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HEAD & NECK

Drain-free parotidectomy: a pilot study using ARTISS fibrin sealant

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Abstract

Purpose Parotidectomy is the definitive procedure for diagnosis and treatment of most parotid masses but, due to the risk of haematoma and seroma formation, has traditionally included a drain. The drain itself comes with its own risks and, in most hospitals, the need for overnight admission, which has significant cost implications (Mallon et al. Ann R Coll Surg Engl 95(4):258–262; 2013). Fibrin glue, with its haemostatic and adhesive properties, reduces the risk of collection or haematoma and therefore may negate the need for a drain. This is the first study to look at the use of ARTISS as an alternative to drains in parotidectomy.

Methods We performed a retrospective study of all the patients who underwent a partial parotidectomy over a 4-year period from 2014 until 2018 under the same senior surgeon. Patients were divided into those that had a drain and those that had ARTISS. Their operative record, inpatient notes and clinic letters were reviewed to record information regarding length of stay, histology, complications and recurrence.

Results A total of 34 patients were identified; 17 ARTISS and 17 drain patients. We showed that the mean length of stay improved significantly from 1.6 days with the drain to 0.5 days with ARTISS (Fig. 1) but without a difference in complication rate (Fig. 2), which was 5/17 (29%) in each group.

Conclusions In conclusion, parotidectomy can be undertaken safely as a day-case procedure with the application of ARTISS. This new approach to parotid surgery not only offers less morbidity for patients but also positive financial revenue for public health institutions.

Keywords Parotidectomy · Fibrin · ARTISS · Drain · Day-case

Introduction

Parotid masses have a 25% risk of being malignant and parotidectomy is the definitive diagnostic and curative procedure for most of these [1]. Due to the well-vascularized parotid bed and the risk of salivary leakage from an incised parotid, postoperative management of parotidectomies have traditionally included a drain. A surgical drain in many institutions is an indication for inpatient stay. It is also associated with risks such as infection, pain, fistula formation and drain failure secondary to obstruction [2].

More recently, the introduction of fibrin glue or sealant has mitigated the use of a surgical drain. Fibrin glue mirrors the final common pathway of the coagulation cascade, thereby facilitating haemostasis and the close apposition of surfaces, giving reduced potential space for collections and improved cosmesis. It has been used in a wide variety of surgeries including liver lacerations in paediatric surgery [3], hepatic resections [4], urology [5], cardiothoracic surgery

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[6], and neurosurgery [7]. It is also increasingly being used in head and neck surgeries such as neck dissections and thyroidectomies. However, only six papers have investigated the use of fibrin glue in parotidectomies [8–13], all of which have used Tisseel, and only three of these have studied whether this can be used as a replacement for the surgical drain [11–13].

In this pilot study, the authors aim to investigate the plausibility of using ARTISS in facilitating day-case parotidectomies as well as evaluate the safety and complications associated with ARTISS. Successful day-cases would not only have important positive implications for the care of patients but also confer significant economic benefit especially to a public funded health institution.

Materials and methods

We performed a retrospective study of all the patients who underwent superficial parotidectomy over a 4-year period from 2014 until 2018, performed by one consultant surgeon. There was a change in practice from using surgical drain to drain-free procedures using ARTISS only from 2017 onwards.

The patients were therefore divided into 2 groups; those that had a surgical drain and those that had ARTISS fibrin glue (without drain). The drain patients would all stay in hospital until the drain was removed; the criteria for removal was < 30mls output over 24 h.

All consecutive patients before and after the change in practice were included. No other changes in technique, instrumentation, or procedure were made throughout the study period.

Their operative record, inpatient notes and clinic letters were reviewed to record information regarding length of stay, histology, complications and recurrence. The median follow-up period was 47 days with a range of 21–663 days.

ARTISS application technique

Once the lesion has been fully excised and the parotid bed is ready for closure, the ARTISS syringe set including applicator should be prepared as per the manual instruction. The parotid bed should be as dry as possible. ARTISS should be applied in a thin and even manner across the bed. Once all areas have been covered, the skin or superficial muscoloaponeurotic system (SMAS) flap should be replaced within 60 s. The flap should then be hold in the desired position by gentle compression for at least 3 min to ensure that the fibrin glue sets properly and adheres firmly to the underlying tissue [14]. When suturing is performed, great care should be taken to ensure there is no excessive pull or retraction as this could potentially cause the flap to dehisce from the underlying tissue.

Results

Overall, 34 patients were included in the study. 17 of them had ARTISS and the other 17 had surgical drains. The median age of the ARTISS group was 49 (range 28–75) and the median age of the drain group was 58 (range 33–76). There were 11 females and 6 males who had ARTISS compared to 9 females and 8 males who had a drain. The median size of the parotid mass was 14.7 cm^3 in the ARTISS group compared to 24.8cm^3 in the drain group. There was no statistically significant difference between the two groups. See Table 1 for comparison.

The histology identified one mucoepidermoid carcinoma and one Mantle cell lymphoma in the ARTISS group and one follicular lymphoma in the drain group but all other histology was benign.

47% (8/17) of the patients whom ARTISS was used on were able to go home on the same day of the procedure (Fig. 1). They were discharged home on the same day if they met the criteria as per the British Association of Day Surgery [15]. The 9 patients who stayed in overnight did

Table 1 Comparison of ARTISS vs Drain patients. The only statistically significant difference was length of stay

	ARTISS	Drain	*P* value
Median age (range)	49 (28–75)	58 (33–76)	
Mean age	52.4	59.2	0.20 (*t* test)
Gender	11F, 6 M	9F, 8 M	0.33 (CHI squared test)
Median lesion size (cm^3)	14.69	24.75	
Mean lesion size (cm^3)	17.5	39.2	0.13 (*t* test)
Histology–malignant	2/17 (12%)	1/17 (24%)	0.30 (CHI squared test)
Mean duration of surgery (minutes)	112	119	0.43 (*t* test)
Mean length of stay (days)	0.52	1.64	**0.00014 (*t* test)**
Complication rate	5/17 (29%)	5/17 (29%)	0.59 (CHI squared test)

Bold indicates statistical significance

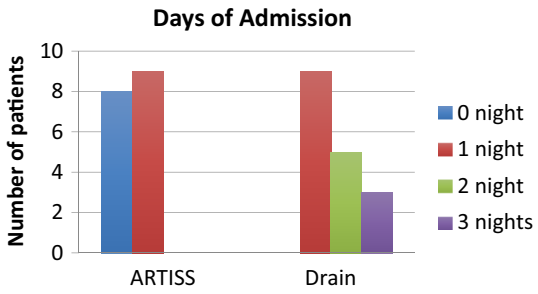


Fig. 1 Comparison of duration of inpatient stays between ARTISS group and drain group

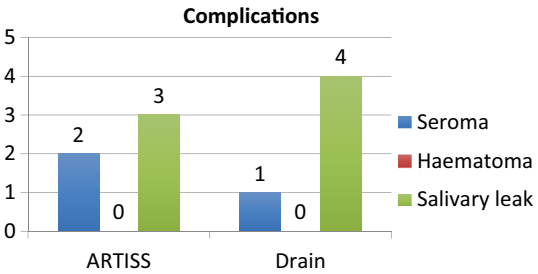


Fig. 2 Comparison of complications between ARTISS group and drain group

so due to a late afternoon finish (after 16:00), living more than 30 min from the hospital or not having an appropriate social situation at home. The average length of stay was 0.52 days. In contrast, patients who had a surgical drain inserted, had a minimum hospital stay of at least 1 day. The average length of hospital stay in this group was 1.64 days (range 1–3 days). A graph of length of stay against time is also included (Fig. 2).

When an unpaired *t* test was performed, the two-tailed *P* value was 0.00014. The Cohen's *d* and Hedges' *g* value for the study were both 1.68. Given the small numbers of the study, a power analysis was also performed. This showed that study has 80.0% power to detect an effect size of 0.658.

Operative time was a little less in the ARTISS patients, with a mean time of 112 min compared to 119 min in the drain patients, but this difference was not found to be significant.

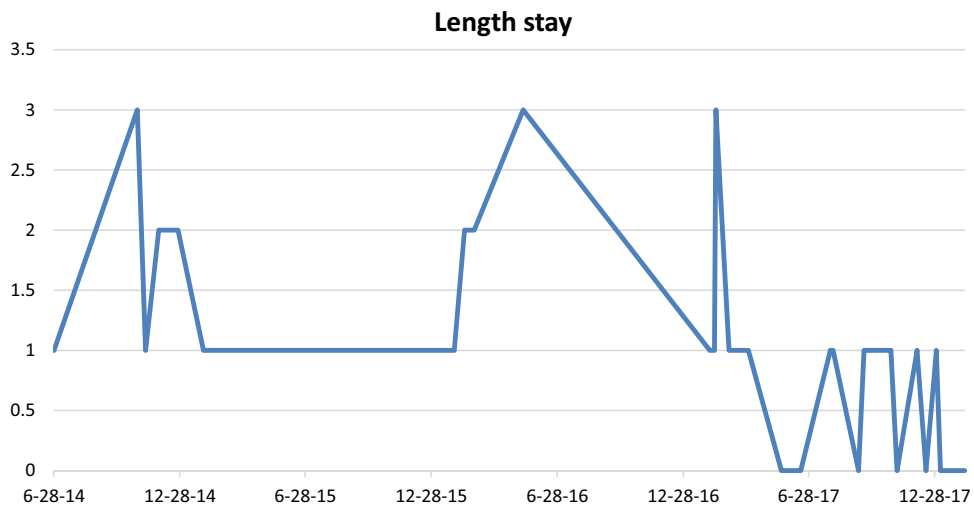
In terms of complications, the numbers were comparable in both groups (Fig. 3). There were 3 (17.6%) incidences of salivary leak and 2 (11.7%) seromas in the ARTISS group and 4 (23.5%) incidences of salivary leaks and 1 (5.8%) seroma in the surgical drain group. All the complications resolved during long term follow up.

Discussion

ARTISS was the first fibrin glue approved by the Food and Drug Administration to be used in facelifts in 2011. It consists of human thrombin, human sealer protein concentrate, synthetic fibrinolysis inhibitor solution (aprotinin) and calcium chloride solution. The low concentration of thrombin (4.5 IU) makes ARTISS an adhesive more than a haemostat [16].

The use of surgical drains was first described by Hippocrates [17]. They are universal in all types of surgery. However, they do come with risks such as infection, pain, dislodgement, subsequent fistula formation and drain failure secondary to obstruction. Research has shown that surgical drains cause a significant increase in patient pain and anxiety and a reduction in comfort post-operatively, based on self-assessment scores [18]. In contrast, fibrin sealant such as ARTISS does not carry the risk of physical pain, dislodgement, drainage failure or fistula formation. No infection or collection had been reported from our ARTISS study group.

Fig. 3 Graph of length of stay against time



A randomized, controlled study showed that adding fibrin glue (Tisseel) to the standard of care (including drain) in parotidectomy significantly reduced drainage volumes from a mean of 65.3–41.3 mls and significantly reduced postoperative seroma rates from 22.7 to 3.6% [8]. From our study, there were 2 incidences of seroma and 3 incidences of salivary leak in the ARTISS group. It is the authors opinion that perhaps the uneven use of fibrin sealant across the parotid bed could cause less adherence in some areas, therefore predispose to seromas and salivary leaks. Another theory is that the lack of manipulation time before polymerization and inadequate compression time could render the flap not to adhere and set properly. It is also noted that, the solidified fibrin sealant only reaches its final strength 2 h after application and this should be something all users should bear in mind [14]. We could not identify any cause for the increased fluid but noted that other factors that theoretically may affect seroma formation did not differ significantly between the groups. For example, 4/17 (23.5%) of the drain patients were suffering from hypertension compared to 6/17 (35.3%) of the ARTISS group. Similarly, surgical technique including raising of the flap, dissection and method used to identify the facial nerve were the same for both groups.

From a cost point of view, ARTISS costs about £165.75 per patient compared to £30.49 for a Blake's drain and bottle in our institution. However, this cost is more than offset by reduced hospital stay. The UK national tariff payment system estimates the cost of an excess bed day on a surgical ward in 2018/2019 to be £241 per night [19], and as our study showed an average decrease in length of stay from 1.6 to 0.5 days with ARTISS, this equates to an average saving of £265.10 per patient.

In the literature, two prospective cohort studies have shown another fibrin sealant (Tisseel) to be effective in facilitating drain-free parotidectomies. A study of 21 patients identified no major surgical complications and only one patient requiring overnight admission for nausea [11]. Another study of 10 patients identified two complications, both temporary facial nerve palsies, and all patients were discharged after one nights planned admission [13]. A prospective randomized case control study of 70 patients showed that there was a significant reduction in the average length of stay from 2.3 days in the drain group to 1.1 days in the Tisseel group. In addition, there was no statistically significant difference in complication rates between patients who had a surgical drain and patients for which Tisseel fibrin sealant was used followed by a pressure bandage for 12 h [12].

Limitations

This is a small single-centre study looking at the operations performed by one consultant surgeon. It would be helpful to perform a larger multi-centre study looking at intra surgeon variability. Furthermore, this is a retrospective study with variation between the two patient groups so it would be beneficial as a next step to perform a prospective study better controlling for demographic variables including age, gender and size of mass. This study selected patients based on chronology, and therefore the last drain patients were compared to the first ARTISS patients. To improve upon this a randomized study should be performed although only the outcome assessor could be blinded. Finally, while this study was focused on superficial parotidectomies, it would also be interesting to study if ARTISS could be beneficial in total parotidectomies.

Conclusions

Albeit the small numbers in our pilot study, it has shown that ARTISS can be used safely in day-case superficial parotidectomies. It is cost effective and offers a number of advantages over surgical drain. It does come with technical drawbacks subjectively (appropriate application) and objectively (time factor). It is however still a useful addition to the armament of options available to close wounds in parotid surgery. It would therefore be interesting to look at the longer-term outcomes and in a larger patient cohort in the future.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval This article does not contain any studies with human participants or animals performed by any of the authors. Informed consent not required.

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