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## Introduction:

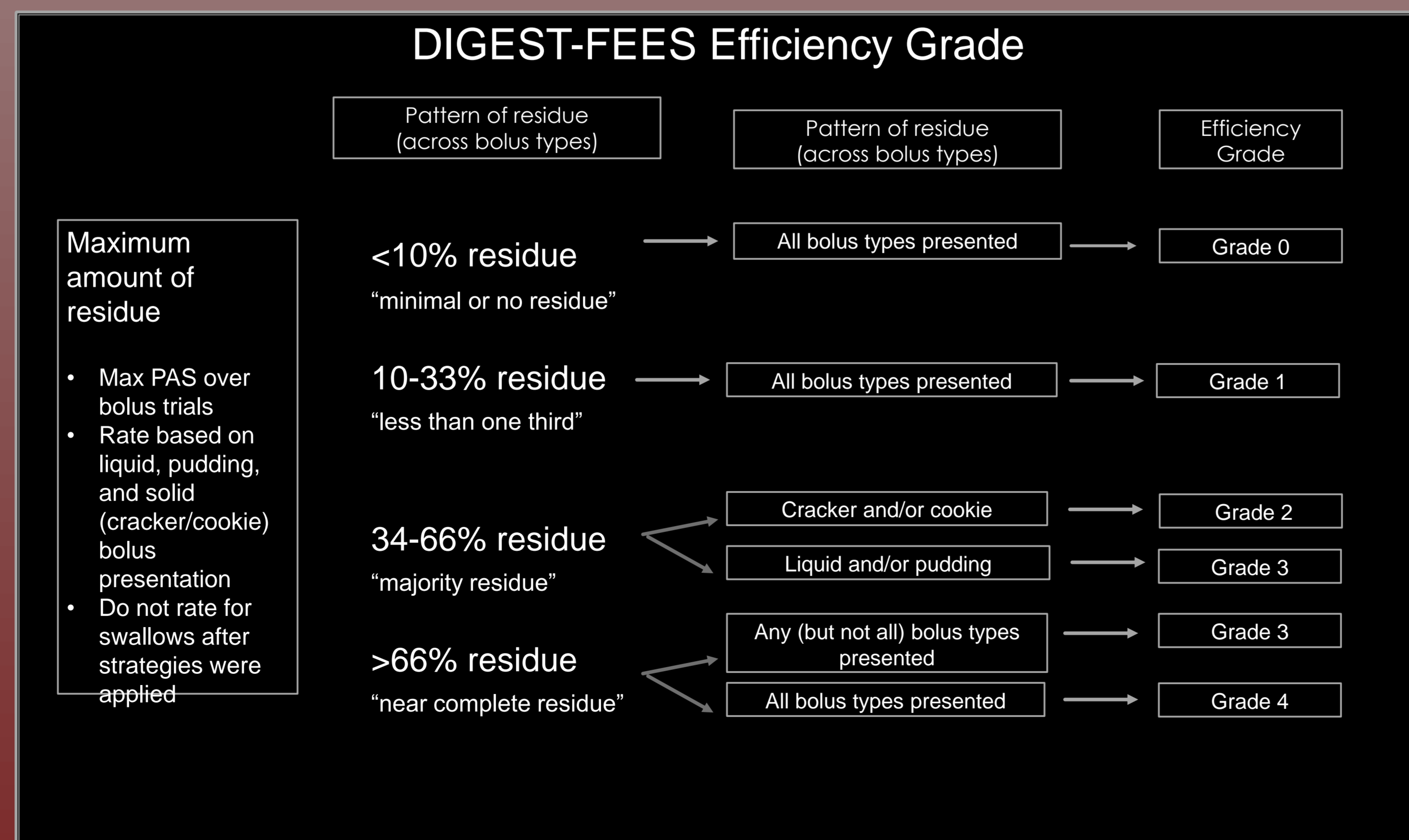
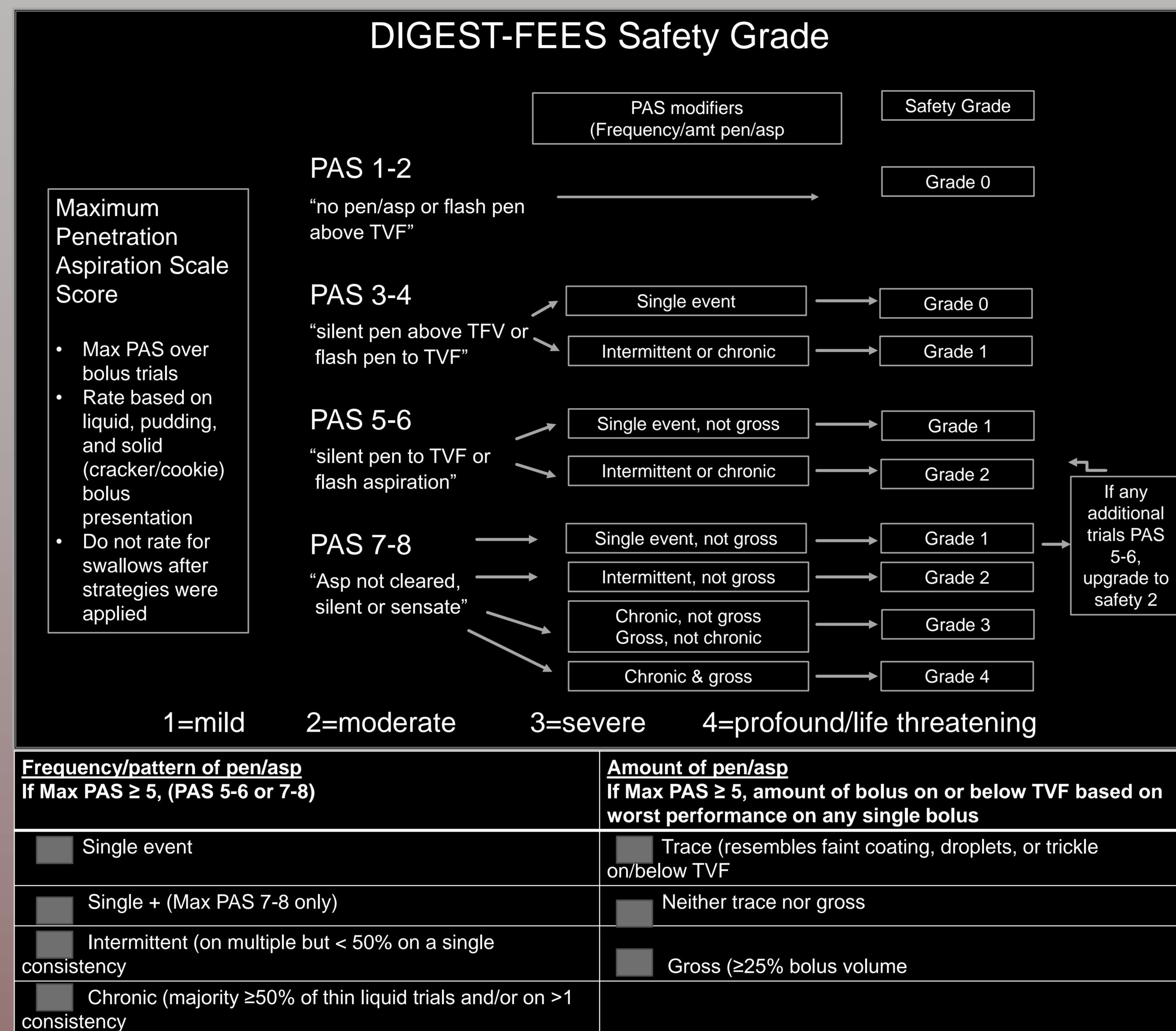
While Flexible Endoscopic Evaluation of Swallowing (FEES) is a common clinical procedure used in the head and neck cancer (HNC) population, extant outcome measures for FEES such as bolus-level penetration-aspiration and residue scores are not well suited as global patient-level endpoint measures of dysphagia severity in cooperative group trials or clinical outcomes research. The Dynamic Imaging Grade of Swallowing Toxicity (DIGEST™) was initially developed and validated for use during videofluoroscopic evaluations as a way to grade safety, efficiency, and overall pharyngeal swallowing impairment. The purpose of this study was to adapt and validate DIGEST™ for use with FEES.

## Methods:

- The DIGEST-FEES instrument was developed based on version 2 of the videofluoroscopic DIGEST™ flowchart including use of the Penetration Aspiration Scale to determine DIGEST<sub>safety</sub> grades and percentage of pharyngeal residue to determine DIGEST<sub>efficiency</sub> grades.
- An existing database of patients undergoing FEES following treatment for HNC was queried to establish a test rating set. In order to include a broad variety of dysphagia severity for validation and reliability purposes, 100 videos were pre-selected purposively by an experienced speech-language pathologist to ensure 1/3 of the exams were reflective of clinically judged normal or mild impairment, 1/3 to reflect moderate impairment, and 1/3 to reflect severe impairment.
- Three blinded, expert raters then evaluated 100 de-identified post-HNC treatment FEES examinations followed by 32 randomly selected videos to determine intra-rater reliability.
- Intra-rater and inter-rater reliability were tested with quadratic weighted kappa.
- Criterion validity against the MD Anderson Dysphagia Inventory (MDADI), Functional Oral Intake Scale (FOIS), Secretion Severity Scale (SSS), and Yale Residue Rating Scale was assessed with Spearman Correlation Coefficients.

**Table 1:** Patient swallowing characteristics (n = 100)

|                                |                                |
|--------------------------------|--------------------------------|
| Mean MDADI                     | 74.25 (range 29-100, SD=17.67) |
| FOIS scores                    |                                |
| 1                              | 1                              |
| 2                              | 4                              |
| 3                              | 5                              |
| 4                              | 1                              |
| 5                              | 29                             |
| 6                              | 24                             |
| 7                              | 36                             |
| Secretion Severity Scores      |                                |
| 0                              | 40                             |
| 1                              | 45                             |
| 2                              | 17                             |
| 3                              | 1                              |
| Yale Pharyngeal Residue Scores |                                |
| Vallecula                      |                                |
| 1                              | 7                              |
| 2                              | 21                             |
| 3                              | 12                             |
| 4                              | 28                             |
| 5                              | 35                             |
| Pyramiform Sinus               |                                |
| 1                              | 18                             |
| 2                              | 46                             |
| 3                              | 20                             |
| 4                              | 14                             |
| 5                              | 5                              |



**DIGEST-FEES Score (Interaction of assigned safety and assigned efficiency grades)**

|    | S0 | S1 | S2 | S3 | S4 |
|----|----|----|----|----|----|
| E0 | 0  | 1  | 2  | 3  | 3  |
| E1 | 1  | 1  | 2  | 3  | 3  |
| E2 | 1  | 2  | 2  | 3  | 3  |
| E3 | 2  | 2  | 3  | 3  | 4  |
| E4 | 3  | 3  | 3  | 4  | 4  |

1=Mild, 2=Moderate, 3=Severe, 4=Life threatening

## Results:

- Inter-rater reliability was almost perfect for overall DIGEST-FEES grade ( $\kappa_w = 0.83$ ) and DIGEST<sub>safety</sub> ( $\kappa_w = 0.86$ ) and substantial for DIGEST<sub>efficiency</sub> ( $\kappa_w = 0.74$ ).
- Exact agreement for overall DIGEST-FEES grade, DIGEST<sub>safety</sub>, and DIGEST<sub>efficiency</sub> was 62%, 73%, and 61% respectively with only 1% of discordant ratings differing by more than one grade.
- Intra-rater reliability was almost perfect across the three raters ( $\kappa_w = 0.9-0.99$ ).
- DIGEST-FEES, DIGEST<sub>safety</sub>, and DIGEST<sub>efficiency</sub> were all significantly associated with all criterion measures (see Table 2).

**Table 2:** Spearman Correlation Coefficients for DIGEST-FEES by criterion measures

|                              | Safety | Efficiency | DIGEST |
|------------------------------|--------|------------|--------|
| MDADI                        | -0.388 | -0.422     | -0.434 |
| MDADI (emotional)            | <.0001 | <.0001     | <.0001 |
| MDADI (functional)           | -0.371 | -0.372     | -0.395 |
| MDADI (physical)             | 0.0001 | 0.0001     | <.0001 |
| Functional Oral Intake Score | -0.307 | -0.310     | -0.315 |
| Secretion severity score     | 0.002  | 0.002      | 0.001  |
| Yale vallecula               | -0.392 | -0.472     | -0.468 |
| Yale pyriform sinus          | <.0001 | <.0001     | <.0001 |
|                              | -0.390 | -0.434     | -0.433 |
|                              | <.0001 | <.0001     | <.0001 |
|                              | 0.419  | 0.503      | 0.469  |
|                              | <.0001 | <.0001     | <.0001 |
|                              | 0.630  | 0.846      | 0.733  |
|                              | <.0001 | <.0001     | <.0001 |
|                              | 0.611  | 0.664      | 0.652  |
|                              | <.0001 | <.0001     | <.0001 |

## Conclusions:

DIGEST-FEES is a reliable scale that can be utilized to describe the severity of safety, efficiency, and pharyngeal stage overall swallowing impairment on FEES among patients with HNC. Consistent with the original videofluoroscopic DIGEST™ scale, strong correlations are noted between DIGEST-FEES and reference measures of swallowing function, including other FEES measures and moderate for other measures of dysphagia including patient perceived quality of life, diet level, and secretion severity.

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