

Does the Mode of Prophylactic Swallowing Therapy Delivery Influence Swallowing Outcomes in Patients Undergoing Definitive Chemoradiation for Oropharyngeal Cancer

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Introduction

- Dysphagia following chemoradiation for oropharyngeal cancer is a common and debilitating long-term survivorship issue.
- Known treatment side effects including odynophagia, mucositis, xerostomia, and dysgeusia may render patients feeding tube dependent for all or part of their nutrition
- Prophylactic swallowing therapy has been demonstrated to be effective in reducing short- and long-term side effects with a lower incidence of feeding tube dependence.
- However, the optimal mode of therapy delivery to improve swallowing outcomes is not well understood.
- The purpose of this pilot investigation was to compare weekly in-person swallowing therapy to home program exercises with respect to immediate and short-term patient swallowing outcomes and quality of life measures.
- It is hypothesized that individualizing swallowing therapy through weekly sessions (clinician-directed) will result in improved swallowing function.

Methods

- Thirty subjects with oropharyngeal cancer (tonsil or base of tongue) treated with definitive chemoradiation were prospectively randomized to one of two groups; 1- clinician directed (weekly therapy); 2- patient directed; and stratified based on gender, age, and site of lesion.
- Both groups were instructed in following a home exercise program and completing log sheets to track adherence.
- Swallowing exercise program consisted of the following exercises: 1) tongue press, 2) Masako maneuver, 3) open mouth swallow, 4) effortful swallow, 5) effortful pitch glide, and 6) jaw opening exercises to be practiced 3 times a day, 3 times each
- Primary outcome measure was the Functional Oral Intake Scale (FOIS) that documents level of oral vs. non-oral feeding on a 7-point scale.
- Secondary outcome measures included DIGEST scores, maximum oral aperture, and Quality of Life Measures (EAT-10; PSS-HN).
- Time points included baseline, last day of treatment (FOIS score only), 1 month and 6 months post-treatment.

Tables and Graphs

Table 1. Demographics (n = 30)

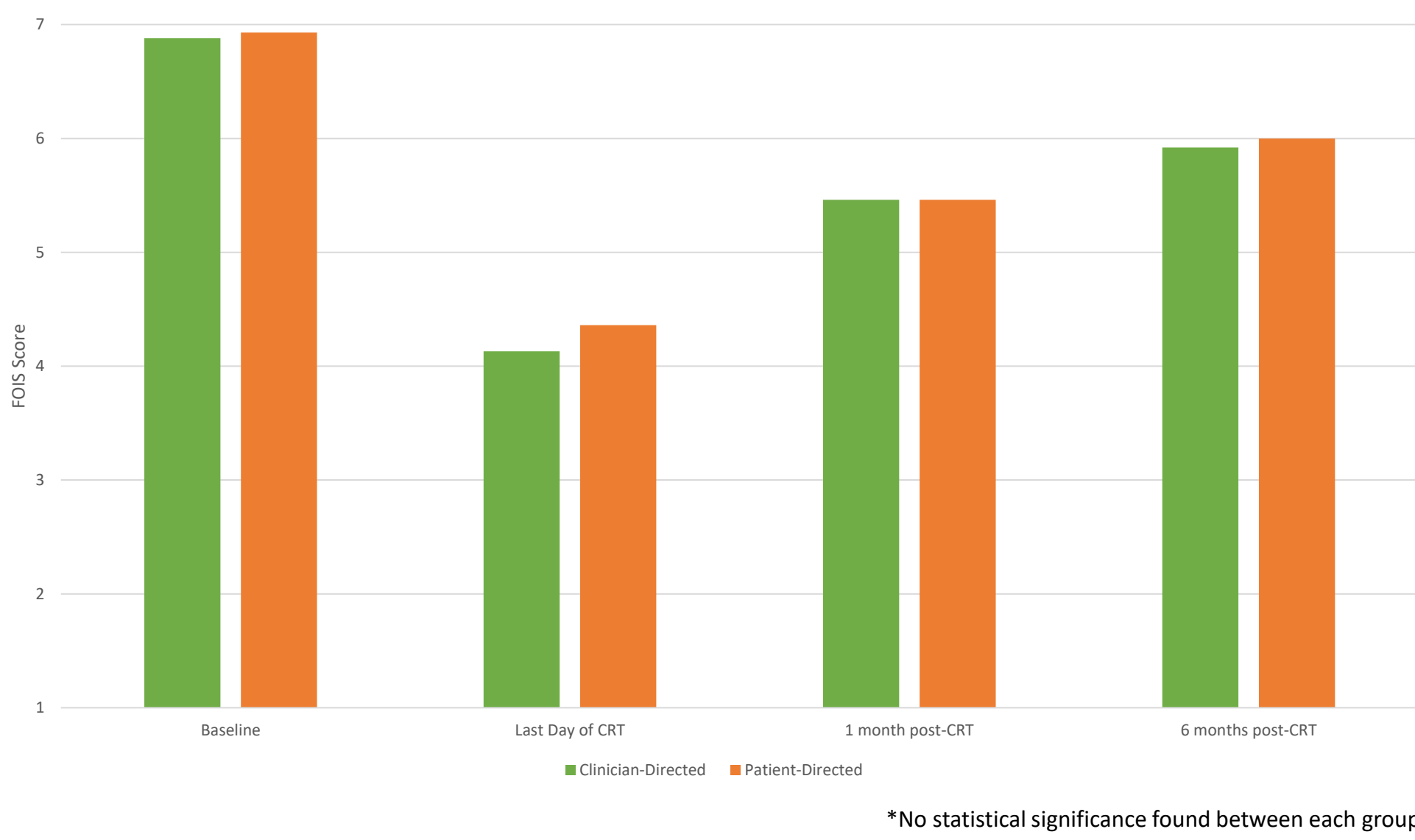
Parameter	Clinician-Directed	Patient-Directed	Total	p value
Age	59.1 (10.3)	58.6 (6.9)	58.9 (8.7)	0.866
Gender				
Male	14 (87.5)	12 (85.7)	26 (86.7)	1.000
Female	2 (12.5)	2 (14.3)	4 (13.3)	
Race				
White	16 (100.0)	12 (85.7)	28 (93.3)	0.209
Black	0	2 (14.3)	2 (6.7)	
Ethnicity				
Non-Hispanic	6 (37.5)	8 (57.1)	14 (46.7)	0.464
Hispanic	10 (62.5)	6 (42.9)	16 (53.3)	
Tumor Subsite				
Tonsil	11 (68.8)	10 (71.4)	21 (70.0)	1.000
Base of Tongue	5 (31.3)	4 (28.6)	9 (30.0)	
T Classification				
T1	6 (37.5)	4 (28.6)	10 (33.3)	0.563
T2	4 (25.0)	7 (50.0)	11 (36.7)	
T3	5 (31.3)	2 (14.3)	7 (23.3)	
T4	1 (6.3)	1 (7.1)	2 (6.7)	
Overall Stage				
I	6 (37.5)	5 (35.7)	11 (36.7)	1.000
II	7 (43.8)	6 (42.9)	13 (43.3)	
III	3 (18.8)	3 (21.4)	6 (20.0)	

Table 2. Quality of Life Scores

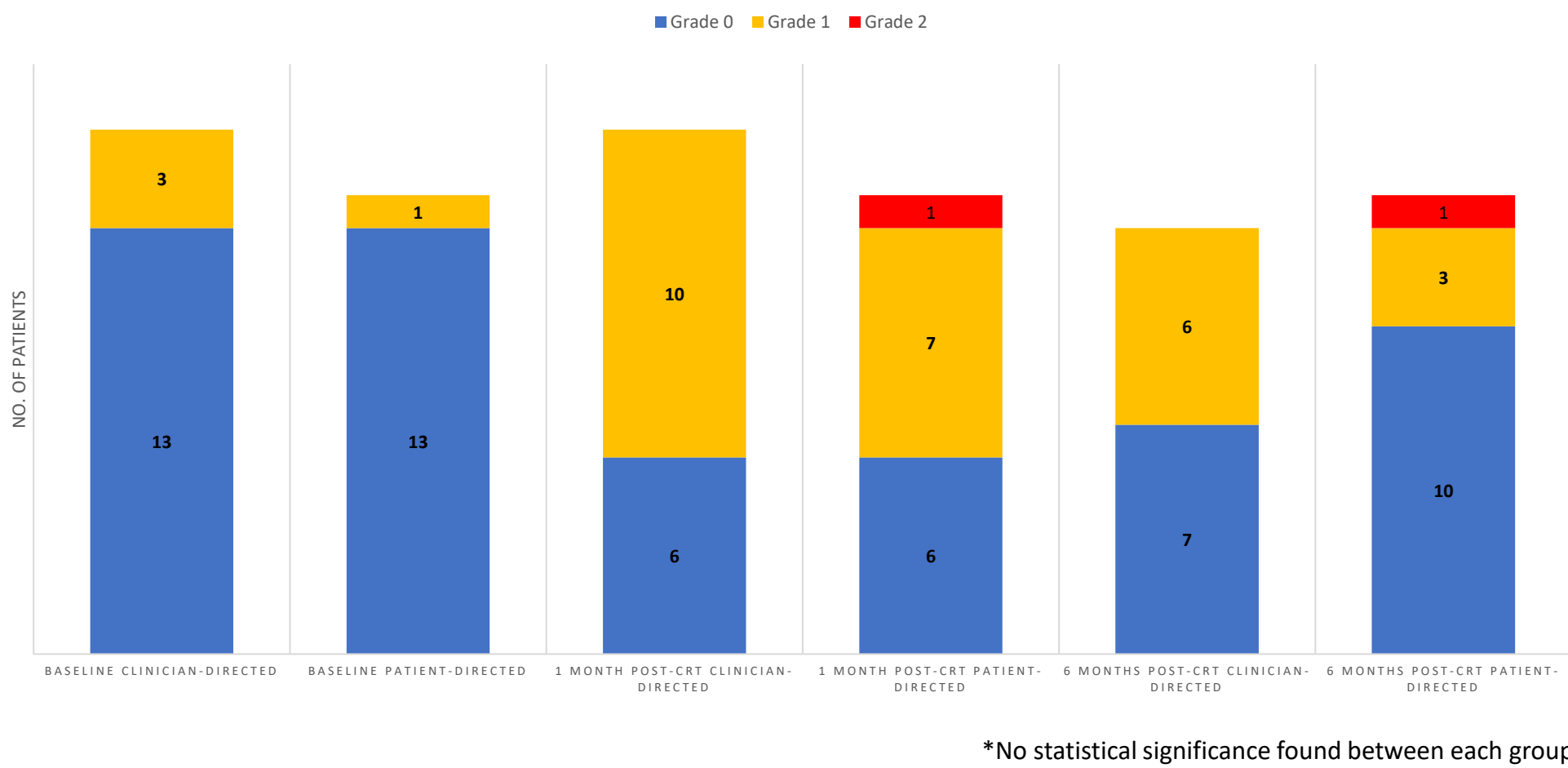
	Clinician-Directed			Patient-Directed		
	Baseline	1-month post CRT	6-month post CRT	Baseline	1-month post CRT	6-month post CRT
EAT-10	2.93	20.31	10.69	2.71	23.71	12.64
PSS-HN (Public Eating)	100	50	80.77	100	58.93	83.93

*No statistical significance found between each group

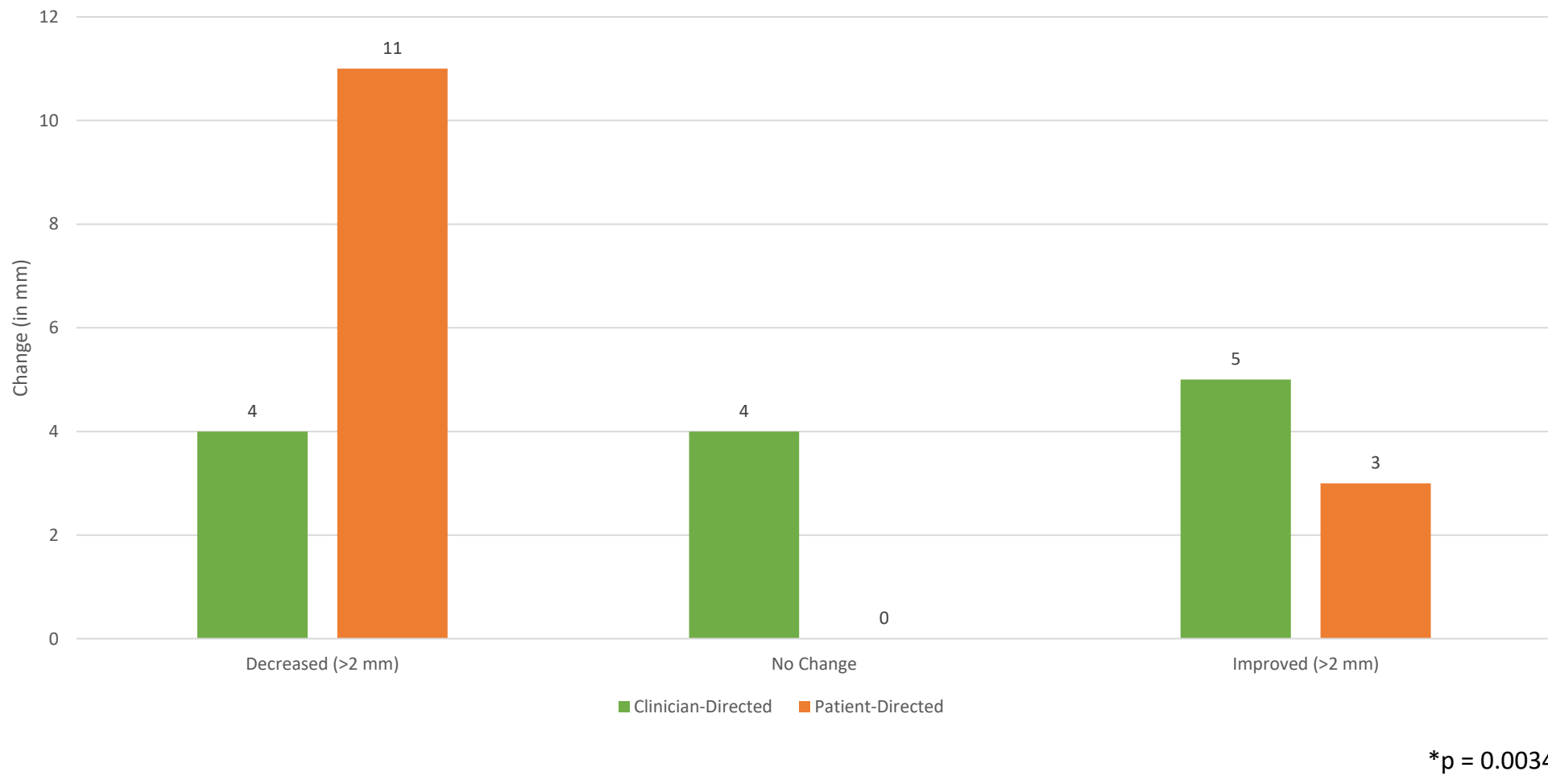
Graph 1. Mean FOIS Scores



Graph 2. DIGEST Summary Grades



Graph 3. Change in Oral Aperture from Baseline to 6-months post-CRT



Results

- Mean age was 58.9 years (44-76) and included 26 males and four females (Table 1).
- Twelve subjects were Caucasian; 16 were Hispanic; and 2 were African-American.
- Site of lesion was tonsil (n=21) vs. base of tongue (n=9) with more tonsil lesions being smaller T size although this was not statistically significant.
- Primary outcome (Graph 1)
- Overall FOIS mean score was 6.93 (FOIS 6-7) baseline, 4.57 (FOIS 4-6) on the last day of radiation therapy, 5.16 (FOIS 3-7) at 1-month post-CRT, and 5.84 (FOIS 3-7) at 6 months post-CRT.
- Three subjects received PEG tubes after their 1-month evaluation and one continued to use their PEG at 6 months post-CRT.
- FOIS score was not significantly different between the two groups (p=0.47) at any of the time points.
- Secondary Outcomes
- All subjects had baseline summary DIGEST <2 (Graph 2). No statistical significance was found between each group. Clinician-Directed group had 10 patients with no change from baseline to 6 months post-CRT. Patient-Directed group had 10 patients with no change from baseline to 6-months post-CRT.
- Oral aperture, measured by maximum interincisal distance (in mm), approached statistical significance with subjects in the Clinician-Directed group measuring 45.00 mm vs. 39.86 mm for the Patient-Directed group at 6 months post-CRT (p=0.06).
- It was then decided to evaluate the degree of change from baseline measure between the two groups. No change was defined as within 2 mm of baseline maximal oral aperture; improved oral aperture was defined as greater than 2 mm increase; and decreased was defined as less than 2 mm below baseline level. A statistically significant difference (p=0.0034) was found with subjects in the Clinician-Directed group maintaining or improving oral aperture from baseline to 6 months post-CRT when compared to subjects in the Patient-Directed group (Graph 3). Additionally, subjects that maintained or improved their maximum oral aperture trended towards improved FOIS scores.

Discussion

- FOIS scores were not significantly different between the two groups at any of the timepoints evaluated.
- A significant difference in oral aperture, trismus, was noted with subjects receiving in-person clinician-directed swallowing therapy maintaining or improving better than those on a patient-directed home program. This impacted FOIS scores favorably and approached statistical significance.
- It is likely that in-person therapy allows for individualized adjustments to be made to a therapy program resulting in improved compliance and better outcomes.
- Limitations/Future Studies:
- Pilot study with small n limited potential for significance
- Need for longer-term follow-up
- Effect of varied intensity of in-person clinician-directed swallowing exercises

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

FOIS items

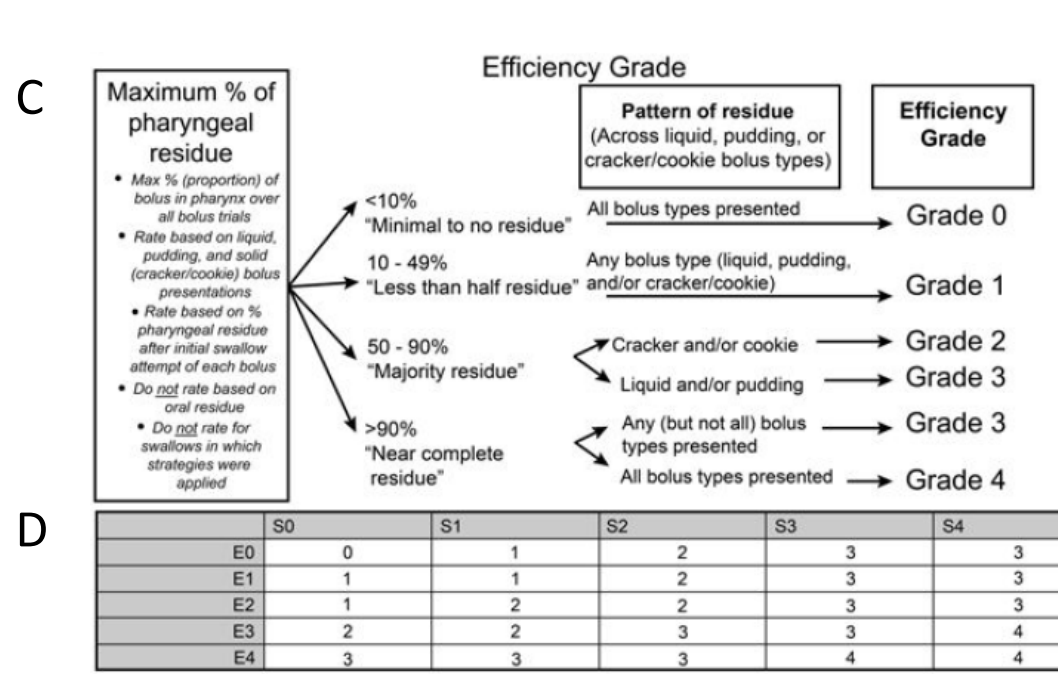
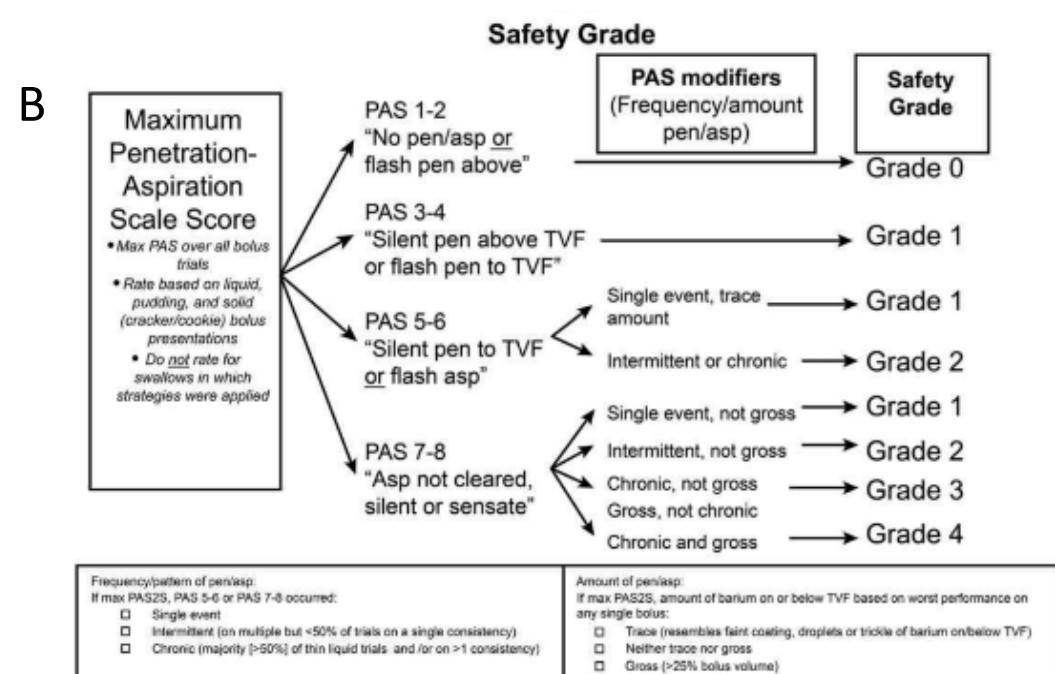


Figure 1. Swallow outcome measurements. A) FOIS scale (adapted from Cray et al., 2005). B) DIGEST safety grade, C) DIGEST efficiency grade and D) DIGEST summary grade (adapted from Hutcheson et al. 2017)