INTERJUDGE RELIABILITY TO ANALYZE THE APPLICATION OF THE FUNCTIONAL ORAL INTAKE SCALE IN HEAD AND NECK CANCER

By

ALLISON MOFSKY

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I also thank my raters: Michael Groher, Jan Pryor, Robert Miller, Cathy Lazarus, and Joy Granziano. As experts in dysphasia with years of clinical experience in head and neck cancer, they provided a perspective necessary to begin the revalidation of the Functional Oral Intake Scale [1] in this population. Without their participation this project would not have been possible.
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INTERJUDGE RELIABILITY TO ANALYZE THE APPLICATION OF THE FUNCTIONAL ORAL INTAKE SCALE IN HEAD AND NECK CANCER

By

Allison Mofsky

May 2012

Chair: Michael Crary
Major: Communication Sciences and Disorders

The Functional Oral Intake Scale (FOIS) is a scale used to document the safe and adequate oral intake of patients with dysphagia. It was initially validated in a population of patients with neurogenic dysphagia. The present study represents an initial psychometric evaluation of the FOIS scale in patients with head and neck cancer.

This is a secondary analysis of a study on prophylactic treatment for dysphagia in head/neck cancer patients treated with chemoradiation. Records from 128 head and neck cancer patients were examined at baseline, 3 weeks, 6 weeks, and 3 months post treatment with dietary data including FOIS score, feeding method, diet type and liquid type. 35 exemplars were randomly selected and provided to 5 expert judges with experience in dysphagia in head and neck cancer and experience using the FOIS scale. Intraclass correlations were completed to evaluate interrater reliability. Reliability was estimated for the overall scale and for each of 7 FOIS levels.

Results demonstrated high overall interrater agreement using the original FOIS scale on exemplars obtained from patients with head and neck cancer. Analysis of individual FOIS Levels revealed high agreement on Levels 1,2,3, and 6. Low
agreement was obtained for Levels 4 and 5, with moderate agreement identified on Level 7.

The FOIS is a reliable scale to document oral intake in patients with head and neck cancer. Clinicians using the scale should exercise caution when scoring oral intake represented by Levels 4 and 5. Level 7 may benefit from simple clarification. Future direction includes possible modifications or clarifications of Level 4, as well as clarification of Levels 5 and 7. If revised, the modified FOIS must be revalidated on a cohort of head/neck cancer patients.
CHAPTER 1
INTRODUCTION

The Functional Oral Intake Scale (FOIS) was initially published in 2005 as a tool to document the level of safe and adequate oral intake in patients with neurogenic dysphagia [1]. Initially validated on a population of acute stroke patients, this tool has been used as an independent outcome measure with traumatic brain injury [2], head and neck cancer [3,4], and pediatrics [5]; however the FOIS has not been validated in these populations.

Just as the prevalence of swallowing impairment is high in stroke, some estimate as high as 65% [6], it is also high in head and neck cancer with prevalence rates as high as 28.2% of patients with stage T2 or more oral cancer, 50.9% of patients with pharyngeal cancer and 28.6% of patients with laryngeal cancer [7]. In the year following treatment, patient reports of swallowing impairment are as high as 23% for surgery alone, 63.6% for surgery with adjunctive radiation, and 70% with adjunctive chemoradiation [8]. Additionally, dysphagia is worse for patients treated with external beam radiation than surgery alone. [9,10,11].

Post treatment features of dysphagia in head and neck cancer are influenced by the nature of treatment [12] but they may include decreased swallowing frequency [13] and aspiration of pharyngeal residue post swallow [14]. Patients report oropharyngeal mucositis, xerostomia, odynophagia, and taste changes as the most troublesome acute effects of radiation on swallow function [15]; however the long term sequela of radiation effects causing dysphagia include tissue fibrosis, altered sensation and necrosis [16]. Functional impacts of dysphagia in this population include increased solid food dysphagia resulting in reliance on a single consistency liquid or puree diet [8,17] as well
as need for alternative feeding methods [18]. The American Head and Neck Cancer Society recommends that “if highly toxic therapy is planned, placement of a percutaneous endoscopic tube (PEG) prior to starting therapy enables a patient to maintain nutrition during therapy and recover more quickly [19].” However, recent research suggests that total nutritional reliance on PEG and prophylactic PEG placement results in worse diet outcomes post-treatment [20].

Documenting functional oral intake in head/neck cancer patients is problematic, as no reliable and valid oral intake scale exists for this population. Though health related quality of life scales might include mention of oral intake limitations they are disease specific [21,22], part of a broader measure of impairment [23,24,25] or lack psychometric data establishing them as reliable and valid outcome measures [26,27].

Reliability refers to results that are consistent and reproducible. Interrater reliability represents agreement between two or more raters [28]. While only two raters are necessary to establish level of agreement, generalizability increases with additional raters [28]. Validity examines whether an instrument measures what it purports to measure [29]. Many types of validity exist including criterion validity: a test’s ability to predict of results based on a gold standard [29], and cross validation: a procedure for estimating performance to predict future data [30]. Reliability and validity are necessary components of evidence-based practice [31] and cornerstones of clinical research [32] and practice [33]. As such, these components can identify which diagnostic tools and interventions are the most effective [34].

The FOIS, which has been used to document oral intake change in diverse dysphagic populations, has only been validated in stroke. In that initial study, multiple
forms of validity were investigated. Consensual validity across raters was high with Kendall’s concordance of .90. Strong criterion validity was demonstrated with significant Chi-square and Cramer’s V correlations on all stroke measures between the FOIS and Modified Rankin Scale [35], Modified Barthel Index [36], and the Mann Assessment of Swallowing Ability [37]. Additionally, cross validation revealed significant associations between the FOIS and videoflouroscopic examinations of swallowing function for the presence of dysphagia and aspiration, as well as severity of dysphagia [1]. Thus, while the FOIS has demonstrated validity and reliability in a neurogenic population, differences in swallowing characteristics and function before and following treatment of head and neck cancer necessitate evaluation of the psychometric properties of the FOIS applied to this population. In this study we estimated interrater reliability of the original FOIS scale applied to oral intake exemplars obtained from a cohort of patients treated for head/neck cancer. Intraclass correlation coefficients (ICC) were calculated from FOIS ratings from 5 expert judges. We further analyzed FOIS levels that resulted in poor interrater agreement to identify any overt patterns among exemplars that might direct modification of the FOIS for application in this population.
CHAPTER 2
METHODS

Overview

This is a secondary analysis of a study on prophylactic treatment for dysphagia in head and neck cancer patients treated with chemoradiation. The study investigated the impact of a high and low intensity treatment of swallowing exercise aimed at maintaining oral and pharyngeal muscle function during radiation therapy. All subjects had a head and neck cancer diagnosis, received external beam radiation and or radiation and chemotherapy, and had no history of non-oral feeding for cancer related illness. No surgical case or case with neurological comorbidities was included. Subjects were examined at baseline (prior to chemoradiation), 3 weeks, 6 weeks, and 3 months post treatment onset. As part of the primary study, nutritional information was collected and two experts interpreted these data into FOIS scores.

Data Collection

All data were collected at a cancer center within a university medical center. Retrospective review of data obtained from 128 head and neck cancer patients who participated in a swallowing treatment study were examined at baseline, 3 weeks, 6 weeks and 3 months post treatment.

Dietary exemplars are composed of multiple aspects of diet data obtained from individual time points (baseline, 3 weeks, 6 weeks, 3 months) recorded in subject books maintained during the initial study. To be included as a dietary exemplar in the present study, the following information must have been present: 1) a description of dietary intake, 2) a FOIS score, and 3) a tri-level diet classification. Refer to Table 2-1 for the tri-level diet classification. Any item in the original study not meeting these criteria was
excluded from consideration in the present study. The only exception to these criteria was for baseline ratings when subjects were identified as Level 6 or 7 reflecting no significant dysphagia prior to cancer treatment. Based on inclusion criteria, 230 dietary exemplars were included in the data set out of a total of 512 potential exemplars. Subsequently, five exemplars for each FOIS level (based on the original FOIS ratings) were selected from the total set of exemplars using a block randomization method to develop a final set of 35 exemplars representing all FOIS levels equally.

**Interrater Reliability**

To evaluate interrater reliability five expert judges with experience in dysphagia in head and neck cancer and prior experience with the original FOIS scale applied FOIS ratings to 35 dietary exemplars. Raters had a mean of 28 years of clinical experience, with a range of twenty five to thirty two years. All raters were asked to assign each dietary exemplar a FOIS rating between Level 1 and Level 7. Refer to Table 2-2 for the description of each FOIS level. Each rater was also asked to provide comment if they had difficulty or confusion with a particular item. No additional training was provided to the expert raters. Agreement between the five expert raters was computed with intraclass correlations both for the overall FOIS ratings and for ratings from each individual FOIS level. In any instance when ICC could not be calculated, Cohen’s κ was computed to estimate agreement.

**Item Analysis**

Any FOIS level demonstrating low interrater agreement, as defined by lack of statistically significant ICC or kappa value less than 0.60, was further analyzed to evaluate potential sources of disagreement. Comments provided by the raters for specific exemplars were qualitatively analyzed to identify patterns across raters that
might address the need to modify or clarify FOIS levels that contributed to poor interrater agreement.
Table 2-1. Tri-level diet classification

<table>
<thead>
<tr>
<th>Feeding Method</th>
<th>Diet Type</th>
<th>Liquid Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. nothing by mouth</td>
<td>1. nothing by mouth</td>
<td>1. nothing by mouth</td>
</tr>
<tr>
<td>2. intravenous diet</td>
<td>2. oral supplements only</td>
<td>2. honey</td>
</tr>
<tr>
<td>3. percutaneous endoscopic gastrostomy tube</td>
<td>3. liquid</td>
<td>3. nectar</td>
</tr>
<tr>
<td>4. nasogastric tube</td>
<td>4. puree</td>
<td>4. thin</td>
</tr>
<tr>
<td>5. oral diet</td>
<td>5. soft mechanical</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6. regular</td>
<td></td>
</tr>
</tbody>
</table>

Table 2-2. The Functional Oral Intake Scale [1]

<table>
<thead>
<tr>
<th>FOIS Level</th>
<th>FOIS level description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>Nothing by mouth</td>
</tr>
<tr>
<td>Level 2</td>
<td>Tube dependent with consistent oral intake of food or liquid</td>
</tr>
<tr>
<td>Level 3</td>
<td>Tube dependent with consistent oral intake of food or liquid</td>
</tr>
<tr>
<td>Level 4</td>
<td>Total oral diet of a single consistency</td>
</tr>
<tr>
<td>Level 5</td>
<td>Total oral diet with multiple consistencies, but requiring special preparation or compensations</td>
</tr>
<tr>
<td>Level 6</td>
<td>Total oral diet with multiple consistencies without special preparation, but with specific food limitations</td>
</tr>
<tr>
<td>Level 7</td>
<td>Total oral diet with no restrictions</td>
</tr>
</tbody>
</table>
CHAPTER 3
RESULTS

Interrater Agreement

Interrater agreement across all FOIS levels was high (ICC = .992) as was
tennrater agreement for FOIS Levels 1 and 6. Refer to Table 3-1 for detailed results.
Interrater agreement at FOIS Levels 4 and 5 was low, while agreement at FOIS Level 7
was moderate. An ICC could not be computed for FOIS Level 2 because one
disagreement was noted across 25 ratings from five judges. Rater five provided the
single discrepant rating. Perfect agreement was noted on Level 2 for raters 1-4.
Cohen’s kappa was computed comparing rater five with each of the other raters on
Level 2. Average kappa value was .60 suggesting good agreement. FOIS Level 3
demonstrated perfect agreement across all raters (κ = 1.00).

Qualitative Analysis

FOIS Level 4 - Total Oral Diet of a Single Consistency

FOIS Level 4 resulted in a total of 12 disagreements among the 25 possible
comparisons. All disagreements resulted from exemplar ratings higher than Level 4,
with nine scored as a Level 5 and three scored as Level 6. Disagreement was present
amongst four out of five raters and all exemplars were involved. Three raters provided
five comments total regarding single consistency oral diets. Comments were provided
for four out of five exemplars.

Analysis of rater comments and scores reveals a pattern of confusion regarding
what constitutes a single consistency diet. All comments were related to thickness of
the single consistency diet. For example, one rater stated that puree with thin liquids is
“multiple consistency with no prep or compensations” while another said that “the score
depends on the level of thickness of the liquids.” The application of higher ratings assigned for this level also revealed rater disagreement about whether to classify puree as a single consistency diet (FOIS Level 4) or a special preparation (FOIS Level 5).

**FOIS Level 5 - Total Oral Diet with Multiple Consistencies, but Requiring Special Preparation or Compensations**

FOIS Level 5 resulted in a total of 8 disagreements among the 25 possible comparisons. All disagreements resulted from higher ratings than the original FOIS scores, with seven ratings being a Level 6 and one rating a Level 7. Disagreements were noted on four out of five exemplars. Comments were provided for two exemplars on this level.

Analysis of rater comments and scores indicates substantial rater confusion about what constitutes a compensation. Rater comments indicate confusion regarding scoring an exemplar that includes “4-6 cans of Ensure® per day,” with one rater postulating that Ensure® is a form of compensation and another stating confusion whether Ensure® is a liquid diet or food limitation. Other disagreements on what constituted a compensation also included confusion over small bites, hypermastication and liquid wash.

**FOIS Level 7 – Total Oral Diet with No Restrictions**

Two raters scored a single exemplar of FOIS 7 as a FOIS 6. The single comment on this item addressed the avoidance of spicy foods with the rater questioning whether avoidance was due to mucositis or subject preference. The exemplar was unclear regarding the reason for this avoidance - preference or swallow related issues.
<table>
<thead>
<tr>
<th>Level</th>
<th>Intraclass Correlation Coefficient</th>
<th>95% Confidence Interval</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Levels</td>
<td>.992</td>
<td>.987 - .996</td>
<td>p&lt;.0001</td>
</tr>
<tr>
<td>Level 1</td>
<td>.972</td>
<td>.902 - .997</td>
<td>p&lt;.0001</td>
</tr>
<tr>
<td>Level 2</td>
<td>.60*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level 3</td>
<td>1.0*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level 4</td>
<td>.495</td>
<td>-.146 - .926</td>
<td>P&lt;.062</td>
</tr>
<tr>
<td>Level 5</td>
<td>.455</td>
<td>-.282 - .923</td>
<td>p&lt;.102</td>
</tr>
<tr>
<td>Level 6</td>
<td>.823</td>
<td>.350 - .980</td>
<td>p&lt;.006</td>
</tr>
<tr>
<td>Level 7</td>
<td>.625</td>
<td>-.329 - .956</td>
<td>p&lt;.071</td>
</tr>
</tbody>
</table>

*Average kappa value included as intraclass correlation coefficient could not be computed
CHAPTER 4
DISCUSSION

Results of this study indicate overall high interrater agreement applying the FOIS scale on dietary exemplars obtained from patients with head and neck cancer. As such, the FOIS appears to be an appropriate tool to document change in functional oral intake in patients with dysphagia following head and neck cancer. However, obtained low reliability on Levels 4 and 5 indicate that caution must be used when scoring these FOIS levels. Furthermore, based on low interrater agreement, these FOIS levels should be examined for revision when applied to this clinical population as substantial variability exits among rater definitions for single consistency diets and for special compensations.

Revision of FOIS levels may include clarification or modification of the descriptions for each level as well as clarification of how these levels apply to patients with head and neck cancer. Clarification would entail additional explanation of the terminology used in level descriptions as well as explanation of appropriate application of each level to a patient’s diet. Modification implies adapting the scale to increase specificity of description related to functional oral intake patterns in patients with head and neck cancer. When examining individual levels, poor agreement is noted on Levels 4 and 5 with only moderate agreement on Level 7. Collective results indicate that Level 4 is an appropriate candidate for modification plus/minus clarification, while Levels 5 and 7 emerge as candidates for clarification without need for modification.

Modification of FOIS Level 4 should address the issue of liquids vs food consumption, both in combination (eg. puree vs thin or thick liquids) and in isolation (eg. puree vs. liquid diet). This FOIS level should be further clarified to indicate that a puree
diet is a single consistency diet and that this item ranks lower than multi-consistency diets that employ compensations. For example, a puree diet with thin liquids ranks lower than a mechanical soft diet with thin liquid wash.

Clarification of FOIS Level 5 should include a description of what constitutes a special compensation/preparation and may also address the role of special compensations and preparation of oral diets. Rater scores on four out of five exemplars varied among Levels 5, 6 and 7; however limited commentary was provided for qualitative review. Overall, raters were inconsistent in their ranking of exemplars including supplemental nutrition, small bites, hyper-mastication, and liquid wash as compensations.

Clarification of FOIS Levels 4 and 5 should also address application of these levels to patients with head and neck cancer. Raters in this study consistently scored these exemplars higher than the expert raters in the initial study. In a clinical environment, a higher FOIS rating may attribute swallowing abilities to patients that do not exist. This is problematic because an accurate assessment of swallowing function at different points along the continuum of treatment is necessary to determine patient progress and treatment success. Likewise, it is problematic to assume a patient with dysphagia has abilities he does not have thereby assigning him a higher FOIS rating. If the patient’s FOIS rating is elevated, the patient may begin a diet he/she cannot manage with complications resulting.

Clarification of FOIS Level 7 should focus on distinctions between food avoidance based on preference vs. based on swallow ability. Likewise, clarification may provide a distinction between FOIS Level 6 and 7 regarding avoidance. FOIS Level 6 includes
avoidance based on swallow function while FOIS Level 7 may include avoidance based on preference with no deficit in swallow function. Clarification of this level would serve to explain that functional oral intake is not based on patient taste preferences or clinician perception of patient physiology. Rather the scale is intended to document a patient’s daily level of functional oral intake.

A limitation of the present study is the small number of exemplars as well as the small pool of raters. The small number of exemplars limits the number of opportunities to identify sources of disagreement amongst raters. Disagreement among raters was targeted in this study as it suggests the scale may require clarification or modification to increase reliability.

The large confidence intervals noted for Levels 4, 5, and 7 reflect the small sample size. They may also indicate difficulty making generalizations about the data because FOIS level agreement in a small number of raters may not reflect agreement in a larger population of clinicians working in head and neck cancer. Expert raters were chosen for this study based on direct clinical experience with head and neck cancer and prior use of the FOIS scale with the direct purpose of identifying limitations in the original FOIS as applied to head and neck cancer. This limitation may be overcome by repeating this investigation following clarification and or modification of FOIS Levels 4, 5 and 7 with a larger sample of clinicians in the area of head and neck cancer.

In summary, current results suggest the FOIS is an appropriate tool to document functional change in oral intake in patients with head and neck cancer. Clinicians using the scale should be sensitive to scoring errors in Levels 4 and 5, especially with items that require modified consistencies or special compensations. Future directions include
additional validation of the FOIS in patients with head and neck cancer by comparing the FOIS with previously validated head and neck cancer performance indexes and increasing the number of raters to minimize limitations in psychometric analysis. Additionally, given the breadth of clinician experience and clinical application in this profession, comparisons should include raters with different amount of clinical experience. Future research should examine whether this disparity in experience is a factor in FOIS rating.
LIST OF REFERENCES


BIOGRAPHICAL SKETCH

Allison Mofsky was born into a family that encouraged excellence in all endeavors. At an early age she was taught the value of persistence, perseverance and work-ethic. Her father, a lawyer and law professor at the University of Miami, was renowned in his field and encouraged all academic pursuits; unfortunately passing before his daughter’s eighth birthday. Her mother, a vice president of mortgage banking in a large local bank in south Florida, encouraged personal growth of any kind.

The seeds of Allison’s avocation were planted in the classroom. She holds a Bachelor of Science in special education and Bachelor of Arts in psychology. Beginning in 2005, she taught special education and English as a foreign language for five years in Miami, Florida and South Korea before returning to school. In 2012 Allison completed her degree in the Department of Communication Sciences and Disorders thereby earning a Master of Arts.

The nature of her student’s disabilities, the accommodations she made for them, and their struggles in literacy and language initially piqued her interest in speech-language pathology. Her research and clinical experiences at the University of Florida helped her to refine her focus and instilled in her a passion for medical speech pathology, particularly for dysphagia. Her externship at MD Anderson Cancer Center in Orlando provided a unique opportunity to train in voice and dysphagia evaluation and rehabilitation with head and neck cancer patients. Allison hopes to continue her clinical and research training in an effort to provide her own patients with the excellent standard of care provided by her supervisors and mentors.