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ORIGINAL ARTICLE

# Efficacy and Safety of Seraseal as a Hemostatic and Dural Sealing Agent in Trauma & Emergency Surgery: A Prospective Post-Marketing Observational Study

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## ABSTRACT

***Background:*** Intraoperative bleeding and cerebrospinal fluid (CSF) leakage are critical challenges in trauma and emergency neurospinal procedures. Failure to achieve watertight dural closure can result in postoperative complications, prolonged recovery, and increased healthcare costs. SeraSeal (3000 IU/mL) is a novel topical hemostatic agent formulated with agar and bovine-derived clotting factors, designed to achieve rapid hemostasis and effective dura sealing. This study aimed to evaluate the real-world efficacy and safety of SeraSeal in trauma and emergency cranial/spinal surgeries.

***Method:*** A prospective, single-center, post-marketing observational study was conducted among 50 patients undergoing brain, spine, or general surgery with active bleeding. SeraSeal was applied topically, and hemostatic outcomes were evaluated at 1, 4, 7, and 10 minutes post-application. Primary endpoints included time to hemostasis, CSF leak incidence, and blood loss volume. Secondary outcomes assessed included rebleeding, surgeon satisfaction, and adverse events.

***Results:*** Of the 50 patients, 100% success rate of watertight dural sealing without intraoperative CSF leak or complications. Postoperative CSF leak was observed

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in only 4 patients (8%), with an overall average leak incidence of 1% per patient. Blood loss significantly reduced from baseline (mean 71.22 mL) to 21.04 mL at 10 minutes post-application ($p < 0.001$). Mean time to hemostasis also significantly decreased from 24.32 seconds to 8.98 seconds ($p < 0.001$). Surgeon satisfaction improved significantly over time ($p = 0.007$), and no adverse drug-related events were reported.

***Conclusion:*** This study suggests that SeraSeal is an effective and safe primary haemostatic and dura sealant agent, offering rapid watertight dura sealing, bleeding control, minimal blood loss, and a favourable safety profile.

**KEYWORDS**

• SeraSeal • Dura Sealing • CSF Leak • Haemostasis • Bleed Control

## INTRODUCTION

The dural membrane plays a critical role in protecting the brain and spinal cord by serving as a physical barrier and maintaining the integrity of the cerebrospinal fluid (CSF) compartment.[1] Trauma, whether accidental or iatrogenic, particularly during spinal or cranial neurosurgical procedures, often compromises the dura mater, leading to complications such as CSF leakage, infection, and neurological deficits.[2] Dural injuries occur in approximately 5.8% of spinal surgeries, frequently resulting in CSF leakage and subsequent complications including pseudomeningocele, severe headaches, nerve root entrapment, and intracranial hemorrhage.[3]

In emergency surgical settings especially in polytrauma and high-velocity impact injuries the risk of uncontrolled hemorrhage and dural compromise is markedly elevated. Rapid control of bleeding and effective dural sealing are critical to minimizing morbidity and preventing long-term complications in these scenarios. Surgical bleeding remains a significant intraoperative challenge, both in elective and emergency surgeries. Hemorrhage continues to be one of the most common causes of intraoperative complications, with direct implications for increased morbidity, mortality, and prolonged hospitalization.[4,5,16]

Massive intraoperative bleeding during cranial and spinal operations occurs in 3% to 8% of cases, with spinal surgeries involving multiple levels or instrumentation being particularly associated with significant blood loss.[6] A retrospective analysis from India reported that among 338 lumbar spine surgery patients, intraoperative bleeding was a prominent contributor to complications in 55 cases.[7] Severe blood loss, defined as exceeding 659.3 ml, was reported in 4% of patients undergoing lumbar spine procedures. Moreover, in a broader study of 25,000 surgical procedures, major bleeding events were observed in over 14,000 cases, despite standard hemostatic measures such as clamps, compression, and tourniquets.[8] These uncontrolled bleeding events were associated with poorer clinical outcomes and increased healthcare costs, underscoring the necessity for more reliable and effective topical hemostatic agents.[9]

SeraSeal is a novel topical hemostatic agent specifically designed to enhance intraoperative hemostasis and tissue sealing. Composed of agar and a combination of bovine-derived coagulation factors IIa, VIIa, IXa, and Xa, SeraSeal promotes rapid clot formation upon application to the bleeding site. Its biocompatibility and non-inflammatory properties make it particularly suitable for neurosurgical applications, including sealing dural tears and controlling bleeding on delicate neural tissues. The use of SeraSeal in such high-risk surgical contexts can improve surgical field visibility, reduce operative time, and potentially prevent post-operative complications associated with bleeding and CSF leakage.[10]

The impact of tourniquet application and the timing of its release on perioperative blood loss has been widely investigated. One RCT reported that releasing the tourniquet intraoperatively, followed by electrocautery for haemostasis, did not significantly reduce total blood loss during orthopaedic surgery.[11] In contrast, another study has indicated that releasing the tourniquet before wound

closure leads to increased blood loss, a higher need for blood transfusions, and prolonged surgical durations, compared to releasing the tourniquet after skin closure with compression bandaging.[12] To further control perioperative bleeding, some studies have explored the use of low-dose vasopressors in combination with surgical drains. Another study demonstrated that clamping the suction drain and infusing saline mixed with a low concentration of epinephrine in a retrograde manner significantly reduced postoperative bleeding in TKA patients. Even saline alone led to reduced bleeding, with epinephrine providing an enhanced haemostatic effect.[13]

Primary hemostatic agents are utilized during surgical interventions or in cases of traumatic injury to achieve rapid bleeding control by promoting the initial phase of hemostasis, wherein platelet aggregation leads to the formation of a temporary hemostatic plug at the site of vascular injury. SeraSeal is indicated for the control of arterial and venous hemorrhage, bleeding from parenchymatous organs, capillary oozing, and vascular anastomoses across a range of procedures, including invasive, semi-invasive, and non-invasive interventions. Its clinical efficacy has been substantiated in multiple studies. Notably, in cases of gastrointestinal bleeding that were otherwise challenging to manage, complete hemostasis was achieved in 87% of patients treated with SeraSeal™. Furthermore, its use in craniosynostosis corrective osteotomies has been associated with reduced intraoperative blood loss and a decreased need for blood transfusion.[14]

A study involving patients with active gastrointestinal bleeding, SeraSeal™ achieved definitive hemostasis in 87% of cases where conventional methods had failed. Application of SeraSeal™ has been associated with a 90% reduction in blood loss in up to 40% of surgical procedures, leading to decreased transfusion requirements and shorter hospital stays.[15] The current study intended to demonstrate the real-world performance of SeraSeal as a primary haemostatic & dura sealant agent in the cessation of CSF leak and bleeding by measuring time to control blood loss, time to hemostasis, rebleeding incidences, and safety profile.

## METHODS

This was a single-center, prospective, post-marketing observational study conducted at Sapthagiri Institute of Medical Sciences and Research Centre, Bangalore. Fifty patients, including pediatric and adult populations, undergoing trauma or emergency surgeries on the brain or spinal cord with active bleeding, were enrolled based on predefined inclusion and exclusion criteria. SeraSeal (3000 IU/ml) was topically applied at the bleeding site and for dura sealing. Hemostasis time was measured using a stopwatch, and follow-up assessments were conducted up to 72 hours post-operatively. Primary endpoints included assessment of dura sealing, CSF leakage, time to haemostasis, and successful blood clotting without any staining. Secondary outcomes included blood loss volume, rebleeding incidence, adverse events, and surgeon satisfaction. Descriptive statistics, paired t-tests, repeated measures ANOVA, and logistic regression analyses were conducted using standard statistical software.

## RESULTS

A total of 50 subjects were enrolled in the study, who received hemostatic treatment with a single application of SeraSeal (3000 IU/mL) on the bleeding site, containing bovine clotting factors IIa/ VIIa/IXa/Xa, was applied. The study subjects' demographic and clinical characteristics were assessed at baseline. Tables 1, 2, 3, and 4 provide the summaries of the subject characteristics for the study population and the continuous and categorical variables, respectively.

Of 50 patients enrolled with trauma and emergency surgery, 56% had spinal surgery (laminectomy, disectomy, spinal fixation & stabilization), 38% of neurosurgery (tumor excision, craniotomy), and 6% underwent general surgery (diabetic foot debridement). 11 out of 50 (22%) required watertight dura mater sealing. Of 50 patients, 72% had mild to severe systemic disease conditions with ASA grade II–III, and fewer than 4% had life-threatening disease conditions (ASA Grade IV) admitted to the ICU for emergency surgery. Intraoperative bleeding was prominently seen in all the patients, with 88% having oozing and 22% having the spurting type of bleeding. Consequently, some patients had ABGEL (12%), cautery (2%), and Tourniquet (2%)

techniques used to control bleeding during the study. On haematological assessment, the mean Prothrombin Time (PT) was 14.52 ± 1.46 sec, and the mean INR was 0.97 ± 0.15, at the baseline. Liver enzymes showed a mean ALT of 32.04 ± 12.83 U/L and AST of 34.64 ± 17.59 U/L. No abnormality was observed in the vitals and physical examination throughout the study.

**Table 1:** Baseline characteristics of study subjects

| Characteristic | Value | 95% CI |
|---|---|---|
| Age (years) | 49.14 ± 16.3 | 44.51 – 53.77 |
| Height (cm) | 162.82 ± 8.7 | 160.35 – 165.29 |
| Weight (Kg) | 65.2 ± 11.73 | - |
| BMI (kg/m²) | 24.86 ± 4.24 | 23.65 – 26.06 |
| **Sex** | | |
| Male | 32 (64%) | |
| Female | 18 (36%) | |
| **Marital Status** | | |
| Married | 46 (92%) | - |
| Unmarried | 4 (8%) | - |
| **Ethnicity** | | |
| Dravidian | 50 (100%) | - |
| Indo-European, Sino-Tibetan, Austroasiatic | 0 (0%) | - |
| **Education Level** | | |
| Less than high school | 9 (18%) | - |
| High school | 14 (28%) | - |
| Intermediate | 12 (24%) | - |
| Degree | 11 (22%) | - |
| Masters | 3 (6%) | - |
| Doctoral | 1 (2%) | - |
| **Past Medical Conditions** | | |
| Hypertension | 10 (20%) | - |
| Diabetes Mellitus | 3 (6%) | - |
| IHD, Epilepsy, Liver Cirrhosis, Seizures | 1 (2%) | - |
| Multiple conditions (e.g., HTN+T2DM) | 1 (2%) | - |
| No comorbidities | 30 (60%) | - |
| **Haematology Parameters** | | |
| Haemoglobin | 13.0 ± 2.3 | - |
| RBC | 4.93 ± 1.5 | - |
| INR | 0.97 ± 0.15 | - |
| Prothrombin Time (PT, sec) | 14.52 ± 1.46 | 14.10 – 14.93 |
| ALT (U/L) | 32.04 ± 12.83 | 28.39 – 35.69 |
| AST (U/L) | 34.64 ± 17.59 | 29.64 – 39.64 |
| **ASA Grade** | | |
| Grade I (Healthy patients) | 12 (24%) | - |
| Grade II (Mild Systemic Disease) | 22 (44%) | - |
| Grade III (Severe Systemic Disease) | 14 (28%) | - |
| Grade IV (Life Threatening Disease) | 2 (4%) | - |

**Table 2:** Baseline clinical characteristics

| Characteristics | | N | % |
|---|---|---|---|
| ***Type of surgery*** | Laparoscopic surgery | 0 | 0 |
| | Open surgery | 50 | 100 |
| ***Bleeder identification*** | Yes | 50 | 100 |
| | No | 0 | 0 |
| ***Nature of Bleed*** | Oozing | 44 | 88 |
| | Spurting | 6 | 12 |
| ***SeraSeal used*** | Direct application | 50 | 100 |
| | Application with a gauze piece | 0 | 0 |
| ***Other modes of bleeding control*** | ABGEL | 6 | 12 |
| | Cautery | 1 | 2 |
| | Tourniquet | 1 | 2 |
| ***Anti-coagulant Therapy*** | Heparin (Dose-60mg) | 24 | 58.53 |
| | Clopidogrel (75 mg) | 12 | 29.3 |
| | Aspirin (75 mg) | 5 | 12.19 |
| ***Distribution of surgical cases*** | Spinal | 28 | 56.0 |
| | Neuro | 19 | 38.0 |
| | General | 3 | 6.0 |

**Table 3.** Clinical distribution of surgeries

| Characteristics | N | % |
|---|---|---|
| General surgeries | 3 | 6 |
| EUA D & D Debridement | 1 | 33.3 |
| EUA Fascotomy & Debridement | 1 | 33.3 |
| Exploration with Splenectomy | 1 | 33.3 |
| Neurosurgeries | 19 | 38 |
| Craniotomy & Excision of Tumor | 8 | 42.1 |
| Craniotomy & Tumor Excision | 6 | 31.6 |
| Craniotomy& Excision of Tumor | 1 | 5.3 |
| Pituitary Macroadenoma | 1 | 5.3 |
| Transphenodial Excision of Tumor | 2 | 10.5 |
| Tumor Excision | 1 | 5.3 |
| Spinal Surgeries | 28 | 56 |
| C1-C2 Fixation, C1 Laminectomy with C1-C2 Posterior Stabilization with C1 Lateral Mass & C2 Pan Screw | 1 | 3.6 |
| C3-C6 Laminacotomy | 1 | 3.6 |
| CRIF With Long Pfn | 1 | 3.6 |
| D9-D12 Decompression with Posterior Stabilization | 1 | 3.6 |
| Formen Magneum Decompression | 1 | 3.6 |
| Implant Removal | 1 | 3.6 |
| L1 L3 Stabilization | 1 | 3.6 |
| L1,L2 Laminectomy with L1-L3 Posterior Stabilisation With Pedical Screw & Rods | 2 | 7.1 |
| L2-L3, L3-L4, L4-L5 Disectomy with Spine Fixation | 1 | 3.6 |
| L3-L4, L4-L5, Disectomy | 1 | 3.6 |

| Characteristics | N | % |
|---|---|---|
| L3-L4, L4-L5, L5-S1 Disectomy | 2 | 7.1 |
| L4,L5 Laminectomy with L4-L5,L5-S1 Disectomy | 2 | 7.1 |
| L4,L5 Laminectomy with L4-L5,L5-S1 Disectomy with L4-L5 Posterior Stabilization | 1 | 3.6 |
| L4-5 Posterior Stabilization | 1 | 3.6 |
| L4-L5 Disectomy | 1 | 3.6 |
| L4-L5 Disectomy with Posterior Stabilisation | 2 | 7.1 |
| L4-L5, L5-S1 Disectomy | 5 | 17.9 |
| L5 Laminectomy with L5-S1 Disectomy | 1 | 3.6 |
| L5-S1 Disectomy | 1 | 3.6 |
| ORIF With Plate & Screws with MIPPO | 1 | 3.6 |

## TRAUMA AND EMERGENCY SURGICAL OUTCOMES: CRANIAL AND SPINAL

Among the brain and spinal surgeries, there were a total of 11 incidences of rupture in the dura mater while performing the major surgery in the cranial and spinal. All surgeries 11 (100%) were completed successfully without any intraoperative or postoperative complications. The hemostatic sealing technique demonstrated a successful watertight dura sealing with a success rate of 100%, effectively preventing cerebrospinal fluid (CSF) leakage in all subjects. The estimated 95% confidence interval (CI) for the proportion of successful sealing was 93.6% to 100%, based on the binomial distribution. These findings suggest that the SeraSeal sealing method was consistently effective across all cases evaluated. (Table 4)

**Table 4:** Summary of dura seal method

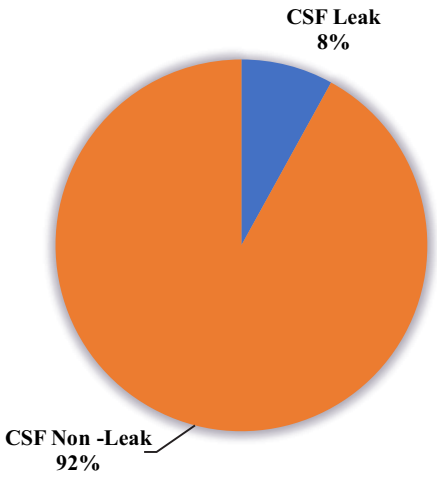
| Characteristics | N (%) |
|---|---|
| Total Surgeries | 11 |
| Successful Surgeries | 11 (100%) |
| Surgeries with no Complications | 11 (100%) |
| Proportion of Successful Sealing | 11/11 = 100% |
| 95% Confidence Interval | 93.6% to 100% (TR, actual estimate= 100%) |

## INCIDENCE OF CEREBROSPINAL FLUID (CSF) LEAKAGE

Out of 50 surgical cases, postoperative cerebrospinal fluid (CSF) leakage was observed in 4 (8%) patients, while no leakage was reported in the remaining 46 (92%) patients. The mean CSF leak rate was 1% per case, with the incidence ranging from 1% to 2% across the study population. The resultant CSF leaks intraoperatively were not observed in any patients, while 92% had no CSF leak post-intervention of SeraSeal. SeraSeal for CSF leaks following dural tears has been shown to have a 92% success rate among spinal and brain surgery it underscoring its potential efficacy in preventing postoperative CSF leaks (Table 5, Figure 1).

**Table 5.** CSF leak status

| Characteristics | | N | % |
|---|---|---|---|
| CSF Leak Status | Yes | 4 | 8% |
| | No | 46 | 92% |
| Average CSF Leak Rate | | 1% per case | |
| Range of CSF Leak Incidence | | 1% to 2% | |
| No CSF Leak Incidence (No Leak) | | 92% | |
| CSF Leak Incidence (Leak) | | 8% | |




## COMPARISON OF MEAN BLOOD LOSS BEFORE AND AFTER SERASEAL APPLICATION

Out of 50 patients, the mean blood loss before SeraSeal application was 71.22 ± 9.37 mL, which constantly reduced post application at 1 min (70.62 ± 3.42 mL, $p = 0.952$), suggesting no significant immediate effect. Further, at 4 min (53.72 ± 2.16 mL, $p = 0.074$) and 7 min (52.64 ± 2.37 mL, $p = 0.070$), there was a notable reduction in blood loss, although these reductions were not statistically significant. At the 10-min time point, there was a significant clinically meaningful control in the blood loss to 21.04 ± 1.83 mL ($p < 0.001$), with a mean reduction of -50.18 mL compared to the baseline, confirming a substantial and statistically significant reduction. These

findings suggest that initially SeraSeal may not exert an immediate haemostatic effect, but its efficacy becomes evident within a few minutes, reaching a significant reduction in blood loss shows therapeutic benefits among the study population. (Table 6)

**Table 6:** Comparing the mean blood loss before and after gel application at different time intervals

| Blood loss before and after applying gel (mL) | Before [n=50] | 1 Min [n=50] | 4 Min [n=50] | 7 Min [n=50] | 10 Min [n=50] |
|---|---|---|---|---|---|
| Mean | 71.22 | 70.62 | 53.72 | 52.64 | 21.04 |
| Standard Deviation | 9.37 | 3.42 | 2.16 | 2.37 | 1.83 |
| Median | 40 | 82 | 53.5 | 53 | 18.5 |
| 95% CI of mean | (52.39 - 90.05) | (63.74 - 77.5) | (49.38 - 58.06) | (47.87 - 57.41) | (17.36 - 24.72) |
| Mean difference in blood loss | - | -0.60 | -17.50 | -18.58 | -50.18 |
| P value* | - | 0.952 | 0.074 | 0.070 | **0.001*** |

Paired t test was performed; *significant at p <0.05; CI – Confidence interval; mL -Milli litre

## TIME-DEPENDENT IMPROVEMENT IN HEMOSTASIS TIME – SERASEAL INTERVENTION

Table 7. demonstrates a change in haemostasis time post applying SeraSeal from baseline to 1 min, 4 min, 7 min, and 10 min, showing a progressive reduction in the mean time required to achieve haemostasis by no blood staining or bleeding at the surgical site. Post application of SeraSeal, there was a significant change in mean time to achieve hemostasis across the time points (24.3 vs 8.9 vs 14.7 vs 8.9 sec, $p < 0.001$), indicating a consistency in hemostasis achievement as time progresses. The mean difference in blood loss shows a significant reduction over time (-6.56 vs -9.54 vs -15.34 sec, $p < 0.001$), time-dependent results show a substantial reduction in blood loss across time points.

**Table 7:** Comparison of mean Time to achieve Hemostasis after SeraSeal (sec) at different time intervals

| Time to achieve Hemostasis after SeraSeal (sec) | 1 Min [n=50] | 4 Min [n=50] | 7 Min [n=50] | 10 Min [n=50] |
|---|---|---|---|---|
| Mean | 24.32 | 17.76 | 14.78 | 8.98 |
| Standard Deviation | 4.17 | 2.83 | 2.23 | 1.32 |
| Median | 15 | 10 | 10.5 | 7 |
| 95% CI of mean | (15.94 - 32.7) | (12.06 - 23.46) | (10.3 - 19.26) | (6.33 - 11.63) |
| Mean difference in blood loss | - | -6.56 | -9.54 | -15.34 |
| P value* | - | **0.001*** | **0.001*** | **0.001*** |

Paired t test was performed; *significant at p <0.05; CI – Confidence interval; sec-seconds

## RELATIONSHIP BETWEEN BLOOD LOSS AND TIME TO HEMOSTASIS FOLLOWING SERASEAL APPLICATION

Figure 2. illustrates the distribution of blood loss (mL) to time to haemostasis at 1, 4, 7, and 10 min following application of the haemostatic gel. At 1 minute, the majority of data points are concentrated in the higher range of blood loss (approximately 70–100 mL), indicating minimal haemostatic effect during the immediate post-application period. Further, a downward trend in blood loss is observed at 4 and 7 minutes, with a modest reduction in values and a slightly wider distribution, reflecting inter-individual variability in response to the gel. By 10 minutes, a consistent reduction in blood loss is evident, with most values clustering below 30 mL. This shift signifies a time-dependent haemostatic effect, with the gel demonstrating optimal efficacy at the 10-minute mark. The progressive narrowing in the dispersion of data over time further suggests enhanced uniformity in haemostatic response, reinforcing the reliability of the agent's effect as time elapses.

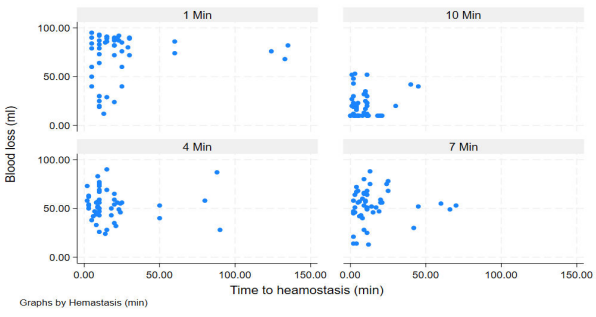



**Figure 2:** Relationship between blood loss (mL) vs time to haemostasis (min) across time points.

Table 7. Repeated measure ANOVA analysis yielded an **F-value of 25.62** with a **p-value < 0.001**, indicating a statistically significant difference in haemostasis time across the timepoints. This suggests that the duration of observation plays a crucial role in haemostasis progression, with a significantly shorter time required to achieve haemostasis at later time points.

**Table 7:** Time to achieve hemostasis from baseline to EOS

| Time to achieve Hemostasis after SeraSeal (sec) | 1 Min [n=50] | 4 Min [n=50] | 7 Min [n=50] | 10 Min [n=50] | F value | P value |
|---|---|---|---|---|---|---|
| Mean | 24.32 | 17.76 | 14.78 | 8.98 | 25.62 | < 0.001* |
| Standard Deviation | 4.17 | 2.83 | 2.23 | 1.32 | | |

Repeated measure ANOVA was performed; *significant at p <0.05; CI – Confidence interval; sec-seconds

## OVERALL HEMOSTATIC & CLINICAL OUTCOMES

The intraoperative and postoperative hemostatic outcomes at different time intervals (1 min, 4 min, 7 min, and 10 min) demonstrate a high efficacy of hemostasis with SeraSeal, with 92% achieved hemostasis within **30 seconds**. All procedures were **open surgeries**, and **bleeder identification was successful in 96–100%** of cases. The nature of bleeding (oozing vs. spurting) remained consistent across time intervals. SeraSeal was used **directly in all cases**, and **re-bleeding within 3 minutes occurred in only 8% of patients** across all time points. Reactionary bleeding within 24 hours was observed in **only 4% of cases**, indicating strong hemostatic stability. These findings suggest that SeraSeal provides rapid and sustained hemostasis with high surgeon satisfaction and minimal postoperative complications. (Table 8)

**Table 8:** Comparison of intra-operative and post-operative hemostatic outcomes across time points

| Characteristics | Levels | Treatment post-operation (min) | | | | Chi-square | P-value |
|---|---|---|---|---|---|---|---|
| | | 1 Min | 4 Min | 7 Min | 10 Min | | |
| | | n (%) | | | | | |
| *Time to achieve haemostasis (sec)* | < 30 sec | 45 (90) | 45 (90) | 45 (90) | 48 (96) | | |
| | 31 - 60 sec | 2 (4) | 2 (4) | 3 (6) | 2 (4) | 3.481 | 0.747 |
| | > 60 sec | 3 (6) | 3 (6) | 2 (4) | 0 (0) | | |
| *Type of surgery* | Open | 50 (100) | 50 (100) | 50 (100) | 50 (100) | NA | NA |
| | Laparoscopic | 0 (0) | 0 (0) | 0 (0) | 0 (0) | | |
| *Bleeder Identification* | Yes | 50 (100) | 50 (100) | 48 (96) | 48 (96) | 4.082 | 0.253 |
| | No | 0 (0) | 0 (0) | 2 (4) | 2 (4) | | |
| *Nature of bleed* | Oozing | 44 (88) | 44 (88) | 44 (88) | 43 (86) | 0.137 | 0.987 |
| | Spurting | 6 (12) | 6 (12) | 6 (12) | 7 (14) | | |
| *SeraSeal used* | Directly | 50 (100) | 50 (100) | 50 (100) | 50 (100) | NA | NA |
| | With gauze piece | 0 (0) | 0 (0) | 0 (0) | 0 (0) | | |
| *Re-bleeding within 3mins* | No | 46 (92) | 46 (92) | 46 (92) | 46 (92) | NA | NA |
| | Yes | 4 (8) | 4 (8) | 4 (8) | 4 (8) | | |
| *Surgeon satisfaction (Clot quality)* | Very poor | 7 (14) | 0 (0) | 0 (0) | 3 (6) | | |
| | Poor | 14 (28) | 11 (22) | 11 (22) | 2 (4) | | |
| | Moderate | 11 (22) | 13 (26) | 14 (28) | 18 (36) | 27.118 | 0.007* |
| | Good | 10 (20) | 14 (28) | 15 (30) | 12 (24) | | |
| | Very good | 8 (16) | 12 (24) | 10 (20) | 15 (30) | | |
| *Reactionary bleed (within 24 hrs of surgery)* | No | 48 (96) | 48 (96) | 48 (96) | 48 (96) | NA | NA |
| | Yes | 2 (4) | 2 (4) | 2 (4) | 2 (4) | | |

**NA:** Not applicable; Chi-square test was done; *significant at 5% level

Figure 3. illustrates a notable proportion of patients who achieved hemostasis within 10 minutes, with minimal variability and fewer outliers, reflecting consistent efficacy. There was clinically meaningful effectiveness, with most patients achieving rapid bleeding control, particularly by the 7 and 10-minute marks.

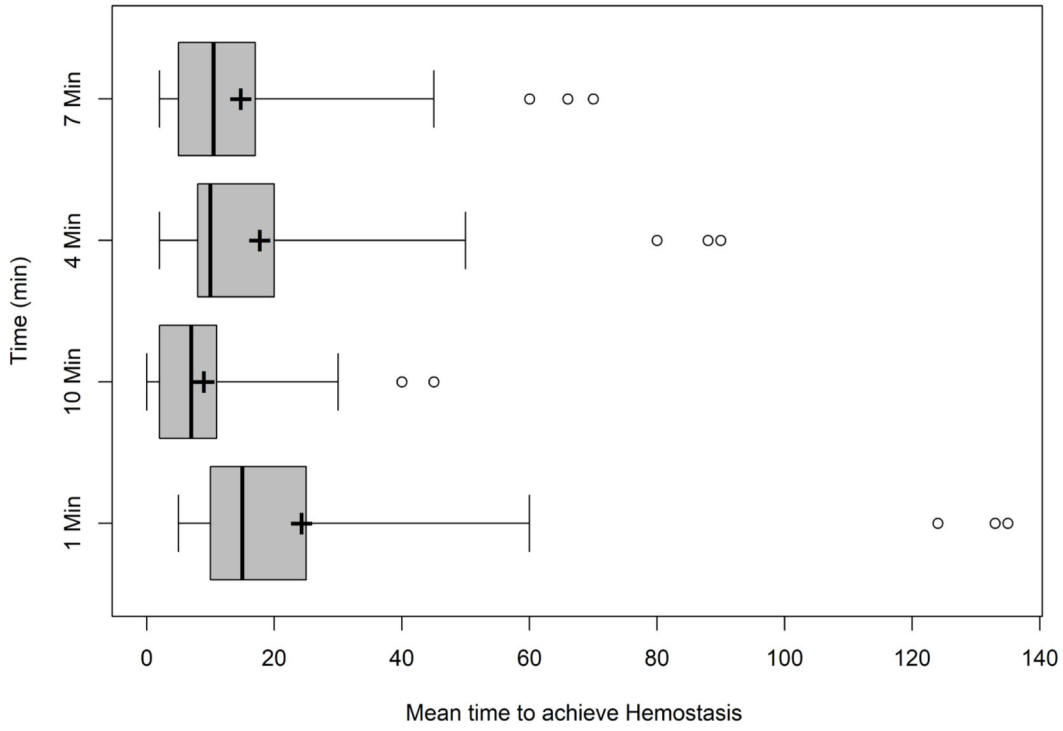



**Figure 3:** Time-Dependent efficacy of hemostatic agent in achieving hemostasis at 1, 4, 7, and 10-minute time points

## SURGEON SATISFACTION

Surgeon-reported satisfaction with clot quality demonstrated a statistically significant difference across the study groups ($\chi^2 = 27.118$, $p = 0.007$). A significantly higher proportion of "very poor" ratings was observed at 1 min (14%) compared to 4 min, 7 min, and 10 min. In contrast, ratings of "moderate," "good," and "very good" increased across the time points, with 10 min receiving the highest proportion of favorable assessments, including 30% "very good" and 24% "good" ratings. These findings suggest a trend toward improved surgeon-perceived clot quality in later timepoints, indicating enhanced hemostatic performance of the intervention across the time points (Table 8).

## SAFETY EVALUATION

Of 50 patients, there was no incidence of study drug related adverse effects. SeraSeal was well tolerated and good safety profile among the study population.

**Table 10:** Adverse events

| Characteristics | n (%) |
|---|---|
| Subjects with at least one Adverse Event [n=50] | 0 (0) |
| Number of Adverse Events | 0 (0) |
| Study Drug Related AEs | 0 (0) |
| Serious AEs | 0 (0) |
| Study Drug-Related Serious AEs | 0 (0) |

## DISCUSSION

Effective hemostasis and reliable dural closure are critical objectives in trauma and emergency-neurosurgical procedures, particularly in brain and spinal surgeries, where any compromise in dura mater integrity may result in cerebrospinal fluid (CSF) leakage a complication associated with increased risk of infection, prolonged hospital stay, and the need for reoperation. Achieving watertight dural sealing is especially challenging in cases of thin or friable dura, revision surgeries, and in anatomically complex regions such as the posterior fossa or spinal canal. Traditional

techniques, including suturing and the use of autologous grafts, may be insufficient or technically demanding, prompting the need for adjunctive hemostatic and sealing agents.[15]

This prospective, post-marketing observational study evaluated the hemostatic performance and safety of SeraSeal 3000 IU/ml in controlling intraoperative bleeding, dura mater CSF leak and sealing across various surgeries, such as spinal, neurological, orthopaedic, and general. The findings affirm SeraSeal's rapid onset of action, progressive and sustained hemostatic effect, high surgeon satisfaction, and an excellent safety profile with no reported adverse events. These results reinforce the clinical utility of SeraSeal as a primary topical hemostatic agent in real-world surgical practice.

SeraSeal, has demonstrated promising results in achieving both hemostasis and water-tight sealing, particularly relevant in neurosurgical contexts. In the present prospective observational study, the application of SeraSeal in cranial and spinal procedures showed a 100% success rate in surgical outcomes and CSF leak prevention, underscoring its efficacy as a dual-function agent for hemostasis and dura sealing.

Among the 50 subjects evaluated, only 4 cases (8%) showed postoperative CSF leakage, with a mean leak incidence of just 1% per case and a narrow observed range (1–2%). Importantly, the proportion of successful intraoperative sealing reached 100%, with no intraoperative CSF leaks reported following SeraSeal application. These findings are consistent with and in some instances superior to previously published outcomes using conventional dural sealants or fibrin glues. Studies evaluating fibrin sealants such as Tisseel or Evicel have reported CSF leak rates ranging between 5% and 12%, particularly in spinal procedures or posterior fossa surgeries.[17] A randomized trial comparing suturing with and without fibrin sealant showed a postoperative CSF leak rate of 7.6% in the sealant group, while another analysis highlighted leak rates of up to 10% with polyethylene glycol (PEG) based sealants in spine surgery. In contrast, SeraSeal achieved a leak rate of only 8% overall (all postoperative), with no intraoperative leaks, highlighting a potentially superior profile, particularly in immediate intraoperative effectiveness.[18]

Additionally, the rapid onset of action observed in our study further distinguishes SeraSeal. While no significant hemostatic effect was evident at 1 minute post-application, a substantial and statistically significant reduction in blood loss (mean difference: –50.18 mL, $p < 0.001$) was observed at 10 minutes. Concurrently, time to achieve hemostasis decreased significantly over time, reaching a mean of 8.98 seconds at 10 minutes, compared to 24.3 seconds at baseline. These results reflect not only the agent's efficacy but also its consistency, as demonstrated by reduced standard deviations and narrower confidence intervals over time.

From a clinical usability perspective, SeraSeal was applied directly in 100% of cases without the need for adjuncts such as gauze, and re-bleeding occurred in only 8% of cases. Surgeon satisfaction, measured via clot quality assessment, improved significantly over time ($p = 0.007$), suggesting favorable handling characteristics and durable hemostatic effect.

On comparing to other topical hemostatic agents, such as oxidized regenerated cellulose, gelatin-based sponges, or fibrin sealants, SeraSeal offers distinct advantages. SeraSeal is composed of bovine-derived clotting factors IIa, VIIa, IXa, and Xa within an agar matrix, promoting clot formation without invoking inflammatory responses or tissue damage, as evidenced by the absence of any adverse effects in our study population.[19]

The time-dependent efficacy trend observed in our study is in line with another study, which demonstrated that local administration of saline and low-dose epinephrine in joint surgeries reduced postoperative bleeding within 10–15 minutes. Although different in mechanism, the implication is similar localized, timely interventions can significantly impact surgical bleeding outcomes.

Re-bleeding was minimal (8%), and no reactionary bleeding occurred in 96% of subjects within the first 24 hours postoperatively. These outcomes underscore the agent's durability in clot stabilization and its ability to maintain hemostasis under physiological stress post-surgery. Additionally, surgeon satisfaction significantly improved across time points, with a clear shift toward moderate-to-very-good ratings for clot quality ($p = 0.007$), reflecting both the clinical confidence and perceived utility of the agent.[20]

Importantly, the agent's safety profile was excellent. No adverse events or complications attributable to SeraSeal were recorded, consistent with previous reports and confirming its suitability for routine surgical use. This distinguishes it from other hemostats that are occasionally associated with allergic reactions, infection risk, or delayed wound healing.

## LIMITATIONS

While the results are encouraging, this study has certain limitations. It was conducted at a single center with a relatively small sample size, which may limit generalizability. Furthermore, the non-comparative design precludes direct head-to-head analysis with other hemostatic products. Long-term outcomes such as wound healing time, delayed hemorrhages, and functional recovery were not assessed.

## CONCLUSION

The findings suggest the clinical utility of SeraSeal (3000 IU/mL) as a highly effective topical hemostatic agent in trauma and emergency (brain and spinal surgeries). Its application resulted in complete intraoperative sealing with no CSF leaks during surgery and a low postoperative CSF leak rate (8%), demonstrating both immediate and sustained efficacy in dural closure. The agent facilitated a significant reduction in blood loss and time to achieve hemostasis, with high surgeon satisfaction and minimal rebleeding or postoperative complications. Future large scale, randomized controlled trials comparing SeraSeal with other hemostatic modalities will further define its role in modern surgical hemostasis.

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**Conflict of Interest:** No conflict of interest

**Ethics Approval and Consent to Participate:** This project was approved by the Research Ethics Committee of the Sapthagiri Institute of Medical Sciences and Research Centre. All the patients were screened, enrolled in the study after obtaining consent.

| Study Information | |
|---|---|
| **Study Centre** | Sapthagiri Institute of Medical Sciences and Research Centre, Chikkabanavara, Bengaluru, Karnataka 560090. |
| **Protocol Number** | **PHAR/2023/WLI3125/05** |
| CTRI Number | **CTRI/2023/12/060763** |

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