

# Fibrin Sealants in Facial Plastic Surgery: A National Database Analysis of Complication Risk

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## Abstract

**Objective.** Fibrin sealants (FS) are gaining popularity in surgical practice. However, limited data exist for most facial plastic surgical (FPS) procedures.

**Study Design.** Retrospective cohort.

**Setting.** The TriNetX Research Network.

**Methods.** The TriNetX national database was utilized to identify patients that underwent select FPS procedures. Cohorts included one group with FS recorded on the same day as the procedure, and another without. Demographics, comorbidities, and postoperative complications were investigated.

**Results.** A total of 550,777 patients underwent an FPS procedure, 600 patients with FS and 550,177 without. There was no difference in the rate of overall complications between groups (adjusted odds ratio [aOR] 0.92, [0.71-1.2],  $P = .54$ ), with adjustment for age, race, ethnicity, marital status, nicotine use, and anticoagulation. However, higher rates of postoperative wound disruption (aOR 1.63, [1.14-2.33],  $P = .008$ ) were seen in the FS group. Patients in the FS group had higher rates of nicotine use (12.7% vs 8.7%,  $P < .001$ ) and anticoagulation (39.2% vs 27.7%,  $P < .001$ ) overall. Subanalyses by procedure found increased rates of any postoperative complications for those with FS (aOR 1.51, [1.01-2.24],  $P = .044$ ) in patients receiving regional flaps. There were no significant differences in postoperative complications between groups in patients receiving grafts, rhinoplasty, or rhytidectomy.

**Conclusion.** There were no differences in the rates of having any complications between groups overall. Patients receiving regional flaps and grafts experienced more complications. There were no significant differences between groups in patients receiving grafts, rhinoplasty, or rhytidectomy. Surgeons may consider utilizing FS for FPS procedures when appropriate.

## Keywords

facial plastic surgery, fibrin sealant, graft, implant, rhinoplasty, rhytidectomy

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Fibrin sealants (FS) promote hemostasis, aid in graft neovascularization, and reduce dead space.<sup>1</sup> This is achieved due to the ability of a fibrin sealant to thoroughly coat and adhere the entire surface of the graft to the wound.<sup>2</sup> They are made of virus-inactivated human fibrinogen, thrombin, and some have additional components such as bovine aprotinin, which are mixed to stimulate clot formation and coagulation.<sup>3</sup> FS mimic the last step of the coagulation cascade but are still effective in patients with coagulation defects because clot formation with these sealants can bypass prior steps of the coagulation cascade.<sup>4</sup> Recent studies have shown FS to have added benefits such as reducing the need for dressing changes or drains, increasing patient satisfaction and convenience, and reducing pain.<sup>5-7</sup>

FS are gaining popularity in surgical procedures with the first report of fibrin sealant use in facial plastic surgery (FPS) dating back to 1988.<sup>8</sup> Reports of its use comment on its utility in minimizing venous bleeding, oozing, drain output, and even capillary arterial bleeding.<sup>3,8</sup> However, its use in FPS in reducing postoperative complications such as hematoma, seroma, or wound infection has not been well studied. Much of the existing research has focused on the use of FS in rhytidectomy,<sup>9-12</sup> with little data on other surgeries such as rhinoplasty or regional

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flaps. Postoperative hematoma is one of the most common complications of rhytidectomy and rhinoplasty and can lead to pain, swelling, and eventual necrosis.<sup>10</sup> Our study aimed to determine the efficacy of the FS on reducing postoperative complications in patients who underwent FPSs.

## Methods

The TriNetX database was queried using Current Procedural Terminology (CPT) codes to identify patients that underwent FPSs, including rhinoplasty, rhytidectomy, regional flaps, and grafts/implants. Two cohorts were created. One cohort contained patients with a fibrin sealant Healthcare Common Procedure Coding System (HCPCS) code (C9250) recorded in their chart on the same day as the procedure, and the other cohort included patients without any documentation of fibrin sealant use. It is important to note that one HCPCS is used for all FS, regardless of the formulation and brand. Demographics and comorbidities, including diabetes mellitus, anticoagulant use, bleeding and clotting disorders, as well as smoking and alcohol use, were collected using the International Classification of Diseases 10 (ICD-10), HCPCS, and CPT codes. All codes used are included in Supplemental Table S1, available online. Rates of postoperative complications including sepsis, surgical site infection (SSI), hemorrhage, hematoma/seroma formation, and wound disruption were analyzed 0 to 30 days following surgery. A separate analysis was conducted for each type of surgery.

Demographic and clinical characteristics were summarized using means and standard deviations for continuous variables and counts and percentages for categorical variables. These measures were compared between those with and without FS using two-sample *t*-tests and chi-square tests. The factors that were significantly different between FS groups were chosen for inclusion as covariates in the multivariable modeling of the outcomes. Each outcome was analyzed using multivariable logistic regression, and results were reported in terms of adjusted odds ratios (aORs) and 95% confidence intervals. A secondary analysis was performed evaluating the same multivariable logistic regression models for each procedure type separately. All statistical analyses were performed using SAS version 9.4 (SAS Institute Inc), and statistical significance was defined as  $P < .05$ .

TriNetX is a global federated health research network providing access to electronic medical records (diagnoses, procedures, medications, laboratory values, and genomic information) from large health care organizations (HCOs). Any data displayed on the TriNetX platform in aggregate form or any patient-level data provided in a data set generated by the TriNetX platform are deidentified per the deidentification standard defined in section 164.514(a) of the HIPAA privacy rule. This study was exempted by the Penn State Institutional Review Board review (STUDY00018629).

## Results

### Demographic Information

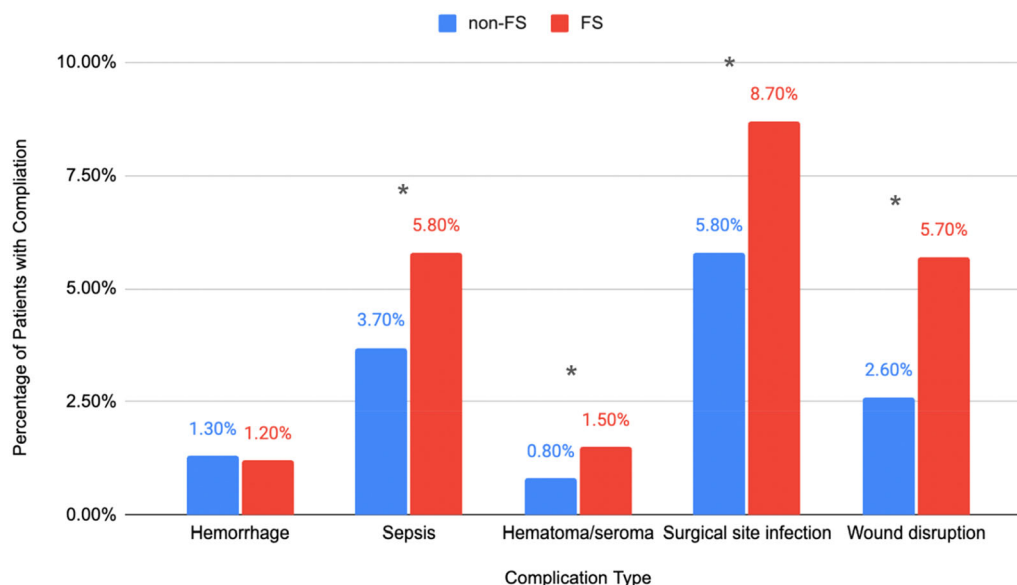
A total of 550,777 patients underwent FPS, 600 patients with FS (cohort 1) and 550,177 without (cohort 2). Cohort 1 was 53.3% male with a mean age of 49.3 years, and cohort 2 was 50.5% male with a mean age of 55.8 years. Groups for subanalyses included patients who received grafts (no FS group  $N = 134,853$ , FS group  $N = 192$ ), regional flaps (no FS group  $N = 223,742$ , FS group  $N = 128$ ), rhinoplasty (no FS group  $N = 113,807$ , FS group  $N = 191$ ), and rhytidectomy (no FS group  $N = 19,479$ , FS group  $N = 58$ ). Baseline demographics and characteristics are shown in **Table 1**.

### Overall FPS Cohort

Before adjusting for demographics, anticoagulation use, and comorbidities, higher rates of sepsis (5.8% vs 3.7%,  $P = .006$ ), SSI (8.7% vs 5.8%,  $P = .002$ ), wound disruption (5.7% vs 2.6%,  $P < .001$ ), and hematoma/seroma formation (1.5% vs 0.8%,  $P = .049$ ) were seen in cohort 1. Patients who received FS also had higher rates of comorbidities such as nicotine dependence and tobacco

**Table 1.** Baseline Demographics

	Fibrin sealant		P-value
	No N = 550,177	Yes N = 600	
Total patients			
Age			<.001
N	526,247	594	
Mean (SD)	55.8 (22.65)	49.3 (21.32)	
Median	60	53	
Range	0.0-123.0	3.0-92.0	
Gender, n (%)			.15992
Female	272,539 (49.5%)	280 (46.7%)	
Male	277,638 (50.5%)	320 (53.3%)	
Race, n (%)			<.0001
American Indian or Alaska Native	1884 (0.3%)	2 (0.3%)	
Asian	13,254 (2.4%)	18 (3.0%)	
Black or African American	31,706 (5.8%)	59 (9.8%)	
Native Hawaiian or other Pacific Islander	1005 (0.2%)	0 (0.0%)	
Unknown	100,831 (18.3%)	58 (9.7%)	
White	401,497 (73.0%)	463 (77.2%)	
Ethnicity, n (%)			<.0001
Hispanic	42,346 (7.7%)	29 (4.8%)	
Non-Hispanic	381,276 (69.3%)	288 (48.0%)	
Unknown	126,555 (23.0%)	283 (47.2%)	
Marital status, n (%)			<.0001
Married	103,711 (18.9%)	55 (9.2%)	
Single	99,727 (18.1%)	103 (17.2%)	
Unknown	346,739 (63.0%)	442 (73.7%)	



**Figure 1.** Unadjusted comparison of complication rates between groups. \*denotes statistical significance at  $P < .05$ . FS, fibrin sealants.

**Table 2.** Adjusted Odds Ratios (aORs) for Complications in the Facial Plastic Surgery Cohort Overall

Rates of complications between groups

Complication	aOR [95% CI]	P-value
Any complication	0.91 [0.71-1.2]	.54
Hemorrhage	0.80 [0.38-1.69]	.55
Sepsis	1.2 [0.84-1.73]	.31
Hematoma/seroma	1.46 [0.75-2.85]	.26
Surgical site infection	1.24 [0.92-1.67]	.15
Wound disruption	1.63 [1.14-2.33]	.0079

**Table 3.** Adjusted Odds Ratios (aORs) for Complications in Patients Receiving Fibrin Sealants in the Regional Flap Cohort<sup>a</sup>

Rates of complications between groups

Complication	aOR [95% CI]	P-value
Any complication	1.5 [1.01-2.24]	<b>.044</b>
Hemorrhage	0.94 [0.30-3.0]	.91
Sepsis	1.30 [0.76-2.19]	.35
Hematoma/seroma	1.78 [0.72-4.38]	.21
Surgical site infection	1.85 [1.20-2.86]	<b>.005</b>
Wound disruption	2.21 [1.38-3.55]	<b>.001</b>

<sup>a</sup>Significant P-values have been bolded.

use (12.7% vs 8.7%,  $P < .001$ ) and anticoagulant use (39.2% vs 27.7%,  $P < .001$ ). After adjusting for demographics and comorbidities, no statistically significant difference in the rate of having any complication between groups (aOR 0.92, [0.71-1.20],  $P = .54$ ) was found. Furthermore, no differences were found between groups for hemorrhage (aOR 0.80, [0.38-1.69],  $P = .55$ ), sepsis (aOR 1.2, [0.84-1.73],  $P = .31$ ), hematoma/seroma (aOR 1.46, [0.75-2.85],  $P = .26$ ), or SSI (aOR 1.24, [0.92-1.67],  $P = .15$ ). Patients in the FS group had higher rates of wound disruption (aOR 1.63, [1.14-2.33],  $P = .008$ ). The unadjusted rates of complications are depicted in **Figure 1**. aORs are represented in **Table 2**.

### Regional Flap Cohort

Before adjusting for demographics and comorbidities, patients receiving FS and regional flap surgery had higher rates of sepsis (13.3% vs 5.2%,  $P < .001$ ), hematoma/seroma formation (3.9% vs 1.1%,  $P = .003$ ), SSI (22.7% vs 7.8%,  $P < .001$ ), and wound disruption

(18.0% vs 4.3%,  $P < .001$ ). These patients also had a higher rate of anticoagulant use (71.1% vs 33.6%,  $P < .001$ ). Following adjustment, patients receiving FS had a higher rate of having any complication (aOR 1.5, [1.01-2.24],  $P = .044$ ), SSI (1.85 [1.20-2.86],  $P = .005$ ), and wound disruption (2.21 [1.38-3.55],  $P = .001$ ). The adjusted comparisons of complication rates are represented in **Table 3**.

### Graft Cohort

Before adjustment, there were increased rates of post-operative sepsis (8.3% vs 3.8%;  $P < .001$ ), SSI (9.9% vs 5.6%,  $P = .010$ ), and wound disruption (5.7% vs 2.2%,  $P < .001$ ) in the FS group for grafts. Anticoagulant use was also higher in patients receiving FS in this group (55.2% vs 29.5%,  $P < .001$ ). No significant differences were noted between groups for rates of any complication following adjustment (aOR 0.79, [0.51-1.22],  $P = .28$ ). The adjusted comparisons of complication rates are represented in **Table 4**.

**Table 4.** Adjusted Odds Ratios (aORs) for Complications in Patients Receiving Fibrin Sealants in the Graft Cohort

Rates of complications between groups		
Complication	aOR [95% CI]	P-value
Any complication	0.36 [0.11-1.16]	.09
Hemorrhage	0.98 [0.31-3.11]	.98
Sepsis	1.3 [0.76-2.25]	.33
Hematoma/seroma	0.90 [0.29-2.84]	.86
Surgical site infection	1.16 [0.71-1.90]	.55
Wound disruption	1.54 [0.82-2.87]	.18

**Table 5.** Adjusted Odds Ratios (aORs) for Complications in Patients Receiving Fibrin Sealants in the Rhinoplasty Cohort<sup>a</sup>

Rates of complications between groups		
Complication	aOR [95% CI]	P-value
Any complication	0.36 [0.11-1.16]	.09
Hemorrhage	0.82 [0.11-5.89]	.84
Sepsis	0.63 [0.08-4.71]	.65
Hematoma/seroma	-	.97
Surgical site infection	0.20 [0.03-1.43]	.10
Wound disruption	-	.95

<sup>a</sup>The sample size was too small for the multivariable model to estimate the odds ratio and 95% confidence interval for some complications. These instances are marked with three dashed lines.

### Rhinoplasty Cohort

Before adjustment for demographics and comorbidities, patients receiving rhinoplasty with FS had a lower rate of SSI (0.5% vs 3.2%,  $P = .034$ ). These patients had a higher rate of anticoagulant use (6.8% vs 16.1%,  $P < .001$ ). Following adjustment, there was no difference in the rate of having any complication between groups (aOR 0.36, [0.11-1.16],  $P = .09$ ). The adjusted comparisons of complication rates are represented in **Table 5**.

### Rhytidectomy Cohort

There were no statistically significant differences in the rates of complications in patients receiving rhytidectomy between groups both before and after adjustment for demographics and comorbidities (aOR 0.54, [0.13-2.26],  $P = .40$ ). Patients in the non-FS group for rhytidectomy (1.7% vs 30.4%,  $P < .001$ ) had higher rates of comorbidities compared to patients who received FS (1.7% vs 30.4%,  $P < .001$ ). The adjusted comparisons of complication rates are depicted in **Table 6**.

## Discussion

FS were approved for facelift surgeries by the Federal Drug Administration (FDA) in 2011. It is applied in a thin

**Table 6.** Adjusted Odds Ratios (aORs) for Complications in Patients Receiving Fibrin Sealants in the Rhytidectomy Cohort<sup>a</sup>

Rates of complications between groups		
Complication	aOR [95% CI]	P-value
Any complication	0.54 [0.13-2.26]	.40
Hemorrhage	-	.99
Sepsis	-	.97
Hematoma/seroma	-	.99
Surgical site infection	0.87 [0.03-1.43]	.10
Wound disruption	-	.97

<sup>a</sup>The sample size was too small for the multivariable model to estimate the odds ratio and 95% confidence interval for some complications. These instances are marked with three dashed lines.

layer on the wound surface using a prefilled syringe and application cannula. Some studies have shown that the use of fibrin sealant can reduce hematoma and seroma formation as well as impart several benefits such as improved graft adherence, patient satisfaction, and an improvement in overall.<sup>2,4,10-16</sup> Most of these studies are small retrospective case series. Additionally, many of the complications are uncommon after FPS procedures, so true differences in outcomes may be challenging to identify in small studies. This study aimed to determine the efficacy of using FS on postoperative complications in patients undergoing FPS using a large national cohort. After adjusting for demographics and comorbidities, our study showed that there were no differences in the rates of any complication, sepsis, SSI, and hematoma/seroma formation between groups when examined as a cohort of FPS. Patients receiving FS did show a higher rate of wound disruption. However, these results should be interpreted cautiously as it is difficult to know whether FS use is more often applied in the case of higher-risk patients predisposed to complications. The finding that FS use was not associated with hematoma/seroma formation may also indicate the impact of patient selection artifacts on our results. A subgroup analysis by type of procedure showed that patients receiving FS and regional flaps had higher rates of having any complications.

The evidence for FS in regional flaps and grafts is very limited. Our analysis showed that patients in the FS group had higher rates of complications for regional flaps, but these patients also had higher rates of anticoagulation use and comorbidities, which are likely driving our results. Clinicians may choose to use fibrin sealant in patients who are known to have comorbidities and those taking anticoagulants due to a perceived benefit in decreasing bleeding or in improving tissue adherence. Fibrin sealant use has been studied as an alternative to staple fixation in patients receiving grafts in burn cases and has been found to produce satisfactory results. The authors hypothesized that the larger contact area provided using fibrin sealant allowed for a reduction in the rates of hematomas and seromas.<sup>17</sup> A systematic review analyzing the use of FS in

soft tissue surgeries of the head and neck showed that there was a tendency for FS to decrease hematoma and seroma formation, but this was not statistically significant.<sup>18</sup> However, the authors note that in these studies many patients are at risk for higher complications (such as previous surgery, radiotherapy, bleeding disorders, or anticoagulation). Due to the heterogeneity of regional flap and graft surgeries, it is difficult to come to a clinically significant conclusion. FS use in these settings may reflect a confounding relationship rather than causation in these settings.

Rhinoplasty is a popular surgery performed by plastic surgeons worldwide, with 44,503 surgeries being performed in 2022.<sup>19</sup> Common complications or side effects of rhinoplasty include postoperative edema, ecchymosis, and infection.<sup>20,21</sup> Our study found no statistically significant differences in the rate of having any complications between groups. There is very little data regarding the use of FS in rhinoplasty, and data on SSI rates following surgery with FS are limited. This may be due to the different indications for use in rhinoplasty with FS being used more as a tissue glue or putty when mixed with cartilage rather than for concern for bleeding, bruising, or tissue adherence. Additionally, suture closure or splint used to maintain adherence to mucoperichondrial flaps in nasal surgery has remained the gold standard during nasal surgery. However, the development of minimally invasive surgical techniques and the desire for increased efficiency with decreased complications make the use of FS for tissue adherence more attractive.<sup>22</sup> There is a lack of literature on this topic and future randomized controlled trials should be conducted to compare FS against conventional suturing or splinting methods.

FS have been most widely studied in the context of rhytidectomy in FPS, where postoperative seromas and hematomas are known complications following surgery.<sup>23,24</sup> Our study found no statistically significant differences in postoperative outcomes in patients receiving rhytidectomy, although the literature on this topic is mixed. In a randomized controlled trial, fibrin sealant was shown to reduce drainage volumes without changing rates of hematoma or seroma formation.<sup>11</sup> Another study compared Artiss (Baxter Healthcare Corp) to a different FS, Tisseel (Baxter Healthcare Corp). Tisseel contains a higher concentration of thrombin and is considered a hemostat, which allows it to form blood clots to reduce bleeding.<sup>4</sup> Unlike Artiss, Tisseel does not allow for skin flap or graft repositioning due to its faster polymerization rate. The study found low rates of hematoma formation with both FS, but the Artiss group reported a greater number of fluid collections requiring drainage.<sup>9</sup> A recent systematic review of tissue sealants in rhytidectomy found that drainage volume and hematoma incidence were decreased in the sealant group, although this group did include non-FS such as platelet-rich and platelet-poor plasma.<sup>12</sup> Another recent review of FS use in drainless rhytidectomy found insufficient evidence to evaluate

seroma formation in these patients. Further randomized controlled trials may be beneficial as there has yet to be a consensus on this topic.

Limitations of our study include its retrospective nature and small sample size in the FS cohort. The small proportion of patients receiving FS among our large cohort may suggest the potential for selection bias. Patients receiving FS had higher rates of comorbidities that may directly increase complication risk. Due to the nature of large databases, it is difficult to truly assess whether FS use was an independent variable for complications or a surrogate marker for comorbidities. However, we did control for potential confounding variables including tobacco and nicotine use, anticoagulation use, and bleeding or clotting disorders within our data set. Additionally, with the low numbers of clinicians utilizing FS in clinical practice, it is difficult to accurately assess its use with a large database such as TriNetX. The decision to utilize FS may be influenced by various unmeasured confounders such as surgeon preference, institutional protocols, and cost-driven factors, which may introduce further bias. Large randomized controlled clinical trials should be implemented to further study the efficacy and safety of FS in FPS. Furthermore, due to the nature of the database, we were not able to analyze patient-specific data such as level of pain, specific indication for use, or esthetic satisfaction, which would have enhanced our analysis. Another major limitation of this study was its retrospective nature as we are limited to what is documented in the database. The investigators were unable to assess the quality of the data collected, and analyses relied on information already available from patient medical records. However, our study encompassed multiple institutions, thereby improving the generalizability of our results.

## Conclusions

After adjusting for demographics and comorbidities, there were no differences in rates of having any complication, sepsis, SSI, hemorrhage, or hematoma/seroma between groups. Higher rates of wound disruption were seen in the FS group, as well as higher rates of comorbidities and anticoagulant usage. Analysis by type of surgery showed mixed results. Patients receiving FS and regional flap surgery had higher rates of complications, whereas there were no differences between groups for patients receiving rhinoplasty, rhytidectomy, and grafts. Given the nature of the data set and the small sample size of patients receiving FS, these results should be interpreted as exploratory rather than conclusive. FS may confer different benefits depending on the type of surgery and patient characteristics. This study highlights potential associations such as patient-specific risk factors, surgeon and institution preference, and intraoperative variables that may prompt further research. Prospective and randomized controlled studies in each surgical category may aid in further elucidating the benefits of using FS.

## Author Contributions

**Hänel W. Eberly**, concept design, acquisition, analysis, or interpretation of data, writing and editing the manuscript, presentation of research; **Sandeep Pradhan**, analysis and interpretation of data, critical editing of the manuscript; **Jacqueline Tucker**, acquisition, analysis, or interpretation of data, critical editing of the manuscript; **Bao Y. Sciscent**, acquisition, analysis, or interpretation of data, critical editing of the manuscript; **Tonya S. King**, analysis and interpretation of data, critical editing of the manuscript; **Jessyka G. Lighthall**, concept design, review of data analysis, critical editing of the manuscript, final approval.

## Disclosures

**Competing interests:** The authors report no conflicts of interest pertinent to this research that are upcoming or have existed in the past 24 months.

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## Supplemental Material

Additional supporting information is available in the online version of the article.

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