

1 **TITLE: Functional fat injection under local anesthesia to treat severe post-surgical**  
2 **dysphagia, a case report**

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4 **Running title: Fat injection in the treatment of dysphagia**

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1 **Abstract**

2 **Background:** in the present study we present the first application of functional fat injection (FFI)  
3 performed under local anesthesia in the treatment of severe dysphagia secondary to head and neck  
4 cancer (HNC) surgery.

5 **Methods:** FFI was performed using a transcervical approach. Control of injection depth and site  
6 was performed through a trans-nasal flexible endoscope. The effect of surgery was evaluated  
7 through videofluoroscopy (VFS), Fiberendoscopic Evaluation of Swallowing (FEES), Functional  
8 Oral Intake Scale (FOIS) and Eating Assessment Tool-10 (EAT-10).

9 **Results:** before the FFI the patient was dependent on permanent tube feeding, the VFS and FEES  
10 revealed a severe impairment of swallowing abilities. The EAT-10 scored 26. Twelve months after  
11 surgery the patient was on oral diet, the VFS demonstrated mild to moderate dysphagia, the FEES  
12 demonstrated aspiration only with liquids and the EAT-10 improved.

13 **Conclusions:** FFI under local anesthesia could be useful in the treatment of chronic dysphagia in  
14 selected patients.

1 **Introduction**

2 Dysphagia occurs frequently in patients with head and neck cancer (HNC); in particular dysphagia  
3 and aspiration pneumonia are common complications after partial laryngectomies (PL) and severely  
4 impact on quality of life (QOL) [1]. Although, behavioural swallowing rehabilitation allows  
5 adequate management in most of the cases, tube feeding is required in a minority of patients.

6 In order to overcome this problem, some authors recently proposed a new treatment for dysphagia  
7 following surgery and/or chemoradiotherapy through polydimethylsiloxane or fat injections [2, 3].

8 In particular, Kraaijenga et al [3] reported their promising experience with lipofilling of the tongue  
9 base in the treatment of six HNC patients with chronic dysphagia secondary to surgery and/or  
10 chemoradiotherapy. Also Navach et al [4], reported satisfactory swallowing results after lipofilling  
11 of the tongue base in a patient treated with radiation therapy for a nasopharyngeal carcinoma and  
12 consequent severe post-radiation dysphagia. In this case report we present the first application of fat  
13 injection performed under local anesthesia in the treatment of severe therapy-refractory dysphagia  
14 secondary to supraglottic laryngectomy. The underlying hypothesis is that in some patients the  
15 tissue loss related to HNC surgery might reduce airway protection acting as a funnel toward the  
16 larynx, thus the correction of tissue loss using fat injection might improve the safety of swallowing.  
17 In addition, local anesthesia could provide a “functional” display of the operative field, since the  
18 patient is awake and able to swallow, thus allowing to monitor the effect of surgery on  
19 swallowing in real-time.

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## 1 **Case report**

2 A 76 years old patient presented at our institution for severe chronic dysphagia. In January 2012 he  
3 underwent a horizontal supraglottic laryngectomy partially extended to the left arytenoid (OPHL  
4 Type I+ARY [5]) at another institution for a T3N0M0 supraglottic laryngeal squamous cell  
5 carcinoma. After the surgery he underwent adjuvant radiotherapy and subsequent oncologic follow-  
6 up was clinically and radiologically negative. However, from the time of the surgery he complained  
7 severe dysphagia and was unable to regain an oral diet. When he presented at our institution in  
8 November 2015 he was feeding tube dependent (Functional Oral Intake Scale [6], FOIS = 1).  
9 Fiberoendoscopic Evaluation of Swallowing (FEES) was performed according to Langmore protocol  
10 [7]. FEES demonstrated a mobile right arytenoid and an important tissue loss in the tongue base,  
11 especially on the left side (see Figure 1a). Solid, semisolid and liquid textures with volumes of 5 ml  
12 and 10 ml were tested and constant intra-swallowing aspiration and moderate pooling of food at the  
13 tongue base with post-swallowing penetration and aspiration was detected with all consistencies  
14 (Penetration Aspiration Score [8], PAS = 7) (see Figure 1b). The patient underwent behavioral  
15 swallowing therapy twice a week for 6 months. Behavioral swallowing therapy included postural  
16 techniques, swallowing maneuver (super-supraglottic swallow), daily muscle strengthening  
17 (Masako and Shaker exercise, tongue reinforcement with IOPI device) and percutaneous  
18 neuromuscular electrical stimulation. Swallowing function modification was checked monthly  
19 through FEES, showing no substantial improvement, although patient motivation and adherence to  
20 therapy were high. Videofluoroscopic (VFS) examination was performed with 5, 10 and 20 mL  
21 with liquid and semisolid textures; solid texture was tested as well. Each volume and consistency  
22 was tested 3 times and revealed severe dysphagia with aspiration due to ineffective airway  
23 protection secondary to surgery (Dysphagia Outcome and Severity Scale [9], DOSS = 1) (see  
24 Figure 2). Aspiration with different consistencies occurred often but in small volume thanks to  
25 cough (Safety, S, = 3 in Dynamic Imaging Grade of Swallowing Toxicity, DIGEST, scale [10]),  
26 while residue was less than half with all consistencies (Efficiency, E, = 1 in DIGEST scale), with a

1 DIGEST scale score of 3. With all consistencies bolus oral transport, initiation of pharyngeal  
2 swallow and soft palate elevation were considered normal, laryngeal elevation and anterior hyoid  
3 bone movements were slightly reduced; laryngeal closure was reduced and tongue base retraction  
4 was slightly reduced. Pharyngeal contraction and stripping wave appeared normal, while  
5 indentation of the UES was visible.

6 Careful analysis of the FEES recording, clearly showed that intra-swallowing aspiration was related  
7 to tongue base tissue loss acting as a funnel on the left side; besides, removal of left arytenoid was  
8 associated with loss of a clear separation between neolarynx and lateral channels. The patient was  
9 offered a functional fat injection (FFI) under local anesthesia in order to improve his swallowing  
10 function. The aim of FFI was to correct the tissue loss by filling the tongue base in order to  
11 facilitate the lateral slipping of the food preventing intra-swallowing aspiration and oro-pharyngeal  
12 pooling. The procedure was performed in an operating room under local anesthesia on a day  
13 hospital basis. This study was carried out according to the Declaration of Helsinki and was  
14 previously approved by Institutional Review Board of our hospital. The patient gave his written  
15 informed consent. The surgeons clearly explained the whole procedure to the patient, whose active  
16 collaboration was necessary.

17

### 18 *Surgical procedure*

19 The patient was initially placed in a supine position. An infiltration of local anesthetic and  
20 vasoconstrictor solution was administered into the low peri-umbilical region, using two 20 cc  
21 syringes connected to a 22 Gauge needle, 9 cm. long. The liposuction was performed in the sub-  
22 cutis of the low peri-umbilical region, using a 10 cc disposable autostatic syringe, connected via  
23 luer-lock to Coleman cannula [11]. Lipoaspirate concentration was achieved through centrifugation  
24 for 3 minutes at 3000 rpm per minute as described by Coleman [11]. The concentrated fat was  
25 placed in 1 mL syringes connected to 20 gauge with blunt tip cannula. Once this task was  
26 completed, the patient was put in a semi-seated position. A 25-gauge needle with 1% lidocaine

1 hydrochloride was used to anesthetize the skin and subcutaneous tissues overlying the thyrohyoid  
2 notch. The flexible endoscope was inserted trans-nasally while FFI was performed using a  
3 transcervical–thyrohyoid approach [12] with a centralized injection. Small aliquots of fat were  
4 transferred with multiple passes at different depths in order to obtain augmentation of the tongue  
5 base [3]. A total volume of 5 cc was injected. This volume was not decided *a priori* but was related  
6 to the desired functional results (i.e. the reduction of tissue loss in the tongue base and improvement  
7 of dysphagia) and only a minor over injection was performed. Control of injection depth and site  
8 was performed through the flexible endoscope since the injection cannula was maintained under the  
9 mucosa and maneuvered in order to reach the chosen areas to be augmented (see the asterisks in  
10 Figure 1). A single injection was performed. In order to evaluate the effect of FFI on swallowing  
11 function, a FEES was performed intra-operatively using liquid and semisolid textures with volumes  
12 of 5 and 10 ml. Trace aspiration was detected only for liquids textures (PAS = 6 for liquids and  
13 PAS = 4 for semisolids) and residue was minimal.

14

#### 15 *Patient evaluation*

16 Information regarding weight, number and type of complications occurred during and after the  
17 surgery were analyzed. In addition, the patient was evaluated before, after 1 week (first post-  
18 operative period), after 1, 6, and 12 months (second, third and fourth post-operative periods) from  
19 the surgical procedure through VFS (after 1 and 6 months) and FEES (after 1 week, 1, 6 and 12  
20 months). During each of the post-operative medical examination patients' oral intake was assessed  
21 using FOIS [6], while information regarding the perceived swallowing disorder were collected  
22 using the Italian version of the Eating Assessment Tool-10 (I-EAT-10) [13]. The scores of the latter  
23 range from 0-40, with higher scores indicating more swallowing problems.

24

#### 25 *Results*

1 The patient well tolerated the liposuction and the surgical procedure and he did not complain any  
2 discomfort or pain during the procedure. No complications during or after the surgical procedure  
3 were reported. In particular, no edema in the neck, hemorrhage at the injection site or in the nose  
4 were noted post-operatively.

5 Before the surgery the patient was dependent on permanent tube feeding (FOIS = 1), the VFS  
6 demonstrated severe dysphagia (DOSS = 1) and also the FEES examination revealed a severe  
7 impairment of swallowing abilities (PAS = 7 with different consistencies) and moderate pooling in  
8 the oropharynx. The I-EAT-10 score before surgery was 26, suggesting perception of a severe  
9 swallowing impairment.

10 After 1 week, the FEES examination revealed a positive evolution of dysphagia since aspiration  
11 was demonstrated only for liquids (PAS = 6) but not for semisolids or solids, (PAS = 4 for  
12 semisolids and PAS = 3 for solids); only coating in the oropharynx was visible with liquids. The  
13 patient was then referred to the SLP of our institution and a modified oral feeding was prescribed.

14 After 1 month, the patient reported a good evolution of his swallowing function and he was able to  
15 again resume consistent oral intake alongside his tube feeding (FOIS = 6). The VFS demonstrated  
16 mild to moderate dysphagia with trace aspiration of thin liquids only but with strong reflexive  
17 cough to clear completely (DOSS = 4) (see Figure 3). Trace aspiration was limited to liquids (S1 in  
18 DIGEST), while residue was minimal with all consistencies (E0 in DIGEST), with a DIGEST score  
19 of 1 (Table 1). With all consistencies bolus oral transport, initiation of pharyngeal swallow and soft  
20 palate elevation remained normal, laryngeal elevation and anterior hyoid bone movements were  
21 slightly reduced; laryngeal closure was almost normal and tongue base retraction was slightly  
22 reduced. Pharyngeal contraction stripping appeared normal, while indentation of the UES was still  
23 visible. Also the FEES examination demonstrated aspiration only with liquids (PAS = 6) but not  
24 with semisolids and solids, (PAS = 3 for semisolids and PAS = 2 for solids) and oropharyngeal  
25 coating with different consistencies. The improvement of PAS score for liquid texture is probably  
26 related to the improvement of airway protection which reduced the amount of aspirated liquid (only

1 trace aspiration was found during FEES). Probably for this reason the reflexive cough was strong  
2 enough to clear completely. The I-EAT-10 improved up to 9. These results were stable also after 6  
3 months and consequently the feeding tube was removed. During the 6 months post-surgery enteral  
4 feeding was progressively reduced and oral feeding increased. With all consistencies bolus oral  
5 transport, initiation of pharyngeal swallow and soft palate elevation were considered normal,  
6 laryngeal elevation and anterior hyoid bone movements were slightly reduced; laryngeal closure  
7 was reduced and tongue base retraction was slightly reduced. Pharyngeal contraction stripping  
8 appeared normal, while indentation of the UES was visible; tube removal was agreed after two  
9 months of full oral feeding without complication. After 6 months, the effects of FFI were still  
10 maintained (Figure 4) and although no volumetric measure was possible during FEES, no  
11 significant reduction of inject fat was noted during endoscopic examination. The patient was on oral  
12 diet (FOIS = 6), the I-EAT-10 score was further improved to 4, a 6-kg increase in body weight was  
13 recorded and no bronchitis or aspiration pneumonia were reported from the time of the surgery.

14

## 15 **Discussion**

16 In the present study our experience in the treatment of chronic dysphagia secondary to surgery and  
17 refractory to behavioral rehabilitation was reported. To the best of our knowledge this is the first  
18 report on swallowing modification after FFI performed under local anesthesia. The results here  
19 reported appear promising and support the applicability of FFI in the treatment of chronic  
20 dysphagia secondary to HNC surgery.

21 Specific findings are noteworthy. In particular, the patient well tolerated both the liposuction and  
22 the FFI phase and no complications during or after the surgical procedure were reported. This  
23 datum could be related to the use of autologous fat. The latter causes less inflammation in the  
24 injection site because is less likely to cause an allergic reaction or local granulomatosis [14]. In  
25 addition, it might also assure the tissue regeneration which is related to the presence of stem cell  
26 included in the centrifuged autologous fat [15].



1 As far as the efficacy of the FFI is concerned, the results here reported suggest that this surgical  
2 technique provides good results both in the short- and in the long-term period. However, it must be  
3 noted that as the patients underwent prolonged swallowing therapy before and after the injection,  
4 the positive outcome should be considered as a result of both treatments provided. Both the VFS  
5 and FEES examinations demonstrated a positive evolution of dysphagia. The oral intake  
6 dramatically improved and the patient was able to remove the tube feeding and regain an oral diet  
7 with restrictions. Finally, also the results obtained in the I-EAT-10 suggested a positive evolution of  
8 swallowing disorder perception after the surgery. It is consequently possible to speculate that FFI  
9 might improve swallowing because the tongue base injection corrected the tissue loss and this  
10 facilitated the lateral slipping of the food, thus improving the airways protection and reducing the  
11 oro-pharyngeal pooling. In addition, the injected fat could also play a role in facilitating bolus  
12 propulsion. In the future, manometry would be a useful tool in investigating this hypothesis.  
13 Moreover, also MRI performed before and after fat injection would be useful in order to evaluate  
14 the amount of fat loss during the follow-up period. Consequently, caution should be applied in  
15 reading the results here reported, as they derive from a single case and no evaluation of fat survival  
16 and/or tissue augmentation was performed.

17 To date, fat injection is rarely used in HNC and only few studies analyzed the efficacy of this  
18 technique in the treatment of oropharyngeal dysfunction following treatment for HNC [2-4]. In  
19 none of the previous studies the fat injections were performed under local anesthesia. The latter  
20 might assure some important advantages, such as the “functional” display of the operative field  
21 since the patient is awake and able to swallow. In addition, the patient is in a sitting position during  
22 the surgery and consequently the relationship among swallowing structures is not influenced by  
23 gravity. Finally, the use of flexible trans-nasal endoscopy during FFI allows a fat injection tailored  
24 to the patient’s needs since it allows to monitor the effect of surgery on swallowing in real-time. In  
25 conclusion, the FFI under local anesthesia could be useful in the treatment of chronic dysphagia in  
26 selected patients with tissue loss secondary to HNC surgery.

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