



FLiGS Score: A New Method of Outcome Assessment for Lip Carcinoma–Treated Patients

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Background: Lip cancer and its treatment have considerable functional and cosmetic effects with resultant nutritional and physical detriments. As we continue to investigate new treatment regimens, we are simultaneously required to assess postoperative outcomes to design interventions that lessen the adverse impact of this disease process. We wish to introduce Functional Lip Glasgow Scale (FLiGS) score as a new method of outcome assessment to measure the effect of lip cancer and its treatment on patients' daily functioning.

Methods: Fifty patients affected by lip squamous cell carcinoma were recruited between 2009 and 2013. Patients were asked to fill the FLiGS questionnaire before surgery, 1 month, 6 months, and 1 year after surgery. The subscores were used to calculate a total FLiGS score of global oral disability. Statistical analysis was performed to test validity and reliability.

Results: FLiGS scores improved significantly from preoperative to 12 months postoperative values ($P = 0.000$). Statistical evidence of validity was provided through r_s (Spearman correlation coefficient) that resulted >0.30 for all surveys and for which $P < 0.001$. FLiGS score reliability was shown through examination of internal consistency and test-retest reliability.

Conclusions: FLiGS score is a simple way of assessing functional impairment related to lip cancer before and after surgery; it is sensitive, valid, reliable, and clinically relevant: it provides useful information to orient the physician in the postoperative management and in the rehabilitation program. (*Plast Reconstr Surg Glob Open* 2015;3:e345; doi:10.1097/GOX.0000000000000306; Published online 30 March 2015.)

Lip cancer represents 25% of all oral cavity carcinomas; it peaks in the sixth and seventh decades, with males predominating by 3 to 1. The lower lip is approximately 12 times more likely to be affected, owing to its greater exposure to the sunlight.

Surgical oncologic and reconstructive treatment of lip cancer has advanced dramatically, but lip dis-

tortion or loss resulting from neoplasms or from their surgical treatment has considerable functional and cosmetic effects with resultant nutritional, physical, and psychological detriments.¹⁻⁸

Traditional indicators, such as survival rate and disease-free interval, are no longer adequate for answering questions on outcome not considering the physical and functional sequelae of treatment.⁹ Questionnaires with a precise number of graded questions are the most practical form of assessment and include a structured approach to capture patient-perceived common problems after treatment and to rank their intensity, providing clinicians with an appropriate outcome evaluation.¹⁰⁻¹³

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Table 1. FIGS Score

FIGS Score	Speaking	Chewing	Swallowing
5	Clearly understood always	Any food, no difficulty	Any food, no difficulty
4	Requires repetition many times	Semisolid food only	Semisolid food only
3	Requires repetition sometimes	Any food, with difficulty	Any food, with difficulty
2	Understood by relatives only	Liquids only	Liquids only
1	Unintelligible	Cannot chew at all	Cannot swallow at all

Proposed by Goldie SJ, Jackson MS, Soutar DS, et al. The functional intraoral Glasgow scale (FIGS) in retromolar trigone cancer patients. *J Plast Reconstr Aesthet Surg.* 2006;59:743–746.

Table 2. FLiGS Score

FLiGS Score	Speaking	Chewing	Swallowing	Drooling	Physical Appearance
5	Clearly understood always	Any food, no difficulty	Any food, no difficulty	Absence of drooling	Very good result
4	Requires repetition many times	Semisolid food only	Semisolid food only	Presence of drooling occasionally during the day	Good result
3	Requires repetition sometimes	Any food, with difficulty	Any food, with difficulty	Presence of drooling during chewing	Acceptable result
2	Understood by relatives only	Liquids only	Liquids only	Presence of drooling also during speaking	Bad result
1	Unintelligible	Cannot chew at all	Cannot swallow at all	Constant drooling with maceration of the mandibular cutaneous region	Very bad result

Numerous tools to assess posttreatment functional outcomes have been developed and tested, but no gold standard exists to evaluate the specific issues of lip cancer–treated patients.

During the last 10 years, we have adopted the FIGS (Functional Intraoral Glasgow Scale) score (Table 1) to assess outcome of patients with oral cancer and reconstructive technique results.^{14–16} The FIGS score is a simple 5-point scale questionnaire designed to determine the ability of oral cancer patients to speak, chew, and swallow before and after surgery. We found this tool more effective than others due to its simplicity, its clinical relevance, and its objectivity for functional results.

However, the FIGS score lacks accuracy for lip localization not taking into account the specific problems related to lip cancer as:

- The presence of drooling, index of poor oral competence.
- The aesthetic impact of the tumor and its surgical treatment.

Adding the analysis of these 2 specific parameters to those assessed by FIGS, we aim to develop a new method of outcome assessment in patients who had

surgical ablation of lip carcinoma with or without reconstruction: the FLiGS (Functional Lip Glasgow Scale) score (Table 2).

MATERIALS AND METHODS

In a preliminary phase of the study, a cohort of 20 patients operated for lip cancer at our institution and on a regular follow-up were asked to indicate in an open-answer form problems related to the presence of the tumor of the lip (before surgery) or to its treatment (postoperatively). In addition to those investigated by the FIGS score, most patients complained the presence of drooling and an aesthetic alteration. No other specific problems were pointed out. Based on these data, we decided to modify the FIGS score to include evaluation of these 2 parameters, scoring them using a 5-point scale, developing FLiGS score.

A cohort of patients affected by squamous cell carcinoma of the lips were recruited between 2009 and 2013 on admission for definitive surgery to test the validity and the reliability of this new scale. Fifty patients were selected on the basis of the following inclusion criteria: adult patients who had received curative treatment for lip cancer and who had an interval of 1-year disease-free survival. Patients who had received palliative treatment, had evidence of recurrence, or had a follow-up time of less than 1 year were excluded from the sample.

Patients were asked to fill the FLiGS questionnaire before surgery, 1 month, 6 months, and 1 year after surgery (assistance was provided by members

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of the head and neck team who were familiar with the scale). The subscores were used to calculate a total FLiGS score of global oral disability. The maximum possible total score is 25, and the minimum score is 5.

All patients participating in the study were asked to reattend the clinic after a 15-day interval to refill the same previously answered questionnaires to calculate test-retest reliability. The interval was considered sufficient to prevent patients from remembering their previous answers and not adequate to allow for any clinically meaningful changes. All related data regarding disease and treatment as well as the demographics of the patients were extracted from the patient's notes.

According to data characteristics and numerosity, analysis of variance for repeated measures has been used to analyze statistical significance.

Validity of FLiGS score was tested using Spearman correlation coefficient comparing results with those of FIGS simultaneously assessed in the same patients. Values of $r_s = 0.30$ and stronger, and for which $P < 0.001$, were considered valid.

FLiGS score reliability was tested through examination of internal consistency and test-retest reliability. Internal consistency was calculated using Cronbach's α , considered valid when α is between 0.7 and 0.9. Values over 0.9 imply the presence of redundant items. Test-retest reliability was measured with intraclass correlation coefficient that measures both the strength of the correlation and the systemic variation.¹⁷

Statistical analysis was performed using SPSS Statistics software (IBM, New York, N.Y.) version 20.0.

P values of 0.05 or less were considered to be statistically significant.

According to Italian rules (art. 13, DLgs n. 196/03), this study did not require authorization by the Institutional Review Board.

RESULTS

Most of the patients completed the questionnaire alone, with few needing help due to being illiterate. Completion time ranged from 10 to 25 minutes (mean, 15 minutes) depending on the education level of the participant.

Analysis of variance for repeated measures showed statistical significance of FLiGS values either for between-stage results or for overall results. FLiGS scores improved significantly from preoperative to 12 months postoperative values ($P = 0.000$).

Generally, there was a fall in the mean score from baseline to 1 month after surgery, with a tendency to gradually improve at 6 months and 1 year postoperative.

One month following surgery, the first 3 parameters examined (speech, chewing, and swallowing) shared the same characteristics of the mean score curve during the study period showing deterioration at 1 postoperative month, starting to improve at 6 and 12 months.

Drooling and physical appearance showed gradual improvement during all the study period.

FLiGS score was screened for validity, reliability, and internal consistency.

Statistical evidence of validity was provided through r_s (Spearman correlation coefficient) that resulted >0.30 for all surveys and for which $P < 0.001$, showing significant correlation between FLiGS score and FIGS score.

FLiGS score reliability was tested through examination of internal consistency and test-retest reliability. The internal consistency of FLiGS score, measured by Cronbach's α values, was 0.88 for preoperative, 0.81 for 1 month postoperative, 0.79 for 6 months postoperative, 0.83 for 12 months postoperative, and 0.88 for overall result. Test-retest reliability as measured by the intraclass correlation coefficient value was statistically significant (0.87; 95% confidence interval: inferior limit, 0.80; superior limit, 0.92).

DISCUSSION

We wish to introduce FLiGS score as a useful tool to measure the effect of lip cancer and its treatment on patients' daily functioning.

Lips play a key role in facial expression, speech, and eating. The primary management of lip cancer is complete surgical resection. Compared with intra-oral cancers, lip cancers present a lower rate of early postoperative complications such as infection and fistulas.¹⁸ However, the management of a lip defect remains a reconstructive challenge, requiring a balance between form, function, and aesthetics.

The presence of drooling, index of poor oral competence (often related to commissural localization of the tumor, orbicularis oris muscular deficit after surgery, and/or lip sensitivity alteration), and the high impact on the physical appearance of the patient are considered to be the specific issues related to lip cancer and its surgical treatment, as confirmed by our preliminary study. Both these parameters showed a gradual improvement during all the study period. This is probably because the presence of the tumor, especially in advanced stages, causing loss or distortion of the labial rim, negatively affects lip function and aesthetic appearance; on the other hand, surgical and reconstructive treatment aims at restoration of the normal oral competence with a consequential improvement of function and

form. This was observed especially in those cases in which a morphofunctional lip reconstruction (ie, through muscular innervated local or free flaps) was performed.^{5,19,20}

We are currently investigating in a prospective study if this scale could also be used to evaluate correlation between tumor characteristics (T stage), or surgical variables (such as surgical resection and method of reconstruction), and the resulting effects on postoperative lip function.

CONCLUSION

FLiGS score is a rapid, simple, and comprehensive (easy to administer, easy to understand, and easy to score) way of assessing functional impairment related to lip cancer before and after surgery; it is sensitive (responds to change in patient's condition), valid (measures what it purports it measures), reliable (produces the same results in the same patient group when repeated), and reproducible. Most importantly, it is clinically relevant: it allows monitoring of postoperative results and provides useful information to orient the physician in postoperative management and in the rehabilitation program.

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