Assessment of the Disabilities of the Arm, Shoulder and Hand (DASH) Questionnaire for use in Patients following Neck Dissection for Head and Neck Cancer

by

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ABSTRACT

In this cross-sectional study, the sensibility, reliability, and validity of the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire were assessed in patients who underwent neck dissection for head and neck cancer. A sensibility questionnaire was used to assess face and content validity. Test-retest reliability was tested by re-mailing the questionnaire; validity, by evaluating differences in scores between patients undergoing different types of neck dissections and by correlating DASH scores with Neck Dissection Impairment Index (NDII) scores. The DASH was considered sensible by both patients and surgeons. The DASH was reliable with an intraclass coefficient of 0.91. The DASH showed differences between patients who underwent accessory nerve-sacrifice and nerve-sparing neck dissection. DASH scores strongly correlated with NDII scores. Thus, the DASH is a sensible, reliable, and valid instrument for assessing shoulder impairments and activity limitations following neck dissection.
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LIST OF ABBREVIATIONS

ANOVA: analysis of variance
ASES: American Shoulder and Elbow Surgeons
CI: confidence interval
DASH: Disabilities of the Arm, Shoulder and Hand
EMG: electromyography
HPV: human papilloma virus
HSD: Honestly Significant Difference
ICC: intraclass correlation coefficient
ICF: International Classification of Functioning, Disability and Health
IJV: internal jugular vein
MRND: modified radical neck dissection
NDII: Neck Dissection Impairment Index
QOL: quality of life
RC-QOL: Rotator Cuff Quality of Life Measure
RCT: randomized controlled trial
RND: radical neck dissection
ROM: range of motion
SAN: spinal accessory nerve
SCM: sternocleidomastoid muscle
SND: selective neck dissection
SF-36: Short Form Medical Outcomes 36
SPADI: Shoulder Pain and Disability Index
SDQ: Shoulder Disability Questionnaire
UW-QOL: University of Washington Quality of Life Questionnaire
VAS: visual analogue scale
WHO: World Health Organization
WOOS: Western Ontario Osteoarthritis Shoulder Index
WORC: Western Ontario Rotator Cuff Index
WOSI: Western Ontario Shoulder Instability index
Chapter 1

INTRODUCTION

Outcomes for head and neck cancer have historically focused on disease recurrence and survival; however, over the past two decades there has been increasing recognition of the need to evaluate treatment-related morbidity and patients’ ability to function in everyday life after cancer treatment.\(^{(1)}\) Consequently, health-status outcome measurement has become a critical issue in both research and clinical endeavors in head and neck oncology. The World Health Organization (WHO) International Classification of Functioning, Disability and Health (ICF) taxonomy identifies the consequences of disease and treatment; namely, impairments, activity limitations, and restrictions in social participation.\(^{(2-4)}\) Impairment is defined by the ICF as a significant deviation or loss in the physiologic function(s) of a body system or an anatomical part of the body.\(^{(2, 4)}\) Activity limitations are difficulties an individual may face in the execution of a task or action, while participation restrictions are problems an individual may experience in involvement in a life situation.\(^{(2, 4)}\) In accordance with the ICF, a complete assessment of outcome for any health condition or intervention requires an evaluation of health-status outcomes in these domains.\(^{(2, 4)}\)

Patients with malignancies of the head and neck frequently experience significant disruptions in their life as a result of the disease and/or its treatment.\(^{(1, 5-8)}\) Interventions for head and neck cancer, which include surgery, radiotherapy, or chemotherapy, can result in significant changes in speech, swallowing, and/or shoulder function. Limitations
in these critical functions have been shown to lead to problems in involvement in life situations and lead to a reduction in a patient’s physical, mental, and social functioning and overall well being.\(^{1, 5, 7, 9-11}\) Shoulder impairments in pain, strength, and range of motion (ROM) are recognized as significant adverse effects of surgical removal of cervical lymph nodes (neck dissection), which is frequently employed in the management of head and neck cancers. Impairment results from either manipulation or resection of the cervical portion of the spinal accessory nerve (SAN), which is the predominant motor supply to the trapezius muscle. Denervation of the trapezius muscle secondary to SAN injury limits elevation, retraction, and rotation of the scapula,\(^{12, 13}\) with resultant impairment of shoulder function, such as pain, loss of strength, and ROM of the shoulder.\(^{14}\) These shoulder impairments have been shown to result in activity limitations such as brushing one’s hair or teeth, lifting or reaching overhead, and performing household chores.\(^{15-17}\)

Measurement of shoulder impairment and activity limitation may include assessment using patient-based self-report questionnaires (i.e., to assess pain and activity limitations), as well as clinician-based assessments of strength and ROM. Appropriately designed and validated patient-based questionnaires are a recognized standard for reporting patient health-status outcomes.\(^{18}\) Many different patient-based questionnaires have been used to assess shoulder pain and activity limitation following neck dissection. The vast majority of instruments previously developed would not meet contemporary standards for measurement.\(^{13, 19-26}\) Some studies have employed questionnaires, which were not specifically developed or evaluated for use in the head and neck cancer population, or do not contain all the relevant content.\(^{27-36}\) Presently, there is no uniformly accepted
patient-based outcome measure of symptoms and activity limitations of the shoulder following neck dissection.

Patients with head and neck cancer have unique problems that require investigations specific to their disease-related issues. The etiology of the activity limitations of the shoulder in head and neck cancer patients, such as SAN injury, differs from that seen in the samples used for the development of most other instruments to assess shoulder impairments (e.g., rotator cuff injury and shoulder instability). SAN injury is relatively unique to head and neck surgery, and deliberate sacrifice of the nerve is relatively specific to patients requiring neck dissection for head and neck cancer. The Neck Dissection Impairment Index (NDII) is currently the only instrument specifically designed to assess shoulder impairment and activity limitation following this procedure, and it has not been uniformly accepted as the instrument of choice. The NDII has some weaknesses in its development and evaluation, and it may fall short in covering all of the relevant content. Therefore, for future research and clinical management, an alternate standardized measure of shoulder impairment and activity limitations that has undergone appropriate methodological evaluation in the head and neck cancer population may be useful.

The Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire is a patient-reported questionnaire that was designed to measure physical symptoms and activity limitations related to any condition of any joint of the upper extremity. The DASH outcome measure has undergone extensive reliability, validity, and responsiveness testing and has been used to assess upper extremity dysfunction in many different musculoskeletal conditions. It has not been used to assess shoulder outcomes in head and neck cancer patients. The goal of this thesis was to evaluate the
clinical utility and measurement properties of the DASH in patients who have undergone a neck dissection for head and neck cancer.

This thesis has been structured in traditional chapter format. The background section provides an overview of head and neck cancer, its treatment, and the shoulder morbidities that can result. The variability in measurement of symptoms and activity limitations of the shoulder, as well as the rationale for consideration of an alternate measurement tool, are presented. The methods section describes the sample population, procedures, and methodology that were employed as well as the statistical analyses that were performed. Following the methods section, the results and discussion are presented.
Chapter 2
BACKGROUND

To facilitate an understanding of head and neck cancer and its impact on patients, the first half of this chapter provides an overview of the disease, its surgical treatment, and the shoulder-related morbidity that can result from neck dissection. The second half of the chapter provides an overview of the strengths and weaknesses of the patient-based measures of shoulder-related symptoms and activity limitations that have been used in the head and neck literature. The need for an alternative measurement instrument and the rationale for selection of the DASH are presented.

2.1 Head and neck cancer

Head and neck cancer is a general descriptor of malignancies arising within the head and neck regions with varying presentations, histopathologies, treatments, and prognoses. Head and neck cancers include those arising from the mucosa of the upper aerodigestive tract (i.e., the oral cavity, oropharynx, larynx, nasopharynx, hypopharynx, cervical esophagus, nose, and paranasal sinuses), skin cancers, thyroid cancers, and salivary gland cancers.

Cancers of the head and neck as a whole represent a significant burden of disease in North America. In 2009, there were an estimated 9250 new cases of head and neck cancer (excluding esophageal and cutaneous malignancies) diagnosed in Canada\(^{(45)}\) and an estimated 750 to 1500 new cases of melanoma of the head and neck.\(^{(45)}\) In the United States, the incidence is approximately 10 times that seen in Canada.\(^{(46)}\) The incidence of
both thyroid and skin cancers are increasing in North America and other industrialized countries.\(^{47, 48}\) In developing parts of the world, squamous cell carcinoma of the upper aerodigestive tract represents one of the most common forms of cancer, and thus worldwide, head and neck cancer represents a major health burden.\(^{46}\)

Squamous cell carcinomas of the head and neck tend to occur in males in their 7\(^{\text{th}}\) and 8\(^{\text{th}}\) decade of life, with a history of smoking and alcohol consumption.\(^{46}\) There is however, a rapidly rising incidence of squamous carcinoma in younger patients (i.e., < 60 years of age), which is believed to be attributable to the human papilloma virus (HPV).\(^{49-51}\) Thyroid cancers tend to occur in young patients, particularly females, and are associated with excellent long-term survival.\(^{46}\) Melanoma and non-melanoma skin cancers occur in both young and older patients.\(^{52}\) Among head and neck malignancies, thyroid cancer, non-melanoma skin cancer and HPV-related oropharynx cancers are associated with relatively favorable outcomes.\(^{47, 50, 51, 53}\) Thus, with a rapidly rising incidence in each of these three forms of cancer, all of which typically develop in young patients, there will be a large number of patients who survive their disease and live for long periods of time with morbidities related to their treatment.

In general, head and neck cancers are treated with varying combinations of surgery, radiotherapy, and chemotherapy. Treatment depends upon a number of variables, including tumor factors (location and extent of the primary tumor and metastatic neck disease, tumor histology, and propensity to metastasize to regional lymph nodes or distant sites); patient factors (co-morbidities, performance status, and patient desires regarding treatment and quality of life (QOL)); and physician/institutional factors (infrastructure for
radiotherapy and chemotherapy and management of their toxicities, and surgeons’ experience with reconstructive and conservation surgery).

2.2 Cervical lymph nodes and their management

Head and neck cancers have a propensity to metastasize to the cervical lymph nodes;\(^{(54,55)}\) squamous cell carcinomas of the upper aerodigestive tract, thyroid cancers, and advanced skin cancers have the greatest risk.\(^{(55)}\) Management of the cervical lymph nodes is one of the key components of treatment. Of the estimated 800 lymph nodes in the body, 300 are situated in the neck.\(^{(55)}\) Treatment of cervical lymph nodes, with surgery and/or radiotherapy, is required for the treatment of existing nodal metastases or prophylactically for those patients at risk of clinically undetectable nodal metastases. Surgical removal of cervical lymph nodes, referred to as neck dissection, is performed when 1) surgery is used to treat the primary tumor and management of the lymph nodes is required; 2) there is incomplete response of metastatic lymph nodes in patients following primary treatment with radiotherapy or chemoradiotherapy; or, 3) recurrence develops in the cervical lymph nodes after an initial complete response to treatment with radiotherapy or chemoradiotherapy.
2.3 Definitions of the different types of neck dissections

Several types of neck dissection are used in the surgical management of patients with cancers of the head and neck. A common nomenclature system has been adopted that takes into account the lymph node groups (levels) that are removed and secondarily the anatomic structures that are either preserved or resected.\(^{(56)}\) The extent of neck dissection is determined by the severity and volume of disease.\(^{(56-59)}\)

2.3.1 Types of neck dissections\(^{(56)}\)

The three main anatomic types of neck dissection include radical neck dissection (RND), modified radical neck dissection (MRND), and selective neck dissection (SND). A RND involves removal of all lymph nodes from one side of the neck along with several surrounding non-lymphatic structures, including the sternocleidomastoid muscle (SCM), the internal jugular vein (IJV), and the SAN. An extended RND involves excision of additional structures that are not routinely removed with RND, such as the deep muscles of the neck, or the carotid artery. While the MRND denotes preservation of one or more non-lymphatic structures under the common nomenclature system, for the purpose of this thesis, MRND has been defined as a neck dissection that involves removal of all lymph nodes on one side of the neck with preservation of the SAN, with or without resection of SCM and/or IJV. A SND includes removal of selective lymph node groups from one side of the neck with preservation of all non-lymphatic structures. A MRND tends to involve more dissection and manipulation of the SAN along its entire course from the skull base.
to the trapezius muscle, whereas with the SND only the proximal segment of the SAN is manipulated from the skull base to the SCM.\(^{(58, 60)}\) Table 1 summarizes the structures that are removed with each type of neck dissection.

Table 1: Types of neck dissections and associated structures removed

<table>
<thead>
<tr>
<th>Type of neck dissection</th>
<th>Anterior neck lymph nodes</th>
<th>Posterior neck lymph nodes</th>
<th>SCM muscle</th>
<th>Internal jugular vein</th>
<th>Spinal accessory nerve</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selective neck dissection</td>
<td>√</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Modified radical neck dissection</td>
<td>√</td>
<td>√</td>
<td>+/-</td>
<td>+/-</td>
<td></td>
</tr>
<tr>
<td>Radical neck dissection</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td>√</td>
</tr>
</tbody>
</table>

√: structure is removed with neck dissection

2.3.2 Indications for the different types of neck dissections

SNDs are typically performed in patients without clinical or radiographic evidence of nodal metastases but who have a greater than 15–20% chance of having microscopic nodal metastases.\(^{(61)}\) MRNDs are performed in patients who present with nodal metastases that do not directly involve the SAN. RNDs are performed in those patients who have either very extensive nodal disease or in those patients where the SAN is invaded by the nodal disease. The goal of any neck dissection is to remove nodal
metastases with clear margins while trying to preserve as many structures (i.e., the IJV, SCM, and/or SAN) as possible. Prior to the 1980s, RND was considered the gold standard neck dissection for all head and neck cancers.\(^{62, 63}\) With increasing recognition that similar oncologic results could be achieved without sacrifice of the SAN, the nerve sparing neck dissections (MRNDs and SNDs) have supplanted the RND in the majority of cases.\(^{62, 63}\) However, RNDs are still required in select cases of advanced or widely invasive nodal disease.

### 2.4 Shoulder function and the spinal accessory nerve (SAN)

There are several types of movements of the shoulder joint, each requiring the coordination of muscles that attach to the scapula, humerus, and clavicle. The muscles involved include the levator scapulae, rhomboid major, rhomboid minor, latissimus dorsi, trapezius, deltoid, supraspinatus, infraspinatus, teres minor, teres major, and subscapularis.\(^{12}\) The trapezius and levator scapulae muscles are the only two muscles involved in shoulder movement that have cervical portions and are therefore at risk of injury during a neck dissection, either directly or through their motor innervation. The trapezius muscle elevates, retracts, and rotates the scapula, which allows the shoulder to elevate and abduct the arm past 90\(^{\circ}\).\(^{12}\) The trapezius muscles also assist the serratus anterior muscle in rotating the scapula when the arm is raised overhead. With shoulder abduction, the upper and lower thirds of the trapezius rotate the scapula and the middle third stabilizes the scapula.\(^{12}\) While the majority of motor innervation to the trapezius is supplied by the SAN, the ventral rami of the 3\(^{rd}\) and 4\(^{th}\) cervical nerves also provide limited motor innervation to the trapezius muscle, although it is variable among
patients. The levator scapulae functions to raise the superior border of the scapula and laterally rotate the scapula. It has a very limited role in arm movement. The levator scapulae is innervated by C3 and C4, along with the dorsal scapular nerve (C5).

The main morbidity from a neck dissection is related to manipulation of the SAN, which is the predominant motor innervation to the sternocleidomastoid and trapezius muscles. Various degrees of SAN injury may occur in the course of a neck dissection. In a RND, injury results from deliberate resection of the nerve. In a MRND, the SAN is preserved, but dissected, and manipulated along its entire cervical course. Temporary or permanent injury may result from stretching the nerve and/or disruption of the neural vasculature. With a SND, nerve injury results from manipulation, dissection, or stretching of the proximal segment of the nerve. The extent of injury and timing of recovery is a function of the degree of manipulation, type of injury, and patient factors such as age and co-morbidity. The nerves to levator scapulae lie deep to the plane of a neck dissection (i.e., the deep cervical fascia) and therefore are not routinely at risk of injury during the course of a neck dissection. However, temporary or permanent nerve injury, either to the SAN or to the motor nerves to the levator scapulae, may also occur from heat or electrical transmission from monopolar cautery dissection in their vicinity.

It has long been recognized that the temporary or permanent denervation of the trapezius muscle secondary to SAN injury during a neck dissection results in shoulder impairments and activity limitations. Ewing and Hayes in 1952 were the first to report that resection of the SAN with a RND resulted in significant shoulder impairments, including pain, and
reduction in strength and ROM. In 1961, Nahum and Marmor further described and reported the shoulder impairment that followed a RND. This impairment was characterized by shoulder droop, winged scapula, inability to shrug, and a dull non-localizing pain, which was exacerbated by movement, particularly shoulder abduction. Similarly, other contemporary authors reported that these shoulder impairments resulted in significant limitations in daily activities, work-related tasks and recreation. Szunyogh in 1959 reported that all of their RND patients experienced problems with performing daily activities such as putting on a coat or shirt, hairdressing or shaving, because of the limitations related to shoulder function.

With recognition of the impact of shoulder impairments and activity limitations on patients, surgeons such as Bocca and Skolnik developed modifications of the RND (i.e., the modified radical and selective neck dissection) that preserved the SAN without compromising oncologic outcomes. However, despite preservation of the SAN, shoulder impairments and activity limitations were still reported following these less radical procedures.

2.5 Literature review on shoulder impairments and activity limitations following neck dissection

Since the original description of shoulder morbidity resulting from RND, there has been a significant amount of literature assessing shoulder impairments and activity limitations in patients undergoing both nerve-sparing and nerve-sacrifice neck dissections. A literature review of shoulder impairments and activity limitations following neck dissection was
performed to highlight the significant variability in assessment of outcomes and results. The review was performed using Ovid Medline and Embase databases (from 1966 to December 2008). The electronic search was restricted to papers published in the English language using the following MESH terms or text words: shoulder, upper extremity, disability, activity limitations, impairment, function, questionnaire, spinal accessory nerve, shoulder syndrome, morbidity, disability, pain, symptoms, QOL, neck dissection, and head and neck cancer. The electronic search was supplemented by cross-referencing potentially relevant citations. For the studies described in the following literature review, Table 2 highlights the year of publication, sample size, comparison groups, outcome measures, and time of assessment.
Table 2: Summary of studies on shoulder morbidity following neck dissection

<table>
<thead>
<tr>
<th>Author</th>
<th>Year publish</th>
<th>Journal</th>
<th>Type of study</th>
<th>Comparison groups</th>
<th>N</th>
<th>Number of neck dissections</th>
<th>Mean Age (years)</th>
<th>Laterality</th>
<th>ROM or strength assessed</th>
<th>EMG</th>
<th>Patient Self-report measure used</th>
<th>Measurement period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carenfelt et al(68)</td>
<td>1981</td>
<td>Acta Otolaryngol</td>
<td>C</td>
<td>RND vs MRND</td>
<td>53</td>
<td>53</td>
<td>Not described</td>
<td>UND</td>
<td>ROM &amp; Strength</td>
<td>No</td>
<td>Pain</td>
<td>2 to 7 yrs post-op</td>
</tr>
<tr>
<td>Schuller et al(13)</td>
<td>1983</td>
<td>Head Neck</td>
<td>C</td>
<td>RND vs MRND</td>
<td>243</td>
<td>Not described</td>
<td>Not described</td>
<td>UND</td>
<td>No</td>
<td>No</td>
<td>Own</td>
<td>Btw 6 mo and 5 yrs post-op</td>
</tr>
<tr>
<td>Short et al(25)</td>
<td>1984</td>
<td>Am J Surg</td>
<td>C</td>
<td>SND vs MRND vs RND vs patients with no ND</td>
<td>35</td>
<td>35</td>
<td>60</td>
<td>UND</td>
<td>ROM &amp; Strength</td>
<td>No</td>
<td>Own</td>
<td>&gt; 6 wks post-op</td>
</tr>
<tr>
<td>Sobol et al(26)</td>
<td>1985</td>
<td>Am J Surg</td>
<td>P</td>
<td>SND vs MRND &amp; RND</td>
<td>35</td>
<td>44</td>
<td>56</td>
<td>UND &amp; BND</td>
<td>No</td>
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<td>Own</td>
<td>Pre-op, Mean 17 wks post-op; range 11–39 wks; EMG at 1 yr post-op</td>
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<td>Saunders et al(72)</td>
<td>1985</td>
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<td>C</td>
<td>RND vs MRND vs RND with cable graft</td>
<td>100</td>
<td>146</td>
<td>57</td>
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<td>No</td>
<td>Own</td>
<td>Mean of 6.2 yrs post-op; and 6 mo–19 yrs</td>
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For type of study column: P= Prospective; C=Cross-sectional; R=Retrospective
For comparison column: SND=Selective neck dissection, MRND=Modified radical neck dissection & RND=Radical neck dissection
For laterality column: UND=unilateral neck dissection; BND=bilateral neck dissection
ROM= Range of motion, EMG= electromyography, Mo=months
Questionnaires: NDII-Neck Dissection Impairment Index; SDQ-Shoulder Disability Questionnaire; UWQOL-University of Washington Quality of Life Questionnaire; VAS-Visual analogue scale; HNQOL-Head and Neck Quality of Life Questionnaire; SPADI-Shoulder Pain and Disability Index
Term “own” refers to questionnaires devised solely for the study without any methodologic principles applied
<table>
<thead>
<tr>
<th>Author</th>
<th>Year publish</th>
<th>Journal Type</th>
<th>Type of study</th>
<th>Comparison groups</th>
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<th>Number of neck dissections</th>
<th>Mean age (years)</th>
<th>Laterality</th>
<th>ROM or strength assessed</th>
<th>EMG</th>
<th>Patient self-report measure used</th>
<th>Measurement period</th>
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<tr>
<td>Remmler et al&lt;sup&gt;(73)&lt;/sup&gt;</td>
<td>1986</td>
<td>Head Neck</td>
<td>P</td>
<td>Pre-op vs Post-op &amp; RND vs SND vs MRND</td>
<td>90</td>
<td>103</td>
<td>56</td>
<td>UND &amp; BND</td>
<td>ROM &amp; Strength</td>
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<td>None</td>
<td>Pre-op, 1 mo, 3 mo, 6 mo &amp; 12 mo post-op</td>
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<td>Fialka et al&lt;sup&gt;(74)&lt;/sup&gt;</td>
<td>1988</td>
<td>J Cranio-Max-Fac Surg</td>
<td>P</td>
<td>Pre-op vs Post-op</td>
<td>43</td>
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<td>Hillel et al&lt;sup&gt;(75)&lt;/sup&gt;</td>
<td>1989</td>
<td>J of Otolaryngol</td>
<td>R</td>
<td>No comparison</td>
<td>11</td>
<td>11</td>
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<td>ROM</td>
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<td>1999</td>
<td>Laryngoscope</td>
<td>P</td>
<td>Pre-op vs Post-op &amp; RND vs SND vs MRND</td>
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<td>84</td>
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<td>No</td>
<td>UWQOL</td>
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<td>Terrell et al&lt;sup&gt;(35)&lt;/sup&gt;</td>
<td>2000</td>
<td>Laryngoscope</td>
<td>C</td>
<td>RND vs SND + MRND vs normal controls (no surgery)</td>
<td>175</td>
<td>224</td>
<td>61</td>
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<td>No</td>
<td>No</td>
<td>HNQOL</td>
<td>Not described</td>
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<td>Cheng et al&lt;sup&gt;(53)&lt;/sup&gt;</td>
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<td>Ann Oto Rhino Lary</td>
<td>P</td>
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<td>21</td>
<td>21</td>
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<td>Strength</td>
<td>Yes</td>
<td>None</td>
<td>1 &amp; 6 mo post-op</td>
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<td>Journal</td>
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<td>EMG</td>
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<td>Laryngoscope</td>
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<td>Yes</td>
<td>None</td>
<td>Pre-op, 3 wk to 3 mo post-op</td>
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<td>Shah et al</td>
<td>2001</td>
<td>Head Neck</td>
<td>C</td>
<td>SND vs MRND vs RND &amp; operated vs non operated side</td>
<td>51</td>
<td>51</td>
<td>62</td>
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<td>No</td>
<td>Own</td>
<td>5– 90 months post-op</td>
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<td>177</td>
<td>181</td>
<td>60</td>
<td>UND &amp; BND</td>
<td>ROM</td>
<td>No</td>
<td>Own</td>
<td>Mean of 13 days post-op</td>
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<td>Salerno et al</td>
<td>2002</td>
<td>Laryngoscope</td>
<td>C</td>
<td>Physiotherapy vs No physiotherapy</td>
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<td>Not described</td>
<td>59</td>
<td>Not described</td>
<td>ROM &amp; Strength</td>
<td>Yes</td>
<td>Constants Score</td>
<td>15, 30, 90 &amp; 180 days post-op</td>
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<td>Taylor et al</td>
<td>2002</td>
<td>Head Neck</td>
<td>C</td>
<td>SND vs MRND</td>
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<td>UND &amp; BND</td>
<td>No</td>
<td>No</td>
<td>NDII</td>
<td>Mean of 34 mo post-op; all &gt;11 mo post-op</td>
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<td>Chepeha et al</td>
<td>2002</td>
<td>Head Neck</td>
<td>C</td>
<td>SND vs MRND</td>
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<td>ROM &amp; Strength</td>
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<td>Constant's Score</td>
<td>Mean of 34 mo post-op; all &gt;11 mo post-op</td>
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<td>EMG</td>
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<td>El-Ghani et al(21)</td>
<td>2002</td>
<td>Clin Otolaryngol</td>
<td>C</td>
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<td>59</td>
<td>80</td>
<td>61</td>
<td>UND &amp; BND</td>
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<td>J Cran Max Su</td>
<td>R</td>
<td>SND (no comparison group)</td>
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<td>60</td>
<td>63</td>
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<td>No</td>
<td>No</td>
<td>No</td>
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<td>113</td>
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<td>UND</td>
<td>ROM</td>
<td>No</td>
<td>Shoulder pain – VAS</td>
<td>&gt; 1 year after</td>
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<td>Head Neck</td>
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<td>Pre-op vs Post-op &amp; RND vs SND + MRND vs no surgery</td>
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<td>92</td>
<td>57</td>
<td>UND &amp; BND</td>
<td>ROM</td>
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<td>Mean of 27 mo post-op; ROM testing btw 4–6 mo post-op</td>
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<td>Laverick et al(29)</td>
<td>2004</td>
<td>Arch Oto HNS</td>
<td>P</td>
<td>SND vs no ND</td>
<td>220</td>
<td>259</td>
<td>62</td>
<td>UND &amp; BND</td>
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<td>No</td>
<td>UWQOL</td>
<td>Pre-op, 6 mo, 12 mo &amp; &gt;18 mo post-op</td>
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<td>Van Wilgen(79)</td>
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<td>J Cran Max Su</td>
<td>R</td>
<td>SND vs MRND</td>
<td>137</td>
<td>137</td>
<td>61</td>
<td>UND &amp; BND</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>&gt; 1 year after</td>
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<td>2004</td>
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<td>C</td>
<td>No comparison</td>
<td>154</td>
<td>Not described</td>
<td>61</td>
<td>UND &amp; BND</td>
<td>ROM</td>
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<td>Shoulder pain</td>
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<tr>
<td>Author</td>
<td>Year</td>
<td>Journal</td>
<td>Type of study</td>
<td>Comparison groups</td>
<td>N</td>
<td>Number of neck dissections</td>
<td>Mean age (years)</td>
<td>Laterality</td>
<td>ROM or strength assessed</td>
<td>EMG</td>
<td>Patient self-report measure used</td>
<td>Measurement period</td>
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<td>Cappiello et al(19)</td>
<td>2005</td>
<td>Laryngoscope</td>
<td>R</td>
<td>SND vs MRND</td>
<td>40</td>
<td>Not described</td>
<td>62</td>
<td>UND &amp; BND</td>
<td>ROM</td>
<td>Yes</td>
<td>Own</td>
<td>&gt; 1 year after</td>
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<tr>
<td>Guldiken et al(80)</td>
<td>2005</td>
<td>Auris Nasus Larynx</td>
<td>P</td>
<td>Pre-op vs Post-op</td>
<td>25</td>
<td>50</td>
<td>Not described</td>
<td>BND</td>
<td>ROM</td>
<td>No</td>
<td>Modified NDII</td>
<td>Pre-op, 1 mo, 3 mo, 6 mo &amp; 18 mo post-op</td>
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<td>Inoue et al(23)</td>
<td>2006</td>
<td>Arch Oto HNS</td>
<td>C</td>
<td>SND vs MRND vs RND</td>
<td>74</td>
<td>115</td>
<td>61</td>
<td>UND &amp; BND</td>
<td>ROM</td>
<td>No</td>
<td>Own</td>
<td>Mean of 36 mo; range 12 mo-23 yrs post-op</td>
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<tr>
<td>Rogers et al(31)</td>
<td>2007</td>
<td>Br J Oral Maxill Surg</td>
<td>C</td>
<td>SND vs MRND &amp; RND</td>
<td>100</td>
<td>87</td>
<td>63 (median)</td>
<td>UND &amp; BND</td>
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<td>No</td>
<td>NDII, SDQ, UWQOL</td>
<td>Mean 12 mo (range 3-38 months)</td>
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<td>Orhan et al(30)</td>
<td>2007</td>
<td>J Laryng &amp; Otolog</td>
<td>P</td>
<td>Pre-op vs Post-op &amp; RND vs MRND</td>
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<td>42</td>
<td>61</td>
<td>BND</td>
<td>No</td>
<td>Yes</td>
<td>NDII, SDQ, UWQOL</td>
<td>Pre-op &amp; 9 mo post-op</td>
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<td>Selcuk(33)</td>
<td>2008</td>
<td>Tumori</td>
<td>P</td>
<td>Pre-op vs Post-op &amp; SND vs MRND</td>
<td>26</td>
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<td>ROM</td>
<td>Yes</td>
<td>SPADI</td>
<td>Pre-op, 6 wks &amp; 6 mo post-op</td>
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<tr>
<td>Stuiver et al(36)</td>
<td>2008</td>
<td>OTO HNS</td>
<td>P</td>
<td>Pre-op vs Post-op</td>
<td>118</td>
<td>118</td>
<td>58</td>
<td>UND &amp; BND</td>
<td>ROM</td>
<td>No</td>
<td>SDQ, RAND-36</td>
<td>&gt; 4 mo post-op</td>
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</table>
It should be noted that there are many weaknesses with the current literature. As can be seen in Table 2, the majority of studies are retrospective and cross-sectional in design with relatively small patient numbers. There is wide variation in inclusion criteria of the different types of neck dissection (i.e., SND, MRND, and/or RND). Furthermore, non-standardized terminologies have frequently been employed to describe the neck dissections. Some studies included only unilateral neck dissections while others included patients who underwent bilateral neck dissections, where the latter patients may have more impairments and functional limitations than the former. Studies varied in terms of comparative groups; some studies compared outcomes between the different types of neck dissections, while others compared preoperative and postoperative differences, or the neck dissection side with the non-surgical side. Other studies provided no comparison group. There was heterogeneity between studies in terms of the time from surgery when patients were assessed: short- (< 6 months from surgery) versus long-term (>12 months) outcomes. Lastly, there was significant variability in patient-based self-report questionnaires used to assess symptoms and activity limitations. Further, confounding the literature are the various terms that were used by investigators to describe shoulder outcomes following neck dissection, including “shoulder-related quality of life,” “shoulder disability,” “shoulder syndrome,” “shoulder dysfunction,” and “shoulder impairment.” Despite using these various terms, none of the authors clearly described the conceptual framework of the “impairment,” “dysfunction,” or “disability” they were measuring or reporting. Upon examining each of the studies, it is apparent that the authors were mainly assessing constructs similar to the WHO ICF definition of impairments and activity limitations, despite using the term “disability.”
limitations make evaluation of the literature difficult and need to be recognized in interpreting the following review.

The literature review is divided into: 1) studies assessing the prevalence of shoulder impairment and activity limitations following nerve-sacrificing and nerve-sparing neck dissections; 2) studies comparing shoulder outcomes (impairment and activity limitations) between the different types of neck dissections; 3) studies assessing differences in scores on health-related QOL questionnaires between the different types of neck dissections; and, 4) studies assessing the impact of shoulder impairment on work status or occupation. For the literature review, the terms used by the authors to describe the shoulder morbidity will be provided in quotations; however, it should be noted that the term “disability” most frequently corresponded to the definition of activity limitations, while the term “complaints” was used to describe any shoulder problems including impairments (pain, decreased range of motion and strength) and activity limitations.

2.5.1 Prevalence of shoulder impairments, activity limitations and participation restrictions following neck dissection

i) Radical neck dissections (nerve-sacrifice neck dissections): van Wilgen et al reviewed the prevalence of shoulder “complaints” reported in the literature, which included shoulder pain, decreased strength and ROM, physical disfigurement (i.e. the physical appearance of the shoulder) and activity limitations following RND. They reported a high prevalence, but a wide range of 50 to 100% of patients reporting some
“complaint” (22, 25, 32, 33, 72, 79, 81) This wide range is likely due to a number of factors including the construct being measured, the outcome measure employed and the time from surgery when patients were assessed. Shoulder pain is the most frequent “complaint” when measured by either visual analogue scales (VAS) or questionnaires. Shoulder pain associated with RND typically is a moderate dull persistent ache that is variable in severity: severe pain requiring daily use of analgesia is unusual. (68, 82) However, the degree of severity of pain is highly variable between studies. Dijkstra et al, using a VAS, reported that 79% of 42 RND patients reported having pain prior to discharge from hospital. (20) Fialka et al, using a pain verbal rating scale, found that 77% of RND patients, assessed between one and six months after surgery, had severe or strong shoulder pain. (74) Shone et al noted that only 30% of 46 patients who were all greater than 6 months from their unilateral RND reported moderate-severe or severe pain related to the shoulder on a questionnaire devised by the authors. (83) An additional 30% of patients in the Shone et al series reported some degree of pain most days or every day. Carenfelt et al assessed 24 patients between two to seven years following RND by using a non-validated questionnaire they designed specifically for the study. (68) They noted that discomfort and pain only became significant beyond three months following surgery. Short et al described 12 patients who had undergone RND between 6 weeks and 6 years previously. (25) Of these 12 patients, 9 had some degree of shoulder pain, the average being 2.7 on a pain scale of zero to five.

Impairments in shoulder strength and ROM have frequently been described. Leipzig et al found that nearly all of their 35 patients who underwent a RND had reduced shoulder strength and ROM measured at 6 months following surgery, compared with their
preoperative assessment. Sixty percent of their patients reported pain, particularly with attempted use of the shoulder (reaching or lifting). The remaining 40% had little or no pain. These authors highlight that many of their patients did “well” despite the loss of trapezius innervation and presence of reduced ROM and strength. However, their patient numbers were small; they did not evaluate pain by using a recognized measure; and, did not use a validated measure to assess activity limitations. Krause et al noted vast differences in both clinical (inspection and palpation of shoulder position and assessment of ROM) and electromyography (EMG) results in 54 patients who underwent RND. Patients were also questioned about their “complaints” and any changes in their personal and professional life following surgery. With a mean time from surgery of 29 months, they found that 31% experienced severe limitations of ROM combined with severe pain, whereas 41% suffered only mild discomfort and 28% were free of “complaints.” Other authors, including Ewing and Martin, Fialka et al, and Saunders et al, have also reported variable results. The authors attribute some of the variability to the different patterns of innervation to the trapezius, with the cervical plexus contributing significant innervation in up to 25% of patients as confirmed by EMG studies. The most commonly reported activity limitations in daily life included lifting, raising or carrying objects, and leaning or lying on the ipsilateral shoulder. Shone et al found that 77% of patients had difficulty with everyday tasks such as dressing, combing their hair, hanging up clothes, and reaching a high shelf. Nine patients (19.5%) reported that they could no longer pursue activities they enjoyed prior to surgery such as tennis, darts, gardening, or fishing.
ii) Selective & modified radical neck dissections (nerve-sparing neck dissections):

There is significant variability in terms of the reported prevalence of shoulder impairments and activity limitations following MRND and SND. Some of the variability can be attributed to how authors defined and measured “disability.” Some authors measured symptoms alone, others evaluated impairments in ROM and strength, while other authors reported on activity limitations. No standard tool used was used to assess activity limitations between studies.

Salerno et al reported that complaints (based on a modified Constant’s Shoulder Score) of “shoulder impairment” following MRND occurred in up to 40% of patients. van Wilgen et al using the Shoulder Disability Questionnaire (SDQ) reported that 28% of 52 patients who underwent SND experienced long-term pain, particularly with activities such as moving the arm or shoulder, reaching above the shoulder, or carrying heavy objects. Guldiken et al assessed 25 patients before and after “functional neck dissection” (with no clarification of the exact type of nerve-sparing neck dissection) using the NDII questionnaire, which had not undergone any psychometric testing following their modification. The mean NDII score at one year after surgery was 98.2 out of 100 (range, 95–100), with higher scores signifying less impairment and activity limitations. While minimal “disability” was noted, pain and stiffness scores at the last follow-up were worse than preoperative scores (p < 0.005). On ROM assessment there were no significant differences between the preoperative and postoperative scores at 18 months. They concluded that function returns to normal following “functional neck dissection” but pain and stiffness persist.
2.5.2 Comparison of shoulder outcomes between the different types of neck dissections

Shoulder impairment tends to occur in the early postoperative period following most RNDs and a significant proportion of nerve-sparing neck dissections,\(^{(34)}\) with SND patients exhibiting less impairment and activity limitations.\(^{(20, 26, 33)}\) The initial decline in shoulder function tends to be followed by progressive improvement in both SND and MRND patients as reinnervation occurs.\(^{(81)}\) This typically takes between six months and one year, depending upon the degree of injury.\(^{(15, 73, 85)}\) Although similar rates of shoulder impairment in the early postoperative period have been reported in RND and MRND patients, RND patients have significantly worse shoulder ROM, strength, pain, and activity limitations than MRND patients in the long-term (i.e., > six months after surgery).\(^{(15, 25, 26, 28, 35, 38, 65, 72, 73, 80, 81)}\)

Using a non-validated questionnaire modified from the NDII in 21 neck dissection patients, Ohran et al noted that MRND patients reported significantly less “disability” compared with the RND patients.\(^{(30)}\) On electrophysiological assessment, decreases in amplitude and EMG scores were more prominent in the RND group compared with the MRND group. The amplitude of the trapezius motor response improved with time in the MRND patients but never reached their preoperative values by nine months following surgery.

Based on patient interviews, El-Ghani et al reported that 50% of patients who underwent a RND reported severe “activity disability,” compared with less than 26% of patients who underwent MRND (p = 0.009).\(^{(21)}\) Pain was also significantly worse following a RND. The largest difference in ROM between the operated and non-operated side occurred in
the RND group compared with those who underwent MRND. Shah et al\textsuperscript{(24)} and Saunders et al\textsuperscript{(72)} reported similar findings with significantly “less disability” or “shoulder-related symptoms” following MRND compared with RND when measured greater than six months from surgery. Both of these authors used their own non-validated questionnaire that they devised for their study.

There is variability in the literature on whether patients who undergo SND have less shoulder-related impairment and activity limitation than patients who undergo MRND. Van Wilgen et al evaluated patients using the SDQ and found that the type of neck dissection was significantly (p < 0.001) associated with postoperative “shoulder complaints,” and there was greater “disability” following MRND compared with SND.\textsuperscript{(79)} Similar results were reported by Taylor et al\textsuperscript{(38)} using the NDII and Chepeha et al\textsuperscript{(27)} using the Constant’s Shoulder Score. Both noted that patients who underwent SND had statistically significantly higher NDII scores (i.e., less pain and activity limitations) than those who underwent MRND. All patients in these three studies were at least 11 months from surgery.

Inoue et al assessed patients who underwent different types of neck dissections greater than one year prior, using their own questionnaire that was never assessed for reliability or validity.\textsuperscript{(23)} Scores for stiffness and appearance were lower in patients who underwent any type of neck dissection compared with a control group of patients who did not undergo a neck dissection (p < 0.001). Scores for pain and numbness in patients who underwent SND were significantly better than those who underwent MRND or RND. Shoulder droop in patients following RND was significantly worse than in those who underwent either SND or MRND. The arm abduction score in the RND group was
significantly lower than for the nerve sparing groups (p < 0.001); however, all neck dissection patients had reduced arm abduction compared with the control group. Rogers et al used three different patient-based “shoulder disability” measures (SDQ, NDII and University of Washington Quality of Life Questionnaire (UW-QOL)) to assess patients who underwent SND, MRND, or RND.\(^{31}\) The mean time from surgery was 1 year. They found that the highest levels of shoulder impairment and activity limitations were reported by patients after RND and the lowest following SND. Scores were similar between the SND patients and those who never underwent a neck dissection. Other authors have reported no significant differences in long-term shoulder-related impairments and activity limitations following MRND compared to SND.\(^{24,28}\)

2.5.3 Studies assessing differences in scores on health related quality of life questionnaires among the different types of neck dissections

Studies have attempted to assess the relationship between the type of neck dissection and scores on QOL questionnaires. Using the UW-QOL, a head and neck cancer-specific QOL questionnaire, Laverick et al found that those who underwent unilateral SND had lower scores (i.e., worse QOL) greater than one year after surgery compared to patients who did not undergo a neck dissection, but better scores than MRND patients.\(^{29}\) van Wilgen et al found that shoulder abduction and pain scores (measured on a VAS) in patients who underwent a neck dissection (RND, MRND, or SND) were significantly related to several domains (social functioning domain and limitation from physical problem domain) on a general overall QOL questionnaire (RAND-36 QOL).\(^{86}\) All 154 patients were more than one year from surgery. The authors concluded that shoulder and
neck morbidity were important outcomes in the assessment of QOL in head and neck cancer patients. In 84 patients with head and neck cancer who underwent a neck dissection, Kuntz et al showed that while the shoulder domain scores on the UW-QOL questionnaire differed based on type of neck dissection, there were no significant differences in the other QOL domain scores (subjective appearance, activity, recreation, chewing, swallowing or speech). Shoulder impairment following neck dissection is one of many adverse effects that patients with head and neck cancer can experience as a result of their treatment. Therefore, attributing a reduction in QOL solely to the type of neck dissection is difficult. Rogers et al reported that despite objective and subjective shoulder deficits after neck dissection, patients reported shoulder impairment as significantly less important to their QOL than other functional deficits such as speech and swallowing difficulties that occurred following treatment. Thus, shoulder impairments and activity limitations may have a relatively small influence on overall QOL when compared with impairments related to speech, swallowing, cognition, etc.

2.5.4 Impact of shoulder impairment on work status or occupation

Shoulder impairment has also been associated with impaired work status. Shone et al evaluated the employment status of patients who were at least six months following RND. Forty-six percent (11 of 24 patients) of patients who were employed before surgery stopped working specifically because of shoulder-related problems. Of those patients still employed at the time of the study, 20 were in manual work and 12 of these patients changed their occupation because of their shoulder problems. Schuller et al found that of 203 patients employed prior to neck dissection, only 104 (51.2%) returned
to their usual occupation after treatment.(13) A similar rate of unemployment was found between MRND and RND patients. Only 39% of patients whose jobs were classified as very strenuous returned to work as compared with 54% of patients whose job were considered less strenuous (p < 0.05). (13)

2.5.5 Summary of the literature review

In summary, manipulation of the SAN at the time of neck dissection does result in shoulder pain, reduction in shoulder ROM and strength, and activity limitations related to the shoulder. The extent of SAN manipulation does influence outcomes. RND is associated with the greatest impairment and activity limitations and SND the least. The extent of shoulder impairment and activity limitations reported in the literature following any type of neck dissection is highly variable. Some of the variability and inability to compare studies is related to the lack of a recognized, uniformly accepted instrument to measure shoulder-related outcomes. The lack of a standard questionnaire makes the comparison of results between studies difficult and the literature is compromised by numerous studies that have reported shoulder outcomes using data from questionnaires that were designed by the investigators without consideration of accepted principles of questionnaire development. (19, 21, 24, 26, 72) While other studies have used questionnaires with acceptable methodological development, many of these questionnaires were developed for evaluation of other pathologies and diagnoses and have not undergone assessment of their psychometric properties (i.e., sensibility, reliability, and validity) in the head and neck patient population. (17, 27, 31, 33, 34, 36, 80, 86)
The variability in the literature on shoulder outcomes following neck dissection highlights the need for further research. Acceptance of a well-designed patient-reported measure of shoulder impairment and activity limitations would help facilitate future studies such as an evaluation of interventions aimed at preventing and rehabilitating shoulder problems following neck dissection. A number of criteria should be considered in the selection of a patient-reported questionnaire to assess shoulder symptoms and activity limitations in head and neck cancer patients undergoing neck dissection. The following sections describe these criteria, as well as the process used in determining a potential measure.

2.6 Criteria for choosing a measurement tool for assessing shoulder impairment and activity limitations

A useful instrument must satisfy several methodological and practical criteria. Scales must possess established measurement properties if they are to be used to discriminate between levels of a respondent’s impairment and activity limitations. These measurement properties include sensibility, reliability and validity. Practical issues include the length of the scale, the time required for scoring, and mode of administration.

The following criteria were used in the selection of a measure. 1) The developers must have clearly defined the construct the questionnaire was designed to assess. For the purposes of this thesis, the questionnaire was required to measure impairments related to the shoulder including physical symptoms such as pain or numbness, and difficulties an individual may have in the execution of a task or action (activity limitations). The
measure had to focus on the actual execution of activities that are important in daily life, rather than on the desire to perform them or the perceived possibility to perform them; 2) Measurements of shoulder strength and ROM should not be included in the questionnaire; 3) It should have been developed as a discriminative index (i.e., it should have the ability to distinguish between individuals or groups on an underlying dimension when no gold standard is available for evaluating these measures). A measurement tool that has the ability to discriminate between groups would be important in future research of shoulder morbidity following neck dissection; 4) Principles of constructing instruments to measure health status outcomes, with proper steps in item selection, item reduction, questionnaire format, and pretesting should have been performed; 5) The questionnaire should be relatively brief and easy to complete, however must include sufficient items to be sensitive to detect differences between groups; 6) A summary score should be easy to calculate and interpret; and, 7) The instrument must have undergone some assessment of sensibility, reliability, and validity.

Sensibility, as defined by Rowe and Oxman, “consists of an aggregate of properties that make up the common sense aspect of an instrument, including face and content validity.” There are many important dimensions of sensibility with respect to devising a measurement instrument, some of which are 1) purpose and framework (i.e., does the instrument have a purpose that is demonstrated by the clinical function it serves, and by the justification for its existence?), 2) comprehensibility (i.e., do we understand what goes into the instrument and what comes out?), 3) replicability (do the instructions clearly stipulate the components that go into the instrument and the way they were put together?), 4) suitability of scale (i.e., does the scale have an adequate scope, a logical
pattern of rating and satisfactory capacity of discrimination?), 5) ease of usage (the amount of time, personnel, risks and efforts involved in getting and organizing the data needed to express the results of the data), 6) face validity (“the instrument appears to assess the desired qualities”), and 7) content validity (“whether the instrument samples the important content or domains”). Sensibility involves surveying prospective users of the instruments, as well as experts in the area/field that the instrument will be being used for assessment.

Reliability refers to the consistency of results obtained under stable patient conditions. The intra-class correlation coefficient (ICC) is used to calculate test-retest reliability for continuous data. Nunnally suggested that an ICC of 0.80 is sufficient in the early stages of development of a measure, with final measure values of 0.90 necessary for group comparisons and 0.95 for individual level measures.

Validity represents the extent to which an instrument measures what it is intended to measure. Assessment of validity has different components. Face and content validity are subjective evaluations of whether the content, wording, and scoring make sense. Construct and known group validity refers to how well a measure conforms to theoretical concepts concerning the entity under study. They are evaluated by testing hypotheses of clinically sensible or known phenomenon in relation to the measure.

A literature review of commonly used measures of shoulder impairment and activity limitations was performed to find an instrument that would meet the above criteria. The following section is a critical appraisal of the commonly used patient-reported measures of shoulder impairment and activity limitations, either generic or disease–specific, used
in the head and neck, orthopedic or musculoskeletal literature. Tables 3a and 3b highlights the disease-specific and generic questionnaires used to assess shoulder impairment and activity limitations in terms of their development and psychometric properties.
<table>
<thead>
<tr>
<th>Scale</th>
<th>Scale designer</th>
<th>Target population</th>
<th>Number of items</th>
<th>Dimensions (domains)</th>
<th>Scale of responses</th>
<th>Time to complete (min)</th>
<th>Ease of scoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASES: American Shoulder and Elbow Surgeons Standardized Form (102)</td>
<td>Research Committee of the American Shoulder and Elbow Surgeons</td>
<td>Pain &amp; function related to shoulder</td>
<td>1 Pain item  10 function items</td>
<td>Pain: 50% Function: 50%</td>
<td>Pain: 10-cm VAS Function: 4-pt scale</td>
<td>4</td>
<td>Difficult</td>
</tr>
<tr>
<td>Constant’s Shoulder Score (103)</td>
<td>Orthopedic surgeon</td>
<td>Pain &amp; function</td>
<td>1 pain item, 4 activity items, ROM and power score</td>
<td>Self report: Pain: 15% Function: 20% Clinical measure: ROM: 40% Strength: 25%</td>
<td>Pain: 4-pt scale Function: work, 0-4; recreation, 0-4; sleep, 0-2; arm position of work 2-10 ROM: 0–10 pt Strength: 1 point/lb, up to 25 lb</td>
<td>3</td>
<td>Moderate</td>
</tr>
<tr>
<td>DASH: Disabilities of the Arm, Shoulder and Hand (39)</td>
<td>American Academy of Orthopedic Surgeons, and Institute for Work and Health</td>
<td>Upper extremity</td>
<td>30</td>
<td>Symptoms and disability: 5-pt scale for symptoms and level of difficulty</td>
<td></td>
<td>6</td>
<td>Easy</td>
</tr>
<tr>
<td>SDQ: Shoulder Disability Questionnaire – UK (104)</td>
<td>Researchers Physical therapists</td>
<td>Shoulder symptoms</td>
<td>22</td>
<td>Pain related Disability: 100%</td>
<td>Dichotomous scale: “yes” / “no” responses</td>
<td>3</td>
<td>Easy</td>
</tr>
<tr>
<td>SDQ: Shoulder Disability Questionnaire – NL (105)</td>
<td>Researchers Physical therapists</td>
<td>Soft tissue, shoulder disorders</td>
<td>16</td>
<td>Pain related Disability: 100%</td>
<td>Dichotomous scale: “yes” / “no” responses</td>
<td>3</td>
<td>Easy</td>
</tr>
</tbody>
</table>
### Table 3a continued

<table>
<thead>
<tr>
<th>Scale</th>
<th>Scale designer</th>
<th>Target population</th>
<th>Number of items</th>
<th>Dimensions (domains)</th>
<th>Scale of responses</th>
<th>Time to complete (min)</th>
<th>Ease of scoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPADI: Shoulder and Pain Disability Index&lt;sup&gt;506&lt;/sup&gt;</td>
<td>Physical therapist Physicians</td>
<td>Shoulder pain</td>
<td>13</td>
<td>Pain: 50%</td>
<td>Function/disability: 50%</td>
<td>7</td>
<td>Difficult</td>
</tr>
<tr>
<td>NDII: Neck Dissection Impairment Index&lt;sup&gt;48&lt;/sup&gt;</td>
<td>Head &amp; Neck Surgeons, Physiotherapist</td>
<td>Neck Dissection patients</td>
<td>10</td>
<td>Symptoms Disability:</td>
<td>5-pt scale for symptoms and level of difficulty</td>
<td>4</td>
<td>Easy</td>
</tr>
</tbody>
</table>

VAS: Visual analogue scale  
ROM: Range of motion
### Table 3b: Summary of shoulder impairment and activity limitation measures used in the literature in terms of reliability, validity, and responsiveness testing

<table>
<thead>
<tr>
<th>Scale</th>
<th>Test retest reliability</th>
<th>Validity</th>
<th>Item selection</th>
<th>Item reduction</th>
<th>Responsiveness testing</th>
<th>Patient characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASES(^{102})</td>
<td>ICC: 0.84-0.94</td>
<td>Content</td>
<td>Experts Investigators</td>
<td>Yes</td>
<td>Yes</td>
<td>Ages: 20-81 yr; unknown. Therapy outpatients with surgical and nonsurgical musculoskeletal disorders; patients with shoulder instability.</td>
</tr>
<tr>
<td>Constant’s Shoulder Score(^{103})</td>
<td>ICC: 0.80</td>
<td>Content</td>
<td>Not mentioned</td>
<td>Not mentioned</td>
<td>Yes</td>
<td>Ages: unknown. Physician outpatient with musculoskeletal disorders; patients with shoulder instability.</td>
</tr>
<tr>
<td>DASH(^{39})</td>
<td>ICC: 0.92-0.96</td>
<td>Content</td>
<td>Patients Experts Investigators</td>
<td>Yes</td>
<td>Yes</td>
<td>Mean age: 45 yr (SD=16.7); unknown. Patients with surgical and nonsurgical musculoskeletal disorders; patients with shoulder instability.</td>
</tr>
<tr>
<td>SDQ: Shoulder Disability Questionnaire – UK(^{104})</td>
<td>Not assessed</td>
<td>Content</td>
<td>Patients Experts Investigator</td>
<td>No</td>
<td>Yes</td>
<td>Mean age: 51-49.6 yr (SD=13-14.4 yr). Physician primary care and therapy patients with musculoskeletal surgical and nonsurgical disorders</td>
</tr>
<tr>
<td>SDQ: Shoulder Disability Questionnaire – NL(^{105})</td>
<td>Not assessed</td>
<td>Content</td>
<td>Experts Investigator</td>
<td>Yes</td>
<td>Yes</td>
<td>Mean age: 51-49.6 yr (SD=13-14.4 yr). Physician primary care and therapy patients with musculoskeletal surgical and nonsurgical disorders</td>
</tr>
<tr>
<td>SPADI: Shoulder and Pain Disability Index(^{106})</td>
<td>ICC range: 0.64-0.96 ICC: 0.91</td>
<td>Content</td>
<td>Experts</td>
<td>Yes</td>
<td>Yes</td>
<td>Ages: 19-82, 28-30; 47-66 yr. Most subjects male. Patients with musculoskeletal and neurogenic shoulder pain, surgical and nonsurgical patients.</td>
</tr>
<tr>
<td>NDII: Neck Dissection Impairment Index(^{38})</td>
<td>Spearman-0.91</td>
<td>Content</td>
<td>Experts</td>
<td>Yes</td>
<td>No</td>
<td>Mean age 56.8 years. Patients with head and neck cancer. Head and neck sites- oral cavity, oropharynx, larynx, unknown primary and other sites. Squamous cell carcinoma most common histology (92.5%)</td>
</tr>
</tbody>
</table>

ICC = intraclass coefficient, SD = Standard deviation
Critical appraisal of disease-specific measures used in literature that have been developed to assess shoulder impairments and activity limitations

A number of self-report questionnaires used in the literature were developed for specific musculoskeletal shoulder disorders or surgeries. These include 1) Bankart Repair Scoring System, which was developed to assess patients undergoing anterior shoulder stabilization;\(^{(107)}\) 2) Western Ontario Osteoarthritis Shoulder Index (WOOS), designed for patients with primary osteoarthritis of the shoulder;\(^{(107, 108)}\) 3) Western Ontario Rotator Cuff Index (WORC), designed to assess rotator cuff tendinosis;\(^{(107, 109)}\) 4) Rotator Cuff Quality of Life Measure (RC-QOL), developed as an outcome tool in patients with the full spectrum of rotator cuff disease;\(^{(107, 110)}\) 5) Oxford Shoulder Score designed for patients having shoulder operations other than stabilization;\(^{(111-113)}\) 6) University of California Los Angeles Shoulder Scale developed for use in studies of patients undergoing total shoulder arthroplasty for arthritis of the shoulder;\(^{(107, 114)}\) 7) Oxford Shoulder Instability Questionnaire developed to assess patients perceptions following surgery for shoulder instability;\(^{(107, 112)}\) and, 8) Western Ontario Shoulder Instability index (WOSI), which was developed as a primary outcome measure in clinical trials evaluating treatments for shoulder instability, usually referring to anterior and posterior dislocations.\(^{(107, 115)}\)

While many of these instruments have undergone appropriate development and psychometric assessment in their respective populations of interest,\(^{(107)}\) the major concern is that the construction of the item pool, item selection, and reduction for these disease-specific questionnaires were performed for the specified population. The etiology of shoulder impairments and resultant morbidity following neck dissection is different from the musculoskeletal etiologies that the above mentioned instruments
were developed to assess. In patients with head and neck cancer, shoulder impairments result from injury to the motor innervation of the muscles of the shoulder girdle, while in the other cases impairments may result from injury to the muscles, joint, bones or tendons of the shoulder girdle. Patient demographics (such as age, gender, comorbidity, socioeconomic status, occupation, commonly performed recreational, and daily activities) and other associated impairments (such as speech and swallowing) may also differ in patients with head and neck cancer compared to patients with musculoskeletal diagnoses who were used in the development and assessment of the measurement properties of these instruments.

2.7.1 Neck dissection impairment index\(^{38}\)

The neck dissection impairment index (NDII) is the only instrument that was specifically designed to assess shoulder impairments and activity limitations in patients undergoing neck dissections for head and neck cancer. It is a 10-item self-administered questionnaire, which was designed to assess “quality of life related to shoulder dysfunction” after neck dissection. For each survey item, a 5-point response option (1 to 5) is provided, with higher responses representing better “quality of life.” The NDII can be completed in less than 10 minutes and is easy to score.

Appropriate psychometric principles were applied to the questionnaire development. Item selection was initially performed by interviewing 40 patients who had undergone a neck dissection. A panel of surgeons, physiotherapists and survey specialists performed further item selection and reduction. Fifteen items were generated, which were then pilot tested.
on a separate group of patients following neck dissection to evaluate comprehension, content and clarity (i.e., sensibility assessment). Items were reduced to the final 10 questions through exploratory factor analysis that identified one 10-item factor that addressed physical abilities and activities. Thus, while the authors labeled their conceptual framework as “quality of life,” the questions addressed in the NDII reflect the conceptual framework of symptoms and activity limitations. Content validity was determined through patient interviews and expert review of the questionnaire and pilot testing.

Psychometric testing was performed in head and neck cancer patients who underwent either SND or MRND. Test-retest reliability was performed for individual items, as well as the total score. The total score correlation using Spearman’s correlation was 0.91 and the individual item correlations ranged from 0.41 to 1.00. Internal consistency (Cronbach’s alpha) was 0.94. Construct validity was assessed by evaluating the association of scores on the NDII with scores on Constant’s Shoulder Score and the Short Form Medical Outcomes 36 (SF-36) questionnaire. The authors felt that a strong correlation between a “functional measure” such as Constant’s Shoulder Score and a measure of QOL would provide support that QOL is affected by shoulder function. Because of the extensive use of the SF-36 across many patient groups as a general measurement of health-related QOL, the authors selected the SF-36 to establish concurrent validity with the NDII. The overall correlation between the NDII and the Constant Shoulder Score was 0.85 (p < 0.001). The correlation of the NDII with the domains on the SF-36 were; role-physical domain (r = 0.60); physical functioning domain (r = 0.50); bodily pain domain (r = 0.32); social functioning domain (r = 0.62);
and mental health domain ($r = 0.56$). The developers also reported that the NDII was able to discriminate between varying degrees of “shoulder disability” after different types of neck dissections.$^{31, 38}$

The NDII is the only instrument developed specifically in patients with head and neck cancer to assess activity limitations of the shoulder following neck dissection. It has undergone recognized methods of item selection and reduction and some limited testing of its psychometric properties. There are some potential weaknesses to the instrument; this may explain why it has not been uniformly adopted in the literature. The items regarding activity limitations related to activities of daily living, work and recreation are broad categories and do not ask about specific activities, although groups of examples are provided. For example, the question on the impact of the shoulder impairment on “self-care” gives a “global” response to self-care with a few examples provided (e.g., combing hair, dressing, bathing, etc). A broad category may create some difficulty with the response in patients who have difficulty with only some of the activities listed among the examples. Given the importance of the shoulder in self-care activities, it may be beneficial to assess these important activities individually rather than bundling them into one global question. The patients included in reliability and validity testing all had nerve-sparing neck dissections and were therefore not completely representative of the range of severity of shoulder morbidity seen in the population in whom this instrument would be used. There are no published data on responsiveness or normative values. The NDII is only available in English and it has not undergone cross-cultural evaluation. One of the main concerns with the NDII is the potential for inadequate sensitivity due to the limited number of items and broad grouping of categories.
2.7.2 Shoulder pain and disability index (SPADI)\(^{(106)}\)

The SPADI is a self-report questionnaire developed to measure “pain and disability” in patients with shoulder pain of musculoskeletal, neurogenic or undetermined origin.\(^{(106, 107, 116)}\) The pain scale was designed to measure the level of shoulder pain experienced in a number of situations, for example “lying on the involved side.”\(^{(106, 116, 117)}\) The disability scale addresses the degree of difficulty experienced performing various shoulder-specific activities of daily living such as “difficulty washing your hair” or “placing an object on the shelf.”\(^{(106, 107)}\) Although the authors use the term “disability” and “impairment” in their original publication and refer to the instrument as a disability measure, they do not define either term.\(^{(106)}\) The instrument appears to measure impairments (pain) and activity limitations, as defined by the WHO ICF.\(^{(117)}\) Although the instrument is not specific to any particular shoulder disorder, it is specific to those suffering from painful shoulder of any etiology.\(^{(106, 107, 117)}\)

The SPADI is a 13-item questionnaire that was designed as both a discriminative and evaluative (i.e., used to measure the magnitude of longitudinal change in an individual or group) instrument.\(^{(107)}\) Item development and reduction was performed with the input of physicians and physical therapists and tested in patients with a complaint of shoulder pain attending an ambulatory care clinic.\(^{(106)}\) Of note, items were eliminated based on poor test-retest reliability or a low correlation with shoulder ROM.\(^{(107)}\) Using these techniques for item reduction, the authors may have eliminated items, which may be important for patients and highly responsive,\(^{(107)}\) particularly since shoulder ROM has been shown to correlate only modestly with patient’s estimation of their subjective functioning.\(^{(107)}\)
The ICCs for test-retest reliability range between 0.66 and 0.91.\textsuperscript{(106, 116-118)} Internal consistency values range from 0.86 to 0.95.\textsuperscript{(18, 116, 117, 119-122)} Construct validity of the SPADI has been assessed in a variety of patient samples in comparison with QOL measures and other shoulder questionnaires.\textsuperscript{(9, 107, 116-118, 121)} Construct validity was assessed by correlating scores with shoulder ROM, which ranged from 0.5 to 0.7.\textsuperscript{(107,116,117)} These physical impairments do not necessarily correlate highly with activity limitations and participation restrictions and, therefore, are not a good criterion for comparison.\textsuperscript{(107)} There has been only limited testing of responsiveness.\textsuperscript{(107,118)} There has been no assessment of sensibility, reliability and validity in the head and neck patient population.

The questionnaire is easy to understand and can be completed in a short period of time.\textsuperscript{(116)} Responses are measured using a 10 cm VAS. A numeric score is calculated for each item by dividing the horizontal line into 12 equal segments. A number ranging from zero to 11 is attached to each segment. The scoring system is relatively complex and time-consuming.\textsuperscript{(118)} The sub-scale scores are calculated by adding the item scores for the subscale and dividing this number by the maximum score possible for the items, which were deemed applicable to the patient. The score is then multiplied by 100. Higher scores indicated greater “impairment.” Patients mark items/activities they do not perform “not applicable,” which are then excluded in the maximum possible score.

Overall, while some of the content contained in the SPADI assesses symptoms such as pain and activity limitations, the focus of the instrument is on shoulder pain. Following neck dissection, shoulder pain is one of many potential symptoms. The extent of pain is highly variable and it is less prevalent in nerve-sparing neck dissections compared with
nerve-sacrificing neck dissection. Even in patients who undergo RND, pain is not present in all patients and therefore a questionnaire with a focus on pain is not ideal. There are only 13 items and, therefore, the SPADI provides little additional content over the NDII and is at risk of not being sufficiently sensitive to detect small differences between groups or changes over time in patients with head and neck cancer. From a practical standpoint, the scoring system is difficult and time consuming to perform. Therefore, the SPADI was determined not to be an ideal instrument for the assessment of shoulder outcomes in patients following head and neck cancer treatment.

2.7.3 The shoulder disability questionnaire\(^{(105)}\)

The SDQ is a measure, which was developed to evaluate “functional status limitation” in patients with soft tissue disorders of the shoulder.\(^{(105)}\) It was specifically designed for a randomized trial on ultrasound and electrotherapy as an adjuvant to exercise therapy.\(^{(105)}\) The construct described is “functional status limitation” but the developers did not clearly define the construct. It was designed as an evaluative.\(^{(105)}\) There are two forms of the SDQ; the original SDQ-NL developed in the Netherlands\(^{(105)}\) and the modified version developed in England (SDQ-UK).\(^{(104)}\) The SDQ-NL is a 16-item tool developed for assessment of pain and its impact on the “functional limitation” of the shoulder in the preceding 24 hours.\(^{(105, 116)}\) Pain assessment related to activities is a major focus of the content rather than the ability to perform the activity.\(^{(105, 116)}\) The SDQ-UK version is a 22-item questionnaire, which assesses physical, emotional and social functioning.\(^{(104, 123)}\) The SDQ-UK version has more items, particularly pertaining to the domains of pain, daily activities, sports/pastimes and work/housework.
Physiotherapists and researchers, without physician or patient involvement, performed item generation and reduction.\(^{(105)}\) Items were selected based on the “functional status limitations” most frequently reported by patients with shoulder disorders and those judged to be important in the evaluation of treatment outcome.\(^{(105)}\) Pretesting was performed in a limited number of patients (n = 12) seen in a physiotherapy practice, which represents a select population of patients. Both versions of the SDQ were developed in a European population and not formally assessed in a North American patient population. It is easy to use and score. However, scoring is based on a “yes,” “no,” or “not applicable (N/A)” answer. An N/A response meant that the activity of the particular item had not been performed in the previous 24 hours. Scoring is performed by determining the ratio of the number of items with an affirmative answer over the number of applicable items and multiplied by 100. The ratio is used as a summary score.

In terms of psychometric analyses, the authors focused on assessment of its responsiveness rather than reliability and validity.\(^{(105,116,124)}\) Test-retest reliability has not been formally tested.\(^{(116,118)}\) Construct validity also was not performed by the developers, although they did report that the SDQ is able to discriminate between self-rated clinically stable and improved subjects as part of their randomized trial.\(^{(105,116,124)}\)

The SDQ has been used by some authors, primarily from European institutions, to assess patients with head and neck cancers.\(^{(30,31,34,36,88)}\) However, it has never undergone assessment of its psychometric properties specifically in patients with head and neck cancer. In addition to the weaknesses in questionnaire development and assessment of psychometric properties, the content is primarily focused on pain.\(^{(116)}\) Similar to the SPADI, the influence of pain on activity limitations rather than the activity limitation
itself is the major component of the instrument. With SAN injury, the activity limitation results from the reduction in shoulder ROM and strength secondary to denervation of the trapezius muscle and not solely from pain. Another significant drawback is the method of scoring with a “yes/no or N/A” option, rather than a scale of responses quantifying the amount of impact of shoulder impairment on a given activity of daily living. This potentially limits sensitivity of detection of differences between groups, particularly subtle differences. The instrument assesses the ability to perform the activity in the preceding 24 hours. If the activity is not performed in that time period, it is counted as a “not applicable.” Therefore, important morbidity may not be recorded if that particular activity was not performed in the preceding 24 hours. The numerous drawbacks to this instrument limit the ability to draw conclusions from the head and neck studies that employed it and as a result, it does not meet the criteria for use in future studies in our patient population.

2.8 Critical appraisal of generic shoulder measures used in the literature that have been developed to assess shoulder impairments and activity limitations

2.8.1 Constant’s Shoulder Score\textsuperscript{(103)}

Constant’s Shoulder Score combines physical examination tests (e.g., active ROM and power testing) with subjective evaluations by the patients.\textsuperscript{(103)} The subjective assessment includes a single item for pain and four items for activity limitations. Kirkely et al highlight the concerns with Constant’s measure for assessing shoulder dysfunction.\textsuperscript{(107)} Reliability has been evaluated only on a limited basis; there are no published data on
formal validity testing or responsiveness;\(^{(107)}\) and there are no published data on the methodology of how the instrument was developed or how items were selected and the weights given.\(^{(107)}\) The instrument is weighted heavily on function and pain rather than activity limitations.\(^{(103, 107)}\) Physical function (i.e., shoulder ROM and strength) and subjective assessment of symptoms and activity limitations are best assessed separately. Thus, there does not appear to be a role for this instrument in the future assessment of shoulder outcomes in patients with head and neck cancer.

2.8.2 Modified American shoulder and elbow surgeons standardized (ASES) form\(^{(102)}\)

The modified American Shoulder and Elbow Surgeons (ASES) shoulder scale was published in 1994 by the Research Committee of the ASES.\(^{(102, 120)}\) The instrument was designed as a generic tool to assess patient-related pain and “function/disability” of the entire extremity rather than only the shoulder.\(^{(102, 117, 120)}\) The definition of function and disability was not clearly described by the developers. However, it has been shown to measure the WHO ICF components of impairment, activity limitation and participation restriction.\(^{(117)}\)

The ASES shoulder scale was developed by the research committee by reviewing all published shoulder questionnaires available at the time and included the committee’s own ideas.\(^{(107)}\) A prototype instrument was designed, however, item selection was not described.\(^{(113)}\) Further revisions were made based on suggestions of clinicians who used the instrument. The patient self-evaluation section contains 11 items divided into two
areas: pain (one item) and function (ten items). The ten function items include self-care activities (i.e., activities of daily living), as well as a general question on work and one question on recreation. Each item is scored on a zero (unable) to three (no difficulty) scale. The patient provides a score for each activity for both the right and left shoulder/elbow. The pain score is measured on a VAS. The final score is tabulated by multiplying the pain score by five and the cumulative activity score by 5/3 for a score out of 100. Lower scores signify greater pain and disability. A scoring system provides weights for the pain and activity items; however, no rationale has been described for the weighting.

The ASES shoulder scale is easy to complete, but difficult to score and it has undergone some limited psychometric testing.\(^{(116)}\) For test-retest reliability Michener et al reported an ICC 0.84 in patients with “shoulder dysfunction,”\(^{(125)}\) while Kocher et al reported an ICC of 0.94 in patients with shoulder instability, rotator cuff disease and glenohumeral arthritis.\(^{(126)}\) Construct validity was demonstrated by correlating with other measures of “limitations and disability” including the SF-36 physical function score (r = 0.41) and the Penn Shoulder Score (r = 0.78).\(^{(91, 116, 117, 125, 126)}\) The correlations were appropriately weak (divergent construct validity), with dissimilar measures such as the SF-36 role emotional domain score (r = 0.24) and mental health domain score (r = 0.05).\(^{(125)}\) Known group validity has also been assessed, with the ASES shoulder scale demonstrating an ability to discriminate between patients with “high and low levels of disability.”\(^{(116, 117)}\)

Compared with other instruments, the ASES shoulder scale has not undergone as extensive assessment of its psychometric properties. It also has never been assessed for these properties in patients with head and neck cancer. Overall, this scale does not
provide any additional content over the NDII questionnaire. Although others have reported it to be easy to score,\textsuperscript{(116)} it does contain a VAS, which requires conversion to a numeric score, thus making scoring more time consuming.\textsuperscript{(118)} Overall, it was not felt to provide any additional benefit over the NDII.

\section*{2.8.3 Disabilities of the Arm, Hand and Shoulder (DASH) questionnaire\textsuperscript{(39)}}

The DASH questionnaire is a generic measure of “disability and symptoms” related to any condition of any joint of the upper extremity.\textsuperscript{(39, 107)} It is a 30-item questionnaire (21 physical function items, six symptom items and three social/role function items) with two optional four-item modules designed to measure the impact of upper extremity “disability” on work (work module) or playing sports or musical instruments (sports and performing arts module).

The DASH questionnaire was developed by the Institute for Work and Health and the American Academy of Orthopedic Surgeons.\textsuperscript{(39)} It was designed to measure several components within the three dimensions of functional status at the level of disability as described by Verbrugge and Jette.\textsuperscript{(127)} These dimensions include physical (main focus), social and psychological. Dixon et al also examined the ability of the DASH to operationalize the WHO ICF model.\textsuperscript{(2)} They demonstrated that the DASH contains items able to measure each of the three ICF outcomes. The DASH contains five pure impairment items, 19 pure activity limitation items and three participation restriction items.\textsuperscript{(2)} In addition, seven items measured both activity limitations and participation restrictions.\textsuperscript{(2)}
The DASH was designed to discriminate (to compare the impact of upper extremity disorders among individuals or groups) and to evaluate (to assess change related to natural history or effect of treatment interventions). The DASH has undergone more extensive development and testing of its psychometric properties than any other patient-based self-report questionnaire of shoulder impairments and activity limitations. Item generation was carried out by first reviewing the literature and producing an item pool of 821 items. Members of a collaborative group reviewed the original items. Items were stripped of attribution to a specific disorder. Items that were repetitive or unrelated to the upper extremity were eliminated. The reduced list was sent to clinician content experts for their input on face and content validity and importance of items. The number of items was reduced to 67, which were then formatted into a questionnaire and tested on 20 patients with upper limb problems to ensure readability, absence of ambiguity and understanding of scale and content. Item reduction was further performed by field-testing in over 400 patients across 20 centers worldwide. Factor analysis was performed. A clinimetric reduction also was performed by including formal patient input using an importance and severity questionnaire. The final questionnaire was reduced to 30 questions plus a work module and a sports/performing arts module that were each scored separately.

The DASH questionnaire has been shown to be a reliable and valid measure by the developers of the instrument, as well as by other authors. Test-retest reliability studies that have been performed in different patient populations similarly have shown excellent reliability scores, with reported ICCs ranging from 0.77 to 0.98. The DASH has been shown to have good internal consistency with a Cronbach’s alpha of...
Convergent construct validity was evaluated by correlating DASH scores with several outcome measures felt to measure similar constructs. It was demonstrated by Turchin et al to correlate with pain \((r = 0.65)\) and function \((r = 0.80)\), both measured on a VAS and scores on the ASES scale \((r = -0.81)\).\(^{(41)}\) It also has correlated highly with other instruments including the SPADI, physical domain of SF-36, pain domain of the SF-36, Constant’s Shoulder Score, and the WOSI.\(^{(40, 116, 117)}\) The developers of the DASH demonstrated construct validity by showing that it can discriminate between different levels of disease and condition severity (both patient and clinician rated).\(^{(40, 127)}\) Beaton et al demonstrated that the DASH was able to discriminate between individuals who can and cannot work due to their upper limb problem.\(^{(40)}\) Known group validity also has been demonstrated by its ability to detect differences between those able to do all activities they want to do and those not able to do so,\(^{(40, 117)}\) between patients with shoulder external rotation > 45° and those with ROM < 45°,\(^{(117, 128)}\) and between workers’ compensation status.\(^{(117, 128)}\) As well, the DASH has been used to assess neural recovery following peripheral nerve injury of the upper extremity.\(^{(129, 130)}\) It has been able to discriminate between patients with and without neural injury, as well as to discriminate between those with and without recovery following nerve injury.\(^{(129, 130)}\) The DASH questionnaire has also been found to be sensitive enough to detect and differentiate small and large changes of “disability” over time in patients with upper extremity musculoskeletal disorders.\(^{(40)}\)

The DASH has been extensively studied with respect to its psychometric properties, demonstrating sensibility, reliability, validity and responsiveness in many different musculoskeletal conditions and following different surgical procedures on the
Its psychometric properties have not however, been assessed in patients with the head and neck cancer.

The DASH is easy to use and takes less than 10 minutes to complete. Respondents circle the appropriate response on a five-point scale. A disability/symptom score is easily determined by placing the summated score of the responses into a devised formula. The lower the score the less upper extremity “disability.” It has been translated into more than 22 languages and has undergone extensive cross-cultural validation. Unlike other instruments, the DASH questionnaire does not combine physical examination findings with subjective evaluations, the weighting of items are not arbitrarily decided and the instrument is not exceedingly long or burdensome. The content is appropriate with an additional 20 items (excluding the work and the sports/performing arts modules) when compared with the NDII.

In summary, after an extensive literature search and review of the existing shoulder outcome measures, as well as corresponding with experts familiar with the different measures, the DASH questionnaire was identified as the strongest instrument to study for use in patients who have undergone neck dissection. While the NDII was specifically designed to assess patients following neck dissection, it has not been uniformly adopted as the instrument of choice by investigators. There are some weaknesses in terms of its development and evaluation, and the most significant concern is the limited content and potential decreased sensitivity to detect differences between groups or over time. The DASH questionnaire may be a valuable tool for measurement of shoulder impairments and activity limitations in this patient population and overcome the shortcomings of the NDII. Nonetheless, the robustness of this measure has not been demonstrated in the head
and neck patient population. The establishment of sensibility, reliability, and validity of the DASH in this patient group, particularly patients who have had neck dissection will provide the opportunity to evaluate shoulder impairments and activity limitations in future investigations. The overall aim of this thesis is to ascertain whether or not the DASH possesses measurement properties that can quantify impairments and activity limitations of the shoulder in the patient population with head and neck cancer undergoing neck dissection.

2.9 Thesis objectives

2.9.1 Primary objective

The primary objective of this study was to assess the sensibility, reliability, and validity of the DASH questionnaire in patients who have undergone neck dissection for head and neck cancer.

2.9.2 Secondary objective

The secondary objective was to determine whether the DASH and NDII questionnaires would have similar results on reliability and validity testing.
2.9.3 Specific objectives

i) **Objective 1** was to evaluate the sensibility of the DASH questionnaire in patients who have undergone neck dissection for head and neck cancer.

ii) **Objective 2** was to evaluate the test-retest reliability of the DASH and NDII questionnaires in patients who have undergone neck dissection for head and neck cancer.

iii) **Objective 3** was to assess known group validity of the DASH and NDII questionnaire by evaluating differences in scores between patients who have undergone different types of neck dissections (RND, MRND, and SND).

iv) **Objective 4** was to assess convergent construct validity by correlating DASH scores with NDII scores, which is itself a validated outcome measure, designed to assess shoulder impairments and activity limitations in those who have undergone a neck dissection for head and neck cancer.

2.10 Study hypotheses

The following specific hypotheses for each of the objectives were tested.

i) **Hypothesis for objective 1**: The DASH questionnaire would be deemed to be sensible based on sensibility questionnaire scores and content analysis from the perspective of both patients who had undergone a neck dissection for head and neck cancer and surgeons specializing in the management of head and neck cancer.
ii) **Hypothesis for objective 2:** The DASH and NDII would exhibit good test-retest reliability with ICCs greater than 0.8.

iii) **Hypothesis for objective 3:** Patients with nerve-sparing neck dissections would have significantly less shoulder impairments and activity limitations, as indicated by lower DASH scores and higher NDII scores, than participants with nerve-sacrifice neck dissections. Furthermore, participants who underwent SND would have significantly less shoulder impairments and activity limitations, as indicated by lower DASH scores and higher NDII scores, than those who underwent MRND.

iv) **Hypothesis for objective 4:** DASH scores would significantly correlate with patient scores on the NDII, with correlations above 0.6.
Chapter 3

MATERIALS & METHODS

The following chapter describes the study design, sample, procedures and statistical analysis.

3.1 Design

A cross-sectional study was undertaken to evaluate the sensibility, reliability, and validity of the DASH questionnaire. Additionally, there was a second administration of the DASH and NDII for evaluation of test-retest reliability.

3.2 Study sample

The sample included subjects who underwent RND, MRND, or SND, as defined in the background section 2.3, at the University Health Network, University of Toronto between January 1998 and July 2005 for primary (non-metastatic) head and neck cancers of the upper aerodigestive tract (oral cavity, oropharynx, nasopharynx or larynx), skin, thyroid or salivary glands. All three types of neck dissection were included to ensure that the spectrum of severity of shoulder morbidity following neck dissection was represented for reliability and validity testing and to maximize generalizability. Participants were greater than 19 years of age and had a neck dissection either as part of their primary treatment or for persistent or recurrent neck disease following radiotherapy (with or without
chemotherapy). All patients included were disease-free at the time of inclusion in the study. Similar to the inclusion criteria used for the development and assessment of the NDII,\(^{(38)}\) all subjects were 11 or more months following surgery. The timing avoids confounding symptoms directly related to wound healing and allows for recovery of the temporary accessory nerve neurapraxia that commonly occurs in nerve-sparing neck dissections.\(^{(38, 73, 131-133)}\) The main interest was with long-term morbidity (i.e., greater than 11 months from surgery), rather than in the early postoperative period. Subjects also had to be able to consent to participate.

The following patients were excluded: (1) Patients who had distant metastases or incurable recurrent disease; (2) Patients who underwent salvage neck surgery for recurrent neck disease after previous neck dissection, which is associated with significant additional morbidities; (3) Patients who underwent extended radical neck dissections with resection of the deep muscles of the neck (sple
dius capitus, trapezius, or levator scapulae muscles), which are also involved in shoulder function and would act as a confounder; (4) Patients who underwent an ipsilateral scapula osteocutaneous free flap, since these flaps require division of the muscles to the scapula and resection of part of the scapula bone, which can further impair shoulder mobility and function; (5) Patients with a history of any shoulder surgery or trauma, rheumatologic disorders requiring disease modifying agents or prior neurological disease affecting the upper extremity such as stroke. These conditions can impair shoulder, arm or hand function independent of the type of neck dissection; (6) Patients who underwent bilateral neck dissection. These patients may potentially have greater impairments and activity limitations than those undergoing unilateral neck dissection and (7) Patients who did not speak any English, (i.e., if it was
noted in their chart that a translator was required for their hospital visits and/or it was noted on their consent for surgery that a translator was required).

For sensibility testing (objective 1), physicians were eligible for inclusion if they had a surgical practice specializing in the management of head and neck cancer. Other disciplines involved in the care of these patients, such as radiation or medical oncologists, were not included since shoulder dysfunction following a neck dissection is primarily assessed and managed by surgeons. Head and neck surgeons practicing at a university/academic centre were deemed to be the most appropriate group to assess the sensibility of the DASH since the majority of patients with head and neck cancer are managed at university-affiliated centers.

3.3 Sample generation

3.3.1 Patient participants

A list of patients who underwent RND, MRND, and SND was generated from a prospective registry of all patients who have undergone surgery for head and neck cancer at the University Health Network since 1992. The search was refined by excluding patients based on the following information available in the database: age <19 years; time from surgery <11 months; and reconstruction using an osteocutaneous scapula flap. This search generated a list of 961 patients to undergo initial chart review in order to determine eligibility for inclusion in the study. Figure 1 is a flow diagram depicting how eligible patients were determined.
Figure 1: Flow diagram of determination of the eligible patient sample

H & N Database
13,911 patients

RND
255 cases from
1992–2005

SND & MRND
706 cases between
2000–2005

All reviewed for
eligibility

300 cases reviewed

192 Ineligible
patients

63 Eligible

141 Eligible
patients

159 Ineligible
patients

Dead or incurable
recurrent disease
N = 169

Bilateral neck
dissections
N = 10

Extended RND or
Previous neck
surgery
N = 8

Other
N = 5

84 SND

57 MRND

Dead or incurable
recurrent disease
N = 51

Bilateral neck
dissections
N = 57

Previous neck
surgery
N = 11

Lost to follow-up
N = 40
Due to the small number of RNDs performed per year and the high mortality rate of these patients (i.e., >50%), all charts of patients (n = 255) who underwent RND generated from the registry were reviewed for eligibility. A total of 63 patients who underwent RND were considered eligible for inclusion. Given the large number of patients who have undergone MRND or SND, a sample of these patients was obtained by reviewing 300 consecutive charts starting from patients treated in January 2005 and sequentially working backward in time in order to determine eligibility. Of these patients, 141 (84 SND and 57 MRND) were eligible for inclusion in the study. Using a random number generator, 90 of these patients (45 SND and 45 MRND patients) were randomly chosen to be included. As shown in Figure 1, the reason for exclusion in the vast majority of patients who underwent RND, MRND, and SND was death or recurrent unresectable local, regional, or distant metastatic disease.

3.3.2 Physician participants

For the physician participants, a sample of academic head and neck surgeons in the United States and Canada were included for sensibility assessment. A list of all academic head and neck surgeons in Canada was generated through correspondence with the directors of the divisions of head and neck oncology at each academic institution. A list of American head and neck surgeons was generated from faculty at the academic centers that offer fellowships in head and neck oncologic surgery\(^{(134)}\) and, therefore, were deemed to be experts in the management of head and neck cancer.
3.4 Procedures

3.4.1 Mail out procedures for participants

Eligible patients were mailed a questionnaire package containing an introductory letter (Appendix A), consent form (Appendix B), instruction sheet (Appendix C), the sensibility questionnaire for the DASH (Appendix D), the DASH questionnaire (Appendix E), the NDII questionnaire (Appendix F) and a self-addressed return envelope with postage. The instruction sheet (Appendix C) explained the order in which patients were to complete the questionnaires. To avoid an order-effect, patients were randomly assigned to receive one of two instruction sheets, each with a different order of completing the NDII and DASH questionnaires. All patients were instructed to complete the sensibility questionnaire after completing the DASH questionnaire.

For assessment of test-retest reliability, a package containing the DASH, NDII and a change in status form (Appendix G) was mailed out approximately 2 weeks after the first package was received back. Only patients who returned their first package were mailed a re-test package. A change in status form, which assessed whether participants thought their shoulder function had changed, was included in order to determine stability for reliability testing. Patients who reported a change in status were excluded from the reliability analysis.

Physician participants in the sensibility assessment were mailed a package with an introductory letter (Appendix A), instruction sheet (Appendix C), consent form
(Appendix B), a clinical practice survey (Appendix H), the DASH questionnaire (Appendix E) and sensibility questionnaire (Appendix D).

A modified Dillman approach was used to maximize response rates.\(^{(135-139)}\) Two weeks after the initial mailing, a postcard (Appendix I) was mailed to the participant thanking them for completing and returning the questionnaire package and reminding them to do so if they had not yet returned it. Two weeks after the postcard mailing, a second questionnaire package was sent to those participants from whom a returned package had not yet been received.

### 3.5 Data collection

#### 3.5.1 Patient descriptives

Data collected for patient participants were from a combination of chart review and mailed questionnaire packages. The data collection forms are in Appendix J. Data obtained from chart review included demographic data (age and gender), clinicopathologic data (cancer site, histology, and pathologic nodal stage), and treatment-related data (type of neck dissection, side of neck dissection, indication for neck dissection, pre- or post-surgical treatment with radiotherapy or chemoradiotherapy, flap reconstruction, and neurorrhaphy status in RND patients). Information on working status, occupation, recreational activities, hand dominance, and primary language spoken at home were obtained from questions either included in the mail-out package as part of the DASH or added on to the end of NDII. To ensure that patients did not have bilateral neck dissections, an additional question was included that asked patients to report whether they
had surgery on one or both sides of their neck. Chart review of nonresponders was not performed since failure to return a package was considered by the institutional ethics board as the patient’s refusal to participate in the study.

3.5.2 Physician descriptives

Practice-related information was obtained from a survey (Appendix H) included in the mail-out package to physician participants. Information contained in the survey included country of practice, years in practice, type of practice (i.e., academic or community practice), prior head and neck fellowship training, the extent to which their practice is devoted to the management of head and neck cancer and the number and type of neck dissections performed each year.

3.6 Standardized Measures

Details on both the NDII and DASH questionnaires are presented in the background chapters 2.7.1 and 2.8.3, respectively. The following section describes the scoring of the questionnaires.

3.6.1 The DASH questionnaire\(^{(39, 127)}\)

The DASH questionnaire consists of three modules, the symptom and disability module (main module), work module (optional module) and the sports and performing arts
module (optional module). For the disability/symptom module, all 30-response scores were added together producing a raw score out of a possible 150 (each individual item is rated with a score from 1 to 5). The raw score was then transformed into a score out of 100 by dividing the summed score by the number of completed responses, then subtracting 1 and multiplying by 25. The transformation was done to make the score more comparable to other measures scaled on a 0–100 scale. The sports/performing arts and the work module were each scored separately using a similar procedure to convert a raw score out of a possible 20 to a score out of 100. For all the modules, a higher score indicates greater impairments and activity limitations.

For the DASH questionnaire, missing data were handled according to the criteria outlined in the user manual. The rules for the DASH were as follows: If ≤ 10% of the items on the main module (i.e., ≤ 3 items) were left blank by the respondent, the mean score of the other items were substituted for the missing score(s). If more than three questions were not answered, a DASH score could not be calculated and the patient was excluded from the analysis. By the same rule no missing values could be tolerated in either the sports/performing arts or work module because these modules consisted of only four items.

3.6.2 The neck dissection impairment index (NDII)

The responses for all 10 items were added together to produce a raw score out of a possible 50 (each individual item is rated with a score from 1 to 5). Raw scores were then
transformed to a score out of 100 by subtracting 10, dividing by 40 and then multiplying by 100.\textsuperscript{(38)} Lower scores indicated greater impairment and activity limitations.

Techniques for handling missing data were not described for the NDII. Missing data were therefore handled in the same way as for the DASH. If \( \leq 10\% \) (i.e., \( \leq 1 \) item) was left blank by the respondent, the mean score of the other items was substituted for the missing score(s). If more than one question was not answered, the NDII score could not be calculated and the patient was excluded from the analysis.

\section*{3.6.3 Sensibility questionnaire}

A sensibility questionnaire (Appendix D) was designed for this study to assess the face and content validity of the DASH questionnaire. Development of the sensibility questionnaire was based on a sensibility questionnaire developed by Rowe and Oxman.\textsuperscript{(98)} The questionnaire consisted of nine questions that assessed clarity of instructions and questions (question 1 and 2); ease of usage (question 3); whether the content was appropriate (questions 4, 5, 6 and 9); any missing items or issues (question 8); and, if the DASH met its overall goal of assessing shoulder impairment (symptoms) and activity limitations after neck dissection (question 7). Patients and physicians completing the sensibility questionnaire were asked to respond to each of the nine questions using a 7-point response key. Items were scored individually and space was provided after each question for additional comments.
3.7 Planned statistical analyses

Sociodemographic, clinicopathologic, and treatment-related data were summarized using descriptive summary statistics such as means, medians, standard deviations, and proportions as appropriate for the type of data. The distributions of the DASH and NDII scores for all patients were evaluated with frequency histograms and tested for normality using kurtosis and skewness. Differences between the neck dissection groups in sociodemographic, clinicopathologic, and treatment-related variables were compared to determine the extent to which they differed in terms of potential confounders. Categorical data were analyzed using chi-square analysis and one-way analysis of variance (ANOVA) test for interval data. All analyses were completed using the SPSSv14 (Statistical Package for the Social Sciences, version 14.0 for Windows, SPSS Inc., Chicago, IL, USA). The following sections are the statistical analyses performed for each of the specific objectives.

3.7.1 Sensibility analysis (objective 1)

A priori criteria, based on Rowe and Oxman’s criteria, was used to assess the sensibility of the DASH questionnaire. Previous reports have identified physicians as being more critical about new instruments than patients, and therefore the sensibility scores for each group were analyzed separately. The DASH questionnaire was judged to be sensible if: 1) the mean scores provided by the patients were greater than or equal to five for at least seven of nine (>80%) of the items in the sensibility questionnaire; 2) mean scores for the physicians were greater than or equal to four for at least seven of nine
of the items on the sensibility questionnaire; and, 3) less than three of the items were given a mean score less than or equal to three by either group.\(^{(98)}\) Content analysis of the written responses for each criterion was performed by identifying similar themes for patients and physicians.

### 3.7.2 Test-retest reliability analysis (objective 2)

Test-retest reliability for both the DASH and NDII was calculated using the ICC with 95% confidence intervals (CI). ICC model 2 was chosen, which is generalizable to other raters.\(^{(100, 139)}\) Test-retest reliability for individual items on the DASH and NDII was planned to be assessed using percent agreement and weighted kappa scores. Row by column tables (i.e., agreement matrices) of test-retest scores for each individual question were generated for the DASH and NDII to determine if the assumptions of the weighted kappa scores were met.

### 3.7.3 Known-group validity analysis (objective 3)

Differences in DASH and NDII scores between SND, MRND, and RND groups were determined by using a one-way ANOVA. If a significant main effect difference was found \((p < 0.05)\), a Tukey’s Honestly Significant Difference (HSD) post-hoc test was performed. Results are presented using boxplots.
3.7.4 **Convergent construct validity analysis (objective 4)**

Association between the DASH and NDII scores, both overall and individual items, was determined using the Pearson correlation coefficient.

3.8 **Sample size calculations**

Sample size calculations were performed for reliability analysis. Since the DASH questionnaire has not been used in the head and neck patient population and the magnitude of score differences between groups was not known, sample size calculations could not be performed for sensibility or validity testing. Therefore, a reasonable sample size was chosen that was expected to show the pattern of expected differences and at least a trend toward statistical significance. The following are the sample size estimates for each of the specific objectives:

3.8.1 **Sample size calculations for reliability analysis**

Based on achieving an ICC of 0.80 with a lower bound 95% CI of 0.70, 47 analyzable cases were required for test-retest reliability analysis.\(^{(140)}\)
3.8.2 Sample size estimates for validity analysis

For validity analysis, sample size was estimated at 30 patients, with analyzable data in each group for a total of 90 subjects. To allow for non-response, a 20% increase in accrual of patients who underwent SND, and MRND was planned to achieve the analytical sample. It was planned that all eligible patients who underwent RND would be mailed a package due to the higher mortality rate and the anticipated death in some of these patients between the date of last follow-up and the inclusion in the study.

3.8.3 Sample size estimates for sensibility analysis

For the sensibility analysis of the patient population a similar sample size to the validity analysis was considered to be reasonable. Sample size for the clinician component of sensibility analysis was conducted based on obtaining a sample of at least 50 experts. The reported response rates for physicians participating in mail-out survey studies ranges between 40% and 60%. (141, 142) Therefore, to account for non-response, 94 physicians were sent packages to achieve the analytical sample.

3.9 Data management

Tracking of response rates for both patients and physicians was performed with a Microsoft Excel database. De-identified clinical and demographic data, as well as responses on the DASH, NDII, and sensibility questionnaires, were recorded in an SPSSv14 (Statistical Package for the Social Sciences, version 14.0 for Windows, SPSS
Inc., Chicago, IL, USA) database. De-identified patient and physician written responses for the sensibility analysis were recorded in a Microsoft Excel database. Double data entry was performed on 20 charts to check accuracy of data entry. If the error rate was < 10%, no further double entry was completed.

3.10 Ethics

Institutional (University Health Network) and University of Toronto ethics review board (REB) approval was obtained. The consent forms are presented in Appendix B and REB approval letters in Appendix K.
Chapter 4

RESULTS

The following chapter presents a summary of the study findings including response rates, description of the patient and physician sample and the results for each study objective.

4.1 Analyzable sample

4.1.1 Response rates

Response rates for the entire cohort of patients mailed a package are presented in Table 4a. Table 4b presents the surgeons’ response rate for the sensibility analysis.

Table 4a: Response rates for patient subjects

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>SND</th>
<th>MRND</th>
<th>RND</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packages mailed out</td>
<td>153</td>
<td>45</td>
<td>45</td>
<td>63</td>
</tr>
<tr>
<td>Family responded that patient died</td>
<td>6 (4%)</td>
<td>0 (0%)</td>
<td>3 (6.6%)</td>
<td>3 (4.8%)</td>
</tr>
<tr>
<td>Packages returned to sender</td>
<td>10 (6.5%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>10 (15.9%)</td>
</tr>
<tr>
<td>Patients alive &amp; able to return packages</td>
<td>137 (89.5%)</td>
<td>45 (100%)</td>
<td>42 (93.3%)</td>
<td>50 (79.4%)</td>
</tr>
<tr>
<td>Packages returned*</td>
<td>109 (79.6%)</td>
<td>36 (80%)</td>
<td>35 (83%)</td>
<td>38 (76%)</td>
</tr>
<tr>
<td>Retest mailed out</td>
<td>52</td>
<td>17</td>
<td>17</td>
<td>18</td>
</tr>
<tr>
<td>Retest returned</td>
<td>44 (84.6%)</td>
<td>14 (82%)</td>
<td>15 (88%)</td>
<td>15 (88%)</td>
</tr>
</tbody>
</table>

*Included are 18 patients who were sent a package and reported having a bilateral neck dissection, who were later excluded from the analysis.

For the initial mailing and the retest mailing there were no significant differences in response rates by neck dissection type (p = 0.94 and p = 0.98, respectively).
Table 4b: Response rates for physician participants

<table>
<thead>
<tr>
<th>Packages mailed out</th>
<th>Total physicians</th>
<th>Canadian physicians</th>
<th>American physicians</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packages returned</td>
<td>94</td>
<td>39</td>
<td>55</td>
</tr>
<tr>
<td></td>
<td>50 (53%)</td>
<td>26 (67%)</td>
<td>24 (44%)</td>
</tr>
</tbody>
</table>

4.1.2 Missing data

For the DASH main module, 18 patients had one or more missing items while only four patients had one or more missing items on the NDII. Breakdown by the number of missing items for the DASH and NDII questionnaires are presented in Table 5.

Table 5: Missing items for the DASH and NDII for the entire cohort returning packages

<table>
<thead>
<tr>
<th>Questionnaire</th>
<th>Number of items missing per questionnaire</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>DASH Initial mailing</td>
<td>0</td>
<td>69</td>
</tr>
<tr>
<td></td>
<td>1-3</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>&gt;3</td>
<td>5</td>
</tr>
<tr>
<td>NDII Initial mailing</td>
<td>0</td>
<td>105</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>&gt;1</td>
<td>3</td>
</tr>
<tr>
<td>DASH retest</td>
<td>0</td>
<td>42</td>
</tr>
<tr>
<td></td>
<td>1-3</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>&gt;3</td>
<td>1</td>
</tr>
<tr>
<td>NDII retest</td>
<td>0</td>
<td>42</td>
</tr>
</tbody>
</table>

The frequency of missing responses for each of the items in the DASH and NDII, excluding the patients who failed to complete the entire questionnaire are presented in Table 6.
Table 6a: Frequency of missing responses for each of the items in the DASH

<table>
<thead>
<tr>
<th>DASH question</th>
<th>Initial mailing N = 96 (%)</th>
<th>Retest N = 37 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (open a jar)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>2 (write)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>3 (turn a key)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>4 (prepare meal)</td>
<td>2 (2)</td>
<td>1 (3)</td>
</tr>
<tr>
<td>5 (open door)</td>
<td>2 (2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>6 (reach above)</td>
<td>2 (2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>7 (house chores)</td>
<td>2 (2)</td>
<td>2 (6)</td>
</tr>
<tr>
<td>8 (garden work)</td>
<td>2 (2)</td>
<td>1 (3)</td>
</tr>
<tr>
<td>9 (make a bed)</td>
<td>1 (1)</td>
<td>1 (3)</td>
</tr>
<tr>
<td>10 (carry bag)</td>
<td>0 (0)</td>
<td>1 (3)</td>
</tr>
<tr>
<td>11 (carry heavy object)</td>
<td>1 (1)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>12 (change light bulb)</td>
<td>1 (1)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>13 (wash hair)</td>
<td>1 (1)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>14 (wash back)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>15 (put on sweater)</td>
<td>2 (2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>16 (cut food with knife)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>17 (RA*- little effort)</td>
<td>2 (2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>18 (RA*- some force)</td>
<td>3 (3)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>19 (RA*- move arm freely)</td>
<td>3 (3)</td>
<td>1 (3)</td>
</tr>
<tr>
<td>20 (manage transport needs)</td>
<td>2 (2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>21 (sexual activities)</td>
<td>9 (10)</td>
<td>5 (14)</td>
</tr>
<tr>
<td>22 (limited social activities)</td>
<td>0 (0)</td>
<td>1 (3)</td>
</tr>
<tr>
<td>23 (limited work)</td>
<td>0 (0)</td>
<td>1 (3)</td>
</tr>
<tr>
<td>24 (pain)</td>
<td>1 (1)</td>
<td>1 (3)</td>
</tr>
<tr>
<td>25 (pain with activity)</td>
<td>2 (2)</td>
<td>1 (3)</td>
</tr>
<tr>
<td>26 (tingling)</td>
<td>0 (0)</td>
<td>1 (3)</td>
</tr>
<tr>
<td>27 (weakness)</td>
<td>1 (1)</td>
<td>1 (3)</td>
</tr>
<tr>
<td>28 (stiffness)</td>
<td>1 (1)</td>
<td>1 (3)</td>
</tr>
<tr>
<td>29 (difficulty with sleeping)</td>
<td>0 (0)</td>
<td>1 (3)</td>
</tr>
<tr>
<td>30 (feel less capable)</td>
<td>0 (0)</td>
<td>1 (3)</td>
</tr>
</tbody>
</table>

*RA=Recreational activities
Table 6b: Frequency of missing responses for each of the items in the NDII

<table>
<thead>
<tr>
<th>NDII question</th>
<th>1st questionnaire N = 96 (%)</th>
<th>Retest N = 37 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (pain)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>2 (stiffness)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>3 (self-care)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>4 (lift light)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>5 (lift heavy)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>6 (reach above)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>7 (overall activity)</td>
<td>3 (3)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>8 (social activities)</td>
<td>2 (2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>9 (recreational activities)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>10 (work)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

4.1.3 Overall analyzable sample

Figures 2, 3, and 4 highlight the breakdown of sample size for each objective and reasons for exclusion of some patients. For the sensibility analysis 96 patients and 50 physicians were included (Figure 2). Thirty-five patients were included in the reliability analysis of the DASH questionnaire, and 36 in the reliability analysis of the NDII questionnaire (Figure 4). Sample sizes were smaller for the reliability analysis of the sports and performing arts module (n = 18) and the work module (n = 21) since these modules were not applicable to all patients. Ninety-one patients were included for known group validity assessment of the DASH, and 93 patients for known group validity assessment of the NDII. For convergent validity, 91 patients were included for analysis (Figure 3).
**Figure 2: Overall analyzable sample for sensibility analysis**

- Sensibility Analysis
  - 109 patient packages returned
  - 96 patients included for analysis
  - 13 patients with bilateral neck dissections excluded from analysis

**Figure 3: Overall analyzable sample for validity analysis**

- Validity analysis
  - 109 patient packages returned
    - 96 patients included for analysis
    - 13 bilateral neck dissections excluded from analysis
      - Known-Group validity for DASH
        - 91 eligible for analysis
        - 5 excluded due to too many missing items
      - Known-Group validity for NDII
        - 93 eligible for analysis
        - 3 excluded due to too many missing items
      - Convergent construct validity
        - 91 eligible for analysis
4.2 Sociodemographic and clinical data of the patient and physician participants

4.2.1 Patient participants

Sociodemographic, clinicopathologic, and treatment-related data for the entire cohort and each neck dissection group are presented in Table 7a. Occupation and recreational activities are presented in Table 7b.
Table 7a: Demographic, clinicopathologic, and treatment-related data for the entire cohort and neck dissection group

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total group (n = 96)</th>
<th>SND (n = 34)</th>
<th>MRND (n = 31)</th>
<th>RND (n = 31)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>61 (63.5%)</td>
<td>17 (50%)</td>
<td>21 (67.7%)</td>
<td>22 (71%)</td>
<td>p=0.167</td>
</tr>
<tr>
<td>Female</td>
<td>35 (36.5%)</td>
<td>17 (50%)</td>
<td>10 (32.2%)</td>
<td>9 (29%)</td>
<td></td>
</tr>
<tr>
<td><strong>Age (in years)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (median)</td>
<td>62.7 (63)</td>
<td>61.6 (60)</td>
<td>60.9 (64)</td>
<td>65.8 (64)</td>
<td>p=0.302</td>
</tr>
<tr>
<td><strong>Tumor site</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SCC UADT</td>
<td>54 (56%)</td>
<td>21 (62%)</td>
<td>10 (32%)</td>
<td>23 (74%)</td>
<td>p=0.001</td>
</tr>
<tr>
<td>Skin</td>
<td>18 (18.7%)</td>
<td>4 (12%)</td>
<td>8 (26%)</td>
<td>6 (19%)</td>
<td></td>
</tr>
<tr>
<td>Thyroid</td>
<td>12 (12.5%)</td>
<td>2 (6%)</td>
<td>9 (29%)</td>
<td>1 (3.2%)</td>
<td></td>
</tr>
<tr>
<td>Salivary gland</td>
<td>12 (12.5%)</td>
<td>7 (21%)</td>
<td>4 (13%)</td>
<td>1 (3.2%)</td>
<td></td>
</tr>
<tr>
<td><strong>Dominant hand</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>89 (92.7%)</td>
<td>31 (91%)</td>
<td>29 (93.5%)</td>
<td>29 (93.5%)</td>
<td>p=0.913</td>
</tr>
<tr>
<td>Left</td>
<td>7 (7.3%)</td>
<td>3 (9%)</td>
<td>2 (6.5%)</td>
<td>2 (6.5%)</td>
<td></td>
</tr>
<tr>
<td><strong>Side of neck dissection</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>44 (45.8%)</td>
<td>14 (41%)</td>
<td>12 (38.7%)</td>
<td>18 (58.1%)</td>
<td>p=.247</td>
</tr>
<tr>
<td>Left</td>
<td>52 (54.2%)</td>
<td>20 (59%)</td>
<td>19 (61.3%)</td>
<td>13 (41.9%)</td>
<td></td>
</tr>
<tr>
<td><strong>Adjuvant treatment</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>37 (38.5%)</td>
<td>17 (50%)</td>
<td>17 (54.8%)</td>
<td>3 (9.7%)</td>
<td>p=.006</td>
</tr>
<tr>
<td>Preoperative RT</td>
<td>21 (21.9%)</td>
<td>4 (12%)</td>
<td>5 (16.1%)</td>
<td>13(41.9%)</td>
<td></td>
</tr>
<tr>
<td>Preoperative CRT</td>
<td>10 (10.4%)</td>
<td>2 (5.9%)</td>
<td>2 (6.5%)</td>
<td>6 (19.4%)</td>
<td></td>
</tr>
<tr>
<td>Postoperative RT</td>
<td>25 (26%)</td>
<td>10(9.4%)</td>
<td>6 (19.4%)</td>
<td>8 (25.8%)</td>
<td></td>
</tr>
<tr>
<td><strong>Time from surgery</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (median) in months</td>
<td>38 (30)</td>
<td>29.2</td>
<td>27.8</td>
<td>59.9</td>
<td>p=0.001</td>
</tr>
<tr>
<td><strong>Neurorrhaphy</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>21 (67.7%)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>10 (32.3%)</td>
<td></td>
</tr>
<tr>
<td><strong>Surgery on side of dominant hand</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>43 (44.8%)</td>
<td>15(44.1%)</td>
<td>12(38.7%)</td>
<td>16 (51.6%)</td>
<td>p=0.591</td>
</tr>
<tr>
<td>No</td>
<td>53 (55.2%)</td>
<td>19(55.9%)</td>
<td>19(61.3%)</td>
<td>15 (48.4%)</td>
<td></td>
</tr>
<tr>
<td><strong>Working status</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unemployed</td>
<td>41(43%)</td>
<td>15 (44%)</td>
<td>12 (39%)</td>
<td>15 (38.4%)</td>
<td>p=0.943</td>
</tr>
<tr>
<td>Employed</td>
<td>48(50%)</td>
<td>16 (47%)</td>
<td>15 (48%)</td>
<td>16 (51.6%)</td>
<td></td>
</tr>
</tbody>
</table>

SCC= Squamous cell carcinoma
*UADT= Upper aerodigestive tract (includes oral cavity, oropharynx, hypopharynx, larynx, nasopharynx, unknown primary carcinoma); RT= radiotherapy; CRT= chemoradiotherapy
Table 7b: Occupation and recreation data

<table>
<thead>
<tr>
<th>Occupation classification of employed patients (n=48)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Manager</td>
<td>8</td>
</tr>
<tr>
<td>Professional</td>
<td>6</td>
</tr>
<tr>
<td>Technician &amp; Associate Professional</td>
<td>7</td>
</tr>
<tr>
<td>Clerical support workers</td>
<td>2</td>
</tr>
<tr>
<td>Service &amp; sales workers</td>
<td>7</td>
</tr>
<tr>
<td>Craft &amp; related Trade workers</td>
<td>2</td>
</tr>
<tr>
<td>Plant &amp; machine operators and assemblers</td>
<td>3</td>
</tr>
<tr>
<td>Armed forces occupations</td>
<td>1</td>
</tr>
<tr>
<td>Not reported</td>
<td>12</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sports or instrument played</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Do not play</td>
<td>44 (46%)</td>
</tr>
<tr>
<td>Do play</td>
<td>49 (51%)</td>
</tr>
<tr>
<td>Missing</td>
<td>3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Musical instruments and sports/hobbies</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Musical instrument</td>
<td>12</td>
</tr>
<tr>
<td>Golf</td>
<td>23</td>
</tr>
<tr>
<td>Aerobics/weight lifting or yoga</td>
<td>7</td>
</tr>
<tr>
<td>Biking, swimming, or skiing</td>
<td>9</td>
</tr>
<tr>
<td>Tennis or badminton</td>
<td>4</td>
</tr>
<tr>
<td>Other</td>
<td>5</td>
</tr>
</tbody>
</table>

As would be expected, differences existed between the groups in terms of cancer site (p = 0.001), histology (p = 0.008), type of adjuvant therapy (p = 0.006) and time from surgery (p = 0.001). Oral cavity carcinomas accounted for the majority (54%) of patients in the SND group, while skin and thyroid cancers accounted for 54% of the patients in the MRND group, and pharynx cancer (oropharynx, larynx, and hypopharynx) accounted for 54% of the patients in the RND group. Histology is a function of the site of cancer, which accounts for the differences in the main histologic types of cancers. The majority of RND patients (28/31, 90%) received radiotherapy (either preoperatively or postoperatively), whereas only 45% of MRND and 50% of SND patients received radiotherapy (p =
0.002). Most RNDs were performed in patients with pharynx cancer for residual or recurrent neck disease following radiotherapy or chemoradiotherapy. The mean time from surgery was greater in the RND group (p = 0.001); since this procedure is less common and also performed in patients with high mortality rates, it was necessary to go back farther in time to obtain enough patients to meet sample size requirements.

4.2.2 Physician participants

Detailed practice related information on the 50 surgeons who returned a package is presented in Table 8. The majority of surgeons were fellowship-trained in head and neck oncology, with 86% (43/50) of surgeons having greater than 50% of their practice devoted to the management of head and neck cancer. Eighty-eight percent of respondents (44/50) reported that they performed more than 25 neck dissections per year, and 48% reported performing more than 50 neck dissections per year. Overall, the surgeons included in the study represented a group of physicians with vast experience in performing neck dissection and managing the associated morbidity.
Table 8: Demographics of physician respondents

<table>
<thead>
<tr>
<th>Country of practice</th>
<th>Number of surgeons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>26 (52%)</td>
</tr>
<tr>
<td>United States</td>
<td>24 (48%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Head &amp; neck fellowship trained</th>
<th>Number of surgeons</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>12 (24%)</td>
</tr>
<tr>
<td>Yes</td>
<td>37 (74%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Years in practice</th>
<th>Number of surgeons</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;10 years</td>
<td>19 (38%)</td>
</tr>
<tr>
<td>10–20 years</td>
<td>18 (36%)</td>
</tr>
<tr>
<td>&gt;20 years</td>
<td>11 (22%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Percentage of practice devoted to head &amp; neck oncology</th>
<th>Number of surgeons</th>
</tr>
</thead>
<tbody>
<tr>
<td>0–25%</td>
<td>3 (6%)</td>
</tr>
<tr>
<td>25–50%</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>50%–75%</td>
<td>8 (16%)</td>
</tr>
<tr>
<td>&gt;75%</td>
<td>35 (70%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of RNDs dissections performed per year</th>
<th>Number of surgeons</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;10</td>
<td>42 (84%)</td>
</tr>
<tr>
<td>11–20</td>
<td>3 (6%)</td>
</tr>
<tr>
<td>21–40</td>
<td>1 (2%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of MRNDs performed per year</th>
<th>Number of surgeons</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;10</td>
<td>27 (54%)</td>
</tr>
<tr>
<td>11–20</td>
<td>8 (16%)</td>
</tr>
<tr>
<td>21–40</td>
<td>7 (14%)</td>
</tr>
<tr>
<td>41–60</td>
<td>3 (6%)</td>
</tr>
<tr>
<td>&gt;60</td>
<td>2 (4%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of SNDs performed per year</th>
<th>Number of surgeons</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;10</td>
<td>3 (6%)</td>
</tr>
<tr>
<td>11–20</td>
<td>10 (20%)</td>
</tr>
<tr>
<td>21–40</td>
<td>16 (32%)</td>
</tr>
<tr>
<td>41–60</td>
<td>9 (18%)</td>
</tr>
<tr>
<td>&gt;60</td>
<td>8 (16%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total number of neck dissections performed per year</th>
<th>Number of surgeons</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;25</td>
<td>3 (6%)</td>
</tr>
<tr>
<td>26–50</td>
<td>20 (40%)</td>
</tr>
<tr>
<td>51–75</td>
<td>11 (22%)</td>
</tr>
<tr>
<td>76–100</td>
<td>6 (12%)</td>
</tr>
<tr>
<td>&gt;100</td>
<td>6 (12%)</td>
</tr>
</tbody>
</table>
4.3 Results for Sensibility Assessment (objective 1)

The sensibility assessment for patients and physician participants are reported separately. A summary of the common concerns and opinions expressed by both groups is also provided.

4.3.1 Sensibility assessment results for patients

Based on the pre-established criteria, the DASH was deemed to be sensible by the patient respondents. The majority of scores for each question were in favor of the DASH being sensible (i.e., scores 5 to 7). There were no questions that had a preponderance of scores less than four. The mean and median scores for all the questions on the sensibility questionnaire were greater than five (Table 9) and this did not vary by the type of neck dissection. While mean scores by RND patients tended to be lower than the MRND and SND patients, the differences were not statistically significant (p = 0.757).
Table 9: Mean and median patient scores for each question on sensibility assessment

<table>
<thead>
<tr>
<th>Question</th>
<th>All Patients</th>
<th>SND</th>
<th>MRND</th>
<th>RND</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 How easy are the questions to understand?</td>
<td>6.26 (7)</td>
<td>6.39 (7)</td>
<td>6.48 (7)</td>
<td>5.90 (6)</td>
<td>p=0.07</td>
</tr>
<tr>
<td>2 Were the instructions easy to understand?</td>
<td>6.22 (7)</td>
<td>6.31 (7)</td>
<td>6.39 (7)</td>
<td>5.97 (6)</td>
<td>p=.258</td>
</tr>
<tr>
<td>3 How was length of time to complete?</td>
<td>6.03 (7)</td>
<td>6.21 (7)</td>
<td>6.14 (7)</td>
<td>5.73 (6)</td>
<td>p=.258</td>
</tr>
<tr>
<td>4 Include important questions on self-care &amp; daily chores?</td>
<td>5.77 (6)</td>
<td>6.03 (7)</td>
<td>5.70 (6)</td>
<td>5.53 (5.5)</td>
<td>p=.325</td>
</tr>
<tr>
<td>5 Include important questions on effect on work?</td>
<td>5.74 (6)</td>
<td>5.68 (6)</td>
<td>5.95 (7)</td>
<td>5.53 (7)</td>
<td>p=.357</td>
</tr>
<tr>
<td>6 Include important questions on effect on recreation?</td>
<td>5.93 (6)</td>
<td>6.03 (6)</td>
<td>6.20 (7)</td>
<td>5.56 (6)</td>
<td>p=.171</td>
</tr>
<tr>
<td>7 Do you think the goal of the DASH has been achieved?</td>
<td>5.70 (6)</td>
<td>5.58 (5)</td>
<td>5.93 (6)</td>
<td>5.62 (6)</td>
<td>p=.521</td>
</tr>
<tr>
<td>8 Does it miss important issues about shoulder problems?</td>
<td>6.15 (7)</td>
<td>6.15 (6.5)</td>
<td>6.44 (7)</td>
<td>5.90 (7)</td>
<td>p=.244</td>
</tr>
<tr>
<td>9 Are the questions too probing (that is, too personal)?</td>
<td>6.75 (7)</td>
<td>6.85 (7)</td>
<td>6.85 (7)</td>
<td>6.55 (7)</td>
<td>p=.131</td>
</tr>
</tbody>
</table>

The frequency of score responses for each item on the DASH were also examined to determine if patients reported greatest difficulty on activity items that involve shoulder abduction (Table 10). As expected, the activity items with the highest mean and median scores (i.e., greater impairment or activity limitation) were those that involved reaching above one's head (change a lightbulb, reach a high shelf) or require full shoulder range of motion (i.e., daily chores, yardwork, moving the arm freely or recreation with force). Activities that were not associated with shoulder abduction, such as writing, turning a key, using a knife etc) had the lowest mean and median scores.
<table>
<thead>
<tr>
<th>Question</th>
<th>DASH SCORE</th>
<th></th>
<th></th>
<th></th>
<th>Mean</th>
<th>Median</th>
<th>Std Dev</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 open jar</td>
<td>47</td>
<td>19</td>
<td>16</td>
<td>5</td>
<td>4</td>
<td>1.90</td>
<td>1.00</td>
</tr>
<tr>
<td>2 write</td>
<td>82</td>
<td>6</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>1.13</td>
<td>1.00</td>
</tr>
<tr>
<td>3 turn a key</td>
<td>83</td>
<td>6</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>1.13</td>
<td>1.00</td>
</tr>
<tr>
<td>4 prepare meal</td>
<td>72</td>
<td>10</td>
<td>5</td>
<td>3</td>
<td>1</td>
<td>1.36</td>
<td>1.00</td>
</tr>
<tr>
<td>5 push door</td>
<td>59</td>
<td>18</td>
<td>7</td>
<td>6</td>
<td>1</td>
<td>1.59</td>
<td>1.00</td>
</tr>
<tr>
<td>6 object on shelf</td>
<td>45</td>
<td>20</td>
<td>14</td>
<td>8</td>
<td>4</td>
<td>1.97</td>
<td>2.00</td>
</tr>
<tr>
<td>7 chores</td>
<td>42</td>
<td>24</td>
<td>12</td>
<td>5</td>
<td>8</td>
<td>2.04</td>
<td>2.00</td>
</tr>
<tr>
<td>8 yard work</td>
<td>49</td>
<td>19</td>
<td>11</td>
<td>7</td>
<td>5</td>
<td>1.90</td>
<td>1.00</td>
</tr>
<tr>
<td>9 make bed</td>
<td>70</td>
<td>9</td>
<td>10</td>
<td>0</td>
<td>2</td>
<td>1.41</td>
<td>1.00</td>
</tr>
<tr>
<td>10 carry a bag</td>
<td>67</td>
<td>8</td>
<td>13</td>
<td>1</td>
<td>2</td>
<td>1.49</td>
<td>1.00</td>
</tr>
<tr>
<td>11 carry heavy object</td>
<td>50</td>
<td>17</td>
<td>11</td>
<td>6</td>
<td>7</td>
<td>1.93</td>
<td>1.00</td>
</tr>
<tr>
<td>12 change light bulb</td>
<td>45</td>
<td>22</td>
<td>13</td>
<td>7</td>
<td>4</td>
<td>1.93</td>
<td>2.00</td>
</tr>
<tr>
<td>13 wash/dry hair</td>
<td>63</td>
<td>14</td>
<td>10</td>
<td>2</td>
<td>2</td>
<td>1.53</td>
<td>1.00</td>
</tr>
<tr>
<td>14 wash back</td>
<td>46</td>
<td>18</td>
<td>12</td>
<td>12</td>
<td>3</td>
<td>1.99</td>
<td>1.00</td>
</tr>
<tr>
<td>15 put on pullover</td>
<td>61</td>
<td>13</td>
<td>13</td>
<td>3</td>
<td>1</td>
<td>1.57</td>
<td>1.00</td>
</tr>
<tr>
<td>16 use a knife</td>
<td>78</td>
<td>9</td>
<td>3</td>
<td>0</td>
<td>1</td>
<td>1.21</td>
<td>1.00</td>
</tr>
<tr>
<td>17 recreation little effort</td>
<td>78</td>
<td>7</td>
<td>3</td>
<td>0</td>
<td>3</td>
<td>1.27</td>
<td>1.00</td>
</tr>
<tr>
<td>18 recreation some force</td>
<td>40</td>
<td>17</td>
<td>18</td>
<td>6</td>
<td>10</td>
<td>2.22</td>
<td>2.00</td>
</tr>
<tr>
<td>19 move arm freely</td>
<td>42</td>
<td>21</td>
<td>16</td>
<td>5</td>
<td>7</td>
<td>2.05</td>
<td>2.00</td>
</tr>
<tr>
<td>20 manage transport</td>
<td>76</td>
<td>9</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td>1.29</td>
<td>1.00</td>
</tr>
<tr>
<td>21 sexual activity</td>
<td>61</td>
<td>13</td>
<td>6</td>
<td>4</td>
<td>7</td>
<td>1.71</td>
<td>1.00</td>
</tr>
<tr>
<td>22 interfere w/ social activity</td>
<td>67</td>
<td>15</td>
<td>6</td>
<td>2</td>
<td>1</td>
<td>1.41</td>
<td>1.00</td>
</tr>
<tr>
<td>23 limited work</td>
<td>63</td>
<td>14</td>
<td>9</td>
<td>5</td>
<td>0</td>
<td>1.52</td>
<td>1.00</td>
</tr>
<tr>
<td>24 pain</td>
<td>44</td>
<td>24</td>
<td>17</td>
<td>6</td>
<td>0</td>
<td>1.84</td>
<td>2.00</td>
</tr>
<tr>
<td>25 pain w/ specific activity</td>
<td>42</td>
<td>26</td>
<td>17</td>
<td>6</td>
<td>0</td>
<td>1.86</td>
<td>2.00</td>
</tr>
<tr>
<td>26 tingling</td>
<td>55</td>
<td>22</td>
<td>9</td>
<td>3</td>
<td>2</td>
<td>1.63</td>
<td>1.00</td>
</tr>
<tr>
<td>27 weakness</td>
<td>38</td>
<td>25</td>
<td>19</td>
<td>7</td>
<td>2</td>
<td>2.01</td>
<td>2.00</td>
</tr>
<tr>
<td>28 stiffness</td>
<td>40</td>
<td>27</td>
<td>16</td>
<td>5</td>
<td>3</td>
<td>1.95</td>
<td>2.00</td>
</tr>
<tr>
<td>29 difficulty sleeping</td>
<td>59</td>
<td>20</td>
<td>5</td>
<td>5</td>
<td>2</td>
<td>1.58</td>
<td>1.00</td>
</tr>
<tr>
<td>30 feel less capable</td>
<td>47</td>
<td>13</td>
<td>12</td>
<td>14</td>
<td>5</td>
<td>2.09</td>
<td>1.00</td>
</tr>
</tbody>
</table>
Content analyses were performed for the written responses to each of the questions. Based on similar themes of responses for each question, responses were summarized into the following broad themes: ease of use, specific missing items, work issues, and extent to which the goals of the DASH were met.

Overall, patients stated that the DASH was a comprehensive questionnaire that was easy to use. Patients in general did not report difficulty with understanding the DASH instructions or the questions. Of the two patients who did comment about having some difficulty, they attributed it to the fact that English was not their first language (for the current study, we used only the English version of the DASH). Two patients reported that the instructions were not clear as to whether they should answer the item based on the arm/shoulder on the side of surgery, or the arm/shoulder they perform the activity with. One patient reported that the formatting of the questionnaire was poor, with the font being too small and the spacing too close together. Some patients were uncertain how to respond if certain items or tasks were never performed (i.e., not applicable), since there is no method for handling items deemed not applicable. For instance, patients commented that hobbies or work might not be applicable if they do not have hobbies, were retired or out of work. One patient commented that the ability to perform certain activities or tasks may be limited by age or co-morbidities and not related to shoulder impairment.

Few patients noted items that were not covered by the DASH. Nine patients felt the questionnaire missed important questions about problems patients face with day-to-day care such as “putting on a coat,” “dental hygiene,” or “shaving.” Regarding recreational activities, three patients felt that the DASH should have specified the height of lifting, since they found it easy to lift to the waist but difficult to lift above the waist, and
particularly hard to lift above the head. Two patients stated that there should be a question about whether they had to stop or modify their recreational activities after their neck dissection.

Several issues arose about employment activity. Three patients expressed concern that the DASH did not assess the effect shoulder impairment had on ability to use a computer for work. These patients reported lower accuracy and slower performance on a computer after their surgery. One patient reported that the DASH should ask about difficulty with multi-tasking at work, such as holding the phone on the shoulder while writing or typing. One patient noted that shoulder impairment and activity limitations would have a greater effect on the occupation of a person who was required to work overhead, and this should be captured by the DASH.

Only five patient respondents felt that the DASH did not completely meet the goal of assessing shoulder impairments and activity limitations. These patients felt that the DASH should have included either assessment of shoulder ROM and strength or assessment of neck impairments following a neck dissection.

4.3.2 Sensibility assessment results for physicians

The responding physicians found the questionnaire to be generally acceptable. Mean and median scores for all of the questions were greater than four. Mean and median scores for each question are presented in Table 11. The majority of scores for each question were in favor of the DASH being sensible (i.e., a score of 4 to 7). The question on length of the questionnaire (question 3) was associated with the lowest mean score (mean = 4.5).
Fifteen respondents (30%) gave the question a score of three or less, i.e., they felt the DASH was too long. No other questions were given a score of one or two by any physician.

**Table 11: Mean and median surgeon scores for each question on sensibility assessment**

<table>
<thead>
<tr>
<th>Question</th>
<th>Physician</th>
<th>Mean score (median)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 How easy are the questions to understand?</td>
<td></td>
<td>5.98 (6)</td>
</tr>
<tr>
<td>2 Were the instructions easy to understand?</td>
<td></td>
<td>5.92 (6)</td>
</tr>
<tr>
<td>3 How was length of time to complete?</td>
<td></td>
<td>4.51 (5)</td>
</tr>
<tr>
<td>4 Include important questions on self-care &amp; daily chores?</td>
<td></td>
<td>5.77 (6)</td>
</tr>
<tr>
<td>5 Include important questions on effect on work?</td>
<td></td>
<td>5.52 (5.5)</td>
</tr>
<tr>
<td>6 Include important questions on effect on recreation?</td>
<td></td>
<td>5.84 (6)</td>
</tr>
<tr>
<td>7 Do you think the goal of the DASH has been achieved?</td>
<td></td>
<td>5.76 (6)</td>
</tr>
<tr>
<td>8 Does it miss important issues about shoulder problems?</td>
<td></td>
<td>6.02 (6)</td>
</tr>
<tr>
<td>9 Are the questions too probing (that is, too personal)?</td>
<td></td>
<td>6.18 (7)</td>
</tr>
</tbody>
</table>

Content analysis was performed for the additional written responses. Responses were summarized based on similar themes of responses for each question. Themes identified included questionnaire length (feasibility), missing items and work. Overall, the majority of physicians responded that the DASH was a very complete questionnaire. One physician remarked that the DASH “is a more accurate and standardized instrument than other tools now available.” Another physician described it as “a simple questionnaire that quickly covers almost all areas related to arm and shoulder problems following neck dissection.”
There were some concerns with the questionnaire. The most frequently reported concern was that the questionnaire was too long and contained too many items. Items that physicians felt could be removed included the item on “turning a key” or “washing one’s back.” The former activity was felt to be more of a wrist and hand problem that should not be affected by shoulder impairment. The latter activity was felt to be a difficult task even in people without shoulder impairments, and therefore should be removed. Two physicians felt that the three recreation questions could potentially be collapsed into one question, thereby reducing the length of the questionnaire. The sports/performing arts module was considered to be irrelevant to most head and neck cancer patients.

Conversely, there were omissions identified by physician respondents. Items related to self-care and day-to-day chores that were felt to be missing included “holding a phone,” “infant or childcare,” “dental hygiene,” and “using a hairbrush.” One area of self-care specific to head and neck cancer patients that physicians felt should be included in the questionnaire was “difficulty with tracheotomy or gastrostomy-tube care.” In terms of work, two physicians felt the DASH should ask whether patients had to quit work or make changes in their work secondary to shoulder impairment. One physician commented that it would be ideal if the DASH questionnaire had an item asking patients to report if they had either a physically demanding job or sedentary work, as shoulder impairment would have a greater impact on the former. Another physician felt the DASH should include a question on whether or not patients require narcotics to manage shoulder pain during their work. They expressed that not only would this be a surrogate for the amount of pain a patient is having, but also narcotic use in itself may force a patient to change or modify their work, as well as their mode of transportation to and from work. It
could also affect the concentration level of patients who perform desk jobs. Similar to patient respondents, physicians felt that there should be a “not applicable” response included, since not all activities are performed by all patients; “not applicable” items may be left blank and therefore scored as a missing item with the DASH questionnaire.

### 4.4 Results for test-retest reliability (objective 2)

The mean and median time between receiving the patient’s initial response and the re-test mailing was 2.8 and 2.5 weeks, respectively. Two patients reported improvement in shoulder function. These latter two patients were excluded from the reliability analysis. Both patients who reported improvement had MRND but were greater than 24 months from their surgery.

#### 4.4.1 Test-retest reliability for the DASH

For test-retest reliability, the ICC for the DASH main module was 0.91 (95% CI, 0.90–0.98). For the work module the ICC was 0.86 (95% CI, 0.69–0.94). The sports/performing arts module the ICC was 0.75 (95% CI, 0.45–0.90). Test-retest reliability for the DASH main module was also assessed separately for the different neck dissection groups. The ICC for patients who underwent SND in the retest sample (n = 14) was 0.97 (95% CI, 0.91–0.99). For patients who underwent MRND (n = 12) the ICC was 0.82 (95% CI 0.56–0.94) and the ICC for patients who underwent RND (n = 9) was 0.95 (95% CI 0.81–0.99). Confidence limits overlap suggesting no statistically significant difference in reliability scores among neck dissection groups.
Weighted kappa scores could not be used to assess reliability coefficients for individual items in the DASH since the distribution of scores on the agreement matrices had zero observations in some of the corners and therefore the assumption for weighted kappa scores was violated. Individual item reliability was therefore assessed by determining for each item the number of patients whose numerical score or ranking was; 1) identical between the test and retest response (percent agreement); 2) differed by a score or ranking of one (in either direction); and, 3) differed by a score ranking of more than one (in either direction). As some variability is expected between tests, a one score difference was still considered to be an indication of reliability for individual questions. These results are presented in Table 12.
Table 12: Frequency of concordant score responses between test and retest for the items of the DASH

<table>
<thead>
<tr>
<th>Question</th>
<th>Number of responses that were identical to those in the initial test (%)</th>
<th>Number of items 1 score difference (%)</th>
<th>Number of items ≥ 2 score difference (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (open a jar)</td>
<td>30/43 (70)</td>
<td>11/43 (26)</td>
<td>2/43 (5)</td>
</tr>
<tr>
<td>2 (write)</td>
<td>39/43 (91)</td>
<td>3/43 (7)</td>
<td>1/43 (2)</td>
</tr>
<tr>
<td>3 (turn a key)</td>
<td>37/43 (86)</td>
<td>5/43 (12)</td>
<td>1/43 (2)</td>
</tr>
<tr>
<td>4 (prepare meal)</td>
<td>40/43 (93)</td>
<td>1/43 (2)</td>
<td>2/43 (5)</td>
</tr>
<tr>
<td>5 (open door)</td>
<td>36/43 (84)</td>
<td>7/43 (16)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>6 (reach above)</td>
<td>28/43 (65)</td>
<td>14/43 (33)</td>
<td>1/43 (2)</td>
</tr>
<tr>
<td>7 (house chores)</td>
<td>39/43 (91)</td>
<td>0/43 (0)</td>
<td>4/43 (9)</td>
</tr>
<tr>
<td>8 (garden work)</td>
<td>31/43 (72)</td>
<td>9/43 (21)</td>
<td>3/43 (7)</td>
</tr>
<tr>
<td>9 (make a bed)</td>
<td>37/43 (86)</td>
<td>6/43 (14)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>10 (carry bag)</td>
<td>36/43 (84)</td>
<td>7/43 (16)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>11 (carry heavy object)</td>
<td>28/43 (65)</td>
<td>13/43 (30)</td>
<td>2/43 (5)</td>
</tr>
<tr>
<td>12 (change light bulb)</td>
<td>25/43 (58)</td>
<td>16/43 (38)</td>
<td>2/43 (5)</td>
</tr>
<tr>
<td>13 (wash hair)</td>
<td>27/43 (63)</td>
<td>13/43 (30)</td>
<td>3/43 (7)</td>
</tr>
<tr>
<td>14 (wash back)</td>
<td>27/43 (63)</td>
<td>14/43 (33)</td>
<td>2/43 (5)</td>
</tr>
<tr>
<td>15 (put on sweater)</td>
<td>31/43 (72)</td>
<td>10/43 (23)</td>
<td>2/43 (5)</td>
</tr>
<tr>
<td>16 (cut food with knife)</td>
<td>40/43 (93)</td>
<td>2/43 (5)</td>
<td>1/43 (2)</td>
</tr>
<tr>
<td>17 (*RA- little effort)</td>
<td>37/43 (86)</td>
<td>4/43 (9)</td>
<td>2/43 (5)</td>
</tr>
<tr>
<td>18 (*RA- some force)</td>
<td>25/43 (58)</td>
<td>12/43 (28)</td>
<td>6/43 (14)</td>
</tr>
<tr>
<td>19 (*RA- move arm freely)</td>
<td>28/43 (65)</td>
<td>11/43 (26)</td>
<td>4/43 (9)</td>
</tr>
<tr>
<td>20 (manage transport needs)</td>
<td>39/43 (91)</td>
<td>3/43 (7)</td>
<td>1/43 (2)</td>
</tr>
<tr>
<td>21 (sexual activities)</td>
<td>35/43 (81)</td>
<td>4/43 (9)</td>
<td>4/43 (9)</td>
</tr>
<tr>
<td>22 (limited social activities)</td>
<td>34/43 (79)</td>
<td>9/43 (21)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>23 (limited work)</td>
<td>34/43 (79)</td>
<td>9/43 (21)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>24 (pain)</td>
<td>31/43 (72)</td>
<td>10/43 (23)</td>
<td>2/43 (5)</td>
</tr>
<tr>
<td>25 (pain with activity)</td>
<td>30/43 (70)</td>
<td>11/43 (26)</td>
<td>2/43 (5)</td>
</tr>
<tr>
<td>26 (tingling)</td>
<td>34/43 (79)</td>
<td>4/43 (9)</td>
<td>5/43 (12)</td>
</tr>
<tr>
<td>27 (weakness)</td>
<td>27/43 (63)</td>
<td>15/43 (35)</td>
<td>1/43 (2)</td>
</tr>
<tr>
<td>28 (stiffness)</td>
<td>30/43 (70)</td>
<td>11/43 (26)</td>
<td>2/43 (5)</td>
</tr>
<tr>
<td>29 (difficulty with sleeping)</td>
<td>37/43 (86)</td>
<td>5/43 (12)</td>
<td>1/43 (2)</td>
</tr>
<tr>
<td>30 (feel less capable)</td>
<td>31/43 (72)</td>
<td>7/43 (16)</td>
<td>5/43 (12)</td>
</tr>
</tbody>
</table>

* RA = recreational activities
For each of the 30 items on the DASH, greater than 50% of patients had test and retest scores that were identical and greater than 85% of patients had test and retest scores that were either identical or within one score difference. Therefore, each of the 30 items exhibited good reliability. The questions that had the most responses with greater than one score difference were questions 18 (recreation with some force), question 26 (tingling) and question 30 (feeling less capable, less confident and less useful).

4.4.2 Test-retest reliability for the NDII

The ICC for the NDII was 0.95 (95% CI, 0.90–0.97). Test-retest reliability was also assessed for the different neck dissection groups. The ICC for patients who underwent SND in the retest sample (n = 14) was 0.87 (95% CI, 0.63–0.96). For patients who underwent MRND (n = 12) the ICC was 0.93 (95% CI, 0.78–0.98) and the ICC for patients who underwent RND (n = 10) was 0.96 (95% CI, 0.83–0.99). Confidence limits overlap suggesting that there were no statistically significant differences in reliability scores between neck dissection groups.

As with the DASH, the retest reliability was examined for each of the individual questions by using agreement matrices because the assumption for weighted kappa scores was violated. Table 13 shows the number of patients whose numerical score or ranking for each question was identical between the test and retest response differed by a score or ranking of one (in either direction), or differed by a score ranking of more than one (in
either direction). For each question, over 90% of patients had responses that were either identical or within one score difference between testing.

Table 13: Frequency of concordant score responses between test and retest for the items of the NDII

<table>
<thead>
<tr>
<th>Question</th>
<th>Number of responses that were equal initial test (%)</th>
<th>Number of items 1 score difference (%)</th>
<th>Number of items ≥ 2 score difference (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (pain)</td>
<td>28/43 (65)</td>
<td>13/43 (30)</td>
<td>2/43 (5)</td>
</tr>
<tr>
<td>2 (stiffness)</td>
<td>28/43 (65)</td>
<td>12/43 (28)</td>
<td>3/43 (7)</td>
</tr>
<tr>
<td>3 (self-care)</td>
<td>35/43 (81)</td>
<td>5/43 (12)</td>
<td>3/43 (7)</td>
</tr>
<tr>
<td>4 (lift light)</td>
<td>37/43 (86)</td>
<td>4/43 (9)</td>
<td>2/43 (5)</td>
</tr>
<tr>
<td>5 (lift heavy)</td>
<td>35/43 (81)</td>
<td>6/43 (14)</td>
<td>2/43 (5)</td>
</tr>
<tr>
<td>6 (reach above)</td>
<td>29/43 (67)</td>
<td>14/43 (33)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>7 (overall activity)</td>
<td>32/43 (74)</td>
<td>11/43 (26)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>8 (social activities)</td>
<td>34/43 (79)</td>
<td>9/43 (21)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>9 (RA*)</td>
<td>31/43 (72)</td>
<td>12/43 (28)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>10 (work)</td>
<td>33/43 (77)</td>
<td>9/43 (21)</td>
<td>1/43 (2)</td>
</tr>
</tbody>
</table>

4.5 Results for known-group validity (objective 3)

Prior to analysis, the distribution of scores for the DASH and the NDII was evaluated to assess for normality of data. For the DASH, the data approximated a normal distribution with a positive skew (skewness = 1.496) and kurtosis was 2.0. For the NDII, the data approximated a normal distribution with a negative skew (skewness = –1.03) and kurtosis of 0.2. Based on the distribution approximating a normal distribution, parametric statistics were used for the statistical analyses.
4.5.1 Known-group validity for the DASH

The mean DASH main module scores and 95% CI for the SND, MRND, and RND patients were 12.0 (95% CI, 6.68–17.4), 13.8 (95% CI, 7.4–20.2), and 26.1 (95% CI, 18.1–33.9), respectively. Lower scores represent less shoulder impairment (symptoms) and activity limitations. Boxplots for the scores are presented in Figure 5. There was a statistically significant difference in DASH scores between the groups (F = 5.60, p = 0.005). On post-hoc analysis, RND patients had higher mean DASH scores (i.e., greater impairment and activity limitations) than both the MRND (p = 0.026) and SND (p = 0.007) groups. There was no statistically significant difference in mean DASH scores between SND and MRND patients (p = 0.917). Thus, the DASH was able to detect differences in impairments (symptoms) and activity limitations amongst patients who underwent nerve-sacrificing neck dissections (RND) compared with nerve-sparing neck dissections (SND or MRND). There were no differences between more extensive nerve-sparing neck dissections (MRND) and more selective neck dissections (SND). There were no statistically significant differences in the DASH main module scores in terms of whether neck dissection was performed on the ipsilateral or contralateral side of the dominant hand either for the entire cohort (p = 0.676), for any of the neck dissection groups: RND (p = 0.230), MRND (p = 0.817) or SND (p = 0.152).
There were no statistically significant differences in mean scores between the different neck dissection groups for the work module ($p = 0.514$) or the sports/performing arts module ($p = 0.115$). Assessment of both modules was limited by small patient numbers. Only 19 patients were included in each group for evaluation of differences in the work module scores, and only 16 patients were included in the evaluation of the sports/performing arts module score.
4.5.2 Known-group validity of the NDII

The mean NDII scores and 95% CI for the SND, MRND, and RND patients were 83.2 (95% CI, 76.1–90.3), 80.1 (95% CI, 71.4–88.7) and 58.7 (95% CI, 49.0–68.4), respectively. Higher scores indicate less shoulder impairments and activity limitations (Figure 6). There was a statistically significant difference in NDII scores between the groups (F = 10.2, p = 0.001). On post-hoc analysis, the RND patients had lower mean NDII scores (i.e., more impairments and activity limitations), than either the MRND or SND patients (p = 0.002 and 0.001, respectively). There were no statistically significant differences in mean NDII scores between the SND and MRND patients (p = 0.858).

Figure 6: Boxplots representing mean NDII scores for each group of neck dissection patients
4.6 Convergent construct validity results (Objective 4)

Convergent construct validity was assessed by correlating DASH (symptom and activity limitations) scores with NDII (symptom and activity limitation) scores for the entire patient cohort. The Pearson product correlation between the DASH main module and the NDII score was $r = -0.916$ ($p = 0.001$). Correlation of individual items was performed using Pearson product correlation for those questions on each instrument that assessed similar types of impairments and activity limitations. For questions assessing pain, the correlation was $r = -0.683$ ($p = 0.001$). For questions asking about shoulder stiffness, the correlation was $r = -0.771$, ($p = 0.001$). Reaching above the head in the NDII correlated with related questions on the DASH, such as placing an object on a shelf and changing a light bulb ($r = 0.813$, $p = 0.001$ and $r = -0.711$, $p = 0.001$, respectively). Carrying a heavy object on the DASH correlated with limitations in lifting a heavy object on the NDII ($r = -0.654$, $p = 0.001$). Interference with social activities on the NDII correlated with participation in social activities on the DASH ($r = -0.769$, $p = 0.001$). There was a weaker correlation between the question on the NDII asking about limitations in leisure or recreational activities and the question on the DASH asking about recreational activities requiring little activity ($r = -0.491$). However, this same NDII question had a stronger correlation with recreational activities with some force on the DASH, and with recreational activity requiring moving the arm freely ($r = -0.640$; $r = -0.631$, respectively). The correlation between questions related to limitations at work was $r = -0.787$, while the correlation between the self-care question on the NDII and DASH questions such as washing one’s hair ($r = -0.595$) or washing one’s back ($r = -0.578$) were...
weaker. Overall, most of the questions with related content exhibited moderate to good correlation, suggesting that the DASH items measure a similar content to the NDII.
Chapter 5
DISCUSSION

This study is the first report on an assessment of the measurement properties of the DASH questionnaire in head and neck cancer patients who have undergone neck dissection. It demonstrated that the DASH questionnaire is a sensible, reliable and valid measure of shoulder impairment and activity limitations in these patients.

5.1 Sensibility assessment of the DASH (objective 1)

While the DASH questionnaire was deemed to be a sensible measure of shoulder impairment and activity limitations by both patients and physicians, the latter group was more critical of the DASH. The major concern among the surgeons was that the questionnaire was too long. Studies have demonstrated that the length of a questionnaire does influence response rates.\(^{143-146}\) Edwards et al conducted a systematic review of randomized controlled trials (RCTs) to evaluate the association between questionnaire length and response rates.\(^{147}\) A total of 38 RCTs were identified in which participants were allocated to questionnaires of differing lengths. In trials of one page compared with either two or three pages, the odds of response per one page increase was 1.01 (95% CI, 0.82–1.24). For one page compared with four or more pages, and for two or more pages compared with longer alternatives, the odds ratios per one page increase were 0.90 (95% CI, 0.83–0.98) and 0.98 (95% CI, 0.96–0.99), respectively. Although the DASH contains 30 items, it can still be considered a short questionnaire. With only two pages in the main module, it can be completed in less than 10 minutes.
Patients did not feel that questionnaire length was a concern. If the physicians had actually completed the questionnaire, they may have been less critical of the length of the DASH. Rowe and Oxman similarly found in their sensibility assessment of an asthma questionnaire that physicians were more critical when compared to patients. The authors hypothesized that the patients who actually completed the questionnaire rated it higher than physicians who were limited to reading the questionnaire.

Some of the physicians who were concerned about the length of the DASH suggested collapsing items into general categories (i.e., recreational activity items or items related to activities of daily living), which is similar to the design of the NDII. While this format would reduce the number of items, there is a risk that it could be associated with a reduction in the ability to detect differences between groups and confusion in completing the questionnaire. With a general question, patients may have difficulty with some but not all activities, which could create uncertainty in selecting the appropriate answer. Respondents may also be more likely to focus only on the activities provided in the examples, and less likely to focus on other commonly performed activities that can be affected by shoulder impairments. Therefore, general questions may cause respondents to either over- or under-report their impairments and activity limitations. The answers may depend upon how much importance the individual assigns to a given activity when completing the question. One of the main reasons for selecting the DASH for assessment is the focus on items related to specific symptoms and activities rather than broad general categories.

Compared with the nerve-sparing neck dissection groups, patients who underwent RND were more critical of the DASH as indicated by the lower scores for each question. In
contrast to patients with RND, those who underwent a nerve-sparing neck dissection may not have experienced many of the impairments and activity limitations addressed by the DASH, therefore making it more difficult to critique the questionnaire.

Other weaknesses of the DASH that were highlighted in the content analysis included the lack of a “not applicable” response option and missing content. Lack of a “not applicable” response option could lead to missing data, and therefore might result in lost information of patients excluded due to missing data. Lack of a “not applicable” response option is not unique to the DASH questionnaire. Few shoulder “disability” questionnaires and general quality of life instruments have provision for patients to indicate that an item has been left blank because it is “not applicable,” and even fewer provide space for reasons to be given. Of the shoulder specific instruments assessing impairments and activity limitations, both the SDQ and the ASES scale provide the opportunity for patients to choose a “not applicable” response. However, “not applicable” responses complicate scoring and interpretation of scores. Similar to the DASH, the NDII does not have a “not applicable” response option; however, it does potentially mitigate this problem by having general categories for items, such as “activities on self-care” with examples provided rather than the specific activities themselves as items.

In content analysis by physicians and patients, some indicated that there were missing items that should have been included. Many of the missing activities mentioned, such as putting on a coat, brushing ones teeth, or shaving, were originally included with the initial item generation for the DASH but later removed based on psychometric and clinometric item reduction. Specific to head and neck cancer patients tracheotomy and
gastrostomy-tube (g-tube) care were not included in the DASH. However, the vast majority of patients who undergo a neck dissection do not require either of these procedures, and those who do require a tracheotomy are usually decanulated prior to hospital discharge. Computer use was also an activity item that was felt to be missing. Invariably there will be activities related to changes in technology and continually updating an instrument based on technology changes is not feasible.

Some physicians and patients felt that the DASH should address neck impairments (i.e., pain, stiffness, loss of ROM) and the associated activity limitations that can also result from neck dissection. Neck impairments are typically related to scarring, fibrosis of the soft tissue and/or injury to the sensory cervical rootlets rather than from SAN injury. Unlike the DASH, which is limited to outcomes of the upper extremity, the NDII was designed to assess neck and/or shoulder impairments and activity limitations following neck dissection. The questions of the NDII do not however, differentiate between the neck or shoulder function. The specific regional impairments and activity limitations following neck dissection should be assessed based upon the objectives of the study.

5.2 Test-retest reliability of the DASH (objective 2)

In patients following neck dissection, the DASH main module exhibited excellent test-retest reliability and also demonstrated good reliability across the spectrum of severity of treatment. The reliability coefficient for the work module was also good. The sports and performing arts module had the lowest reliability score with the widest CI. This module was felt by surgeons to be the least relevant to the head and neck cancer population, and
likely of no benefit for use in future studies of this patient population. Although the sample size requirements were not met, the CI for the main module was relatively narrow.

The reliability scores (i.e., ICC) of the DASH in patients with head and neck cancer is comparable to the reliability scores reported in other patient samples with different upper extremity conditions.\(^{(40, 41, 152, 153)}\) The reported ICC values in the literature range from 0.86 to 0.98, with the vast majority of ICCs greater than 0.90.\(^{(116-118)}\) Beaton et al reported a reliability ICC score of 0.96 in a patient sample with diverse disorders of the upper extremity.\(^{(40)}\)

Interpretation of reliability depends upon how a measure is to be used or applied.\(^{(40, 97, 139)}\) If the DASH is going to be used at a group level for research purposes as was originally intended, lower reliability limits can be tolerated (i.e., less than 0.90).\(^{(40, 97, 139)}\) If the DASH is to be used as a clinical tool upon which individual treatment decisions are to be based, higher test-retest reliability coefficients are required (upwards of 0.90, to ensure limited measurement error and valid interpretation of findings).\(^{(40, 154)}\) Based on the excellent reliability coefficient for the main module, the DASH can be used for either the research or clinical applications.

### 5.3 Validity assessment of the DASH (objective 3)

The DASH was developed to measure “disability based upon physical function and symptoms.”\(^{(127)}\) Convergent construct validity of the DASH has been previously demonstrated in many different patient samples with varying disorders of the upper
extremity. In these samples, the DASH was strongly correlated to other measures of shoulder impairments and activity limitations including the SPADI ($r = 0.85$), SF-36 (physical function and pain domains) ($r = 0.73$), Constant’s Shoulder Score ($r = -0.76$), ASES scale ($r = -0.81$) and VAS pain intensity ($r = 0.73$). To assess validity in our patient sample, the DASH was correlated with the NDII, a previously validated measure of shoulder impairment and activity limitation following neck dissection. A strong correlation ($r = -0.96$) was found between the scores on the two instruments, implying that the DASH and the NDII measure a similar construct. The DASH and NDII have some similar questions that may account for the very strong correlation between the two questionnaires. The items that exhibited the strongest correlation were those related to activities most affected by SAN injury, i.e., reaching above one’s head on the NDII with placing an item on a shelf or changing a light bulb ($0.71–0.81$).

Further validity assessment was performed by comparing DASH scores between patients undergoing different types of neck dissection (SND, MRND, or RND) and based on the extent of SAN manipulation, where score differences were expected. The results of this analysis demonstrated that the DASH was able to discriminate between patients who underwent nerve-sparing neck dissection (SND or MRND) and those who underwent nerve-sacrificing neck dissection (RND). Other studies, which used different outcome measures have similarly reported differences in shoulder impairment and activity limitations between these groups.

No difference was found in the mean scores between patients who underwent MRND and those who underwent SND. There are a number of potential explanations for this finding. It is possible that no difference existed between the two groups. Other authors have
similarly shown that with time (>6 months) the majority of patients with any nerve-sparing neck dissection experience recovery and a reduction in impairment and activity limitations.\(^{(19, 21, 28)}\) All patients evaluated in the current study were greater than 11 months from surgery, and thus a significant amount of recovery was expected.\(^{(19, 21)}\) To ensure an ability to detect differences in the DASH scores between SND and MRND evaluation could have been performed in the early postoperative period (<6 months), when a greater difference in shoulder morbidity would be expected.\(^{(20, 32, 80)}\) Because most of the debate regarding morbidity following neck dissections surrounds long-term shoulder impairments and activity limitations in nerve-sparing neck dissection, patients who were more remote from their surgery were deliberately selected in order to determine if the DASH, with its increased content, could detect more subtle potential differences between these groups.

Another possible explanation is that despite its increased content, the DASH was not sensitive enough to detect small changes; or that a small difference could not be detected due to an inadequate sample size. Since there were no existing data for the DASH in this patient population on which to base a sample size calculation, the chosen sample size of 30 patients per group was deemed appropriate. While this sample size may have been adequate to detect a difference between nerve-sparing and nerve-sacrifice neck dissection groups, it may have been inadequate to detect a difference in scores between MRND and SND groups.

Lastly, confounding variables that could not be controlled also may have been present. For example, patients in the MRND group may have been more likely to be offered physiotherapy, or to be reminded to perform shoulder exercises, since they underwent
more extensive neck dissections. Physiotherapy has been shown to improve shoulder outcomes following neck dissection and thus may have reduced the extent of impairment and activity limitations in these patients.\textsuperscript{(155-157)} The use or amount of physiotherapy could not be determined from chart review.

\textbf{5.4 Measurement properties of the NDII}

The NDII also exhibited excellent test-retest reliability, which validates the findings by Taylor et al.\textsuperscript{(38)} The strength of the current study was that reliability was assessed with ICC in comparison with Taylor et al who assessed reliability using Spearman correlation coefficients.\textsuperscript{(38)} Spearman’s correlation provides information about how the scores vary together, but cannot determine the extent of agreement between two sets of measurements.\textsuperscript{(100)} For most research and clinical applications, the essence of reliability is agreement between the two sets of data, as assessed with ICC for continuous data.\textsuperscript{(100)}

In the study by Taylor et al, the NDII was validated by correlation with Constant’s Shoulder Score and the SF-36\textsuperscript{(38)}, but there was no correlation to another patient-based self-report measure of shoulder impairment and activity limitations, such as the SDQ, SPADI, or ASES scale. The current study demonstrated that the NDII correlated highly with the DASH score, which has been shown to measure the construct of shoulder impairment and activity limitations\textsuperscript{(40, 116, 117, 127)}, lending further support that the NDII and the DASH are measuring a similar construct.

For known group validity, the NDII was not able to detect differences between patients who underwent MRND and those who underwent SND. These findings are in contrast to
the results reported by Taylor et al, who reported that the NDII was able to detect differences between these two groups of patients.\(^{(38)}\)

In a multivariable regression analysis, the authors reported that neck dissection type; patient age, weight and radiation treatment contributed most to the NDII scores. However, in their model of best fit, neck dissection type was not statistically significant and carried the least weight of all the variables in the model based on the magnitude of the coefficient. Therefore, the findings from that study are likely very similar to the current study.

In the original assessment of the measurement properties of the NDII, patients who underwent RND were excluded from the study and therefore, the full spectrum of severity of treatment was not included.\(^{(38)}\)

The current study included these patients, and demonstrated that the NDII was able to detect differences between patients who underwent RND and those that underwent nerve-sparing neck dissection.

### 5.5 Comparison of the DASH with the NDII

Overall, the DASH and NDII demonstrated similar measurement properties. Reliability scores were similar for the two instruments. On validity assessment, both instruments failed to detect a statistically significant difference between nerve-sparing neck dissection groups. The NDII did exhibit some strengths compared with the DASH questionnaire. There were fewer missing items on the NDII, and therefore fewer patients were excluded due to missing items. “Not applicable” responses were not an issue with the NDII since specific activities were not assessed, but rather general categories were used in the areas of activities of daily living, occupation and recreational activities. The general impression among the surgeons was that the DASH was too long, which raises the concern that it
may not be widely accepted for use in either research or clinical practice. The NDII is a substantially shorter questionnaire compared to the DASH, which would make it more acceptable to physicians and researchers.

5.6 Strengths of the thesis

A high response rate was necessary to limit the extent of non-response bias and was achieved (response rate of 80%) using a modified Dillman approach. This response rate is substantially higher than rates reported in the literature for survivors of other cancers, which range from 47% in bladder cancer patients, to 64% in childhood cancer survivors. Multiple mailings were important in yielding a high response rate. The Ethics Review Board deemed that patient non-response was indicative of refusal to participate in the study, and therefore, these charts could not be reviewed to assess for differences in sociodemographic, and clinicopathologic variables of non-responders. Kotaniemi et al demonstrated that the most common reasons for non-response are lack of interest and forgetting to return the questionnaire. The major limitation for this study would be if non-response was directly related to shoulder impairment. However, denervation of the trapezius muscle does not substantially affect the ability to write, which was evidenced by the patients who reported having “no difficulty” with writing. This finding was consistent across all neck dissection groups, with almost all patients reporting normal writing ability and only a few reporting mild or moderate difficulty (<10 patients).
Neck dissections are performed in a wide variety of head and neck cancers. A strength of this study was the heterogeneous sample of head and neck cancer patients that was included; varying demographics (age and gender), histologies, head and neck sites, and indications for neck dissection. To maintain generalizability and external validity, a sample of patients was chosen that was representative of patients who are managed with neck dissection.

5.7 Study limitations

5.7.1 Response rate of physicians

While the response rate for physicians was consistent with that reported in the literature,\(^{142, 162, 163}\) the rate was low at only 50%. Physician non-responders may have felt that the issue of shoulder morbidity was either not important or that the pre-existing instruments were adequate, and therefore a response was not necessary. Studies suggest that the most common reason for physician non-response is lack of time.\(^{142}\) The sample of head and neck surgeons that were asked to participate in the current study represent a homogenous group of academic surgeons, whose clinical practice is primarily focused on the management of patients with head and neck cancer. Leslie reported that with homogeneous groups response-rate bias is probably unlikely.\(^{164}\)
5.7.2 Missing data

Missing data are a common problem in postal design studies involving self-report questionnaires.\(^{165,166}\) Loss of data can lead to loss of statistical power and bias, and can threaten the external validity of a study by yielding non-generalizable results.\(^{165,166}\) While there are no empirical guidelines to suggest what constitutes excessive missing items, some researchers feel that when up to 15% of cases have missing data on a given variable, the extent of missing data is not extensive, and thus the variable should be retained.\(^{166-168}\) Other authors have estimates that are more liberal with a variable being deleted only when 40% or more of cases have missing data.\(^{166}\) Based on the above guidelines, missing data were not a significant problem with either the DASH or NDII. The one item that had 10% of cases with missing items was the question on the DASH that inquired about the effect of shoulder impairments on sexual activities. Since this is a personal question, it was likely that patient’s chose not complete the question. However, on the sensibility assessment the majority of patients did not feel that any of the questions were too probing.

Some patients who left an activity item blank wrote “not applicable” above it, signifying that the item was not missed but rather the activity not performed. There was no single item for which multiple patients wrote “not applicable.” The questionnaire layout may have also accounted for missing items. It was noted on sensibility analysis that questionnaire format needed to be improved. The first 21 items are grouped close together and with a small font. Improvements in the format of the questionnaire may help to reduce the number of missing items.
5.7.3 Sample size

Forty-seven analyzable cases were required for reliability analysis\(^{(140)}\) and only 36 cases were eligible for analysis. Despite the lower sample size, the ICC confidence intervals for the DASH main module and the NDII were relatively narrow.

Bias may have occurred with the selection of patients from a recent time period and consecutively working back in time. While shoulder related morbidity could potentially vary over the decades due to differences in treatment techniques, the goal was to have results generalizable to current times rather than to a past cohort of patients. Therefore, patients who underwent a nerve-sparing neck dissection in the most recent time period were selected. In order to achieve the sample size requirements for RND patients, some of the RND patients were selected from a cohort treated in an earlier time period than the other neck dissection groups. It is possible that with improvements in current surgical and radiotherapy techniques, the patients who underwent RND in an earlier time period may have had greater impairments. However, the majority of patients in the RND group were treated within a similar time period to the patients in the nerve-sparing group.

5.7.4 English as a second language

There were eleven patients included in the study who reported English as a second language. Patients with English as a second language may not have understood the instructions or questions. None of these patients required a translator, and overall the number of patients with English as a second language was relatively small and unlikely to have had a significant effect on the study results. One of the strengths of the DASH
The questionnaire is that it has undergone extensive cross-cultural evaluation in many languages and cultures.\(^{(169)}\) The NDII has not undergone cross-cultural evaluation.

### 5.7.5 Confounding variables

Pre-existing shoulder dysfunction (i.e., history of arthritis, shoulder surgery or trauma), and the extent to which patients underwent postoperative physiotherapy or undertook shoulder exercises, are two potential confounding variables. Through chart review, patients with a documented history of a pre-existing shoulder disorder were excluded. However, this review was limited by the information within the medical chart. Postoperative physiotherapy has been shown to reduce the amount of postoperative shoulder impairment following RND and to reduce the risk of adhesive capsulitis in patients undergoing MRND.\(^{(155-157)}\) It is likely that patients who underwent either RND or MRND compared to SND would have been referred to physiotherapy. It was not possible to determine the extent of physiotherapy or shoulder exercises from the chart review. While patients may be offered physiotherapy as an out-patient treatment, the clinical impression is that many patients do not undergo physiotherapy. Therefore, it is likely that physiotherapy was not a significant confounder in our patient population.

Approximately one-third of the patients who underwent a RND had the SAN reconstructed by neurorrhaphy to a cervical motor rootlet. Although it was not statistically significant, there was a trend towards lower DASH and NDII scores in the nerve reconstruction group, which suggested less impairment and activity limitations in these patients. Because of the small number of patients who underwent a RND, patients who underwent nerve reconstruction were included. It is also recognized that a subset of
patients who undergo RND or MRND will have reduced impairment due to innervation of the trapezius muscle via the cervical plexus. Intraoperative EMG studies were not performed, and therefore, it was not possible to determine the innervation patterns in these patients.

Denervation of the levator scapulae muscle from electrocautery dissection in the vicinity of the dorsal scapular nerve could potentially result in additional shoulder impairment and activity limitations independent of SAN injury. The details of the instrument (i.e., cautery vs. scalpel or scissors) used for dissection is typically not noted in operative reports.

Radiotherapy, delivered either in the preoperative or postoperative period, was more common in patients who underwent RND. It is possible that morbidity associated with radiation therapy may have contributed to the difference in shoulder impairment and activity limitations between patients who underwent RND and those who underwent nerve-sparing neck dissection. The findings in the literature are inconsistent with respect to the effect of preoperative or postoperative radiation on shoulder impairments and activity limitations. Comparisons are difficult because many of the studies are methodologically flawed, the sample sizes are typically small, different measures are used, and there is frequently an inadequate comparison group.

5.8 Future directions and significance of the research

The use of the DASH and the NDII in longitudinal studies requires the establishment of responsiveness. The ability to detect change over time or following an intervention has
yet to be performed for either instrument in patients undergoing neck dissection. The most practical instrument with the strongest measurement properties can then be used to evaluate interventions, such as physiotherapy regimens, to minimize and reduce shoulder impairment following neck dissection. Research is also needed to help surgeons predict which patients will have impairments and activity limitations following neck dissection and to evaluate if early intervention can help reduce the extent of shoulder-related morbidity. Neck dissection remains an integral component of the management of head and neck cancer. While there is a significant amount of literature on shoulder outcomes following head and neck surgery, there is no standard questionnaire used to assess outcome, which makes interpretation of the literature difficult. Determination of an ideal questionnaire to assess shoulder impairment, activity limitation, and disability is paramount. The first step in getting physicians to use a standardized instrument would be to ensure that there is adequate literature supporting the use of the instrument(s) for a given objective. The results of this thesis, along with additional responsiveness testing, should provide physicians with the evidence to support the use of either one or both instruments. Once the evidence is available in the literature, consensus building mechanisms sponsored by the American Head and Neck Society, ideally in conjunction with the European counterpart, need to evaluate the literature and make a recommendation or endorsement of the most suitable instrument for use in future studies of shoulder morbidity following neck dissection.

5.9 Conclusion
The current research demonstrates that the DASH is a sensible, reliable, and valid measure of shoulder impairment and activity limitations in patients who undergo neck dissection for head and neck cancer. The NDII has similar reliability and validity to the DASH, is shorter in length and has fewer missing items. Establishment of the responsiveness for both instruments in this patient population will provide the necessary data for selection of a patient-based, self-report questionnaire on shoulder impairment and activity limitations.
REFERENCES


2. Dixon D, Johnston M, McQueen M, Court-Brown C. The Disabilities of the Arm, Shoulder and Hand Questionnaire (DASH) can measure the impairment, activity limitations and participation restriction constructs from the International Classification of Functioning, Disability and Health (ICF). BMC Musculoskelet Disord 2008;9:114.


134. AHNS. Head & Neck Fellowship Programs. In; 2008.


APPENDIX A: Introductory letters (patients and physicians)

*Introductory letter to patients*

Patient name

Patient address

**RE: Assessment of the measurement properties of Disabilities of the Hand, Shoulder and Arm (DASH) questionnaire in patients who have undergone neck dissections**

Dear Mr./Mrs./Ms. __________,

I have been contacted by the researchers in the above-mentioned disability study and, after reviewing the study, I have agreed to forward the study questionnaire to you. The principal investigator is Dr. David Goldstein, a head and neck surgeon at the Princess Margaret Hospital, and the research team is comprised of Drs. Aileen Davis, Jonathan Irish, Douglas Chepeha, and Jolie Ringash. The research assistant is Colleen Simpson.

The researchers of the study are interested in problems with the shoulder that result from an operation to remove neck lymph nodes from head and neck cancers. This operation is called a neck dissection. The purpose of the study is to determine if the DASH Questionnaire developed by the Institute for Work and Health is a good questionnaire for assessing how shoulder problems after neck dissection affects your life.

Three questionnaires will need to be completed for the study. It will take less than 30 minutes to complete all the questionnaires. Some patients will be asked to complete two of the questionnaires a second time two weeks later. An envelope (postage-paid) is included so you can return the questionnaire to the study investigators. If you complete and return the questionnaire to them, they will have an opportunity to learn about shoulder problems after neck dissection and perform future studies to lessen this disability.
The questionnaire *does not* have a place for your name or address, it is marked only with a study number. This ensures that confidentiality is maintained since you can only be identified by the number on the questionnaire. When the study is finished, data will be presented in grouped format only and no individuals will be identified. We are asking you to participate in the study by completing the questionnaire. The potential benefits of this study to physicians and future patients of head and neck cancer include improved understanding of shoulder problems after neck dissection, as well as allow us to perform future studies of ways to lessen these problems and improve patients’ quality of life. There are no risks associated with completion of the study. Completing and returning the questionnaire to the investigators implies that you are consenting to your data being included in the study. Please note that completion of the questionnaire is completely voluntary; if you choose not to complete it, this will not affect your future medical care.

If you have any questions about your eligibility for this study, the study itself or the questionnaire you can contact either myself, Colleen Simpson (416-946-4501) or the principal investigator Dr David Goldstein (416-946-4501, ext 2301). If you have questions regarding the ethics approval process for the study, please contact **Dr. R. Heslegrave, Chair of the University Health Network Research Ethics Board** at (416) 340-4557.

Sincerely,

David P Goldstein
Dear Dr: 

We would like to invite you to participate in a study. We are conducting a study to evaluate the Disabilities of the Arm, Shoulder and Hand (DASH) Questionnaire in patients who have had a neck dissection. The co-investigators for this study include Dr. Jonathan Irish, Dr. Douglas Chephea, Dr. Jolie Ringash, and Dr. Aileen Davis. Collaborators include the following head and neck surgeons: Patrick Gullane, Ralph Gilbert, and Dale Brown.

As you know shoulder pain, weakness, and possible deformity are common problems occurring after neck dissection, the extent of which depends upon the type of neck dissection. There are very few questionnaires specifically designed to assess shoulder function in the head and neck patient population.

The Disabilities of the Arm, Shoulder and Hand (DASH) Questionnaire is a generic measure of disability and symptoms related to any condition of any joint of the upper extremity. It has undergone extensive development and analysis. You have been asked to participate in this study because you have experience with treating patients who have had a neck dissection for head and neck cancer. The study involves reading the DASH questionnaire and filling out the sensibility questionnaire. Please read the instructions if you agree to participate. The study should only take 15 to 20 minutes of your time.

Thank you for your participation.

David Goldstein
APPENDIX B: Consent forms (patients & physicians)

Patient Consent

12/10/06

STUDY ID NUMBER __________

CONSENT TO PARTICIPATE IN A CLINICAL STUDY

TITLE: Assessment of the Disabilities of the Arm, Shoulder and Hand (DASH) outcome measure for use in patients following neck dissection

INVESTIGATORS: Dr. David Goldstein (phone: 416-946-2301)
Dr. Jonathan Irish
Dr. Aileen Davis
Dr. Jolie Ringash

You are being asked to take part in a research study. Before agreeing to participate in this study, it is important that you read and understand the following explanation of the proposed study procedures. The following information describes the purpose, procedures, benefits, discomforts, risks and precautions associated with this study. It also describes your right to refuse to participate or withdraw from the study at any time. In order to decide whether you wish to participate in this research study, you should understand enough about its risks and benefits to be able to make an informed decision. This is known as the informed consent process. Please ask the study doctor or study staff to explain any words you don’t understand before signing this consent form. Make sure all your questions have been answered to your satisfaction before signing this document. Once you have signed the consent form please place one copy in the return envelope provided and keep the other copy for your records.

Background

Shoulder pain and weakness are common problems that can develop after removal of lymph nodes from the head and neck (neck dissection). People vary in the extent of pain and weakness depending upon the extent of cancer and neck dissection. Severe problems occur with neck dissections that involve removal of the nerve that helps move the shoulder (the accessory nerve). There are very few questionnaires that assess shoulder problems following neck dissection. We feel that the “Disabilities of the Arm, Shoulder and Hand (DASH) Questionnaire” is a good questionnaire for assessing shoulder problems.

Purpose

You have been asked to participate in this study because you have previously had a neck dissection (removal of lymph nodes from the neck). This study is designed to determine if the Disabilities of the Arm, Hand and Shoulder (DASH) Questionnaire is an appropriate for
assessing shoulder dysfunction in patients who have had neck dissections. This information can be used to determine if the DASH questionnaire can be used in future studies of prevention of shoulder morbidity following neck dissections or after other treatment modalities.

**Procedures**

The study involves filling out three questionnaires. One is the questionnaire that assesses shoulder function (Disabilities of the Shoulder, Arm and Hand Questionnaire, DASH) and the other is the Neck Dissection Impairment Index, another questionnaire on quality of life after a neck dissection. Each questionnaire takes less than 10 minutes to complete. The third questionnaire gives us your feedback about the DASH questionnaire.

Some patients will be randomly picked to complete only the DASH questionnaire for a second time approximately 2 weeks later. You might receive a phone call as a remainder to fill out the questionnaire.

We would like your permission to review information in your chart about your previous treatments.

**Risks & Benefits**

Your participation in this study is very much appreciated but there is no direct benefit to you for participating. There is no known or anticipated harm that would come to you from participation in this study.

**Confidentiality**

All information obtained during the study will be held in strict confidence. Study number will identify you only. No names or identifying information will be used in any publication or presentations. No information identifying you will be transferred outside the investigators in this study or this hospital.

**Participation**

Your participation in this study is voluntary. You can choose not to participate or you may withdraw at any time without affecting your medical care.

**Questions**

If you have any general questions about the study, please call the doctor in charge of this study, Dr David Goldstein at 416-946-2301.

If you have any questions about your rights as a research participant, please call Dr. R. Hesgrave, Chair of the University Health Network Research Ethics Board at (416) 340-4557. This person is not involved with the research project in any way and calling him will not affect your participation in the study.
**Consent**

I have had the opportunity to discuss this study and my questions have been answered to my satisfaction. I consent to take part in the study with the understanding I may withdraw at any time without affecting my medical care. I have received a signed copy of this consent form. I voluntarily consent to participate in this study.

_______________________  ______________________    ____________  
Study participant name                 Study participant signature     Date

I confirm that I have explained the nature and purpose of the study to the subject named above. I have answered all questions.

_________________________ ______________________      _____________  
Name of person                    Signature          Date

obtaining consent

**IF THIS CONSENT HAS BEEN VERBALLY TRANSLATED:**

I confirm that I have verbally translated this consent form for the patient noted above, and in my opinion, the patient has understood what I have explained to them.

_________________________          ________________________        ____________  
Name of translator  Signature       Date

Language of translation  Relationship to subject (if applicable)

(Name and signature)       Date
Physician consent

10/10/06

Study ID Number_____

CONSENT FOR PHYSICIANS TO PARTICIPATE IN A CLINICAL STUDY

TITLE: Assessment of the Disabilities of the Arm, Shoulder and Hand (DASH) outcome measure for use in patients following neck dissection

INVESTIGATORS: Dr. David Goldstein (phone: 416-946-2301)
Dr. Jonathan Irish (phone: 416-946-2149)
Dr. Aileen Davis
Dr. Jolie Ringash
Dr. Douglas Chephea

COLLABORATORS: Dr. Patrick Gullane
Dr. Ralph Gilbert
Dr. Dale Brown

You are being asked to take part in a research study. Before agreeing to participate in this study, it is important that you read and understand the following explanation of the proposed study procedures. The following information describes the purpose, procedures, benefits, discomforts, risks and precautions associated with this study. It also describes your right to refuse to participate or withdraw from the study at any time. In order to decide whether you wish to participate in this research study, you should understand enough about its risks and benefits to be able to make an informed decision. This is known as the informed consent process. Please ask the study doctor or study staff to explain any words you don't understand before signing this consent form. Make sure all your questions have been answered to your satisfaction before signing this document. Once you have signed the consent form please place one copy in the return envelope provided and keep the other copy for your records.

Background

Shoulder pain, weakness, and deformity are common side-effects of surgical removal of lymph nodes of the head and neck (neck dissection). The degree of severity of symptoms depends on the extent of cancer and therefore the extent of neck dissection. Severe and profound shoulder dysfunction may occur with neck dissections that involve sacrifice of the nerve involved in shoulder movement (the accessory nerve). Studies have shown that patients that have had a neck dissection that requires removal of the accessory nerve have a lower quality of life than those who do not. While there has been a lot of research on shoulder function after surgery, there are very few questionnaires specifically designed to assess shoulder function in the head and neck
patient population. As well, many of the questionnaires used in previous studies have not undergone a rigorous process of analysis needed before application. The Disabilities of the Arm, Shoulder and Hand (DASH) Questionnaire is a generic measure of disability and symptoms related to any condition of any joint of the upper extremity. It has undergone extensive development and analysis, and we feel it can be a standard questionnaire used to assess shoulder disability and dysfunction following neck dissections.

Purpose

You have been asked to participate in this study because you have experience with treating patients who have had a neck dissection for head and neck cancer. This study is designed to determine if the Disabilities of the Arm, Shoulder and Hand (DASH) Questionnaire is appropriate for assessing shoulder dysfunction in patients who have had neck dissections. This information can be used to determine if the DASH questionnaire can be used in future studies of prevention of shoulder morbidity following neck dissections or after other treatment modalities.

Procedures

The study involves reading the DASH questionnaire and filling out a sensibility questionnaire, which gives us your feedback on how well the DASH questionnaire assesses shoulder disability in patients following neck dissections.

Risks & Benefits

Your participation in this study is very much appreciated but there is no direct benefit to you for participating. There is no known or anticipated harm that would come to you from participation in this study.

Confidentiality

All information obtained during the study will be held in strict confidence. Study number will identify you only. No names or identifying information will be used in any publication or presentations. No information identifying you will be transferred outside the investigators in this study or this hospital.

Participation

Your participation in this study is voluntary. You can choose not to participate or you may withdraw at any time without affecting your medical care.

Questions

If you have any general questions about the study, please call the doctor in charge of this study, Dr David Goldstein at 416-946-2301.
If you have any questions about your rights as a research participant, please call Dr. R. Heslegrave, Chair of the University Health Network Research Ethics Board at (416) 340-4557. This person is not involved with the research project in any way and calling him will not affect your participation in the study.

Consent

I understand the nature of this study and the terms of participation. I have been given ample opportunity to ask any questions I may have. If I have any further questions, I can contact Dr. David Goldstein at (416) 946-2301. I may keep a copy of this consent form. My signature on this form indicates that I understand to my satisfaction the information regarding participation in the research project and agree to participate. In no way does this waive my legal rights nor release the investigators or involved institutions from their legal and professional responsibilities.

Dated this ______ day of ________________________ 200__. 

I have read this information and by signing this consent form, I agree to participate by completing the questionnaires

________________________                _________________________
(Signature of Participant)      (Print Name of Participant)
APPENDIX C: Instruction sheets

INSTRUCTIONS FOR PATIENTS

Thank you for agreeing to participate in this study. Please follow the instructions below

1. Please read the informed consent form entitled FORM 1. These forms explain the study and give your permission to participate in this study. There are 2 copies of FORM 1. Please read and sign ONE copy and put in the return envelope. The other copy if for you to keep.

2. Please complete FORM 2, which is the Neck Dissection Impairment Index (NDII) questionnaire.

3. Please complete FORM 3, which is the DASH questionnaire

4. Please complete Form 4 “The Sensibility Questionnaire” right after you have completed Form 4. This questionnaire asks your opinion about the DASH questionnaire.

5. After you have completed Forms 1 to 4, place them all in the return envelope and mail back to us. ALL POSTAGE HAS BEEN PAID.

Once again, thank you for participating. If you have any questions at all, please call the research assistant Colleen at 416 946-4501, ext. 4729 or the study coordinator Dr David Goldstein at 416-946-2301.
INSTRUCTIONS FOR PATIENTS (alternate instructions)

Thank you for agreeing to participate in this study. Please follow the instructions below

1. Please read the informed consent form entitled FORM 1. These forms explain the study and gives your permission to participate in this study. There are 2 copies of FORM 1. Please read and sign ONE copy and put in the return envelope. The other copy if for you to keep.

2. Please complete FORM 2 which is the DASH questionnaire

3. Please complete FORM 3 – “The Sensibility Questionnaire” right after you have completed Form 4. This questionnaire asks your opinion about the DASH questionnaire.

4. Please complete FORM 4, which is the Neck Dissection Impairment Index (NDII) questionnaire.

5. After you have completed Forms 1 to 4, place them all in the return envelope and mail back to us. ALL POSTAGE HAS BEEN PAID.

Once again thank you for participating. If you have any questions at all please call the research assistant Colleen at 416 946-4501, ext 4729 or the Study Coordinator Dr David Goldstein at 416-946-2301.
INSTRUCTIONS FOR PHYSICIANS

1. Please read the consent to participate form labeled FORM 1. Sign one copy and place in the return envelope. Keep the other copy for your records.

2. Fill out the brief questionnaire form labeled FORM 2 and place in the return envelope.

3. Read through the items in the DASH Questionnaire, labeled FORM 3.

4. Fill out the Sensibility Questionnaire, labeled FORM 4.

5. Please place all FORMS in the return envelope and send back to us.

Thank you for your participation.
APPENDIX D: Sensibility Questionnaire for the DASH

Study Number ______

1. How easy are the questions to understand?

1  2  3  4  5  6  7
Very difficult  Difficult  Easy  Very easy

Please indicate in the space below any questions, if any that are not easy to understand (list the question number) and explain why you thought so:

__________________________________________________________________
__________________________________________________________________

2. Were the instructions for completing the DASH easy to understand?

1  2  3  4  5  6  7
Very difficult  Difficult  Easy  Very easy

If you found the instructions difficult, please provide an explanation why in the space below.

__________________________________________________________________
__________________________________________________________________
3. **How is the length of time it took to complete the DASH questionnaire?**

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Too long</td>
<td>Could be shorter</td>
<td>About right</td>
<td>Just right</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. **Does the questionnaire include the important questions about problems patients with head and neck cancer experience with self-care and day-to-day chores (e.g., brushing hair or teeth, cooking, housework, etc.)?**

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Many missing</td>
<td>Few missing</td>
<td>Includes most questions</td>
<td>Includes all questions</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

What important questions on self-care or daily chores do you feel were missing? Please indicate in the space below.

_____________________________________________________________________________

_____________________________________________________________________________

What questions on self-care or daily chores do you feel did not need to be included? Please indicate in the space below.

_____________________________________________________________________________

_____________________________________________________________________________
5. Does the questionnaire include important questions about problems patients with head and neck cancer experience with doing their paid job or work?

*Check the box if you do not work & you may skip to question 6*

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Many missing</td>
<td>Few missing</td>
<td>Includes most questions</td>
<td>Includes all questions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

What important questions on work were missing? Please indicate in the space below.

_____________________________________________________________________________

_____________________________________________________________________________

6. Does the questionnaire include the important questions about problems patients with head and neck cancer experience with doing their hobbies or activities you do for fun?

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Many missing</td>
<td>Few missing</td>
<td>Includes most questions</td>
<td>includes all questions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

What important questions on hobbies or recreational activities do you feel were missing? Please indicate in the space below.

_____________________________________________________________________________

_____________________________________________________________________________
What questions on hobbies or recreational activities do you feel did not need to be included? Please indicate in the space below.

_____________________________________________________________________________
_____________________________________________________________________________

7. The DASH questionnaire was designed to assess shoulder function and problems after neck dissection for head and neck cancer. Do you think this goal has been achieved?

1  2  3   4   5  6  7
Very unlikely Unlikely Likely Very likely

8. Does the questionnaire miss any important issues about your shoulder or arm problem?

1  2  3   4   5  6  7
Crucial gaps Important Minor gaps Minimal gaps

What issues do you think the questionnaire is missing and should have been included?

_____________________________________________________________________________
_____________________________________________________________________________

9. Are the questions too probing (that is, too personal)?

1  2  3   4   5  6  7
Many probing Some probing Few probing None probing

Please list the questions you found too personal or probing.

_____________________________________________________________________________
_____________________________________________________________________________
Are there any other comments you would like to make about what you think is good or problematic about the DASH if we were to use it to ask about shoulder problems following neck surgery for head and neck cancer?

_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________

Thank you for taking the time to complete this questionnaire
APPENDIX E: DASH Questionnaire

INSTRUCTIONS
This questionnaire asks about your symptoms as well as your ability to perform certain activities.

Please answer every question based on your condition in the last week, by circling the appropriate number.

If you did not have the opportunity to perform an activity in the past week, please make your best estimate on which response would be the most accurate.

It doesn’t matter which hand or arm you use to perform the activity; please answer based on your ability regardless of how you perform the task.
# Disabilities of the Arm, Shoulder and Hand

Please rate your ability to do the following activities in the table below by placing the number below the appropriate response.

<table>
<thead>
<tr>
<th>Activity</th>
<th>No Difficulty</th>
<th>Mild Difficulty</th>
<th>Moderate Difficulty</th>
<th>Severe Difficulty</th>
<th>Unable</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Open a tight or new jar.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>2. Write.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>3. Turn a key.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>4. Prepare a meal.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>5. Push open a heavy door.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>6. Place an object on a shelf above your head.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>7. Do heavy household chores (e.g., wash walls, wash floors)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>8. Garden or do yard work.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>9. Make a bed.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>10. Carry a shopping bag or briefcase</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>11. Carry a heavy object (over 10 lbs.)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>12. Change a light bulb overhead.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>13. Wash or blow dry your hair.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>14. Wash your back.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>15. Put on a pullover sweater.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>16. Use a knife to cut food.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>17. Recreational activities which require little effort (e.g., cardplaying, knitting, etc.)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>18. Recreational activities in which you take some force or impact through your arm, shoulder or hand (e.g., golf, hammering, tennis, etc.)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>19. Recreational activities in which you move your arm freely (e.g., playing frisbee, badminton, etc.)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>20. Manage transportation needs (getting from one place to another)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>21. Sexual activities.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
# Disabilities of the Arm, Shoulder and Hand

<table>
<thead>
<tr>
<th>Question</th>
<th>Scale</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>During the past week, to what extent has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups? (circle number)</td>
<td>NOT LIMITED AT ALL</td>
<td>SLIGHTLY LIMITED</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>NOT LIMITED AT ALL</td>
<td>SLIGHTLY LIMITED</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem? (circle number)</td>
<td>NONE</td>
<td>MILD</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Please rate the severity of the following symptoms in the last week. (circle number)</td>
<td>NO DIFFICULTY</td>
<td>MILD</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Arm, shoulder or hand pain.</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Arm, shoulder or hand pain when you performed any specific activity.</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Tintling (pins and needles) in your arm, shoulder or hand.</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Weakness in your arm, shoulder or hand.</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Stiffness in your arm, shoulder or hand.</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand? (circle number)</td>
<td>STRONGLY DISAGREE</td>
<td>DISAGREE</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>I feel less capable, less confident or less useful because of my arm, shoulder or hand problem. (circle number)</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

**DASH Disability/Symptom Score** = \( \frac{\text{sum of } n \text{ responses}}{n} \times 25 \), where \( n \) is equal to the number of completed responses.

A DASH score may not be calculated if there are greater than 3 missing items.
## Disabilities of the Arm, Shoulder and Hand

### Work Module (Optional)

The following questions ask about the impact of your arm, shoulder, and hand problem on your ability to work (including homemaking if that is your main work role).

Please indicate what your job/work is: [ ] I do not work. (You may skip this section.)

Please circle the number that best describes your physical ability in the past week. Did you have any difficulty:

<table>
<thead>
<tr>
<th></th>
<th>NO DIFFICULTY</th>
<th>MILD DIFFICULTY</th>
<th>MODERATE DIFFICULTY</th>
<th>SEVERE DIFFICULTY</th>
<th>UNABLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. using your usual technique for your work?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>2. doing your usual work because of arm, shoulder, or hand pain?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>3. doing your work as well as you would like?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>4. spending your usual amount of time doing your work?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

### Sports/Performing Arts Module (Optional)

The following questions relate to the impact of your arm, shoulder, or hand problem on playing your musical instrument or sport or both.

If you play more than one sport or instrument (or play both), please answer with respect to that activity which is most important to you.

Please indicate the sport or instrument which is most important to you: [ ] I do not play a sport or an instrument. (You may skip this section.)

Please circle the number that best describes your physical ability in the past week. Did you have any difficulty:

<table>
<thead>
<tr>
<th></th>
<th>NO DIFFICULTY</th>
<th>MILD DIFFICULTY</th>
<th>MODERATE DIFFICULTY</th>
<th>SEVERE DIFFICULTY</th>
<th>UNABLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. using your usual technique for playing your instrument or sport?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>2. playing your musical instrument or sport because of arm, shoulder or hand pain?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>3. playing your musical instrument or sport as well as you would like?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>4. spending your usual amount of time practising or playing your instrument or sport?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

**Scoring the Optional Modules:** Add up assigned values for each response: divide by the number of items; subtract 1; multiply by 25.

An optional module score may not be calculated if there are any missing items.
APPENDIX F: NDII Questionnaire

INSTRUCTIONS: Many patients with head and neck cancer receive radiation treatment, surgery, or both to their neck as part of the overall care of their cancer. This survey is designed to evaluate how much your neck and/or shoulder currently affect you as a result of the treatment you received in your neck during the overall management of your cancer. Please answer every question. Mark the ONE box that best applies to you.

As a result of the cancer TREATMENT OF YOUR NECK, how much have you been bothered in the following over the past 4 WEEKS:

1. Are you bothered by neck or shoulder pain or discomfort?
   
   Not at all    A little bit    A moderate amount    Quite a bit    A lot
   [ ]     [ ]     [ ]     [ ]     [ ]

2. Are you bothered by shoulder stiffness?
   
   Not at all    A little bit    A moderate amount    Quite a bit    A lot
   [ ]     [ ]     [ ]     [ ]     [ ]

3. Are you bothered by difficulty with self-care activities because of your neck or shoulder (for example, combing hair, dressing, bathing)?
   
   Not at all    A little bit    A moderate amount    Quite a bit    A lot
   [ ]     [ ]     [ ]     [ ]     [ ]
As a result of the cancer treatment of your neck, how much have you been limited in the following over the past 4 WEEKS:

4. Have you been limited in your ability to **lift light** objects because of your shoulder or neck?
   - Not at all
   - A little bit
   - A moderate amount
   - Quite a bit
   - A lot

5. Have you been limited in your ability to **lift heavy** objects because of your shoulder or neck?
   - Not at all
   - A little bit
   - A moderate amount
   - Quite a bit
   - A lot

6. Have you been limited in your ability to **reach above** for objects because of your shoulder or neck (for example, from shelves, tables, or counters)?
   - Not at all
   - A little bit
   - A moderate amount
   - Quite a bit
   - A lot

7. Are you bothered by your **overall activity level** because of your shoulder or neck?
   - Not at all
   - A little bit
   - A moderate amount
   - Quite a bit
   - A lot

8. Has the treatment of your neck affected your participation in **social activities**?
   - Not at all
   - A little bit
   - A moderate amount
   - Quite a bit
   - A lot

9. Have you been limited in your ability to do **leisure or recreational activities** because of your neck or shoulder?
   - Not at all
   - A little bit
   - A moderate amount
   - Quite a bit
   - A lot
10. Have you been limited in your ability to do **work** (including **work** at home) because of your neck or shoulder?

<table>
<thead>
<tr>
<th>Not at all</th>
<th>A little bit</th>
<th>A moderate amount</th>
<th>Quite a bit</th>
<th>A lot</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

11. My **leisure and recreational** activities are important to me:

<table>
<thead>
<tr>
<th>Definitely True</th>
<th>Mostly True</th>
<th>Don’t Know</th>
<th>Mostly False</th>
<th>Definitely False</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

12. My **work** (including **work in home**) is important to me:

<table>
<thead>
<tr>
<th>Definitely True</th>
<th>Mostly True</th>
<th>Don’t Know</th>
<th>Mostly False</th>
<th>Definitely False</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please complete each question below by checking the appropriate box. The following questions will provide information relating to the treatment you received in your neck as a part of your overall cancer treatment.

13. Which **side of your neck** did you receive surgery as part of your overall cancer treatment?

<table>
<thead>
<tr>
<th>Left</th>
<th>Right</th>
<th>Both</th>
<th>Not Sure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please indicate whether you are right handed or left handed; for example, the hand you write with

- Right handed
- Left handed
APPENDIX G: Change in status form

Change in status of symptoms

Do you think there has been a change in your shoulder disability or function since the last time you completed the questionnaire?

Please put an “X” beside the answer.

__________ About the same

__________ Better

__________ Worse
APPENDIX H: Clinical practice survey for physicians

FORM 2

Please answer the following questions:

1. Are you practicing in Canada or the United States?
   
   CANADA   UNITED STATES

2. Do you mainly have an academic or community practice?
   
   COMMUNITY   ACADEMIC

3. Did you complete a fellowship in head and neck oncology?
   
   YES   NO

4. How many years have you been in practice?
   
   Less than 10 years   10–20 years   >20 years

5. Approximately what percentage of your practice is devoted to the management of malignancies of the head and neck?
   
   0–25%   25–50%   50–75%   >75%

6. In the space provided please provide the approximate number of neck dissections you perform per year:
   
   Radical neck dissections   _____________
   Modified radical neck dissections   _____________
   Selective neck dissections   _____________
REMINDER

This is a friendly reminder if you could kindly complete and mail the Forms we sent you regarding the Disabilities of the Arm, Shoulder and Hand (DASH) Questionnaire in the self-addressed stamped envelope included with the package. If you have already completed and mailed in the Forms, please ignore this postcard and thank you for your participation.

Thank you very much for your attention and participation.

David Goldstein
APPENDIX J: Data collection form

Data Abstraction Form

1. Patient ID __________________

2. Surgeon

   0. Brown
   1. Gilbert
   2. Goldstein
   3. Gullane
   4. Irish
   5. Rotstein

3. Date of Birth _________________ (DD.MM.YY)

4. Gender

   0. Female
   1. Male

5. Date of right neck dissection _______________ (DD.MM.YY)

6. Indication for right neck dissection

   0. Single modality therapy
   1. Planned neck dissection following radiation or chemoradiation
   2. Salvage surgery for persistent disease
   3. Salvage of recurrent disease

7. Type of right neck dissection

   0. None
   1. Selective neck dissection
   2. Modified Radical neck
   3. Radical neck dissection

8. Right level dissected

   0. Ia
   1. Ib
   2. Ila
   3. IIb
   4. III
   5. IV
6. Va
7. Vb

9. Right structures sacrificed
   0. SCM
   1. IJV
   2. CNXI (SAN)

10. Right neuroraphy
    0. ----
     1. No
     2. Yes
     3. 888 not applicable

11. Date of left neck dissection ________________ (dd.mm.yy)

12. Indication for left neck dissection
    0. Single modality therapy
     1. Planned neck dissection following radiation or chemoradiation
     2. Salvage surgery for persistent disease
     3. Salvage of recurrent disease

13. Type of left neck dissection
    0. None
     1. Selective neck dissection
     2. Modified Radical neck Dissection
     3. Radical neck dissection

14. Left level dissected
    0. Ia
     1. Ib
     2. IIa
     3. IIb
     4. III
     5. IV
     6. Va
     7. Vb

15. Left structures sacrificed
    0. SCM
     1. IJV
     2. CNXI (SAN)

16. Left neuroraphy
    0. ---
     1. No
     2. Yes
     3. 888 not applicable
17. Tumor site
   1. Larynx
   2. Hypopharynx
   3. Oral cavity
   4. Oropharynx
   5. Nasopharynx
   6. Skin
   7. Thyroid
   8. Salivary gland
   9. Unknown primary
  10. Other

18. Histology
   1. ------
   2. SCC
   3. WDTC
   4. Medullary
   5. Melanoma
   6. Salivary gland malignancies
   7. Other ___________________________

19. Radiation therapy
   0 None
   1. Preoperative radiation alone
   2. Preoperative concurrent chemoradiation
   3. Preoperative neoadjuvant chemo followed by radiation
   4. Postoperative radiation alone
   5. Postoperative concurrent chemoradiation

20. Employment
   1. Yes; employed
   2. No; not employed

21. Flap
   0 None
   1. Pec flap
   2. Latissmus flap
   3. Scapula flap with bone
   4. Scapula flap w/o bone
   5. Other flap
APPENDIX K: University of Toronto and University Health Network Ethics Board approval letters

University of Toronto
Office of the Vice-President, Research
Office of Research Ethics

PROTOCOL REFERENCE #25002

March 1, 2010

Dr. Aileen Davis  
Division of Health Care and Outcomes Research  
Toronto Western Hospital  
399 Bathurst St.  
Toronto, ON M5T 2S8

Dr. David Goldstein  
Surgical Oncology – Head and Neck Surgery/Otolaryngology  
Princess Margaret Hospital  
610 University Ave.  
Toronto, ON M5G 2M9

Dear Dr. Davis and Dr. Goldstein:

Re: Administrative Approval of your research protocol entitled, "Assessment of the Disabilities of Arm, Shoulder and Hand (DASH) Questionnaire in Patients Following Neck Dissection"

We are writing to advise you that the Office of Research Ethics has granted administrative approval to the above-named research study. The level of approval is based on the following role(s) of the University, as you have identified with your submission:

- Graduate Student research – hospital-based only
- Storage or analysis of De-identified Personal Information (data)

This approval does not substitute for ethics approval, which has been obtained from your hospital Research Ethics Board. Please note that you do not need to submit Annual Renewals, Study Completion Reports or Amendments to the ORE unless the involvement of the University changes so that ethics review is required. Please contact the ORE to determine whether a particular change to the University's involvement requires ethics review.

Best wishes for the successful completion of your project.

Yours sincerely,

S. Lanthier
Research Ethics Coordinator
Notification of REB Continued Approval

To: Dr. David Goldstein
3-130, PMH

Re: 05-0078-CE
Assessment of the Disabilities of Arm, Shoulder and Hand (DASH) Questionnaire in Patients Following Neck Dissection

REB Review Type: Expedited
REB Initial Approval Date: May 19th, 2005
REB Expiry Date: May 19th, 2009

Consent Form(s) Currently Approved for Use:
- Main Consent Form
- Consent Form for Physicians (version # 3)

The above-named study has received continued approval from the University Health Network Research Ethics Board until the expiry date noted above. If the study is expected to continue beyond the expiry date, you are responsible for ensuring the study receives re-approval. The REB must also be notified of the completion or termination of this study and a final report provided.

If, during the course of the research, there are any serious adverse events, confidentiality concerns, changes in the approved project, or any new information that must be considered with respect to the project, these should be brought to the immediate attention of the REB. In the event of a privacy breach, you are responsible for reporting the breach to the UHN REB and the UHN Corporate Privacy Office (in accordance with Ontario health privacy legislation ? Personal Health Information Protection Act, 2004). Additionally, the UHN REB requires reports of inappropriate/unauthorized use of the information. As the Principal Investigator, you are responsible for the ethical conduct of this study.

The UHN Research Ethics Board operates in compliance with the Tri-Council Policy Statement, ICH/GCP Guidelines, the Ontario Personal Health Information Protection Act (2004), and Part C, Division 5 of the Food and Drug Regulations of Health Canada.

Sincerely,

Larissa Petanina
Research Ethics Coordinator

For: Ronald Haslegrave, Ph.D.
Chair, University Health Network Research Ethics Board
APPENDIX L: Approval letters to use the DASH and NDII

As long as Dr. Goldstein acknowledges IWH as creators of the DASH, that’s fine. If any images of the DASH are being included in the materials, we ask that you include a watermark that reads “SAMPLE ONLY”, and our copyright information (“© Institute for Work & Health 2006. All rights reserved.”).

Thank you for following up. Please don’t hesitate to ask if you require more information.

Kristina

-----Original Message-----
From: Kristina Buccat [mailto:kbuccat@iwh.on.ca] On Behalf Of Dash
Sent: Thursday, November 13, 2008 11:19 AM
To: Simpson, Colleen
Subject: RE: copyright of DASH questionnaire

Hi Colleen,

There is no cost to using the DASH as long as it’s non-profit use. The DASH can be downloaded in PDF form, free of charge from the Conditions of Use page of our website:
http://www.dash.iwh.on.ca/conditions.htm

Hope this helps,
Kristina

-----Original Message-----
From: Kristina Buccat [mailto:kbuccat@iwh.on.ca] On Behalf Of Dash
Sent: Tuesday, November 11, 2008 10:22 AM
To: Simpson, Colleen
Subject: RE: copyright of DASH questionnaire

Thank you for your inquiry with regard to the above.

Please find attached a copy of the DASH User Profile, which we use to help us track how the DASH is being used. Many of the completed profiles we receive are deemed to be for non-profit use and require no further follow-up.

Kindly take a moment to complete and return the Profile (fax and email are both fine). We will send you a reply as soon as it is processed.

If you require further information, please do not hesitate to contact me.

Kristina Buccat
Administrative Assistant
Institute for Work & Health
Knowledge Transfer & Exchange
461 University Avenue, Ste. 800
Toronto, ON M5G 2E9
dash@iwh.on.ca
http://www.dash.iwh.on.ca/
From: Douglas Chepeha [mailto:dchepeha@med.umich.edu]
Sent: Sunday, May 02, 2010 12:20 PM
To: Goldstein, David
Subject: Re:

You have permission to use the NDII
Too bad I did not see you at the AHNS
Thanks again

>>> "Goldstein, David" <David.Goldstein@uhn.on.ca> 4/30/2010 6:17 PM >>>