvale and Brinkmann 2009), might have added additional difficulties and consequences than those found here. Achieving saturation was not possible within the time and resources of this PhD thesis. Four of the participants were interviewed only once, which could have been a weakness, as repeated interviews (Brinkmann and Tanggaard 2010) might have produced more information and increased the trustworthiness of the statements given by the participants.

The SWAL-QOL and CARE are not well-known and the Danish version used in this thesis (Appendix 3) is not forward-backward translated and validated in a Danish context, but it is validated in its original language English (McHorney and others 2002), Dutch (Bogaardt and others 2009) and Swedish (Finizia and others 2012). It is mostly validated in patients with head and neck cancer (Rinkel and others 2009). It is a relevant tool enabling data collection on both the patient perspective of difficulties in swallowing and eating and the related care received and the responsiveness to processes of change. It is, however, difficult to directly implement it in a Danish neurorehabilitation context. Such a tool needs to be completed by both patients and/or their relatives; otherwise it will not capture the experiences of patients with severe ABI. The contents also need to be extended with questions about having or having had a feeding tube.

## 8.4 Implications for clinical practice

Effective swallowing, food and drink are essential parts of human life. The ability to swallow and eat without difficulty provides satiety and pleasure and is one of the most important aspects of social life. The complexity of having difficulties in swallowing and eating following ABI places special demands on the healthcare professionals, who are taking care of the patients with ABI and their relatives. Both specialized professional knowledge and understanding of the patient's perspective are required.

In order to provide the best available assessment and treatment of the difficulties in swallowing and eating during inpatient neurorehabilitation, the implications for clinical practice are:

- A clinical non-instrumental assessment like the F.O.T.T. approach and an instrumental assessment like FEES are of equal clinical importance to prevent aspiration pneumonia.
- Since F.O.T.T. is a simple, readily available and repeatable assessment that can provide a 24/ picture, it is recommended as a standard procedure.
- The chance of recovery to total oral intake before discharge is found to depend on age and FIM score changes, length of stay and the number of dysphagia interventions, which implies that additional considerations in clinical practice have to be given to those factors identified as predictive for the initiation of and recovery to total oral intake to achieve optimal outcome.
- Feeding by tube provides an impact on the quality of life and is an experience that the person with ABI prefers to repress. Clinical practice has to be aware of not prolonging the use of PEG and how important the first oral intake is.
- Initiation of oral intake is the main treatment goal when the person with ABI has no oral functions and first oral intake provides strong impressions.
- The mouth is a very intimate area, but at the same time an area that needs professional attention in relation to treatment of swallowing and eating difficulties. Therapists treat for example reduced sensibility and motor functions in the tongue and other structures in the oral cavity to enable or improve the person's abilities to swallow and eat. Therefore, it is important for the therapist to understand that the mouth is an intimate area for the patient, but at the same time an area that may require professional attention. Hence it is important for clinical practice to use meaningful activities related to treatment of the difficulties in swallowing and eating, and when using exercises like oral stimulation it is very important to inform the patient either verbally or tactilely about the purpose of the stimulation. Alternatively, the

therapist may use another strategy like the daily activity mouth hygiene, where it is possible to reach the same treatment goal as using oral stimulation.

- Eating together with other patients during inpatient neurorehabilitation is an important issue. Therefore it is important for the clinician not just to focus on safe swallowing, while the person eats and drinks the right consistencies in a quiet room in the ward with a proper head and body position. The person also needs to be able to do the same together with other people, which need to be included in the treatment planning along with the focus on swallowing safety, so that the patient is not discharged without trying out these, very important activities.
- It is important that the therapist stimulates and guides the individual's process of adaptation and provides the right local environment, which the person understands, to allow him to perform both competently and appropriately, so he is able to make adaptive transitions and applications of his repertoire to new circumstances. Interpretation of the participants' experiences in relation to the concept of adaptation contributes insight to the strategies employed by ABI survivors. It prompts the therapists to think not only about major life changes as something that occur solely within the individual person but as a change in the relationship between the person and his environment over time, which may involve changes in both entities and interaction between them. This information is valuable for both treatment planning, common goal-setting and enabling the therapist in supporting our clients to maintain continuity and a coherent life story in times of change.



## 9. CONCLUSIONS AND FURTHER STUDIES

### 9.1 Main conclusions

Based on the results from the two studies the following main conclusions were drawn:

- Dysphagia is frequent in patients with ABI in inpatient neurorehabilitation.
- A non-instrumental based approach like F.O.T.T. to assess swallowing disorders in patients with ABI may be as effective in predicting safe swallowing (safe in terms of no or minimal aspiration) and suitable time for initiation of oral intake as an instrumental approach like FEES. Thereby it may be possible to avoid costly and time-consuming instrumental examinations.
- There is no need (in terms of predicting safe swallowing) for FEES to guide the level of oral intake until recovery of total oral intake during inpatient neurorehabilitation.
- The chance of recovery to total oral intake before discharge is found to depend on age and FIM score changes, LOS and the number of dysphagia interventions.
- Living with difficulties in swallowing and eating following ABI varies depending on the different phases of the illness trajectory.
- The reduced or lost ability to swallow and eat, even temporarily, is unexpected, difficult and arouse strong emotional reactions even 18 months after the injury.
- The participants experienced that it was possible to adapt and to develop new strategies for valued activities related to swallowing and eating, as they strived to live their everyday life.

## 9.2 Further studies

Future research should include a validation of the F.O.T.T. assessment of mouth and oral tract, used in this thesis. Other studies of relevance include interventional RCT studies of F.O.T.T. against other standard treatment approaches with studies of swallowing and eating disabilities in IRP, as well as evaluation of long-term outcomes of persons with ABI. Therefore, a future RCT study related to F.O.T.T. could be an efficacy study of the oral stimulation routine. Another intervention study related to F.O.T.T. could be tongue motor training, which has also been shown to be a very strong peripheral sensory stimulation (Martin 2009). Both tongue motor training (Davies 1994) and oral stimulation routine (Kjærsgaard 2005a) are very well defined F.O.T.T. interventions that are possible to isolate from the more holistic approach, which makes it easier to investigate e.g. an RCT against other standard interventions.

Finding reliable and validated outcome measures within rehabilitation of difficulties in swallowing and eating of patients with ABI (both stroke, TBI and other severe ABI) is still a challenge. A suggestion for future research is to evaluate the FOIS in relation to documentation of modified consistencies of food and liquid to evaluate if the level of modified consistencies provides a more reliable and clinically relevant description of the patient's level of functioning than FOIS.

A holistic perspective is needed in future studies of dysphagia in persons with ABI, research should include not just safe and efficient swallowing, but also the whole eating process and the person's whole life situation, in order to develop theories and to test them in clinical settings. Based on these theories and exploration of the complex eating process, more sensitive instruments and methods have to be developed in a European or even better in a Scandinavian neurorehabilitation context. A translation and validation of The SWAL-QOL and CARE questionnaire into Danish and modifying it to inpatient neurorehabilitation of patients with ABI would be one way to collect more qualitative data from a patient's perspective.

When evaluating the symptom dysphagia, physiological measures for protection of the airway are important to use in combination with self-report instruments representing the patient's perspective (Finizia and others 2012). Using self-report instruments within IRP need a focus on the persons taking nutrition non-orally (feeding by tube) for a long period of time (McHorney and others 2002) and should consider the average reading level needed to understand a particular Patient-related outcome questionnaire when administering it to a patient or his/her proxy (Zraick and others 2012; Finizia and others 2012).

The mouth and its importance for the person with ABI would be interesting to explore in further studies within a humanistic health research paradigm. The correlation of this phenomenon and the impact of e.g. the therapeutic intervention oral stimulation are suggested as subjects for

investigation. The mouth - the oral structures and sensory/motor functions are an important area of concern in rehabilitation of swallowing and eating, but it is for the patient a very intimate area and therefore the therapist often triggers some very basic and human reactions that we may not be quite aware of.

Another area of concern within the humanistic health research paradigm that needs investigation is the importance of the social life around meals at the ward, which should be seen both from a patient and a professional perspective.

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