Olfactory function after total laryngectomy in
Swedish patients after rehabilitation with the
Nasal Airflow-Inducing Maneuver

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Göteborg 2008
ABSTRACT

After a total laryngectomy the upper and lower airways are disconnected resulting in a wide range of adverse effects, e.g. deterioration of nasal functions in breathing, loss or decrease of normal sense of smell and taste, as well as loss of normal voice. Recently, a new method that can restore the sense of smell in laryngectomized patients has been developed, the Nasal Airflow-Inducing Maneuver (NAIM). The overall aims of this thesis were: 1) to describe the olfactory function in laryngectomized patients and to assess the results of repeated interventions with the NAIM; 2) to evaluate the long-term results 6 and 12 months after intervention; 3) to assess olfaction, health-related quality of life (HRQL) and communication 36 months after NAIM intervention; and 4) to use a clinical protocol to follow changes in the NAIM technique over time.

The study population consisted of 24 laryngectomized patients. Olfaction acuity was examined with the Scandinavian Odor Identification Test (SOIT). The patients were categorized as smellers (normosmia or hyposmia) or non-smellers (anosmia) based on the SOIT results. Their self-estimation of smell, taste, health-related quality of life and communication were measured with validated questionnaires. According to SOIT, 18 of 24 patients (75%) had impaired sense of smell before NAIM rehabilitation and 72% improved their sense of smell after 3 NAIM rehabilitation sessions. Further improvement was also seen at the 6 and 12 month follow-up, i.e. 83% and 88% respectively, were categorized as smellers according to SOIT results. Three years after NAIM rehabilitation all patients still alive (n=18) were re-examined and as many as 78% were still smellers. In addition, the patients reported an overall good HRQL and no mental distress. According to a structured protocol it was possible to identify improvements in NAIM key variables associated with improvements of the sense of smell over time.

It was concluded that olfactory impairment is common in laryngectomized patients, that NAIM is an effective method for restoring the sense of smell, and that the improvements endure in long-term. Consequently, olfactory rehabilitation according to the NAIM should be incorporated into routine rehabilitation programs for all laryngectomized patients. Furthermore, a protocol is a useful and reliable tool for evaluating use of the NAIM. Moreover, HRQL questionnaires should be complemented with more diagnose specific questionnaires when evaluating olfaction and communication in laryngectomized patients.

Key words: olfaction, total laryngectomy, Nasal Airflow-Inducing Maneuver, health-related quality of life.
LIST OF PUBLICATIONS

This thesis is based on the following papers, referred to in the text by their Roman numerals:

I. Screening and rehabilitation of olfaction after total laryngectomy in Swedish patients
   *Results from an intervention study using the Nasal Airflow-Inducing Maneuver*
   Risberg-Berlin B, Ylitalo R, Finizia C

II. Effectiveness of olfactory rehabilitation with the Nasal Airflow-Inducing Maneuver after total laryngectomy
   *One-year follow-up study*
   Risberg-Berlin B, Ylitalo Möller R, Finizia C.

III. Effects of total laryngectomy on olfactory function, health-related quality of life, and communication: A 3-year follow-up study
   Risberg-Berlin B, Rydén A, Ylitalo Möller R, Finizia C
   Submitted Arch Otolaryngol Head Neck Surg

IV. Development of a clinical instrument improving rehabilitation of olfaction with the Nasal Airflow-Inducing Maneuver in Swedish laryngectomized patients
   Risberg-Berlin B, Rydén A, Ylitalo Möller R, Finizia C
   In print Acta Oto-Laryngologica

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### ABBREVIATIONS

<table>
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<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>CCCRC</td>
<td>Connecticut Chemosensory Clinical Research Center</td>
</tr>
<tr>
<td>CN</td>
<td>Cranial Nerve</td>
</tr>
<tr>
<td>EORTC</td>
<td>The European Organization for Research and Treatment of Cancer</td>
</tr>
<tr>
<td>EORTC QLQ-C30</td>
<td>The EORTC Quality of Life Questionnaire Core 30</td>
</tr>
<tr>
<td>EORTC QLQ-H&amp;N35</td>
<td>The EORTC Quality of Life Questionnaire Head and Neck Module</td>
</tr>
<tr>
<td>HADS</td>
<td>The Hospital Anxiety and Depression Scale</td>
</tr>
<tr>
<td>H&amp;N</td>
<td>Head &amp; Neck</td>
</tr>
<tr>
<td>HEOG</td>
<td>Human Electro-Olfactogram</td>
</tr>
<tr>
<td>HME</td>
<td>Heat and Moisture Exchange</td>
</tr>
<tr>
<td>HRQL</td>
<td>Health Related Quality of Life</td>
</tr>
<tr>
<td>NAIM</td>
<td>Nasal Airflow-Inducing Maneuver</td>
</tr>
<tr>
<td>OERP</td>
<td>Olfactory Event-Related Potential</td>
</tr>
<tr>
<td>POPS</td>
<td>Present Odor Perception Scale</td>
</tr>
<tr>
<td>QoL</td>
<td>Quality of Life</td>
</tr>
<tr>
<td>QOTA</td>
<td>Questions on Odor, Taste and Appetite (later called AHSP; The Appetite, Hunger feelings and Sensory Perception questionnaire)</td>
</tr>
<tr>
<td>SEMA</td>
<td>Swedish Emergency Management Agency</td>
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<tr>
<td>SLP</td>
<td>Speech Language Pathologist</td>
</tr>
<tr>
<td>SOIT</td>
<td>Scandinavian Odor Identification Test</td>
</tr>
<tr>
<td>S-SECEL</td>
<td>The Swedish Self-Evaluation of Communication Experiences after Laryngeal Cancer</td>
</tr>
<tr>
<td>TNM</td>
<td>Classification system for malignant tumors; Tumor, Node, Metastases</td>
</tr>
<tr>
<td>UICC</td>
<td>Union International Contre le Cancer</td>
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INTRODUCTION
In Sweden the incidence of head and neck (H&N) cancer is around 1500 cases annually. Cancer in the larynx is the most common H&N site, with approximately 200 new cases per year [1]. During the last 10 years the incidence of laryngeal cancer in the Western world has increased among women by 4.9% but decreased with 0.8% among men [2]. Tobacco and alcohol use, particularly in combination, are considered the main predisposing factors [3, 4]. The dominating histopathological type of laryngeal cancer worldwide is squamous cell carcinoma. The laryngeal tumors are classified according to a global standard, the TNM-staging system and developed by the International Union against Cancer [5]. This classification describes tumor stage (T1-4), regional metastases (N0-3) and distant metastases (M0-1). For description of the localization of the tumor the larynx is divided into three anatomical regions 1) the supraglottic 2) the glottic and 3) the subglottic (Figure 1 and Table 1).

Figure 1. The three anatomical regions of the larynx.
## Table 1. TNM-classification and staging of laryngeal cancer (UICC, TNM, Classification of Malignant Tumors 6th ed, 2002)

<table>
<thead>
<tr>
<th>T-stage</th>
<th>Supraglottic</th>
<th>Glottic</th>
<th>Subglottic</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>T1</strong></td>
<td>One subsite, normal vocal cord mobility</td>
<td>Limited to vocal cord (s), normal mobility T1a one vocal cord T1b both vocal cords</td>
<td>Limited to subglottis</td>
</tr>
<tr>
<td><strong>T2</strong></td>
<td>Mucosa of more than one adjacent subsite of supraglottis or glottis or region outside the supraglottis; without fixation of the larynx</td>
<td>Supraglottis, subglottis, impaired vocal cord mobility</td>
<td>Extends to vocal cord (s) with normal/ impaired mobility</td>
</tr>
<tr>
<td><strong>T3</strong></td>
<td>Vocal cord fixation or invades postcricoid area, pre-epiglottic tissues, paraglottic space, thyroid cartilage erosion</td>
<td>Vocal cord fixation, paraglottic space, thyroid cartilage erosion</td>
<td>Vocal cord fixation</td>
</tr>
<tr>
<td><strong>T4a</strong></td>
<td>Through thyroid cartilage; and/or invades tissues beyond the larynx</td>
<td>Through thyroid cartilage and/or invades tissues beyond the larynx</td>
<td>Through cricoid or thyroid cartilage and/or invades tissues beyond the larynx</td>
</tr>
<tr>
<td><strong>T4b</strong></td>
<td>Prevertebral space, mediastinal structures, carotid artery</td>
<td>Prevertebral space, mediastinal structures, carotid artery</td>
<td>Prevertebral space, mediastinal structures, carotid artery</td>
</tr>
</tbody>
</table>

**Regional lymph nodes (N-stage)**

N1 Ipsilateral single \( \leq 3 \) cm

N2

(a) Ipsilateral single \( > 3 \) cm to 6 cm

(b) Ipsilateral multiple \( \leq 6 \) cm

(c) Bilateral, contralateral \( \leq 6 \) cm

N3 \( > 6 \) cm

**Distant metastasis (M-stage)**

M1. Distant metastasis present

<table>
<thead>
<tr>
<th>Staging of laryngeal cancer</th>
<th>T</th>
<th>N</th>
<th>M</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stage I</strong></td>
<td>T1</td>
<td>N0</td>
<td>M0</td>
</tr>
<tr>
<td><strong>Stage II</strong></td>
<td>T2</td>
<td>N0</td>
<td>M0</td>
</tr>
<tr>
<td><strong>Stage III</strong></td>
<td>T1, T2</td>
<td>N1, N0, N1</td>
<td>M0, M0</td>
</tr>
<tr>
<td><strong>Stage IVA</strong></td>
<td>T1, T2, T3, T4a</td>
<td>N2, N0, N1, N2</td>
<td>M0, M0</td>
</tr>
<tr>
<td><strong>Stage IVB</strong></td>
<td>T4b, Any T</td>
<td>Any N, N3</td>
<td>M0, M0</td>
</tr>
<tr>
<td><strong>Stage IVC</strong></td>
<td>Any T</td>
<td>Any N</td>
<td>M1</td>
</tr>
</tbody>
</table>
The treatment for laryngeal cancer includes surgery, radiation and chemotherapy, or a combination of these, depending on type and size of the tumor. In most cases radiation is sufficient, but sometimes surgery is performed, i.e. in small tumors (laser surgery) or in larger tumors and cases of recurrence (laryngectomy). In Sweden approximately 50-60 patients are operated annually with a total laryngectomy due to laryngeal cancer. Total laryngectomy will lead to loss of natural voice, decreased lung function and sense of smell and taste with associated physical and psychological consequences [6]. The prevalence of hyposmia (reduced olfactory acuity) and anosmia (no olfactory acuity) in this patient population ranges from 68% [7] to 100% [8], depending on method of assessment. Despite these well-known side effects, there is a scarcity of studies on sense of smell and taste as well as their impact on quality of life in patients with laryngectomy [6, 7].

Olfactory system

Olfaction is a chemical sense which is important for detecting and identifying pleasant and unpleasant, as well as dangerous, odors in our environment and for triggering distinct memories or emotional moments. Our ability to recognize and remember 10000 different odors was not understood until 1991 when Axel and Buck (awarded the 2004 Nobel Prize in Medicine) published their description about one thousand different genes for odorant reception [9]. A schematic description is given in Figure 2.

The olfactory system comprises the olfactory epithelium and olfactory nerves, the olfactory bulb and tract, and several areas of olfactory cortex [10]. The olfactory epithelium is located at the top of the nasal cavities and consists of olfactory neurons with olfactory hairs, cilia. The cilia contain receptors for capturing the odorant molecules and the odorant information is passed on to the brain via nerve processes. As soon as olfactory information reach the brain, the odor can be detected, consciously or unconsciously, and thereby an action or reaction may be initiated.
Odorant Receptors and the Organization of the Olfactory System

1. Odorants bind to receptors

2. Olfactory receptor cells are activated and send electric signals

3. The signals are relayed in glomeruli

4. The signals are transmitted to higher regions of the brain

Figure 2. http://nobelprize.org/nobelpries/medicine/aureates/2004/press.htm
Different ways of smelling

*Orthonasal and retronasal olfaction*

The ability to smell is a natural function that is permanently and unconsciously ongoing. Breathing in and out through the nasal cavity is a major part of this process. The odorant molecules automatically reach the olfactory epithelium in two ways during breathing: through the anterior nasal entrance via the inspiratory airflow (i.e. by orthonasal olfaction), or through the posterior nasal entrance via the expiratory airflow (i.e. by retronasal olfaction), Figure 3. Adequate delivery of the odor molecules via the nasal airflow to the peripheral olfactory epithelium is crucial for stimulation of the orthonasal olfaction. In normal situations there is “passive” smelling during passive orthonasal breathing, and “active” smelling by deeper orthonasal breathing through the nose [11]. Sniffing increases the volume and flow rate of the incoming air augmenting sense of smell in the nose and to the olfactory region [12]. The positive correlations between orthonasal airflow and various olfactory parameters, e.g. estimation of odor intensity [13], percentage of correctly recognized odors [14], and magnitude of activated odorant receptors [15], is well documented.

Smelling may also occur on an expiratory airflow from the oral cavity via the nasopharynx to the olfactory epithelium when breathing out, swallowing or chewing [16, 17]. This is called the retronasal olfaction and plays an important part in identifying the gustation [18]. Chewing to intensify retronasal olfaction can be compared to sniffing for intensifying orthonasal olfaction (Figure 3).

*Figure 3.* Normal smelling with orthonasal and retronasal airflow. The anatomical image by courtesy of Atos Medical AB.
Olfaction – Cranial Nerves

Odorant molecules may also stimulate free nerve endings of three cranial nerves: the trigeminal nerve (CN V), glossopharyngeal nerve (CN IX), and vagus nerve (CN X). A chemosensation is perceived as irritation, tickling, burning, warming, cooling and stinging [19]. These nerves are, therefore, considered as protecting against irritating odors [20].

Reduced sense of smell

Reasons for reduced (hyposmia) or complete loss (anosmia) of olfactory function may be perceptive or conductive. A perceptive olfactory disorder is caused by damage to the olfactory epithelium, the olfactory bulb or the cerebral nerves involved in the olfactory function, and is therefore usually irreversible. Possible causes for perceptive disorders are, for instance, trauma, toxic chemicals (cytostatic drugs), radiation, virus infection, or disease states like Parkinson’s and Alzheimer’s diseases [21, 22].

An olfactory disorder caused by a physical obstruction of the orthonasal airflow is conductive. Potential reasons for conductive disorders may be swollen nasal mucosa, e.g. as a consequence of virus infection or allergy, nasal polyps or other tumors, chronic rhinosinusitis, or a deviated nasal septum.

Furthermore, several studies have shown that increasing age is associated with perceptive olfactory dysfunction [23, 24]. In a recent Swedish study the ability to smell was deteriorated in more than 20% of persons older than 60 years [25]. Moreover, there is a widespread belief that smoking has adverse effects on detection sensitivity and perceived intensity for certain odors, however, results from scientific evaluations are conflicting [26, 27].

These factors are also related to laryngectomized patients as the majority of the patients are male, former or present smokers, of older age (> 60 years) and often have received radiotherapy and/or chemotherapy.

Gustatory system

The sense of taste is also described as a chemical sense. The sensation of taste occurs when tastant molecules are released from food, dissolved in saliva and reach taste receptors in the taste buds on the surface of the tongue and on the soft palate, pharynx, larynx, epiglottis, uvula and upper oesophagus [28]. We are able to perceive thousands of taste sensations and these are based on different combinations of the five basic tastes: salt, sour, sweet, bitter, and umami [28, 29]. The role of gustation is important for nutritional intake, nutritional regulation (e.g. sodium, salt) [30], as well as for protection of the body against external toxins
Reduced taste is referred to as hypogeusia, whereas ageusia is complete loss to perceive taste.

**Smell and taste**

During eating, a combination of smell and taste including texture and temperature of the food contribute to the perception of flavors. Of the two senses, smell is the main determinant of a flavor [31]. While taste of food, as mentioned above, is limited to the five basic tastes, the smell of food is potentially limitless. Consequently, impaired olfaction affects perception of flavor more than impaired gustation [31]. In contrast to taste, a smell can be detected at a far distance. Pleasant and unpleasant memories with associated emotions can be recalled by the sense of smell, e.g. experiences with unpleasant flavor from food combined with nausea [32]. Similarly, pleasant flavor from food may lead to food preferences [33, 34].

**Olfaction following total laryngectomy**

Total laryngectomy results in a permanent disconnection of the upper and lower airways with breathing through a permanent opening in the throat, a so called stoma (Figure 4). Consequently, the natural orthonasal airflow will be considerably decreased or totally missing. Olfactory acuity is regarded as a function of nasal airflow, and therefore the reduction in nasal airflow is considered as the key contributing factor to impaired olfaction following laryngectomy [14, 19, 35, 36]. This theory is supported by the fact that when nasal airflow, resembling natural breathing, and sniffing is re-established using puffs of air from squeeze bottles [35] or prosthetic devices (e.g. larynx bypass) that reconnect the nose and the lungs [14, 36], improvement in olfactory acuity is evident. However, histological examination of the olfactory mucosa in laryngectomized patients has shown various degrees of epithelial degeneration [37]. Miani et al concluded that it is the combination of loss of nasal airflow and degenerative phenomena of the epithelium that contributes to the olfactory deficits in patients following total laryngectomy. Obviously, as mentioned before the laryngetomees’ sense of smell may also be affected by age, gender and environmental factors.
Gustation following total laryngectomy

Following total laryngectomy the sense of taste is also impaired, however not to the same extent as the sense of smell. According to a study by Ackerstaff et al [38], including a structured interview with 63 laryngectomized patients, 15% of the patients reported a decreased sense of taste (dysgeusia) while 52% of them had hyposmia. However, smell and taste were closely related as a significant correlation was found between hyposmia and dysgeusia ($r=0.43$, $p<0.001$), where all patients with a taste problem also reported reduced sense of smell. These findings are in concordance with those found by Finizia et al [39] where 21% of the laryngectomized patients reported reduced taste perception and 50% reduced smell perception according to the EORTC QLQ-H&N35 questionnaire.

Methods to restore olfaction after total laryngectomy

Prosthetic devices

Several prosthetic devices for establishing nasal airflow are presented in the literature. However, they are inconvenient to handle and therefore unlikely to be used outside the clinical setting. Bosone [40] was the first to describe a simple device, *the nipple tube*, to improve olfactory function after laryngectomy (Figure 5). Furthermore, Knudson et al [41] introduced *an oral tracheal breathing tube* enabling the patient to inhale and exhale through the nose in the same manner as used with the larynx bypass (Figure 6).
Larynx bypass

The larynx bypass consists of a plastic tube that connects the sealed tracheostoma to the mouth with a mouthpiece (Figure 6). With lips sealed around the mouthpiece a negative pressure, developed in the lungs, leads to orthonasal airflow through the nose where odorant receptors may be stimulated. Goktas et al. [42], having studied the efficacy of this device, showed that laryngectomees examined with a larynx bypass had a better sense of smell than those without an aid. Even if smelling by using a larynx bypass is troublesome and unpractical in everyday life it can be used as a screening method to exclude anosmia in laryngectomees.

Maneuvers

Various maneuvers to detect odors have been developed for laryngectomees. The principle is to create an inflow of air through the nose by changing volume in the oral cavity and oropharynx while the lips are closed. Examples of these maneuvers are glossopharyngeal press, buccopharyngeal sniffing, and buccopharyngeal maneuver [14, 35]. However, these maneuvers have not been incorporated into routine rehabilitation methods, nor have their effectiveness been systematically evaluated [36].
Nasal Airflow-Inducing Maneuver

Several authors had previously discovered that laryngectomized patients who perceived smell were more active in using face and neck muscles compared to patients not able to smell [7, 14, 35]. As a result from observations of actions and methods applied by these patients, Hilgers and his co-workers [6] developed a new technique for smelling, The Nasal Airflow-Inducing Maneuver (NAIM) or “Polite Yawning Technique.” This rehabilitation technique creates a negative pressure in the oral cavity and oropharynx to induce orthonasal airflow, thus enabling odorous substances to reach the olfactory epithelium. Patients are instructed to make an extended yawn while keeping their lips closed and simultaneously lowering their jaw, floor of the mouth, tongue, base of tongue and soft palate (Figure 7). To increase effectiveness, the movement has to be repeated rapidly while breathing has to be calm and independent of the movement. As a second step the patient may try a refined polite yawning technique to make the maneuver less conspicuous in public. This could be achieved by isolated pumping movements of the back of the tongue and the floor of the mouth to eliminate lowering of the jaw. The first intervention study, performed on 33 laryngectomized patients categorized as non-smellers, showed a success rate of 46% after a single 30-minute NAIM therapy session [6]. Evidently, this technique is more patient-friendly than the earlier described maneuvers.

Figure 7. NAIM – Nasal Airflow-Inducing Maneuver (“polite yawning”). The anatomical image by courtesy of Atos Medical AB
Methods to restore gustation after total laryngectomy

Although little can be done to restore sensation of taste if permanently affected after radiation or surgical damage, there are ways to optimize residual taste function and flavor perception. This can be achieved by instructing patients to use intensive chewing and back and forth movements of food in the mouth [11]. An increased chewing results in increased release of odorant molecules from food that will lead to an increased oral airflow that enhances the retronasal olfaction [11, 43]. In addition, chewing with lips closed is thought to result in transient increases in the closed oral cavity volume. This generates transient negative pressures, inducing nasal airflow, and thus also encourages orthonasal olfaction [11, 43].

Considering that flavor perception is an integration of taste, smell, temperature and texture, altering the texture or temperature of food may further enhance the sensory experience of oral intake and stimulate enhanced flavor perception.

TESTING OF OLFACTION

Psychophysical olfactory tests

A multitude of psychophysical olfactory tests have been developed for clinical use in various cultural settings. They can be divided into different subgroups and some of these are listed here:

- **Odor threshold or detection test**: Measures the ability of the olfactory system to detect low concentrations of an odor e.g. The Butanol Odor Detection Test [44].

- **Odor identification test**: Measures the ability to identify different odor stimuli out of predetermined alternatives e.g. The Scandinavian Odor Identification Test (SOIT) [45] or The Smell Diskettes Test [46].

- **Odor discrimination test**: Measures the ability to discriminate one odor that is different from a set of three stimuli with the same odor, e.g. part of the olfactory function test “Sniffin´ Sticks” [47].

- **Odor memory test**: Measures the ability to remember a presented odor stimulus e.g. The Odor Recognition Memory Test [48].

To correctly identify and categorize anosmic, hyposmic and normosmic patients the recommendation in clinical settings is to use a combination of olfactory tests, for example CCCRC (odor threshold test and identification test) and “Sniffin´ Sticks” (odor threshold, odor identification and odor discrimination tests).
In the present studies the odor identification test SOIT was used as it predominantly tests the presence of normal orthonasal airflow, which is crucial for evaluating NAIM rehabilitation. Furthermore, the SOIT includes odorants familiar to a Scandinavian population and has demonstrated satisfactory reliability and validity in earlier clinical use [45].

**Neurophysiological tests**

It is also possible to measure the olfactory function using neurophysiological tests. These are methods for studying the effects of odorants on human electrophysiological responses by using an olfactometer. Two examples are the Human Electro-Olfactogram (HEOG) and the Olfactory Event-Related Potential (OERP). Results from scientific evaluations are conflicting. According to Doty [49] these methods are not yet as reliable as the psychophysical methods for olfactory measuring but can still be used in clinical research, as in a recently published study by Brämerson et al [50]. Despite poor reliability a combination of electrophysiological measures and psychophysical tests are suggested when assessing olfactory function in several disorders, such as congenital anosmia, head trauma and Alzheimer’s disease [51].
AIMS OF THE PRESENT STUDY

The overall aim of this thesis was to increase our knowledge of olfactory impairment and evaluate the effect of NAIM rehabilitation, HRQL and communication in patients with total laryngectomy.

The specific aims of the present studies were:

- To examine and describe the olfactory function in Swedish patients having undergone total laryngectomy (Study I).
- To evaluate the results of repeated interventions with the odor rehabilitation NAIM (Study I).
- To assess the long-term results of olfaction training with NAIM 6 and 12 months after primary treatment (Study II).
- To assess changes in olfaction, HRQL and communication during a 3-year period in laryngectomized patients having received olfactory rehabilitation with NAIM (Study III).
- To develop a reliable and easily administered protocol to be used by SLPs in daily clinical practice to assist in early identification and improvement of patients’ NAIM technique (Study IV).
MATERIALS AND METHODS

Subjects

Patients who had undergone total laryngectomy at least five months prior to study start and living in the catchment area (i.e. western part of Sweden) were identified (n=35, Table 2). Conditions for study inclusion were a mental and physical condition good enough to cope with the intervention and a proficiency in Swedish not requiring an interpreter. Eleven patients (all men) could not participate due to poor general health (n=6); lack of motivation (n=3); and residing outside the catchment area at the time of the study (n=2). Thus, 24 patients (21 males, 3 females, mean age 68) served as subjects in study I and II.

Table 2. Clinical data

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Study patients (n=24)</th>
<th>Nonparticipating patients (n=11)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time since radiotherapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median years (range)</td>
<td>9 (1-30)</td>
<td>8 (1-32)</td>
</tr>
<tr>
<td>Time since laryngectomy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median years (range)</td>
<td>7 (0.4-29)</td>
<td>10 (0.4-32)</td>
</tr>
<tr>
<td>Use of voice device or technique; n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voice prosthesis</td>
<td>16 (67)</td>
<td>7 (64)</td>
</tr>
<tr>
<td>Electrolarynx</td>
<td>6 (25)</td>
<td>3 (27)</td>
</tr>
<tr>
<td>Oesophageal voice</td>
<td>2 (8)</td>
<td>1 (9)</td>
</tr>
<tr>
<td>Smoking; n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ex-smoker</td>
<td>20 (83)</td>
<td>10 (91)</td>
</tr>
<tr>
<td>Smoker</td>
<td>1 (4)</td>
<td>1 (9)</td>
</tr>
<tr>
<td>Nonsmoker</td>
<td>3 (13)</td>
<td>0</td>
</tr>
</tbody>
</table>

The laryngectomized patients in study III and IV were initially included in the rehabilitation program from 2002 through 2005. All patients still alive (n=18) accepted to attend a follow-up appointment and participate in study III, whereas 21 of 24 patients with evaluable video documentations were included in study IV.

Furthermore, for comparison of HRQL and communication an age- and gender-matched control group with laryngeal cancer treated with radical radiotherapy and preserved larynx was recruited from the clinical records at the Department of Otolaryngology, Sahlgrenska University Hospital, Göteborg and used in study III. The control group was only examined once. In this study EORTC QLQ-C30 results from the study group were also compared to those of a reference group, i.e. a random sample of 234 men aged 70-79 in the Swedish population drawn from a population-based registry (SEMA) including all Swedish inhabitants born between 1918 and 1979 [52]. Summary information about study I, II, III and IV are shown in Table 3.
Table 3. Type of studies, patients, methods and analyses in study I-IV

<table>
<thead>
<tr>
<th>Type of study</th>
<th>Patients</th>
<th>n (male/female)</th>
<th>Mean age (Range)</th>
<th>Methods</th>
<th>Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>I Intervention</td>
<td>Study patients</td>
<td>24 (21/3)</td>
<td>68 (53-83)</td>
<td>Flexible nasal endoscopy, Semi-structured interview, Larynx bypass SOIT, Manometer Video</td>
<td>Olfactory obstruction, Olfactory function, NAIR feedback</td>
</tr>
<tr>
<td></td>
<td>Nonparticipating patients</td>
<td>11 (11/0)</td>
<td>72 (51-84)</td>
<td>Questionnaire: QOTA, EORTC, HAD, S-SECEL</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Olfactory function, Global QoL/Senses, Mental distress, Communication</td>
</tr>
<tr>
<td>II NAIM follow-up</td>
<td>Study patients</td>
<td>23 (20/3)</td>
<td>68 (53-83)</td>
<td>SOIT, Manometer Video</td>
<td>Olfactory function, NAIM feedback</td>
</tr>
<tr>
<td>6 months</td>
<td>Study patients</td>
<td>24 (21/3)</td>
<td>69 (54-84)</td>
<td>Questionnaire: QOTA, EORTC, HAD, S-SECEL</td>
<td>Olfactory function, Global QoL/Senses, Mental distress, Communication</td>
</tr>
<tr>
<td>12 months</td>
<td>Study patients</td>
<td>24 (21/3)</td>
<td>69 (54-84)</td>
<td>Questionnaire: QOTA, EORTC, HAD, S-SECEL</td>
<td>Olfactory function, Global QoL/Senses, Mental distress, Communication</td>
</tr>
<tr>
<td>III NAIM follow-up</td>
<td>Study patients</td>
<td>18 (15/3)</td>
<td>71 (57-83)</td>
<td>SOIT, Video</td>
<td>Olfactory function, NAIM feedback</td>
</tr>
<tr>
<td>36 months</td>
<td>Study patients</td>
<td>18 (15/3)</td>
<td>72 (52-82)</td>
<td>Questionnaire: QOTA, EORTC, HAD, S-SECEL</td>
<td>Olfactory function, Global QoL/Senses, Mental distress, Communication</td>
</tr>
<tr>
<td></td>
<td>Control patients</td>
<td>18 (15/3)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IV NAIM Evaluation</td>
<td>Study patients</td>
<td>21 (18/3)</td>
<td>68 (59-83)</td>
<td>Revised protocol (Hilgers et al 2002) Videotape</td>
<td>NAIM evaluation</td>
</tr>
</tbody>
</table>

Examinations

Clinical examinations were performed by speech-language pathologists at five different hospitals (Sahlgrenska University Hospital; Södra Älvsborg Hospital; Kärnsjukhuset, Skaraborg Hospital; Norra Älvsborg Hospital; Varberg Hospital) in the western part of Sweden. Collection of data was carried out at the Department of Otolaryngology, Head and Neck Surgery, Division of Logopedics and Phoniatrics, Sahlgrenska University Hospital, Göteborg.

Pre-inventory interview

Pre-inventory a semi-structured interview was conducted by SLPs at the first study visit. It comprised two questions on patients’ self-estimation of olfaction and gustation before and
after laryngectomy and, in addition, one question about deterioration of olfaction and gustation after laryngectomy. The patients were also asked whether they used any technique to influence the ability to smell. Whenever possible video documentation was used at the pre-inventory interview and repeatedly at each rehabilitation session (Study I), as well as at long-term follow-up (Study II and Study III).

Pre-inventory flexible nasal endoscopy

All patients underwent a flexible nasal endoscopy to rule out nasal obstruction that could prevent nasal airflow to stimulate the olfactory epithelium in the nasal cavity. Anatomical and neurological deficits that might interfere with lip closure, intra- and extraoral mobility or swallowing were evaluated.

Assessment of olfaction

Olfaction was tested before intervention with a larynx bypass. An odor was brought to the first visit by the patient (a well-known odor e.g. perfume or after shave), which was applied in front of the nose while a nasal airflow was induced by means of a larynx bypass [14]. Olfaction was also tested with the odor identification test SOIT.

The SOIT

The SOIT consists of 16 different odors (pine-needle, peppermint, juniper berry, violet, anise, clove, vanilla, almond [bitter], orange, cinnamon, lemon, lilac, vinegar, tar, ammonia, and apple) with 4 response alternatives per odor to choose from with no time limit for answering procedure (Figure 8). Three of the odors - peppermint, vinegar and ammonia – are trigeminal stimulants. The smell consists of five milliliters of odor stimulus placed in a 10 ml glass jar. The test has age- and gender-related cut-off scores (Table 4). According to results of the sense of smell patients can be categorized as having normosmia, hyposmia or anosmia. The SOIT was used at each of the three intervention sessions (Study I) and at long-term follow-up (Study II and III) for testing olfactory acuity and intervention results (Figure 9).
Table 4. SOIT. Olfactory diagnoses dependent of age- and gender cut-off scores [45]

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Normosmia</th>
<th>Hyposmia (-2SD)</th>
<th>Anosmia (-4SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>15-34</td>
<td>13-16</td>
<td>10-12</td>
<td>&lt; 9</td>
</tr>
<tr>
<td>35-54</td>
<td>12-16</td>
<td>9-11/10-11 *</td>
<td>&lt; 8/&lt; 9 *</td>
</tr>
<tr>
<td>55-74</td>
<td>11-16</td>
<td>8-10</td>
<td>≤ 7</td>
</tr>
</tbody>
</table>

* Men/women

Video recordings

Video recordings of the NAIM technique were made in studies I, II and III on Mini Digital Video Cassettes (FujiFilm, Japan) with a Sony DCR-PC8E video camera (Sony Corporation, Japan) in a clinical setting. For best visualization patients’ NAIM performance was recorded in lateral position. The recordings were used for real-time biofeedback during olfactory training and follow-up sessions (studies I, II and III), and for evaluation of different aspects and overall performance of the NAIM (Study IV).

In study IV video samples of >10 seconds in random order from the first (baseline) and third (after treatment) intervention sessions and from follow-up 6 and 12 months after primary intervention were evaluated. Raters were three SLPs educated and trained in NAIM rehabilitation and with many years professional experience working with laryngectomized patients. Prior to evaluation, the raters attended a training session to become accustomed to the protocol and the response alternatives. Evaluation was made on a protocol sheet, one for each video sample.
Olfactory rehabilitation

The olfactory rehabilitation (Study I) consisted of restoring sense of smell with the NAIM. Aim of the maneuver is to create orthonasal airflow through the nose by creating a negative pressure in the oral cavity and oropharynx, while keeping the lips closed, the soft palate relaxed and simultaneously actively lowering the base of the tongue and the floor of the mouth. This could easiest be explained as an extended polite yawning. A water manometer (Figure 10) was consistently used for real-time visual feedback during practice and long-term follow-up (Study I and II). The manometer training was performed correctly when the fluid fluctuated in the manometer and moved towards the nose of the patient. For memorizing the technique the patients received a written program with instructions on the NAIM technique and how to perform the maneuver with the manometer. The patients were instructed to actively use the maneuver as often as possible between interventions and to try to integrate the NAIM technique into daily life situations. The manometer in our study, accepted for use in Sweden, was designed by a Swedish SLP (Claes Österlind) involved in the study.

![Figure 10. Manometer with nose tube and colored water for better visualization of the movement. Photo taken by Jan Persson](image)

Questionnaires

Patients completed all questionnaires during each clinical session.

*Questionnaire on Odor, Taste and Appetite*

The Questionnaire on Odor, Taste and Appetite (QOTA) [53, 54, 55] (Study I, II and III) consists of several multiple-choice questions addressing the situation both before and after laryngectomy as well as the present situation.
Questions are divided into five scales: 1) present odor perception (POPS, 3 items, score range from 3 to 15); 2) present odor perception compared with past (3 items, score range from 3 to 15); 3) present taste perception (8 items, score range from 8 to 40); 4) appetite (6 items, score range from 6 to 30); 5) daily feelings of hunger (9 items, score range from 9 to 45). A low score indicates bad function or that these scales have deteriorated compared to pre-operative or previous test situations. Conversely, a higher score indicates good function or improvement in these domains.

The QOTA questionnaire was translated into Swedish in 2002, using a formal method of forward-backward translation by two independent bilingual translators. The wording of some of the items in the final QOTA version was slightly modified to avoid ambiguity in Swedish. The translated Swedish version has been pre-tested in 22 laryngectomized patients and none found the questions upsetting, disturbing or hard to understand [56, unpublished data]. Translation was carried out with permission from the authors [55].

**EORTC QLQ-C30 and QLQ-H&N35**

The European Organization for Research and Treatment of Cancer (EORTC) study group on quality of life has developed a modular measurement system for evaluating health-related quality of life in cancer patients. We used the EORTC QLQ-C30 (Study I, II and III) consisting of 30 questions to assess the patients’ general physical and psychosocial functioning and symptoms [57, 58]. This questionnaire incorporates five functional and three symptom scales, a global QoL scale, and six single items.

To address additional symptoms we used the EORTC QLQ-H&N35 (Study I, II and III), a supplement to the QLQ-C30 consisting of questions relevant to head and neck cancer patients [59, 60]. Both the QLQ-C30 and the QLQ-H&N35 have demonstrated good reliability and cross-cultural validity. These questionnaires can distinguish between patient groups differing in clinical status, as well as detecting changes in patients over time. All scale and item scores range from 0 to 100, where higher scores for functioning scales and global quality of life represent better functioning. For symptom scales and items a higher score corresponds to more severe symptoms. In general, score changes over time of at least 10 points could be interpreted as indicating clinically important changes [61]. In study I & II only the scales and items most relevant for smell and taste are presented (i.e. global quality of life scale, senses scale and single items for taste and smell).
**HADS**

The Hospital Anxiety and Depression Scale questionnaire (HADS) is a tool detecting mood disorders in somatically ill patients [62] and has frequently been used in cancer studies, for example lung cancer [63] and head and neck cancer [64, 65]. The two-factor structure has been confirmed in many studies [66, 67]. The Swedish version has been documented in a study by Sullivan et al [68]. HADS consists of 14 items on a four-point response scale ranging from 0-3. The summary scale scores for anxiety (7 items) and depression (7 items) thus range from 0-21. Each person is also grouped according to a clinically tested classification of psychiatric morbidity. A scale score < 8 is within the normal range, a score 8-10 indicates a possible and a score >10 indicates a probable mood disorder.

**S-SECEL**

The original Self Evaluation of Communication Experiences after Laryngectomy (SECEL) was developed to assess communication dysfunction in laryngectomized patients and has demonstrated satisfactory psychometric properties [69]. The Swedish version (S-SECEL) was adapted for use in patients receiving different treatments for laryngeal cancer. It has proved to be reliable and shown both convergent and discriminant validity, as well as, satisfactory internal consistency [70, 71, 72, 73]. S-SECEL consists of 35 items addressing communication experiences and dysfunction in patients receiving different treatments for laryngeal cancer. Thirty-four of the items are aggregated into 3 subscales to measure general (5 items; score range 0-15), environmental (14 items; score range 0-42) and attitudinal (15 items; score range 0-45) communication experiences, as well as a total scale (score range 0-102). Each item is rated on a four-point scale ranging from 0 (never) to 3 (always) and addressing the last 30 days. Scoring of subscales and a total scale is carried out by simple addition (0-102). A higher score indicates greater perceived communication dysfunction. Item no. 35: “Do you talk as much now as before your laryngeal cancer?” is answered by three response categories (Yes/More/Less), and is not included in the scoring system.

**Appendix I.**

**NAIM protocol**

The NAIM protocol used in study IV is a revision of the original protocol used by Hilgers et al [74]. The original protocol consisted of only dichotomized variables (Yes/No) that may lack in both sensitivity and reliability. For example, when evaluating item *lowering floor of the mouth* a positive score could represent a perfect execution as well as a partially acceptable
execution. With the purpose of increasing the sensitivity to detect change we therefore revised the protocol by adding response options wherever possible.

Response alternatives are Totally correct/Partly correct/Totally incorrect (question 1a and 2) and Tense/Partly tense/Relaxed (question 1d). Response alternatives for items 1b-c are dichotomized (Yes/No). Calculated scores range between 0-22 (item 1a-d) and 0-2 (question 2), with higher scores representing better NAIM technique. Appendix II.

STATISTICAL ANALYSIS

Study I, II and III
As data in our studies were on ordinal scale level and not normally distributed we have only used nonparametric tests. Pearson correlation coefficient was calculated for all correlation analyses and formally tested with Pitman’s nonparametric permutation test. For comparison between groups the Fisher nonparametric permutation test was used. For comparison over time within groups the Fisher nonparametric permutation test for matched pairs was used. The subjects were their own controls. All tests were 2-tailed and conducted at a 5% significance level [75]. When estimating clinical significance in the EORTC questionnaires, changes over time within the study group and differences in mean scores between groups were assessed according to recommendations by Osoba, where a difference in HRQL scores of 10 points or more is regarded clinically significant [61].

Study IV
For comparison between groups Wilcoxon’s paired sign rank test and Sign test were used and conducted at a 5% significance level. The interrater reliability of the perceptual evaluations of questions 1-11 in the protocol was calculated with Spearman’s rank order correlation coefficient (Spearman rho). This coefficient calculates a value from -1 to +1. The higher the positive value is the better interrater reliability. Cohen’s kappa was used for measuring intrarater reliability of questions 1-11 in the protocol. A kappa coefficient < 0.20 indicates that agreement between raters is non-existing or very low; 0.21-0.40 low; 0.41-0.60 moderate; 0.61-0.80 good; and 0.81-1.00 very good [76].

ETHICS
The studies were approved by the Ethical Committee for Human research at Sahlgrenska University Hospital and were conducted in accordance with the Declaration of Helsinki.
RESULTS

Study I
The purpose of this study was 1) to examine and describe olfactory function in Swedish patients having undergone total laryngectomy, and 2) to evaluate the results of repeated interventions with the odor rehabilitation NAIM. All patients reported having normal sense of smell before laryngectomy. After laryngectomy, before NAIM intervention, olfactory testing with a larynx bypass enabling orthonasal airflow revealed that only 5 patients were unable to smell with the tube. However, a majority of the patients considered their sense of smell to have deteriorated compared to pre-surgery.

According to SOIT, 18 of 24 patients (75%) had impaired sense of smell before NAIM rehabilitation (baseline). After NAIM rehabilitation 72% with impaired sense of smell improved (Figure 11). Of the 14 non-smellers, 7 converted to smellers after only one intervention session, resulting in a success rate of 50% after a single session. Of the remaining 7 non-smellers, 3 converted to smellers after repeated sessions, while 4 non-smellers showed no improvement. Moreover, 75% of the patients with hyposmia converted to normosmia after 1, 2 and 3 interventions, respectively. Of the 5 patients with larynx bypass not able to smell before intervention, 2 were categorized as smellers after NAIM rehabilitation. The SOIT score significantly improved (p=0.005) for non-smellers after intervention. In addition, the non-smellers’ subjective estimation of their olfaction and gustation were significantly higher compared to before treatment (p<0.001 and p=0.02 respectively). Although not statistically significant, non-smellers showed an improvement according to the smell item on QLQ-H&N35. In addition, based on their subjective estimation smellers had significantly better sense of smell (p=0.03), and significantly better appetite (p=0.03), and taste (p=0.47) according to QOTA.

Study II
The aim of this study was to assess long-term results of the NAIM by re-examining the patients 6 and 12 months after primary rehabilitation. One patient could not be examined at the 6-month follow-up due to concomitant disease but participated in the 12-month follow-up (Figure 11).

At the 6-month follow-up 83% were smellers. Based on their subjective estimation both non-smellers and smellers had significantly better sense of smell at the 6-month follow-up (p< 0.001 and p=0.004, respectively) compared to before intervention. However, sense of smell according to SOIT scores was significantly better only for non-smellers (p= 0.004).
At the 12-month follow-up rehabilitation results were further improved, with only 3 patients (12%) remaining non-smellers (Figure 11). Again, according to their subjective estimation, both non-smellers and smellers had better sense of smell at the 12-month follow-up (p=0.004 and p=0.003, respectively) compared to pre-intervention. Furthermore, 88% were active users of the NAIM with 8 patients using it on a daily basis, 7 using it frequently but not daily, and 6 patients using it infrequently. The 3 patients never having used NAIM prior to the 12-month follow-up were all non-smellers.

**Study III**

The purpose of this study was to assess long-term results in laryngectomized patients concerning olfactory function, HRQL and communication 36 months after primary NAIM rehabilitation (study group n=18). In addition, we wanted to compare results between the study group and an age- and gender-matched control group (i.e. patients with laryngeal cancer with preserved larynx, control group n=18)

**SOIT and QOTA**

According to SOIT scores, 78% of the study group was categorized as smellers (Figure 11). Twelve of the 18 patients (67%) used the NAIM technique “automatically”, i.e. on a daily basis.

Comparison between the study group and the control group showed that the controls had significantly better sense of smell according to both SOIT and QOTA scores (p<0.001 and p<0.001, respectively).

**EORTC QLQ-C30 and QLQ-H&N35**

In general, the score values within the study group were stable over time. However, between group comparisons showed significant differences regarding Sleep disturbances and Senses scale with less problems in the control group and Sexuality with less problems in the study group.

**HAD**

At all measurement points the study group reported stable and low score values regarding anxiety and depression and no differences were found when compared to the control group.

**S-SECEL**

There were no significant differences in S-SECEL scores for the study group over time with most communication problems found in the Environmental scale. When dividing the study
group into smellers and non-smellers the total score values showed a deterioration of the communication in non-smellers over time whereas smellers improved. The study group, as a whole reported more problems with speech and communication than the control group (Table 6).

Table 6. Mean (CI) S-SECEL scores from baseline to 36 months after treatment in study group and control group

<table>
<thead>
<tr>
<th>S-SECEL</th>
<th>Study group (n=18)</th>
<th>Control group (n=18)</th>
<th>p value study/control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>6 mo</td>
<td>36 mo</td>
</tr>
<tr>
<td>General*</td>
<td>4.2 (3.0-5.5)</td>
<td>4.8 (3.4-6.3)</td>
<td>4.3 (3.2-5.5)</td>
</tr>
<tr>
<td>Environment*</td>
<td>13.4 (11.0-15.9)</td>
<td>12.4 (9.5-15.4)</td>
<td>14.8 (10.7-18.9)</td>
</tr>
<tr>
<td>Attitudinal*</td>
<td>7.4 (5.2-9.6)</td>
<td>7.8 (4.3-11.4)</td>
<td>10.7 (6.8-14.7)</td>
</tr>
<tr>
<td>Total*</td>
<td>25.1 (20.2-29.9)</td>
<td>25.1 (19.1-31.2)</td>
<td>29.8 (21.7-37.9)</td>
</tr>
</tbody>
</table>

Abbreviations: CI = Confidence interval; S-SECEL The Swedish Self-Evaluation of Communication Experiences after Laryngeal Cancer.
*Minimum-maximum: 0-15 (General), 0-42 (Environmental), 0-45 (Attitudinal), and 0-102 (total), low value = better communication
p-value significant at < 0.05, comparison between study group at 36 month and control group
All 24 laryngectomized patients at the baseline

Non-smellers n=14 (58%)
Anosmia n=14 (58%)

Smellers n=10 (42%)
Hyposmia n=4 (17%)
Normosmia n=6 (25%)

NAIM Rehabilitation (n=24) after 3 sessions

Non-smellers n=4 (17%)
Anosmia n=4 (17%)

Smellers n=20 (83%)
Hyposmia n=7 (29%)
Normosmia n=13 (54%)

Patients at the 6-month follow-up (n=23)

Non-smellers n=4 (17%)
Anosmia n=4 (17%)

Smellers n=19 (83%)
Hyposmia n=12 (52%)
Normosmia n=7 (31%)

Patients at the 12-month follow-up (n=24)

Non-smellers n=3 (12%)
Anosmia n=3 (12%)

Smellers n=21 (88%)
Hyposmia n=6 (25%)
Normosmia n=15 (63%)

Patients at the 36-month follow-up (n=18)

Non-smellers n=4 (22%)
Anosmia n=4 (22%)

Smellers n=14 (78%)
Hyposmia n=6 (33%)
Normosmia n=8 (45%)

Figure 11. SOIT results before and after treatment and at 6, 12 and 36 months follow-up
Study IV

The aims of this study were to: 1) assess variables important for effective execution of the NAIM and 2) develop a structured NAIM protocol for these evaluations to be used by SLP in daily clinical practice.

When assessing execution of the NAIM technique using the protocol a significant improvement compared to baseline was seen throughout the study. The improvement in olfactory technique at different measurement points after intervention was shown both in the summary scores of the first 11 NAIM protocol variables and for the overall technique (item 12). Key variables such as lowering floor of mouth and lowering jaw improved most. In addition most patients also normalized their breathing over time. Significant improvements in olfactory function compared to baseline were also seen according to SOIT scores (Table 7).

Table 7. Mean (SD) NAIM and SOIT scores at baseline, after treatment, and at 6 and 12 months follow-up

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>After treatment</th>
<th>6 mo</th>
<th>12 mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>NAIM / 1-11*</td>
<td>11.84 (3.69)</td>
<td>13.85 (3.73)</td>
<td>13.85 (3.93)</td>
<td>15.12 (3.06)</td>
</tr>
<tr>
<td>p†</td>
<td>…</td>
<td>0.009</td>
<td>0.029</td>
<td>0.001</td>
</tr>
<tr>
<td>NAIM / 12**</td>
<td>0.29 (0.46)</td>
<td>0.76 (0.54)</td>
<td>0.86 (0.57)</td>
<td>1.19 (0.60)</td>
</tr>
<tr>
<td>p†</td>
<td>…</td>
<td>0.008</td>
<td>0.005</td>
<td>0.001</td>
</tr>
<tr>
<td>SOIT</td>
<td>8.86 (2.58)</td>
<td>10.14 (3.23)</td>
<td>9.86 (3.28)</td>
<td>11.57 (3.43)</td>
</tr>
<tr>
<td>p†</td>
<td>…</td>
<td>0.015</td>
<td>0.046</td>
<td>0.002</td>
</tr>
</tbody>
</table>

* Minimum -maximum 0-22; ** Minimum-maximum 0-2, for item scoring see Appendix II.
Higher scores = better NAIM function
† Wilcoxon signed rank test, comparison to baseline data
GENERAL DISCUSSION

Impaired olfactory function

One of the major findings in study I was the high prevalence (75%) of impaired sense of smell in patients after total laryngectomy. This finding was independent of time since the operation and in concordance with studies previously described [7, 8].

All 24 patients in our study reported an impaired sense of smell after laryngectomy compared to pre-surgery. However, since olfaction was not measured before the operation these results were not objectively confirmed. In future studies we therefore suggest, as part of the pre-operative examination, systematical psychophysical olfactory testing before laryngectomy to identify patients’ sense of smell.

Other factors that might influence the olfactory capacity are age, gender, smoking, chemo- and radiotherapy. Several studies [23, 25, 77] report an age- and gender-related olfactory dysfunction, especially in elderly people and males. These are factors that probably are relevant also in our study as a majority of the patients were men and over 60 years of age. Furthermore, radiotherapy and exposure to cytostatic drugs might adversely influence the sense of smell [78, 79]. However, the radiation field in laryngeal cancer patient does not involve the olfactory epithelium, which makes any influence on sense of smell in these patients less likely. Whether or not tobacco smoking affects sense of smell is subject for controversy. Some studies have shown negative effects [26, 80] on the olfactory function whereas others [25, 81] have found no such effect.

Olfaction results from NAIM intervention and long-term follow-up

A second important finding in study I was the improvement in olfactory function after NAIM rehabilitation in 72 % of patients with anosmia and hyposmia. After only one intervention session 50% of the non-smellers converted to smellers, this is in line with results also found by Hilgers et al [6]. Despite these promising results, Hilgers et al [6] discussed the possibility if more intervention sessions would further improve the rehabilitation results. Hence, our rehabilitation program was designed to include three interventions within six weeks. This extended program proved advantageous as we did note further improvement in the olfactory function following the second and third intervention session.

In study II and III we confirmed that our treatment regime results, with repeated NAIM-interventions persist 12 and 36 months later. The percentage of smellers was very similar post-treatment in study I (83%) to those in study II (88%) and III (78%). These results are, to some extent, better than those published by Hilgers et al [74]. However, the studies are not
totally comparable as the study design by Hilgers et al, with a single intervention session and one follow-up visit between 4 and 24 months post-intervention differed from ours. Furthermore, we used different olfactory tests. The identification olfactory test SOIT used by our research group seems more discriminatory than the Smell Diskettes olfactory test [46] used by Hilgers et al, due to the use of more test stimuli (16 instead of 8) and with four verbal alternative responses instead of three picture-verbal alternatives. Moreover, the Smell Diskettes olfactory test is only categorizing the patients into two groups (normosmia and hyposmia/anosmia), whereas the SOIT also recognizes hyposmic patients, probably making it more suitable for evaluating NAIM rehabilitation over time.

During follow-up, however, there was a fluctuation in the level of sense of smell. In study II, at the 6-month follow-up, the number of patients with normosmia was nearly halved compared to post-intervention results (30% vs. 54%). This might be explained by problems with the NAIM technique or in the implementation of NAIM in daily life and the rather long period between the intensive training episode and the first follow-up. According to Hilgers et al [74], a correct execution of the NAIM is important for creating a sufficient orthonasal airflow leading to improved olfactory function. As with other aspects of post-laryngectomy rehabilitation (e.g. voice, pulmonary status) repeated and intensive training is necessary to gain full control of the technique. It is important for the patient to understand that the NAIM is an active process that needs to be incorporated in the daily activities to reach as normal a sense of smell as possible. Consequently, the increase in number of patients with normosmia, may depend on repetition and improvement of the NAIM technique after follow-up at 6 and 12 months.

**Evaluation of treatment**

**Olfactory test**

For several reasons we used the Scandinavian Odor Identification Test (SOIT) when evaluating the NAIM treatment. The SOIT has demonstrated satisfactory reliability and validity in clinical use [25, 45], it includes odorants familiar to a Scandinavian population, and it predominately tests the orthonasal airflow, which is crucial for evaluating NAIM rehabilitation. Based on results from study I, II and III we found the SOIT to be easy to perform, well accepted and the best Scandinavian option when testing olfactory function after NAIM rehabilitation in laryngectomized patients. We therefore recommend the use of SOIT in Scandinavian NAIM rehabilitation programs in laryngectomized patients.
Questionnaires

For evaluation purposes in clinical research it is important to use questionnaires with good psychometric properties. One of the most commonly used validated HRQL instruments are the EORTC questionnaires. However, some studies highlight the need to add more disease specific questionnaires when measuring HRQL, communication and olfaction, especially in laryngectomized patients [73, 82, 83]. Therefore, we complemented the EORTC questionnaires with the QOTA and the S-SECEL. Results from our studies confirm the need for such specific questionnaires in laryngectomized patients.

An interesting finding according to EORTC-H&N35 was the lack of a significant difference in olfaction (the Senses scale; “Problems with smell” and “Problems with taste”) between the study group and the control group. We agree with Bindewald et al who suggested that these two items should be analyzed separately since the scale has previously shown low internal consistency [59, 84]. This would be especially relevant in laryngectomized patients due to the varying meaning of the questions for these patients. According to recent studies impaired sense of smell is associated with a deteriorated quality of life [85, 86]. Even if we could not confirm an association between olfaction and HRQL when measured with the EORTC questionnaires, both smellers and non-smellers reported improved quality of life when interviewed about the importance of olfactory rehabilitation in daily situations. All patients stressed the importance of regaining both pleasant and unpleasant odors, e.g. odors in nature, when dealing with food and cooking, and personal hygiene. Furthermore, both smellers and non-smellers seemed motivated to apply NAIM when olfactory training was integrated in daily life and the learning effect was positive and remained even after a long period of time. The six patients in study III who did not use the NAIM regularly were two smellers and four non-smellers. The two smellers reported good olfaction acuity and one of them explained that he was a smeller as a consequence of using oesophageal voice, the other claimed to have a smelling technique of his own similar to the NAIM. Reasons for the non-smellers not to use the NAIM were finding it too conspicuous in public, difficult to apply, bad motivation to learn or poor general health.

One could expect the study group with alaryngeal communication to score higher on the QLQ-H&N35 Speech scale than the control group with laryngeal communication but our results indicated no significant difference. However, the S-SECEL questionnaire indicated to be more sensitive to differences between the alaryngeal speakers with higher levels of reduced conversational abilities than the laryngeal speakers treated with radical radiotherapy. This may be explained by the fact that everyday communication requires adaptation to background noises which are unfavorable to laryngectomized patients, e.g. in a bus or a car,
at a party or over the telephone. In addition, patients categorized as smellers seemed to judge themselves as more successfully rehabilitated regarding communication compared to non-smellers. The three patients who were non-smellers throughout study I-III also demonstrated the highest levels of communication dysfunction among the study patients.

Results from both groups on the HAD scale corresponds well to other studies with laryngeal cancer patients [73, 83, 87]. Only one of the study patients, who had swallowing and communication problems, exceeded the cut-off value (>10) for depression at the 36-months follow-up.

In conclusion, our study group proved to have HRQL scores comparable to those of the controls and better than those reported in previous studies after total laryngectomy [39, 82, 88, 89]. Somewhat surprisingly, both the study group and the control group also reported better HRQL compared to reference data from a general age-matched Swedish population sample [52]. One reason for this may be the time interval between treatment and start of the study which allowed our study patients to recover from anatomic and functional alterations. Additionally, it can be speculated that the improved rehabilitation program now available after total laryngectomy affects HRQL positively (e.g. voice prostheses, hands-free and HME devices).

NAIM protocol

One of the major findings in study IV was that raters were able to reliably evaluate performance of the NAIM technique over time using our revised NAIM protocol. A second important finding was that certain movements, e.g. closing lips, lowering floor of mouth and jaw and normal breathing, seem to be more important than others for a successful olfactory rehabilitation with NAIM. There are several reasons for using a protocol in clinical practice, one being to observe and follow performance of such key variables throughout the rehabilitation program. Another reason is to use the protocol to assist in early identification and improvement of the patient’s NAIM technique irrespective of the SLP’s experience working with laryngectomized patients. However, subjective ratings such as visual analyses are not enough to track technique changes but ought to be complemented with olfactory testing.

Limitations

Although the study group included all available laryngectomized patients in our catchment area at start of the study the size of the cohort is relatively small. Also, the majority of the
study group was successfully rehabilitated and had completed their therapy concerning communication, breathing and swallowing which may have influenced the HRQL.

Who will gain?

Patient selection

In accordance with our data, we conclude that the majority of the laryngectomized patients can improve their olfactory function and should be offered NAIM rehabilitation. In study I, even patients categorized as smellers post-inventory became “better smellers”. The improvement was not statistically significant, however, this might be due to ceiling-effects in the SOIT test. In addition, two of the five patients not able to smell with the larynx bypass became smellers after NAIM rehabilitation. Thus, the results from olfactory testing with a larynx bypass may indicate but not predict with certainty if a patient would benefit from olfactory rehabilitation.

Pre-operative counseling

Impaired olfaction in laryngectomized patients and, more importantly, its rehabilitation has not received as much focus as the more obvious consequences, such as changes in voice, pulmonary and swallowing function. Van Dam et al [7] reported that 50% of patients were not even informed during pre-operative counseling about post-operative changes in smell and taste. Furthermore, 91% of the laryngectomees were not given any rehabilitation instructions involving compensation for reduced sense of smell and taste. These results are in line with the outcome in our study where 42% of the patients were not pre-operatively informed about the smell and taste deficits, nor were smell and taste rehabilitation instructions given. In a study by Lennie et al [90], the laryngectomized patients wanted post-operative changes in smell and taste to be discussed during the pre-operative counseling, a finding in line with our clinical experience. Even though patients have a lot of information to cope with in pre-operative counseling, we conclude that information concerning smell and taste is a necessity.

Recommendations

If there are no complications post-laryngectomy, olfactory rehabilitation can be integrated in speech therapy and start 3-4 weeks post-operatively. One of our study patients became an excellent TE-speaker, even using a hands-free speech, during olfactory rehabilitation training. Data from our studies suggest that a minimum of three sessions is recommended, but the exact number of sessions should be in concordance with each patient’s need. Furthermore, we recommend follow-up after 3, 6 and 12 months with further NAIM training for better long-
term results. We also suggest that the number of follow-up sessions can be individualized with regard to the patients’ ability to perform NAIM. Although NAIM is an effective method for improving olfactory function the patient has to be made aware that passive olfaction never returns after total laryngectomy, and that the NAIM is an active procedure that needs repetition and intensive training to be incorporated into the patients’ everyday behavior. Video documentation and a water manometer for use in clinic and home practice are useful tools for technique improvement, making the patient aware of details disturbing the maneuver. Furthermore, we suggest the use of validated questionnaires for evaluation purposes. However, if short of time, a few questions about smell and taste repeatedly asked (i.e. before laryngectomy, before and after NAIM intervention, and at follow-up) can provide important information when combined with the objective olfaction test results.
CONCLUSION

The present studies rendered the following conclusions:

- Olfactory impairment is common in patients after total laryngectomy.

- The NAIM is a patient-friendly, easy to learn, inexpensive and effective method for restoring olfactory function after total laryngectomy.

- Long-term improvements were seen following olfactory rehabilitation with NAIM.

- Laryngectomized patients that are successfully rehabilitated regarding smell and communication had an overall good HRQL.

- We recommend that NAIM rehabilitation should be offered to all laryngectomized patients and incorporated into their routine rehabilitation program.

- An odor identification test predominantly testing orthonasal airflow and categorizing sense of smell in olfactory diagnoses, e.g. the SOIT, is suitable for assessment and evaluation of the NAIM technique after total laryngectomy.

- We suggest that validated HRQL questionnaires should be complemented with more diagnose specific questionnaires for evaluation of olfaction and communication after total laryngectomy in clinical research.

- For evaluation of the technique a NAIM protocol is helpful for the SLP to identify important NAIM variables and to assess the progress of the rehabilitation.
FUTURE RESEARCH AND GOALS

Investigation of NAIM rehabilitation prospectively - a multi-center study involving two different University Hospitals (Göteborg and Linköping) with the aim to “normalize” olfaction and gustation in laryngectomies by rehabilitation of sense of smell in direct conjunction with the post-operative rehabilitation. The study includes subjective and objective screening of patients’ sense of smell and taste pre- and post-operatively, early onset of NAIM rehabilitation and a more intensive follow-up regime.

NAIM rehabilitation courses for speech language pathologists in the Nordic countries in order to incorporate the NAIM in ordinary rehabilitation programs for laryngectomized patients.

Development and evaluation of a standardized video manual.
ACKNOWLEDGEMENTS

I would like to express my gratitude to all of you who have contributed to this thesis. In particular I would like to express my sincere gratitude to:

Associate professor Caterina Finizia, my supervisor and co-author, for guiding me in the field of research with enthusiasm and support and for believing in me.

Associate professor Riitta Ylitalo Möller, my assistant supervisor and co-author, for your scientific knowledge and encouraging comments.

Research assistant and co-author Anna Rydén for proof-reading and sharing her expert assistance during the statistical process.

Professor Gösta Granström, Head of the Department, for his interest and personal support.

Eva Jensen, secretary at the Department, for her assistance and help with the practical matters.

Gunnar Ekeroth at Statistiska Konsultgruppen AB for skilful guidance and help with statistics.

All laryngectomized patients who participated in the studies and made this work possible. A special word of thanks to Mona and Tore for your patience in front of the camera, several times throughout the studies.

Photographer Jan Persson for photos of the patients and valuable help with technical assistance and ENT-doctor Lena Folkestad for her drawing skills.

All my colleagues, Inga Eliasson, Inger Johansson, Ulla-Britt Tengstrand, Claes Österlind and Ingrid Fridén, Västra Götaland and Halland and Christina Danbolt, University Hospital Linköping for valuable help during the studies. A special word of thanks to my colleagues Ulla-Britt Tengstrand for sharing with me your knowledge in NAIM and Claes Österlind for designing the manometer.

Special thanks to the Swedish Medical Company ENTpro AB for providing the silicon nose adapters for the manometers used in the study.

Atos Medical AB and the Nobel Committee for the anatomical images.

Monica Käll-Guldbrand, Head of the Division of Logopedics and Phoniatrics, for encouraging scientific studies and sharing with me your interest in laryngectomized patients.

ENT-doctor Henrik Bergquist for stimulating discussions concerning quality of life after total laryngectomy.

Most of all, I want to thank my beloved husband Rolf for your systematical and structural support and never-ending patience throughout this work.

The studies were supported by grants from the Assar Gabrielsson Foundation, Göteborg, the Laryng Foundation, Stockholm, the Research and Development Council (FoU), Västra Götaland County, and the Medical Faculty of Göteborg University.
Efter total laryngektomi är övre och nedre luftvägar separerade, vilket resulterar i en rad oönskade effekter såsom avsaknad av andning via näsa och mun, nedsatt förmåga att uppfatta lukt och smak samt förlust av normal röstfunktion. Nyligen presenterades en metod kallad Nasal Airflow-Inducing Maneuver (NAIM) för rehabilitering av luktförmågan efter total laryngektomi. Målsättningen med denna studie var: 1) att beskriva luktförmågan hos laryngektomerade patienter och att mäta luktförmågan efter behandling med NAIM (Studie I); 2) att utvärdera resultaten 6 och 12 månader efter intervention (Studie II); 3) att utvärdera luktförmåga, hälsorelaterad livskvalitet (HRQL) och kommunikation 36 månader efter intervention (Studie III); och 4) att utveckla ett kliniskt protokoll för att följa förändringar i NAIM teknik över tid (Studie IV).


Vid lukttstning före intervention hade 18 av 24 patienter (75%) nedsatt luktförmåga. Efter 3 behandlingar med NAIM hade 72% av patienterna förbättrat sin luktförmåga. Vid uppföljning 6 och 12 månader efter avslutad NAIM behandling var 83% respektive 88% luktare enligt SOIT resultaten. Vid uppföljning 36 månader efter avslutad behandling var 78% luktare av de 18 patienter som fortfarande var i livet. Därutöver uppgav patienterna god livskvalitet. Med hjälp av ett strukturerat protokoll var det möjligt att följa förbättrad NAIM teknik över tid.

Slutsatser: Försämrad luktförmåga är vanligt hos laryngektomerade patienter (75%), rehabilitering med NAIM är lätt att lära ut och ger utmärktta långtidsresultat och bör därför inkluderas i existerande rehabiliteringsprogram. För att utvärdera tekniken är ett protokoll med NAIM varibabler till god hjälp. Slutligen föreslår vi att livskvalitetsformulären kompletteras med specifika frågeformulär för analys av luktförmåga och kommunikation.
REFERENCES


APPENDIX I    S-SECEL
**INSTRUCTIONS:**
Here are 35 statements about experiences with communication after a laryngectomy. 
Read each of the statements carefully and place a firm tick in the box beside each question that describes you NOW or in the last 30 days.

<table>
<thead>
<tr>
<th>Question</th>
<th>Always</th>
<th>Often</th>
<th>Sometimes</th>
<th>Never</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Are you relaxed and comfortable around other people in speaking situations?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Would you describe yourself as a low-keyed, calm person?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Are you an active, &quot;outgoing,&quot; talkative person?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Do you admit to the person you are speaking to that you had a laryngectomy?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Do you think your speech improves with the amount of time you use it?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Do you find that you frequent clubs, meetings, or lodges less often because of your speech?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Do you have difficulty getting people’s attention to speak?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Do you have difficulty yelling or calling out to people?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Do you find that people are unable to understand you?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Do you find you have to repeat things a number of times during conversations to be understood?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Do you have trouble with speaking:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. - in large groups of people?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. - in small groups of people?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. - with one person?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. - in different rooms of your house (apartment, residence)?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. - in loud or noisy places?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16. - on the telephone?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17. - in the car, bus or while traveling?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Question</td>
<td>Always</td>
<td>Often</td>
<td>Sometimes</td>
<td>Never</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>--------</td>
<td>-------</td>
<td>-----------</td>
<td>-------</td>
</tr>
<tr>
<td>18. - have difficulty when attending parties or social gatherings?</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>19. - use the telephone less often than you would like?</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>20. - feel left out when you are with a group of people?</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>21. - limit your social life or personal life?</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td><strong>Does your speech cause you to feel:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>22. - depressed?</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>23. - frustrated when talking to family and friends and they can’t understand you?</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>24. - different or peculiar?</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>25. - Do you hesitate to meet new people because of your speech?</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>26. - Do you get left out of conversations because of your speech?</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>27. Do you avoid speaking with other people because of your speech?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>28. Do people tend to fill in words or complete sentences for you?</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>29. Do people interrupt you while you are speaking?</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>30. Do people tell you that they can’t understand you?</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>31. Do the people you speak with get annoyed with you because of your speech?</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>32. Do people avoid you because of your speech?</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>33. Do people speak to you differently because of your speech?</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>34. Do your family and friends fail to understand what it’s like to communicate with this type of speech?</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>35. Do you talk the same amount now as before your laryngectomy?</td>
<td>YES</td>
<td>MORE</td>
<td>LESS</td>
<td></td>
</tr>
</tbody>
</table>
NAIM Evaluation Protocol

Variables used for evaluation of the NAIM technique (revised 2007 from Hilgers et al (2002))

Patient performance of NAIM variables*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Totally correct</th>
<th>Partly correct</th>
<th>Totally incorrect</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Lip closure</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>2. Lowering floor of mouth</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>3. Lowering jaw</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>4. Bite gesture</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>5. Chewing movement</td>
<td>2</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>6. Facial movements</td>
<td>0</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>7. Doing something with stoma</td>
<td>0</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

Type of breathing
8. Sniffing                          | 0               | 2              |                   |
9. Deep                              | 0               | 2              |                   |
10. Normal                           | 2               | 0              |                   |

11. Head/neck position               | Tense           | Partly tense   | Relaxed           |
                                | 0               | 1              | 2                 |

12. Overall rating of NAIM technique** | Totally correct | Partly correct | Totally incorrect |
                                | 2               | 1              | 0                 |

* NAIM 1-11, execution of 11 NAIM variables, score range minimum-maximum 0-22
** NAIM 12, overall rating of NAIM technique, score range minimum-maximum 0-2