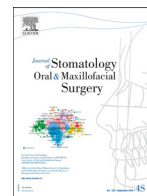




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Original Article

Reconstruction of oral mucosal defects with regenerative dermal matrix after T1-T2 squamocellular carcinoma resection



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ABSTRACT

Objective: Resection of tumors of oral cavity usually causes short- or long-term sequelae such as chewing, speech and swallowing impairment. To preserve this function it is necessary to maintain the lining of the oral cavity, the mobility and sensitivity of the tongue. Reconstructive options for oral mucosal defects resulting from tumor resection included primary closure, mucosal and skin grafts, pedicle and microvascular free flaps, and dermal matrix.

Study design: Retrospective study on patients undergoing reconstruction of intraoral defects, after removal of T1, T2 malignant tumors, by placement of bilayer dermal matrix.

Methods: From 2021 to 2022, 47 patients with oral mucosa defects after removal of squamous cell carcinoma were treated. All patients were affected by a T1-T2 squamous cell carcinoma.

For each patient, data were collected regarding the site of the disease, the initial staging, the size of the surgical defect, the complications and the outcome months after the operation.

Results: In all treated cases the surgical defect involved the mucosa of the cheek, the oral floor or the tongue with an average size of 5.45cm².

Patients who underwent this type of reconstruction benefited from excellent healing of intraoral wounds and good restoration of oral function 6 months after surgery. Out of the total number of patients, membrane attachment failure was reported in only two cases.

Conclusion: As emerges from the data reported in our study, the dermal matrix represents a valid alternative in oncological reconstructive surgery for small/medium-sized intraoral mucosal defects because it allows re-epithelialization of the wound.

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1. Introduction

Squamous cell carcinoma is the most frequent malignant tumors affecting the oral cavity, localizing mainly in the mucosa of the oral cavity. The development of this pathology is caused by several risk factors including tobacco smoking, the intake of alcoholic beverages, genetics, and also chronic traumatism.

The treatment of squamous cell carcinomas of the oral cavity involves multiple therapeutic strategies. When possible, the gold standard is resective surgery. However, it presents numerous limitations because in the head and neck regions, and even more in the oral cavity, it is necessary to include safety margins at the resection

area to achieve radicality. This could lead to significant functional damages and morphological alterations [1].

Reconstructive options for oral mucosal defects include primary closure, mucosal and split thickness skin grafts, pedicle flaps, and microvascular free transfer of tissues [2].

The main goal in the reconstruction of oral cavity defects is to ensure optimal reconstruction of the mucosa lining of the oral cavity defect and to minimize scar retractions in order to ensure phonation, nutrition, swallowing and basic activities.

Therefore, in some cases the use of dermal matrix such as Integra[®] plays a key role in the healing of small and medium-sized defects, facilitating the healing of the mucosa of the oral cavity, since it allows a more rapid restoration of normal mucous membrane, significantly decreasing the possibility of creating huge losses of substance and minimizing the presence of fibrosis and incongruous healing [3].

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Table 1
Patient demographic and clinical details.

	Number of patients	Percentage (%)
HTN	19	40.42
DM	7	14.8
History of oral cavity resection	4	8.5
History of head and neck radiation therapy	2	4.2
Cancer Type		
SCC	37	78.72
Verrucous Carcinoma	8	17.02
Adenoid Cystic Carcinoma	2	4.2
WHO Grade		
Well-differentiated	20	43
Moderately differentiated	15	33
Poorly differentiated	12	24
Oral cavity subsite		
Palate	2	4.2
Floor of mouth	13	27.65
Cheek	9	19.14
Oral tongue	23	48.93
Involvement of multiple oral cavity subsites		
Multiple subsites	2	4.2
Isolated subsites	45	95.8
Primary oral cavity malignancy		
Primary	44	93.6
Recurrence	3	6.38
Treatment		
No bone resection	45	95.8
Marginal bone resection	2	4.2
Drilling of the bone	0	0
Dental extraction		
Yes	39	82.97
No	8	17.02

The aim of this study is to analyze the morpho-functional results of the reconstruction of moderate defects of the oral cavity with Integra® membrane placed in our department after squamous cell carcinoma removal.

2. Materials and methods

2.1. Patient selection

Our study identified patients who received Integra® Bilayer Wound Matrix (Integra Life Sciences, Princeton, USA) after intraoral cancer resection (T1, T2) between January 2021 and December 2022 by a single Head and Neck (H&N) oncological surgeon at the Maxillofacial surgery department of Ancona. Study participants who had undergone skin grafts, biosynthetic mucosal substitutes, or previous free flap reconstruction of the oral cavity were not included in the study. We reviewed medical records and extracted data for all variables listed in Table 1. Medical records were analyzed to extract information on patient demographics, comorbidities, disease stage, treatment options, and surgery outcomes.

For each patient, data were collected regarding the site of the disease, the initial staging, the size of the surgical defect and the complications and the long-term outcomes. The data were collected from the department's internal database and from the Ormaweb® surgery archiving program (Dedalus, Florence, IT).

Patients were evaluated at the preoperative time, at 1 postoperative week, after 3 postoperative weeks, at 1 and at 4 postoperative months to analyze the healing process of the intraoral wounds and any complications.

In all patients the surgical procedure consisted in two phases: resection of the tumor and reconstruction. The resection of the tumor tissue was performed with macroscopically healthy margins of 1 cm (Fig. 1).

The reconstruction consisted of an Integra® sheet appropriately shaped to cover the defect and fixed with stitches to the mucosa. Transmucosal fixation was used to securely hold the graft to its receiving site. The compression was performed with Vaseline gauze which will be removed on average around the seventh post-operative day. The silicone sheet was removed 14 days after surgery. In all patients, no skin graft was added over the double-layered Integra® sheet. (Fig. 2).

Different parameters were analyzed in order to evaluate the quality of the reconstruction with Integra® of the oral cavity defects. In particular, we evaluated the difference between preoperative and postoperative opening after 6 months, the appearance of the reconstruction through an objective assessment of the colour of the internal lining, the quality of the re-mucosization and the comfort reported by the patient, the functional recovery at the level of the oral cavity (chewing, phonation and deglutition) (Fig. 3).

2.2. Follow up

After surgery, patients were asked to start an oral soft diet and return to follow-up 3 weeks later to evaluate healing, to remove the bolster and the outer layer of Integra. After that, patients were advised to follow up every 2 to 3 months depending on their healing, risk factors, and other suspicious lesions. At each clinical visit, the status of the surgical wound was assessed until full healing was reported.

2.3. Statistical analysis

Statistical analyses were performed using JMP SAS (JMP®, Version 16. SAS Institute Inc., 1989–2021). Distribution analysis was performed for all collected parameters. Pearson's χ^2 test was used to determine a correlation between patients, wound characteristics and Integra failure. A P value less than 0.05 was considered statistically significant.

3. Results

Overall, 47 cases of treatment of the oral cavity neoplasm at the Maxillofacial surgery department of Ancona Hospital, over a period of 2 years (2021 - 2022), were analyzed. Reconstruction was performed using dermal matrix substitute membrane by a single head and neck surgeon.

The mean age of treated patients is 64.7 years (ranging from 42 to 87 years old), with a male/female ratio of 3:1.

Only 6 patients had a remote pathological history positive for malignant tumors of the oral cavity and of these 3 came to our attention due to local disease recurrence. 2 patients (4.2 %) had an history of head and neck radiotherapy treatment (RT).

Histological examinations revealed that 37 cases were affected by squamous cell carcinoma (78.72 %), 8 cases by verrucous carcinoma (17.02 %), and 2 cases by adenocarcinoma (4.2 %).

Concerning the grading of the malignant pathology removed, a G1 was found in the 43 % of cases, a G2 grading in the 33 % and a G3 in the 24 % (Table 1).

The most affected site of the oral cavity by the pathology was the tongue with 23 cases (48.93 %), mainly at the right lingual border, followed by the oral pelvis with 13 cases (27.65 %), the cheek with 9 cases (19 %) and the palate with 2 cases (4.2 %).

Regarding the staging, the resected tumors had a dimension of T1 in 32 cases (68.4 %) and T2 in 15 cases (31.6 %). Clinical and radiological involvement of cervical lymph nodes and distant metastases, at the preoperative stage, was not found in any patient (all cN0 and cM0 cases).

The average size of the surgical defect obtained from the removal of the lesions was 5.45 cm².



Fig. 1. Intraoral defect before resection of a G2 squamocellular carcinoma of the tongue.

In 15 cases (33 %) a simultaneous lateral cervical lymph node dissection ipsilateral to the lesion was performed in accordance with the multidisciplinary head and neck oncological group of our hospital and in accordance with the NCCN guidelines. Lymph node histology was found to be positive in 9 % of cases with a pN of N1. The average duration of the surgery was 74.82 min. The mean hospitalization time was 5.7 days. In all cases in which laterocervical lymph node

dissemination was found, an indication was given to carry out adjuvant radiotherapy treatment.

In patients undergoing post-operative radiotherapy, no negative effect on healing of our type of reconstruction was found in the medium and long term.

Arterial hypertension was reported in 19 out of 47 cases with only 1 case of delayed intraoral wound healing in patients suffering from

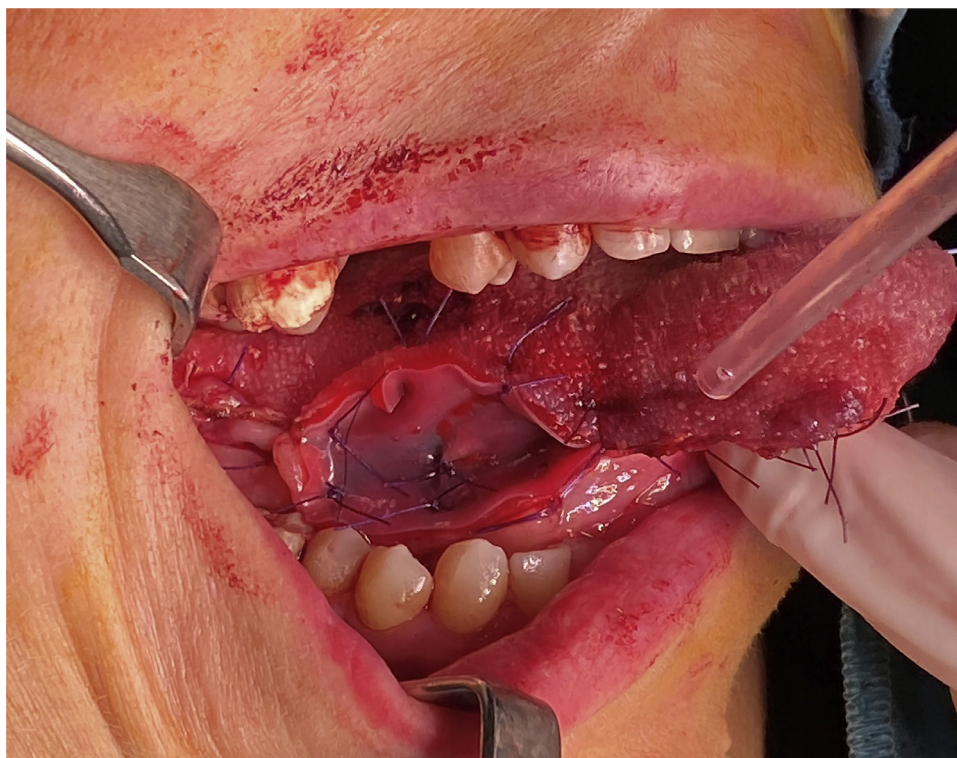


Fig. 2. Reconstruction of mucosal tongue defect with acellular dermal matrix graft.



Fig. 3. Result with complete mucosal healing, 6 month after silicone sheet removal.

this clinical condition. Diabetes mellitus, on the other hand, proved to be a significantly important factor in intraoral wound healing with 7 patients suffering from this condition and 3 of these with delayed or failed matrix engraftment.

Among the patients analyzed, 6 subjects had a history of previous carcinoma of the oral cavity and 4 of these had previous radiotherapy treatment in the head and neck area. 3 patients came to our observation for recurrence of oral cavity carcinoma. Only 2 patients presented multiple intraoral localization of the disease.

Resection of bone portions was carried out only in 2 cases at the level of the mandible; this factor did not influence intraoral wound healing. In total, 8 teeth related to the carcinomatous lesions were extracted, and delayed wound healing was found in 2 patients.

The outer layer of Integra dressing was removed on average 22 days (SD: 5 ± 2) after the first follow-up visit. In 44 patients (93%), wound healing was complete with good cellular integration.

Of the total number of patients, 2 cases (4.2%) of failure of engraftment of the Integra® membrane were found with subsequent reoperation and preparation of myomucosal flaps of the cheek to fill the surgical defect.

Of the 45 patients in whom we noted complete healing of intraoral wounds with good cellular integration, 2 patients presented delayed healing which led to complete healing after approximately 6 weeks. Poor oral hygiene and subsequent surgical site infections were the main reasons for the Integra® membrane's failure to engraft.

In 5 of the cases, we found infection of the operating site within the first week after surgery with the need to prolong the antibiotic therapy by an average of 6.45 days.

During the fourteen postoperative days there were only 5 cases of infections, dehiscences, lamina dislocations or rejection. Complete re-epithelialization of the defect was achieved approximately one month after surgery, with the exception of 2 cases which presented delayed healing and 2 cases of failure.

A study of the buccal opening difference between pre and post-surgery was performed for all 47 patients included in the present study. The mean preoperative buccal opening was 49.7 mm while the mean postoperative buccal opening, after 6 months was 47.2 mm. The patients followed a scheme of exercises aimed at preserving the buccal opening for the first 2 postoperative months consisting of forced mouth openings in 3 daily repetitions, using specific devices such as TheraBite® (Atos Medical Srl, Padova, IT.).

The majority of the patients examined achieved a buccal opening similar to the preoperative condition 3 months after surgery while in 4 cases a reduction in buccal opening was found following poor patient compliance with the medical indications for exercise and post-operative massage.

After 4 months, we observed a reduction in tongue motility in 3 patients. These patients recovered good functionality in the following months. Complete re-epithelialization of the defect was achieved approximately 4 weeks after surgery. In long-term monitoring, a minimal contraction of the scar tissue was appreciated, without causing any functional problems. During the follow-up period (clinical evaluation every 3 months with instrumental tests every 6 months), no initial process recurrences were observed.

Only the presence of a history of diabetes mellitus and previous radiotherapy treatment was associated with delayed recovery in univariate analysis: 42.85% versus 2.56% in patients with or without diabetes mellitus ($P = 0.03$) and 75% versus 2.32% in patients who had previously received head and neck radiation treatment (0.05) as shown in Table 2.

4. Discussion

Oral cavity cancer is one of the most frequently treated pathology in maxillofacial surgery departments. In fact, it occurs with an incidence of 6.4 per 100,000 patients. Specifically, the main affected areas by this pathology are the tongue, the buccal mucosa, the oral pelvis and the lips.

Lesions of the oral cavity, at the time of diagnosis, are predominantly small in size, with a prevalence of T1 and T2 staging [2].

Squamous cell carcinomas (SCC) constitute more than 90% of all oral cancer. Other malignant tumours can arise from the epithelium, connective tissue, minor salivary glands, lymphoid tissue and melanocytes or from metastasis from a distant tumour, the latter being well known to have a tendency for local, lymph node and distant aggression [4].

The reconstruction of oral cavity defects has always been an essential element of oncological surgery in the head and neck areas.

At an academic level, numerous articles have been published on the various reconstructive options of the oral cavity for each dimension, ranging from direct closure, to intraoral local flaps, to extraoral pedicle flaps and free flaps [5,6]. However, a possible reconstructive option that has not been widely taken into consideration is represented by dermal matrix substitutes such as Integra® [7].

Integra® is widely used in reconstructive surgery, mainly for small and medium sized skin defects throughout the body, either alone or with subsequent overlying skin grafting [8,9].

The idea behind this study was to exploit the properties of the dermal matrix substitute to reconstruct small and medium sized defects of the oral cavity and to avoid, when possible, the comorbidities of local, pedicled or free flaps.

In a recent review of 400 patients, an Italian multidisciplinary board recommended Integra for scalp reconstruction following ablative surgery [10]. This procedure is recommended for elderly patients whose anesthetic risk is lower, their postoperative care is less complicated, and there is less morbidity at the donor site. In addition, they emphasized Integra's advantage in reconstructing skin defects with exposed bone. According to Schiavon et al. [11], Integra® is significantly cheaper than complex microvascular reconstructions (€ 23,244 vs € 11,825) in

Table 2
Association of patient clinical data with wound healing in univariate analysis.

	Number of patients with normal healing	Number of patients with delayed healing	P values
HTN			0.14
No	25	3	
Yes	18	1	
DM			0.07
No	39	1	
Yes	4	3	
Cancer Type			0.60
SCC	33	4	
Verrucous Carcinoma	4	0	
Adenoid Cystic Carcinoma	2	0	
WHO Grade			0.73
Well-differentiated	18	2	
Moderately differentiated	15	0	
Poorly differentiated	10	2	
History of oral cavity cancer			0.09
No	38	3	
Yes	5	1	
History of head and neck radiation therapy			0.37
No	42	1	
Yes	1	3	
Involvement of multiple oral cavity subsites			0.9
Multiple subsites	2	0	
Isolated subsites	41	4	
Primary oral cavity malignancy			0.14
Primary	41	3	
Recurrence	2	1	
Treatment			0.11
No bone resection	41	4	
Marginal bone resection	2	0	
Drilling of the bone	0	0	
Dental extraction			0.68
Yes	37	2	
No	6	2	

large scalp defects (>100cm²) without compromising wound healing. It has been shown that Integra is effective in resolving surgical defects in other head and neck sites [12].

However, Integra has been limited in use in the oral cavity. As an alternative to autogenous soft tissue grafts other biological dressings, such as acellular dermal allografts, have been used in previous publications for root coverage and vestibuloplasty procedures.

The main advantages of Integra® in intraoral mucosa defects are the rapid healing process without minimal scar contraction, the graft adaptability, the reduction of surgical time and the elimination of the morbidity of other more invasive reconstruction techniques.

Moreover, Integra® can be used in a hostile environment, such as an oral cavity with poor general hygiene, without infection or destruction by germs.

Compared to other reconstructive options, such as skin grafts, dermal matrix offers a reduction in inflammation, fibrosis, and keratinization, and eliminates donor site morbidity. In all treated patients after removal of Integra® the mucosal wound was covered by granulation tissue and re-epithelialization proceed with minimal wound contraction. Intraoral healing was complete after twenty-eight days after surgery. None of the operated patients presented complications, in particular limitations to the opening of the oral cavity.

Acellular dermal matrix (ADM) also provides a matrix consisting of collagen, elastin, vascular channels and proteins that support tissue revascularization, cell repopulation, tissue remodelling for enhanced intraoral wound healing. Significant revascularization is already noticeable on average 7 days after surgery [13].

The success of dermal matrix in the oral cavity is well documented. One study used dermal matrix membranes to repair buccal, palatal, gingival, labial, sulcus, and maxillary sinus mucosal defects with 94.4 % of defects successfully replaced with new mucosa-like tissue [14].

After removal of the protective membrane and complete healing of surgical wounds, it is indicated to practice oral cavity opening exercises for six months to prevent scar contraction. Our opinion is that the daily application of forced mouth opening exercises has been very important for the management of the main results of this reconstructive technique. As a short and long-term consequence of the reconstruction of intraoral mucosal defects, a reduction in the maximum buccal opening is commonly reported in the literature [15,2].

Scar contraction is an intrinsic property of wound healing and can have significant aesthetic and functional implications at the intraoral level. For this reason, before surgery, all 47 patients examined in the present study were informed that the mouth opening exercises had to be performed with particular attention to achieve excellent results. We obtained that 4 out of 47 patients did not follow our instructions precisely reporting a reduction of the average buccal opening of about 1 cm while the remaining 43 patients recovered almost completely the buccal opening prior to the six months after surgery (Mean difference one month after surgery of 2.5 mm).

In long-term monitoring, a minimum scar tissue contraction without functional sequelae was reported only in a few cases. No complications or recurrences were observed during the first year of follow-up.

Of the total number of patients who did not achieve immediate wound healing, 2 cases of failure of engraftment of the Integra® membrane with subsequent reoperation were found and 2 patients presented delayed healing which led to complete healing after approximately 6 weeks.

Among the factors that have proven to be relevant in the healing process and above all as a cause of a possible delay or failure in the engraftment of the membrane, diabetes mellitus and previous radiotherapy treatment in the head and neck region stand out. This is explained by the fact that both of these factors negatively influence tissue blood supply by acting at the microcirculation level, the first

favouring arterial micro thrombosis and the second causing tissue fibrosis and an alteration of the vascular network of the radio-treated region.

In the cases presented by us, we did not witness any alterations in the healing of surgical wounds after placement of Integra following radiotherapy treatment (carried out in 9 % of cases). This data is probably associated with the limited sample of patients examined in the present study; furthermore, the attention that was placed on the prevention of severe scar retraction certainly had a positive influence on avoiding some of the long-term post-RT sequelae.

Following the failed Integra surgery, one of the two patients developed an infection which was subsequently healed by secondary intention. The success rate of using the Integra® bilayer wound matrix dressing in this study was 93.4 % with a statistically significant difference in the onset of failure related to prior radiation therapy in the head and neck area and the concomitant presence of diabetic pathology.

4.1. Limitations

Several limitations were present in this study. Since this is a single-center study with only one surgeon involved, selection bias clearly exists. The effectiveness of Integra® Bilayer wound matrix for oral cavity reconstruction should be better evaluated through a multicentre randomized clinical trial that includes more patients and different surgeons. Since the study was designed without a control group, the results cannot be compared with those of patients who were not reconstructed or reconstructed with skin grafts or other skin substitutes. We investigated whether the Integra® Bilayer wound matrix could be used for oral cavity reconstruction, with particular focus on its feasibility and take-up rate. An analysis of subgroups with reconstruction failure compared different risk groups. Furthermore, surgeons assessed and reported healing subjectively, and no standardized grading system was used to report scarring, tethering, or healing, which is typical of retrospective studies in general and of this study in particular. Currently, skin substitutes only replace the epidermis and dermis of the skin, without taking into account the subcutaneous fat during skin reconstruction. This represents one of their main disadvantages because it can reduce skin mobility and makes wound tethering more evident. Similar results are often observed in the reconstruction of mucosal defects.

5. Conclusions

Reconstructive surgery for oral mucosal defects due to tumor resection is a very frequent problem in maxillofacial surgery. Resection of this type of tumors can have an important impact on masticatory, swallowing and speaking function; therefore, in order to preserve these functions it is necessary to maintain the lining of the oral cavity the mobility and sensation of the tongue. As emerges from the data reported in our study, the dermal matrix represents a valid alternative in oncological reconstructive surgery for small/medium sized intraoral mucosa defects.

The simplicity of the reconstructive act using Integra®, the reduced duration of the reconstructive phase, the good restoration of functionality and the low percentage of complications are the strong points of this reconstructive option which will certainly be implemented in the future years and increasingly applied for the reconstruction of oral cavity defects.

Ethical approval

This article does not contain any studies with human participants or animals performed by any of the authors. The treatment of the presented patient was not in any way influenced due to this article.

Informed consent

The patient provided informed consent.

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Authors' contributions

All authors contributed equally to the manuscript and read and approved the final version of the manuscript.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

CRediT authorship contribution statement

Giuseppe Consorti: Visualization, Validation, Conceptualization. **Gabriele Monarchi:** Writing – review & editing, Writing – original draft, Visualization, Validation, Methodology, Investigation, Formal analysis, Conceptualization. **Mariagrazia Paglianiti:** Supervision, Formal analysis, Data curation. **Lucrezia Togni:** Validation. **Marco Mascitti:** Validation. **Paolo Balercia:** Validation. **Andrea Santarelli:** Supervision.

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