

Use of a novel sealant film in head and neck surgery

G. Tirelli^a, A. Gatto^a, S. Brancatelli^b, A. Piccinato^c, V. Longoni^a, M. Tofanelli^{a,*}

^a Department of Medical, Surgical and Health Sciences, Section of Otolaryngology, University of Trieste, Trieste, Italy

^b Clinic of Otorhinolaryngology, Azienda ULSS-4 Veneto Orientale, Portogruaro, Venice, Italy

^c Department of Otorhinolaryngology-Head and Neck Surgery, Mestre Hospital, via Paccagnella 11, 30174 Venice, Italy

ARTICLE INFO

Keywords:

Surgical defect
Surgical sealant films
Tissuepatch
Salivary fistula
Wound dehiscence
Head and neck surgery

ABSTRACT

In head and neck surgery, sealant films represent a useful adjunct to ensure a reinforcement preventing leakages, dehiscence or oozing. The aim of this pilot study is to present the potential applications of a new sealant sheet in head and neck surgery, reporting outcomes, advantages and limitations.

The sample included 32 patients, that underwent oncologic or elective surgery between January 2019 and January 2021 at the Cattinara Hospital in Trieste, Italy. Data regarding the patient, the surgical procedure and the postoperative course over hospitalization in terms of surgical complications were retrospectively collected. In this study, nor complication during the regular follow-up period occurred neither difficulties emerged in TP use in any head and neck subsites.

In our experience, TP represented a valid aid in suture strengthening, easy to apply and suitable also for oncologic surgery in which the closure of some surgical defects may need a greater sealing effect.

1. Introduction

Head and neck surgery includes a group of such different types of interventions extended from otomicrosurgery to oncologic invasive resections, encompassing surgical defects reconstructions.

Common aims are to restore a mucosal layer, to cover exposed bone or to re-establish the division between two adjacent subsites. Therefore, there is often the need to resort to a material able to reinforce sutures in that cases in which the primary tissue has been weakened.

Recently, adhesive patches have been introduced in several surgical sites by reinforcing these areas of surgical trauma, such as neurosurgery, abdominal surgery or thoracic surgery [1,2].

One type of this device is TissuePatch™ (Tissuemed, Leeds, UK) that is a transparent absorbable sealant made of bio-adhesive polymers characterized by self-adhesive properties.

In head and neck, some authors have already illustrated its use in the management of chyle leaks after major neck surgery [3], while in thyroid surgery it has been used not only to prevent leakage but also to protect recurrent laryngeal nerve and parathyroid gland from the vacuum suction drain [4,5].

We aim to present our experience in using TissuePatch™(TP) in a wide spectrum of head and neck surgery evaluating the handling

properties and the outcomes. We have tested this film to create a further barrier preventing leakage and oozing in both oncologic and elective surgery.

2. Materials and methods

In this pilot study, we collected clinical data of 32 patients who underwent head and neck surgery during which at least one TP has been employed from January 2019 to January 2021 at the Cattinara Hospital in Trieste, Italy. One or more TP were used in this group, and the sizes we have chosen were TP-02 and TP-03 that correspond to 50 × 50 and 50 × 100 mm, respectively.

We retrospectively collected data regarding the patient, the surgical procedure and the postoperative course over hospitalization in terms of surgical complications, such as suture dehiscence, wound infection or the onset of a salivary fistula.

2.1. Surgical technique

The TP application does not require any changes in the standard surgical steps. In each of these cases, the surgeon applied TP at the end of suturing process, to cover and protect the suture line. The TP placement

* Corresponding author at: Department of Medical, Surgical and Health Sciences, Section of Otolaryngology, University of Trieste, Starda di Fiume 447, Trieste, Italy.

E-mail address: mtofanelli@units.it (M. Tofanelli).



Fig. 1. Tissuepatch layer: application during lateral pharyngotomy approach in oropharyngeal cancer. TP is used to cover and reinforce the suture between oropharynx and neck.

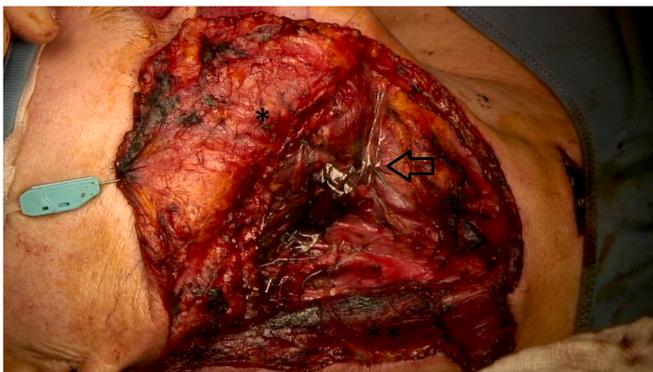


Fig. 2. After TP positioning, the film is firmly bonded to the underlying tissue. Mandible (*), Sternocleidomastoid muscle (**), bonded Tissuepatch (arrow).

requires a gentle pressure of 60 s to bond to the tissue surface and wetting TP with hyaluronic acid is advisable (Figs. 1-2).

3. Results

The sample is composed by 32 patients, 12 females and 20 males, with a median age of 54.7 years (range 34–78 years) and Table 1 summarizes clinical features of this series.

The surgical procedures during which at least one TP was used are: 7 total laryngectomies, 1 case of salvage total laryngectomy in recurrence of laryngeal cancer after radiotherapy and 1 case of revision surgery in salivary fistula occurrence after total laryngectomy; 5 myringoplasties, 9 parotidectomies, 7 cases of oropharyngeal cancer resections treated with lateral pharyngotomy approach [6] and 2 cases of revision surgery in cochlear implants.

Oncologic cases underwent conventional postoperative radiotherapy when it was recommended and we observed no complication during the regular follow-up period.

In this study, no difficulties emerged in TP positioning in any head and neck subsites. The device does not require pre-treatment and all TP were absorbed with no evidence of material-related inflammation or rejection. In one patient, a seroma occurred after a partial parotidectomy.

4. Discussion

The application of TP during head and neck surgery has the advantage to be *à la demande*, without the need to modify surgical steps or to plan to use it in advance.

This device comes in different sizes, the two types we found to be most appropriate and versatile in head and neck are TP-02 and TP-03.

Technically, we observed that the pressure of 1 min improved the bond to the tissue below, but it should be notice that this procedure is irreversible because the patch cannot be re-positioned. An overlapping patch could be added, but patch-over-patch adhesion is weaker than patch fixed directly over the tissue.

Although bleeding in the receiving sites could interfere with TP adherence, wetting TP with hyaluronic acid ameliorated the handleability and cut-ability making the film properly tailored to the receiving site [7]. In fact, we found that though TP is quite thin, if dry, it

Table 1
Summary of case series.

Nr. patients	Pathology	Surgical operation	Indications to TissuePatch™ usage	Surgical outcomes
1	Salivary fistula after total laryngectomy	Revision surgery	To protect and reinforce the suture line	No salivary fistula
1	Recurrence of laryngeal cancer treated with radiotherapy	Salvage total laryngectomy	To prevent salivary fistula occurrence in irradiated tissues	No salivary fistula occurrence
7	Laryngeal cancer	Total laryngectomy	To reinforce T-shape pharyngeal anastomosis line	No salivary fistula occurrence
5	Post-traumatic tympanic perforation of the anterior quadrants	Myringoplasty	To cover the defect of the tympanic membrane	Completely absorbed after 1 month
5	Warthin tumour	revision surgery in wound dehiscence after superficial parotidectomy	To cover the residual glandular tissue	No dehiscence neither Frey's syndrome occurrence
3	Pleomorphic adenoma	Superficial parotidectomy	To cover the residual glandular tissue	No dehiscence neither Frey's syndrome occurrence; 1 case of seroma formation.
1	Recurrence of pleomorphic adenoma	Superficial parotidectomy (re-intervention)	To cover the residual glandular tissue preventing fistula in scarred tissue	No dehiscence neither Frey's syndrome occurrence
7	Oropharyngeal squamous cell carcinoma	Surgical resection adopting the lateral pharyngotomy approach	To reinforce/seal suture plane between oropharynx and neck	No pharyngocutaneous fistula occurrence
1	Recurrent skin infections after bone-conduction hearing device implant placement	Revision surgery for pillar removal and substitution with magnetic plate	To insert an additional layer to cover the magnetic plate allowing direct suture of the skin.	Regular wound healing without scars formation.
1	Extrusion of receiver/stimulator after cochlear implant surgery	Revision surgery in cochlear implant	To cover the new receiver/stimulator preventing extrusion and favoring surgical suture of scarred skin of the scalp.	No extrusion occurred

preserves a certain rigidity making the adjustment on uneven and irregular receiving area challenging especially during pharyngotomic approaches in restricted surgical view; by contrast, the positioning resulted very easy in otosurgery and during total laryngectomy where the surgical field is usually smooth and well exposed.

In our experience, no complications related to TP use were observed, no intolerance or rejection occurred. We registered only a seroma formation in correspondence of the surgical wound after a superficial parotidectomy, and the resolution happened spontaneously.

In literature Trotter et al. [2] documented a worsening in intestinal anastomotic healing after colorectal procedure during which a TP was used to cover the anastomosis. The authors postulated that a sealant effect provided resistance to development of vascular granulation tissue. One possible explanation is that application of a patch around a fresh anastomosis precludes local adhesion formation and isolates the anastomosis [2]. This could be, by contrast, the reason why TP worked well in our cases: we were right looking for sealing achievement.

In our experience the application of TP resulted in a safe, fast and easy procedure. It became completely integrated with the target tissue without interfere with radiological follow-up, performed with both computed tomography and magnetic resonance.

The main advantage we observed is the suitability for oncologic surgery and, in that cases, the possibility to reinforce surgical defects not apt for a free flap reconstruction and involving a peculiar anatomic site that requires an additional layer over the suture to prevent fistula and infections occurrence. Moreover, it provides an immediate watertight closure able to control low pressure bleeding (see VIDEOCLIP).

In two cases the patients underwent adjuvant radiotherapy and no side effects were registered.

Aiming to generalize the indications to use TP in head and neck surgery, we can summarize that the common aim was to achieve sealing: mainly to prevent fistula occurrence and wound dehiscence; moreover, to reduce implant extrusion or pathological inter-subsites communication. Therefore, TP helped to reinforce suture line and to enhance tissue thickness for surgical closure whereby original layers are scarce/insufficient or have been damaged due to previous surgery, radiotherapy or infections.

CRediT authorship contribution statement

The authors disclose a liberal contribution between the company Tissuemed (Leeds, UK) and the University Department to which they belong.

Funding

The present work was partially supported by Tissuemed Ltd. (Leeds, UK).

Declaration of competing interest

The authors disclose a liberal contribution between the company and the university department to which they belong.

References

- [1] Zhang R, Bures M, Höfller HK, Zinne N, Länger F, Bisdas T, Haverich A, Krüger M. TissuePatch™ as a novel synthetic sealant for repair of superficial lung defect: in vitro tests results. *Ann Surg Innov Res* 2012;6:12. <https://doi.org/10.1186/1750-1164-6-12>.
- [2] Trotter J, Onos L, McNaught C, Peter M, Gatt M, Maude K, et al. The use of a novel adhesive tissue patch as an aid to anastomotic healing. *Ann R Coll Surg Engl* 2018; 100:230–4. <https://doi.org/10.1308/rcsann.2018.0003>.
- [3] Cheng L, Lau CK, Parker G. Use of TissuePatch™ sealant film in the management of chyle leak in major neck surgery. *Br J Oral Maxillofac Surg* 2014;52:87–9. <https://doi.org/10.1016/j.bjoms.2013.09.007>.
- [4] Cheng L, Thaim A, Ali S, Blanchard J, Johnston L, Leungh H, Jones A, Grant C. The use of TissuePatch™, a self-adhesive sealant film to prevent postoperative vascular leakage after thyroid surgery. *Int J Oral Maxillofac Surg* 2017;46:342. <https://doi.org/10.1016/j.ijom.2017.02.1153>.
- [5] Cheng LH, Hutchison IL. Thyroid surgery. *Br J Oral Maxillofac Surg* 2012;50: 585–91. <https://doi.org/10.1016/j.bjoms.2011.11.002>.
- [6] Tirelli G, Bertolin A, Guida F, Zucchini S, Tofanelli M, Rizzotto G, et al. Post-operative outcomes of different surgical approaches to oropharyngeal squamous cell cancer: a case-matched study. *J Laryngol Otol* 2021;135:348–54. <https://doi.org/10.1017/S0022215121000876>.
- [7] Marcuzzo AV, Tofanelli M, Boscolo Nata F, Gatto A, Tirelli G. Hyaluronate effect on bacterial biofilm in ENT district infections: a review. *APMIS* 2017;125:763–72. <https://doi.org/10.1111/apm.12728>.