Use of a novel sealant film in head and neck surgery

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\begin{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.
\end{abstract}

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 \cite{1,2}.

One type of this device is TissuePatch\textsuperscript{TM} (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 \cite{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 \cite{4,5}.

We aim to present our experience in using TissuePatch\textsuperscript{TM}(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

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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 handle-ability 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.

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

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