



Tissue sealant versus surgical drain following parotidectomy

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ABSTRACT

Purpose: Sialocele and salivary fistula are recognised complications of parotid surgery and have been reported to be more common with less extensive parotidectomy. We investigated the efficacy of tissue sealant (Cunniffe et al., 2019)¹ as an alternative to surgical drainage in terms of length of hospital stay (LOS), cost, and incidence of wound complications.

Methods: The study comprised a retrospective review of a prospectively maintained parotidectomy database at a single tertiary Head and Neck referral centre between 2009 and 2020. Cases undergoing concomitant neck dissection or major skin resection were excluded. Patients were divided into Group 1 (without tissue sealant), and Group 2 (with tissue sealant). Patients were also divided based on extent of surgery 1) Extracapsular dissection/Partial superficial parotidectomy 2) Superficial/total parotidectomy.

Results: Of 202 included patients, there were 146 in Group 1 (143 with drain), and 56 in Group 2 (7 with drain). Compared to Group 1, Group 2 had a significantly shorter LOS (mean 1.4 ± 0.98 versus 3.1 ± 1.29 days, $p < 0.05$) and estimated cost (€1386 versus €2736). There was no significant difference in the complication rates (15.8% Group 1 versus 10.7% Group 2, $p = 0.50$). Group 1 showed a higher incidence of complications in patients undergoing less extensive parotidectomy (19/70 versus 4/76, $p = 0.02$), whereas in Group 2, the difference was not significant (5/30 versus 1/26, $p = 0.20$).

Conclusion: The use of tissue sealant as an alternative to surgical drains after parotidectomy facilitates reduced LOS and cost savings without increase in morbidity.

Level of evidence: 3.

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Introduction

Reported surgical complications after parotid surgery include facial nerve paresis/paralysis, haematoma, sialocele, fistula formation, numbness, contour change and Frey's syndrome. Of these, sialocele and salivary fistula are thought to be due to continued salivary secretion by non-resected salivary tissue in the postoperative period.^{2,3} Although generally self-resolving within 6 weeks, they may be a source of patient anxiety and distress during this period, as well as predisposing to risk of secondary infection. Paradoxically, sialocele and salivary fistula appear to occur with greater frequency with less

extensive parotid surgery. In a previous paper, we reported a higher incidence of these wound complications among patients undergoing less extensive surgery.⁴ However, less extensive parotidectomy confers other benefits onto patients, including lower risk of facial nerve paresis, numbness, and less disruption to facial contour.

In order to minimize the risk of such complications, use of drainage after parotidectomy for anything between 1 and 3 postoperative days, depending on the amount of drainage and local practice, is commonly employed.^{5,10} The use of a surgical drain helps facilitate adherence of the skin flap to the surgical bed which in most patients can prevent these complications. However, use of a surgical drain carries morbidity and in

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many healthcare systems necessities hospital admission, with the added economic costs associated with this.⁶

Fibrin glue tissue sealant is being increasingly used across a number of surgical specialities including craniofacial surgery, aesthetic as well as otolaryngologic surgery.⁷ Fibrin sealants combine human thrombin and fibrinogen in combination with antifibrinolytic inhibitors to delay clot degradation and aid in haemostasis helping initiate the final anticoagulation pathway helping mechanically oppose tissue surfaces. The predominant tissue sealants in use are Artiss (Baxter, CA, USA) and Tisseel (Baxter, CA, USA). The lower concentration of thrombin in Artiss (4.5 IU) versus Tisseel (500 IU) makes Artiss an adhesive rather than a haemostat, providing the surgeon with up to 60 s to position skin flaps prior to fixation.⁸ When applied to parotid surgery, tissue sealant may promote early adherence of the skin flap to underlying tissue, and potentially obviate the need for a surgical drain.^{9,10} Theoretically, this may also reduce the risk of sialocele and salivary fistula.

The objective of this study was twofold: First, we wished to study the impact of use of tissue sealant (Artiss) on incidence of wound complications and hospital stay following parotid surgery. Secondly, we wished to investigate whether use of tissue sealant can offset the previously reported increased risk of wound complications with less extensive parotidectomy.

Methods

The present study comprised a retrospective study of consecutive patients undergoing parotidectomy at the South Infirmity Victoria University Hospital (SIVUH), Cork, over an 11-year period between January 2009, and May 2020. Patients were identified by review of a prospectively maintained database of parotid surgeries performed by the senior author.

Inclusion criteria were patients undergoing parotid surgery during the study period. Exclusion criteria were concomitant performance of neck dissection, skin resection, temporal bone resection, or flap reconstruction, as it was considered these patients would require wound drainage irrespective of use of fibrin sealant. Patients undergoing concomitant cervical lymph node excision biopsy, or highly selective dissection of lymph nodes in level II only, were eligible for inclusion.

Clinical data for the study was obtained by review of the database and patient charts. Data prospectively recorded on the parotid database included demographic details, preoperative radiological findings, pathology, type of surgery performed, use of drain, use of tissue sealant, and wound complications. This information was generally entered on the day of surgery and updated after patients' follow-up clinic visits with results of histology and occurrence of any wound complications. Data regarding length of hospital stay and re-admission was obtained by review of the Citrix (Fort Lauderdale, FL, USA), in-patient management system.

In the initial period of the study, all patients with parotidectomy underwent drain insertion, and stayed in hospital until drain removal. Drains were generally removed when drainage was <25 ml in a 24-h period. Around 2017, we switched to using Artiss fibrin sealant (Baxter, CA, USA) after surgery, without use of a drain. Artiss was applied using the

pneumatised spray system ensuring complete coverage of wound flaps which were then lowered over the surgical bed and pressure applied for 2 min to allow polymerisation as per the manufacturers guidelines. Patients not undergoing drainage were sent home the day following surgery as long as there were no early wound complications. Patients were discharged with instructions to contact ENT if they developed any wound swelling or wound leakage in the postoperative period. Patients were generally followed up in the out-patient clinic 2–3 weeks after surgery, at which time enquiry was also made regarding occurrence of any wound complications.

Patients in the present study were divided into 2 groups. Group 1, who underwent parotidectomy without use of fibrin sealant, and Group 2, who underwent parotidectomy with use of fibrin sealant. Sialocele was defined as a collection of fluid in the wound in the postoperative period, which was clinically palpable, and confirmed by aspiration. Sialoceles were generally treated by serial aspiration and pressure dressings, until resolution, as appropriate. Salivary fistula was defined as leakage of saliva through suture line while eating and was generally treated with use of pressure dressing while eating.

Extent of surgery was defined as follows: Extracapsular dissection (ECD) was removal of parotid tumour without formal identification of main trunk of facial nerve; partial superficial parotidectomy (PSP) was removal of parotid tumour with identification and dissection of main trunk and one division (upper or lower) only of facial nerve; superficial parotidectomy⁵ was removal of superficial parotid gland with identification and dissection of main trunk and both divisions of facial nerve, and total parotidectomy (TP) was removal of superficial and deep parotid gland. For cases undergoing ECD, the practice of the senior author was to excise parotid fascia in the vicinity of the tumour, without any attempt to re-oppose the fascial edges. For the purpose of the surgery, less extensive surgery was considered to include cases of ECD and PSP, and more extensive surgery cases of SP and TP.

Length of hospital stay was defined from the day of surgery to the day of discharge. Where patients were admitted to hospital the day before surgery for any reason, this was not included in the length of stay. Estimated costs of procedures were calculating using the average cost per inpatient stay per night; the cost of an AMSINO AMSURE® surgical drain (1/8") and cost of 1 unit of 2 ml Artiss.

Statistical analysis was performed using IBM, SPSS statistics version 25. Data was analysed with an independent sample t-test for independent means and Fisher's exact test for categorical values, with a significance level of $p < 0.05$.

This study was approved by the clinical research ethics committee of the Cork teaching hospitals.

Results

During the study period 279 patients underwent parotid surgery. 77 were excluded due to due to concomitant neck dissection and/or lateral temporal bone resection (18), partial mandibulectomy (5), or pinnectomy/major skin resection (25). The final study population thus consisted of 202 patients. 146 of these did not have tissue sealant and comprised group 1. 56 patients had tissue sealant and comprised group 2. 143/146

Table 1 – Clinical features of Group 1 (no tissue sealant) versus Group 2 (with tissue sealant).

		Group 1 (n = 146)	Group 2 (n = 56)	p-value
Mean Age (range)		51.4 (9–86)	50.4 (13–85)	0.16
Gender (Female:Male)		80:66	36:20	0.27
Median lesion size (range) (mm)		22 (5–56)	20 (4–52)	0.22
Histology	Pleomorphic	85 (58.2%)	38 (67.9%)	0.21
	Warthin's	29 (19.7%)	5 (8.9%)	0.06
	Other Benign	26 (17.8%)	5 (8.9%)	0.12
	Malignant	6 (4.1%)	8 (14.3%)	0.02
Extent of surgery	Extracapsular dissection	34 (23%)	20 (36%)	0.07
	Partial superficial	34 (23.3%)	7 (12.5%)	0.05
	Superficial/Total	78 (53.4%)	29 (51.8%)	0.96
	Total	146	56	
Mean (median) length of hospital stay		3.1 (3)	1.4 (1)	<0.01
Wound Complications	Haematoma	1	0	>0.99
	Sialocele	15	4	0.79
	Fistula	7	2	>0.99
	Total	23 (15.8%)	6 (10.7%)	0.50

Table 2 – Incidence of complication according to extent of surgery.

	n = 202	Haematoma	Sialocele	Fistula	Total
Drain	n = 146				
Extracapsular dissection/Partial superficial parotidectomy	70	0	14	5	19 (27%)
Superficial/total parotidectomy	76	1	1	2	4 (6%)
p-value					p = 0.02
ARTISS	n = 56				
Extracapsular dissection/Partial superficial parotidectomy	30	0	4	1	5 (17%)
Superficial/total parotidectomy	26	0	0	1	1 (4%)
p-value					p = 0.20

patients in Group 1 had a surgical drain, versus 7/56 in Group 2 ($p < 0.01$). There were more malignant cases in Group 2. Otherwise, there were no significant differences in age, gender, lesion size, or extent of surgery between both the groups (Table 1).

There was a significant reduction in length of stay (days) in the group 2 (Group 2: Mean 1.4 ± 0.98 , Group 1: Mean 3.1 ± 1.29 , $p < 0.01$). There was no significant difference in incidence of wound complications between Group 1 (23/146, 15.8%) and Group 2 (6/56, 10.7%) ($p = 0.50$) (Table 1).

We then examined incidence of wound complications according to extent of surgery performed within each of Group 1 and Group 2. Within group 1, there was an increased incidence of wound complications in patients who underwent less extensive surgery (ECD/PSP) than those undergoing more extensive surgery (SP/TP) (19/70 versus 4/76, $p = 0.02$). Among Group 2, the difference was not significant (5/30 ECD/PSP versus 1/26 SP/TP, $p = 0.20$) (Table 2).

The average cost per patient stay per night at our institution was calculated at €878. The cost of a surgical drain was €14.80 and, and that of 1 unit of 2 ml Artiss was €157. Taking these costs into account the average cost per patient for Group 1 was €2736 versus €1386 for Group 2 (Table 3).

Discussion

In the present study, we report a significantly reduced need for surgical drainage and shorter hospital stay among patients in

Group 2, with use of tissue sealant. There was no significant difference between the groups in incidence of wound complications. These findings would appear to support a role for tissue sealant as a means for avoiding drains, and shortening hospital stay, among patients undergoing parotidectomy.

Sialocele and salivary fistula typically have onset 1 or 2 weeks after parotid surgery and are usually self-resolving within 6 weeks. For this reason, they are often under-reported in the literature. However, they may be a source of distress anxiety to patients in the post-operative period. Wax & Tarshis in their 10 year review of parotidectomy patients reported an overall incidence of 14% for sialocele or fistula formation, while Laskawi et al. identified persistent parotid fistula in 4% of parotidectomy patients.^{11,12} These findings are consistent with those of the present study where we found an overall incidence of fistula or sialocele rate of 12.4%.

In order to minimize incidence of wound complications after parotidectomy, surgical drains have been commonly used. However, in many healthcare systems, including our own, presence of a drain necessitates in-patient stay. Mofle et al. in their review of 96 superficial parotidectomies identified a median length of stay of 2 days (min 1, max 3).¹³ The potential benefit of avoiding need for surgical drainage with tissue sealant prompted us to change our practice in 2017 towards use of tissue sealant without drain after parotidectomy.

These findings are consistent with those of previous authors. In a retrospective review of 34 patients, 17 who had Artiss and 17 drains, Cunniffe et al. reported a significant

Table 3 – Cost breakdown drain v ARTISS.

	Group 1	Group 2
Mean length of stay (days)	3.1	1.4
Cost (euro)		
Drain (1 × 1/8")	14.1	
ARTISS (1 × 2 ml unit)		157
*Cost per inpatient stay	2722	1229
Total	2736	1386

* Mean Hospital Stay × Average cost per inpatient stay per night.

reduction in length of hospital stay in the Artiss group with no difference in complications rates.¹ Maharaj et al. in their randomised trial of 60 patients in whom Tisseel, an alternative to Artiss, was used with a surgical drain finding found a reduction in mean total drainage volume and frequency of post-operative seroma compared to the control.¹⁴ Chudek and colleagues in their retrospective prospective analysis of 29 patients who underwent parotidectomy with Artiss and no drain found a reduced incidence of wound complications compared to the control group (n = 31) who had a surgical drain, however, the authors acknowledge that a larger prospective study is needed.¹⁵ Chorney & Ryan, showed no significant difference in wound complications with respect to seroma, sialocele, abscess or haematoma formation with the use of fibrin sealant.¹⁶ Similarly, Duffin et al. in their review of drainless day case parotidectomy surgery looked at superficial parotidectomy and reported comparable rates of complications in those with tissue sealant alone as well as reduced length of stay.¹⁷

The present study, which includes the largest number of cases undergoing tissue sealant reported thus far in the currently published literature, adds further support to the findings of these previous studies.

Besides clear benefits to the patient, shortened hospital stay should intuitively lead to cost savings for healthcare providers. In the present study, we also attempted to additionally quantify the estimated cost saving for our healthcare system. We estimated a saving of €1350 per case, which represents a significant financial benefit to our hospital. A shortened hospital stay also provides additional benefits in the present climate of global infectious disease pandemic by reducing social interactions with healthcare providers and other patients. We did not take into consideration the costs of complications including return hospital visits, but as there was no significant differences between the groups, it is probably reasonable to assume that these were equivalent.

Our second objective was to investigate whether the use of tissue sealant offset the previously reported increased risk of wound complications among patients undergoing less extensive parotid surgery, attributed to the presence of a greater volume of residual salivary tissue, which is stimulated to secrete when eating. We previously reported a paradoxically higher incidence of wound complications among patients undergoing less extensive parotidectomy (ECD or PSP) than among patients undergoing more

extensive surgery (SP or TP), despite use of drain in nearly all patients in both groups.⁴ Among the present series, the increased incidence of wound complications with less extensive surgery in Group 1, without tissue sealant, was confirmed. In contrast, among Group 2, with tissue sealant, the difference in wound complications according to wound complications was not significant. However, the number of events in Group 2 was quite low, so we may well have been underpowered to detect a significant difference. It is notable that there was a higher incidence of wound complications among patients undergoing ECD/PSP (17%) than SP/TP (4%) in Group 2, even with the use of tissue sealant, although not reaching statistical significance. Among all patients undergoing ECD/PSP, those in Group 2 (17%) had a lower incidence of wound complications than those in Group 1 (27%), however, again, this was not significant. Therefore, while there may well be a trend for tissue sealant to offset the increased risk of wound complications among patients undergoing less extensive surgery, we are not able to confirm this in the present study.

Limitations

Limitations of the present study include the fact that despite being drawn from a prospective database, it was nevertheless retrospective. Thus, although we had a full dataset for all the surgical data, we cannot rule out the possibility that some complications may have been missed due to the database not having been updated. We did review patient charts to ensure there were no cases of documented complications that were not captured by the database. It is also possible that some complications occurred after the patient's outpatient appointment with us, and thus not brought to our attention. There is also the possibility of selection bias within the cohort, however, the risk of this is likely minimized by inclusion of all consecutive patients undergoing surgery who met the inclusion criteria. Finally, facial weakness was not included among study complications.

However, while salivary fistula and sialocele may last up to 6 weeks, most cases will have onset within the first 2–3 weeks, and patients were given instructions to contact us if any symptoms developed after this time. A further limitation was despite this series having the largest number of patients undergoing tissue sealant reported to our knowledge thus far, this number is still quite low, and our study was likely underpowered to detect any reduction in incidence of complications with use of fibrin sealant. On the other hand, advantages of this study include the prospective recording of data and the complete data available for all patients.

Conclusion

The use of tissue sealants such as Artiss represent an effective alternative to a surgical drain following parotidectomy, resulting in a significant reduction in length of hospital stay

and cost savings. It is possible that tissue sealants may also offset the increased risk of wound complications associated with less extensive surgery, or at least reduce the risk of wound complications relative to those not undergoing tissue sealant, however, our study was underpowered to draw firm conclusions regarding same.

Declaration of competing interest

None of the authors have any conflicts of interest to disclose.

Ethics approval

This research received ethical approval from the Cork Clinical Research Ethics Committee of University College Cork.

Consent to participate

Not required in this retrospective study.

Consent for publication

All authors give consent for publication.

Availability of data and material

All data presented in manuscript.

Code availability

Not applicable.

Authors contributions

Nicholas A. O’Keeffe: Data collection and analysis. Paper write up.

Catherine Brophy: Data collection. Critical edit of paper prior to submission.

Patrick Sheahan: Conceived subjected for study, maintenance of parotid surgery database. Conceived and designed statistical analysis. Review and critique of paper prior to submission.

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