

Real-World Economic and Clinical Outcomes Associated with Current Hemostatic Matrix Use in Spinal Surgery

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Background

- ❖ Spinal disorders are leading contributors to disability worldwide, with neck and back pain accounting >50% of the burden. Failure to manage spinal pain often results in surgery.¹⁻²
- ❖ Invasive spinal surgeries have significant risk of blood loss that is affected by the complexity and duration of the procedure.³⁻⁴
- ❖ Surgical hemostasis is often required to prevent bleeding events and reduce avoidable complications and associated economic burden.⁵⁻⁷
- ❖ Surgiflo[®] and Floseal have proven to shorten surgery time, reduce transfusion need, better manage an anticoagulated patient, improve recovery time, and reduced wound exposure.⁸
- ❖ Despite the proven efficacy in controlling surgical bleeding, there is lack of head-to-head comparison between Surgiflo[®] and Floseal assessing their clinical effectiveness and economic impact in the real-world setting.

Objective

To compare the economic and clinical outcomes of patients treated with current formulation of Surgiflo[®] versus Floseal during spinal surgeries

Methods

- ❖ This is a retrospective study using Premier Healthcare Database (PHD).
- ❖ Eligible patients included individuals:
 - With an inpatient spinal surgery between 1/1/2013-06/1/2018
 - ≥ 18 years at the time of procedure
 - Received Surgiflo[®] or Floseal during surgery
- ❖ Patients were excluded if they had an outlier value for operating room time (<1 or > 12 hours), had incomplete information on hospital stay, had a non-specific hemostatic product description, or received both products in same surgery
- ❖ Patients in the two groups were matched using their calculated propensity scores (1:3 variable ratio matching) with exact match on surgery year and type of surgery (i.e., aortic, coronary artery bypass grafting, valve, other); sampling weights were applied, rendering the weighted post-match sample to be 1:1.
- ❖ Outcomes included bleeding event, blood transfusion, length of stay (LOS), intensive care unit (ICU) admission, total costs, operating room time, and readmission within 30-60-90 days.
- ❖ Outcomes were reported using descriptive analysis and compared between the groups using generalized estimating equations.

Results

Patient Demographics

- ❖ The final weighted matched sample included 28,910 patients for each group (post-match mean age=59.2 years; 47% males).
- ❖ After propensity score matching, all baseline patient and hospital characteristics were balanced between the two groups except hospital bed size (101 to 500 beds: Surgiflo[®] 68.4% vs, Floseal 63.5%; standardized difference: 10.38)
- ❖ In the post-matching sample, more than 81% patients were White, at least 42% had Medicare coverage and 88% underwent elective surgery
- ❖ Patients in both groups had Charlson Comorbidity Index scores of 0.8.
- ❖ Most of the procedures were fusion surgeries (90%) , 50.9% were performed in lumbar region, and 54.1% followed an anterior technique across both groups.

Hospital Characteristics

- ❖ More than half of the patients in both groups received surgeries in the Southern region of the United States and over 91% had surgeries in urban hospitals.
- ❖ Majority of the procedures included in the analysis were performed at mid-size hospitals (i.e., 101-500 beds).

The Surgiflo[®] group had significantly lower admission costs, shorter LOS, and shorter operating room time compared to Floseal (Table 1)

- ❖ Patients receiving Surgiflo[®] had lower average cost of hospitalization (\$29,949 vs. \$30,399 P<0.05), shorter LOS (3.4 vs. 3.5 days, P<0.05), shorter operating room time (247 vs. 250 minutes, P<0.05), and 5% fewer patients had an ICU admission (P<0.05).

Table 1: Multivariable Regression for Continuous Outcomes

Outcomes ^a	Surgiflo [®] Mean (SD)	Floseal Mean (SD)	IRR ^b	95% CI		P-Value *
	N=28,910	N=28,910		Low	High	
Length of stay (LOS) (days)	3.41 (3.16)	3.50 (2.30)	0.98	0.96	0.99	0.0007*
Number of days in ICU (days) ^c	3.32 (4.62)	3.47 (3.06)	0.96	0.89	1.03	0.2306
Total cost (USD)	29,949 (20,226.88)	30,399 (16,125.35)	0.99	0.98	1	0.0152*
Operating room time (hours)	4.11 (1.75)	4.17 (1.28)	0.99	0.98	0.99	<.0001*

a. Based on a Generalized linear model with Generalized Estimating Equations (negative binomial distribution and log link for LOS, number of ICU days, operating room time; gamma distribution and log link for costs) weighted and adjusted for unbalanced characteristics after PSM and marital status.
b. Incidence Rate Ratio indicates the relative risk of an outcome in Surgiflo[®] as compared to Floseal
c. ICU admission is defined using chargemaster description
* p<0.05 is significant

Floseal and Surgiflo[®] had comparable outcomes for bleeding, readmission and mortality (Table 2)

- ❖ Overall, less than 2% of patients undergoing spinal surgery experienced bleeding.
- ❖ Outcomes including bleeding, readmission rates within 30-60-90 days, and mortality were comparable (all P>0.05) between groups.

Risk of transfusion was similar for Surgiflo[®] and Floseal (Table 2)

- ❖ In both Floseal and Surgiflo[®], approximately 6% of patients required blood transfusions on or within 1 day of surgery (p>0.05) and 2% within 2-4 days of surgery (p<0.05).

Table 2: Multivariable Regression for Binary Outcomes

Outcomes ^a	Surgiflo [®] , N (%)	Floseal, N (%)	OR ^b	95% CI		P-Value*
	N=28,910	N=28,910		Low	High	
Any Bleeding ^c	445 (1.5%)	438 (1.5%)	0.97	0.86	1.09	0.6229
Any post operative bleeding ^d	6 (0.0%)	10 (0.0%)	0.52	0.19	1.45	0.2111
Any transfusion ^e	2,339 (8.1%)	2,333 (8.1%)	1.01	0.96	1.07	0.6029
Any transfusion on or 1 day after surgery	1,738 (6.0%)	1,689 (5.8%)	1.03	0.97	1.1	0.3174
Any transfusion within 2-4 days of surgery	534 (1.8%)	637 (2.2%)	0.85	0.76	0.94	0.0019*
PRBC transfusion on or 1 day after surgery	672 (2.3%)	523 (1.8%)	1.31	1.18	1.45	<.0001*
PRBC transfusion within 2-4 days of surgery	351 (1.2%)	288 (1.0%)	1.23	1.08	1.41	0.0026*
Any ICU admission	1,894 (6.6%)	3,328 (11.5%)	0.55	0.52	0.58	<.0001*
Mortality	63 (0.2%)	58 (0.2%)	1.01	0.73	1.39	0.9727
Any Readmission						
Within 30 days	945 (3.3%)	880 (3.0%)	1.08	0.99	1.17	0.0811
Within 60 days	2,003 (6.9%)	1,958 (6.8%)	1.03	0.97	1.09	0.3124
Within 90 days	2,378 (8.2%)	2,301 (8.0%)	1.04	0.99	1.1	0.1575

a. Based on a GLM with GEE (binomial distribution and logit link), weighted and adjusted for unbalanced characteristics after PSM and marital status.
b. The odds ratios indicates the probability of having an outcome in Surgiflo[®] as compared to Floseal
c. Any bleeding event identified using ICD 9/10 diagnosis not present on admission OR any ICD procedures during the hospitalization
d. Bleeding event identified using ICD procedures when the procedure was performed after the day of the index surgery
e. Blood transfusion was identified using ICD procedure codes and searching for text strings in hospital charge description

Discussion and Conclusion

- ❖ Our study is one of the largest retrospective studies presenting real-world clinical and economic outcomes related to Surgiflo[®] versus Floseal use in patients undergoing spinal surgeries.
- ❖ Compared to prior analyses, this study considers the latest product formulations, allowing appropriate time for market penetration. The robust PSM matching methodology also accounts for potential confounders such as type of the surgery, patient and hospital characteristics.
- ❖ The study suggests that, Surgiflo[®] is associated with lower hospitalization costs, decreased risk of ICU admission, slightly shorter LOS and shorter operating room time among spinal surgery patients.
- ❖ Overall the probability of requiring transfusion is comparable for Surgiflo[®] and Floseal (8.1%). The study also suggests that bleeding, mortality and readmission up to 90 days post-discharge were comparable across the products.
- ❖ The study had inherent limitations of using retrospective data such as PHD, including non-random assignment to Surgiflo[®] or Floseal groups, using text searches to define outcome variables, information limited to only continuously contributing hospitals and underestimation of re-hospitalization rate involving multiple hospitals
- ❖ Despite the limitations, this study suggest that although the clinical outcomes are relatively comparable between Surgiflo[®] and Floseal in spinal surgeries, Surgiflo[®] is associated with reduced cost and resource use compared to Floseal.

References

1. Vos, T., Amanuel Alemu Abajobir, Kalkidan Hassen Abate, Cristiana Abbafati, Kaja M. Abbas, Foad Abd-Allah, Rizwan Suliankatchi Abdulkader et al, Global, regional, and national incidence, prevalence, and years lived with disability for 328 diseases and injuries for 195 countries, 1990–2016: a systematic analysis for the Global Burden of Disease Study 2016. The Lancet, 5. 2017. 390(10100): p. 1211-1259

2. Raciborski F, G.R., Kłak A, Disorders of the spine. A major health and social problem. Reumatologia, 2016. 54(4): p. 196-200.

3. Verma K, Errico TJ, Vaz KM, Lonner BS. A prospective, randomized,6. double-blinded single-site control study comparing blood loss

4. Hassan N, Halanski M, Wincek J, et al. Blood management in pediatric spinal deformity surgery: review of a 2-year experience. Transfusion. 2011;51(10):2133-2141.

5. Krishnan S, Conner TM, Leslie R, Stemkowski S, Shander A. Choice of hemostatic agent and hospital length of stay in cardiovascular surgery. Paper presented at: Seminars in cardiothoracic and vascular anesthesia2009.

6. Li G, Sun T-W, Luo G, Zhang C. Efficacy of antifibrinolytic agents on surgical bleeding and transfusion requirements in spine surgery: a

7. meta-analysis. European spine journal. 2017;26(1):140-154.

8. Makhija D, Rock M, Ikeme S, et al. Cost-consequence analysis of two different active flowable hemostatic matrices in spine surgery patients. Journal of medical economics. 2017;20(6):606-613.

9. Vyas KS, Saha SP. Comparison of hemostatic agents used in vascular surgery. Expert opinion on biological therapy. 2013;13(12):1663-1672.