Spine surgery can result in substantial blood loss, which can raise several issues in the operating room, such as limiting the amount of surgery that can be performed and increasing the duration of the procedure. The operating field may be obscured, reducing the accuracy and safety of the surgical technique. Increased bleeding and longer procedure times can lead to a higher risk for infection for the patient. Post-operative recovery and healing times may also be adversely affected. Substantial blood loss can lead to a drop in blood pressure and, consequently, increased risk for morbidity and mortality. This highlights the need for blood-sparing techniques that can help achieve rapid and effective hemostasis, thereby preventing blood loss.

Effective intraoperative control of bleeding during spinal surgery procedures can reduce the need for both blood transfusions and blood salvage devices. This is beneficial as allogenic transfusion is associated with complications, such as allergic reactions and the risk for infection. Furthermore, blood-salvaging techniques that can transfuse a patient's blood back into his or her circulation are only 50% efficient.

This article will provide an overview of the blood-sparing techniques for spinal surgery and discuss any recent additions to the surgeon's toolbox.

Bleeding in Spinal Surgery and the Need for Blood-sparing Techniques

Resection of bone during spinal surgery often results in a type of bleeding characterized as oozing. However, in certain procedures—for instance when resecting a vertebra in order to correct a spinal deformity or decompress the spinal canal—a large quantity of blood can be lost quickly (flowing or pulsatile bleeding). This is because of the large blood vessels present within the vertebra. Similarly, in front of the spine are the vena cava and the aorta, and damage to these vessels can result in substantial blood loss within seconds. Bleeding from bone is hard to stop as it is a raw, bony surface and therefore, unlike a blood vessel, it cannot be tied or cauterized. The epidural veins are a plexus of blood vessels that surround the spinal cord and spinal nerves. Any manipulation to these vessels can result in substantial bleeding. Bleeding from these vessels can be hard to stop because they lie next to the nerves and so conventional procedures, such as cauterization or pressure, must be applied with caution.

Reducing bleeding during spinal surgery is important because of the vicinity of major and highly fragile neurological structures. Conventional blood-sparing procedures, including cauterization and suturing, are not always practical in spinal surgery due to the risk of damaging these delicate structures. In addition, bleeding during spinal surgery is diffuse and cannot be effectively controlled by cauterization.

Conventional Blood-sparing Techniques

Conventional hemostasis procedures, such as suturing and cauterization, have been proved to be effective in controlling blood loss in most types of surgery. In spinal surgery, monopolar electric cautery is usually highly effective in terms of controlling bleeding around muscles, but not very effective in terms of controlling bleeding around bones. Another procedure is bipolar electric cautery, which allows the control of bleeding. However, as previously mentioned, the anatomy of the spine can make the use of these tools impractical or ineffective. In such cases, hemostasis agents are used to control bleeding. These agents either act mechanically to block or seal the bleeding site, such as bone wax, or act on the clotting cascade to enhance blood clot formation, such as fibrin sealants and thrombin.

Bone wax acts by sealing the bony surface that is oozing blood. However, it can interfere with bone fusion as it is placed across the surface of the bone where fusion may take place. Another commonly used agent is a gelatin-base sponge called Gelfoam, which is usually soaked with thrombin. The spongy physical properties of Gelfoam hasten clot formation and provide structural support for the forming clot, while thrombin catalyzes the conversion of fibrinogen to fibrin monomers and thereby facilitates blood clot formation. However, Gelfoam is a mass-occupying substance and can swell up when filled with blood or fluid. It is often used around the nerves during spinal surgery, and the swelling can lead to potential neurological compression. Fibrin sealants are also hemostasis agents; they act by reproducing the last phase of coagulation (the formation of a fibrin clot). Other hemostasis agents include oxidized regenerated cellulose, microfibrillar collagen, and tranexamic acid. The above-mentioned agents have demonstrated variable efficacy and their use is often hindered by difficulty in application, especially over-aggressive bleeding sites or difficult-to-reach locations.

As discussed, there are issues associated with the use of conventional blood-sparing procedures during spinal surgery, and the above-mentioned hemostasis agents have a negative cost-benefit ratio. Therefore, there is a need for new techniques to improve hemostatic control.
need for more cost-effective agents that can rapidly and effectively control actively bleeding sites during spinal surgery.

A Novel Hemostasis Agent for Blood Sparing During Surgery

FloSeal™ is a fibrin sealant that consists of a gelatin matrix (cross-linked gelatin granules) and a human thrombin component.10 It has been successfully used to control bleeding caused by various types of surgery, including vascular,11,12 pituitary,13 cardiac,14 and spinal surgery.7

Regarding its mechanism of action (see Figure 1), the gelatin granules swell by 10–20% on contact with blood or body fluids.10 This allows the granules to conform to irregular bleeding sites and restrict blood loss by blocking the entire bleeding surface.10 The swelling gelatin granules also provide a mechanically stable matrix around which the fibrin clot can form.10 Blood flowing through the granules comes into contact with the thrombin, allowing the latter to act on the clotting cascade and enhance blood clot formation. Most of the FloSeal can be resorbed by the body during the normal wound-healing process,10 and any excess can be removed by gentle irrigation.

FloSeal takes only one to two minutes to prepare and is easy to use. It is topicaly applied to the bleeding site using a syringe and needle. It is then pressed with a small sponge to put a little pressure on the bleeding surface. Once the sponge is removed, the bleeding stops.

Clinical Evidence for the Efficacy of FloSeal

Renkens et al. carried out a multicenter, prospective, randomized trial involving 127 patients who were undergoing spinal surgery. Patients in whom surgical means of controlling blood loss had failed received either FloSeal (treatment) or Gelfoam–thrombin (control). The application of the agent was considered successful if bleeding stopped within 10 minutes. Table 1 shows the number of patients in whom hemostasis was reached within 10 minutes. Time to hemostasis was significantly shorter in the treatment group than in the control group. No adverse events were reported in the treatment group, indicating that FloSeal is safe to use. The results of this study demonstrate that FloSeal is more efficacious than Gelfoam and that its application leads to rapid and effective hemostasis. Therefore, it can be used to deal with moderate bleeding during spinal surgery when the use of ligatures or conventional procedures is impractical or ineffective.

Weaver et al. and Oz et al. evaluated the efficacy of FloSeal against Gelfoam-Thrombin treatment in patients undergoing vascular and cardiac surgery, respectively.12,14 FloSeal stopped bleeding in earlier and in more bleeding sites than the control. This shows that FloSeal has superior efficacy to Gelfoam–thrombin and can also effectively control severe bleeding. Oz et al. also demonstrated that FloSeal had a safety profile similar to that of Gelfoam–thrombin, with both drugs generally being very safe.

The Use of FloSeal During Spinal Surgery

At the St Joseph Hospital and Children Hospital of Orange County, California, we have used FloSeal extensively for all spinal surgeries carried out each year. We have found this agent to be very consistent and effective in controlling blood loss. The number of FloSeal syringes used per case depends on the magnitude of the operation. In the spinal surgeries we have carried out, the number of syringes has varied from one to 10 or even 20 per case, determined by the amount of bleeding that needs to be controlled.

Visualization of the operating field is crucial for a safe and effective procedure, especially in minimally invasive surgeries. These surgeries often require a nerve to be retracted and so some bone has to be resected. This can lead to bleeding from the bone and epidural vessels, and subsequently blood filling the surgical field. This hole is one inch wide but six to eight inches deep, and the blood makes visualization difficult. In such cases we have successfully used FloSeal to seal the hole and stop bleeding from the bone and vessels. We have also used it to control the significant amount of bleeding that can take place in some procedures due to the vertebra being resected. This novel hemostasis agent is important for spinal surgery as it has been demonstrated to rapidly and effectively stop bleeding during spinal surgery and can also prevent some of the issues that arise due to blood loss, such as obscured vision of the operating field.

The disadvantages of using conventional hemostasis agents, as already discussed, include inhibiting bone fusion (bone wax), nerve compression due to sponge swelling (Gelfoam), and the inability of the solid substances to conform to the irregular bleeding sites and effectively control bleeding. FloSeal does not have these complications as it is not a mass-occupying substance and it can be resorbed by the body or easily washed off. As FloSeal can conform to and pack the various bleeding sites, it has the ability to control the diffuse bleeding common during spinal surgery. Unlike the other

<table>
<thead>
<tr>
<th></th>
<th>First Bleeding Site Only</th>
<th>All Bleeding Sites</th>
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<tbody>
<tr>
<td>FloSeal (treatment)</td>
<td>64/65 (98%)</td>
<td>179/180 (99%)</td>
</tr>
<tr>
<td>Gelfoam–thrombin (control)</td>
<td>56/62 (90%)</td>
<td>158/170 (93%)</td>
</tr>
<tr>
<td>p value*</td>
<td>0.042</td>
<td>0.001</td>
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*Coehran-Mantel-Haenzel test.

Source: Renkens et al., 2001.”
Please visit our website, www.floseal.com, to access additional materials about FLOSEAL Hemostatic Matrix and learn about how surgeons are using FLOSEAL in joint replacement surgery.

Please see Important Safety Information on the next page.
**FLOSEAL [Hemostatic Matrix] Indications**

FLOSEAL is indicated in surgical procedures (other than ophthalmic) as an adjunct to hemostasis when control of bleeding by ligature or conventional procedures is ineffective or impractical.

**Important Safety Information**

- FLOSEAL must not be injected into blood vessels, or allowed to enter blood vessels. Do not apply in the absence of active bleeding. Extensive intravascular clotting and even death may result. Do not use FLOSEAL in the closure of skin incisions because it may interfere with the healing of the skin edges.
- Do not use FLOSEAL in patients with known allergies to materials of bovine origin.
- FLOSEAL is made from human plasma. It may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent.
- FLOSEAL is not intended as a substitute for meticulous surgical technique and the proper application of ligatures or other conventional procedures for hemostasis.
- The maximum swell volume of approximately 20% is achieved within about 10 minutes. Excess FLOSEAL (material not incorporated in the hemostatic clot) should be removed from the site of application using gentle irrigation.
- FLOSEAL should not be used in conjunction with methylmethacrylate or other acrylic adhesives.

RX only: For safe and proper use of this device, please refer to full device Instructions For Use.

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**Spine**

agents, it can control wet, actively bleeding sites, the major source of blood loss during surgery of the spine. Moreover, it can control all types of bleeding (oozing, pulsatile, and flowing), and has been demonstrated to control even high-pressure arterial bleeding (pulsatile bleeding). FloSeal seems to be generally safe with few disadvantages. The nurse needs to have the training to prepare FloSeal; nevertheless, preparation takes only a few minutes and the method is reproducible. When considering adjunct therapies for surgery, cost is often an issue. However, while FloSeal is not cheap, the benefits of using it—including rapid and effective control of blood loss and shortening of the procedure time—outweigh its disadvantages.

**Conclusion**

Spinal surgery can result in substantial blood loss, which can raise various issues in the operating room, such as limiting vision, lengthening procedure times, and increasing the risk for infection and mortality. Blood-sparing techniques are needed to control blood loss to prevent bleeding-related issues and the need for transfusions. Conventional blood-sparing procedures, such as cauterization and suturing, have been proved to be successful in many types of surgery. However, these techniques are usually either impractical, due to the risk of nerve injury, or ineffective, as there is diffuse bleeding during spinal surgery. Hemostasis agents, such as bone wax, gelatin sponges (Gelfoam), and fibrin sealants, are often used to stop bleeding. However, these agents have demonstrated variable efficacy and are associated with complications, such as interfering with bone fusion or nerve compression.

FloSeal, a novel hemostasis agent, is a gelatin-based fibrin sealant. It can rapidly and effectively control all types of bleeding and has been successfully used during spinal surgery. It can work on wet, actively bleeding sites, is generally safe to use, and is not associated with the disadvantages of other currently available agents. Although FloSeal is an additional expense, its benefits outweigh any disadvantages, making it a novel hemostasis agent that rapidly and effectively controls blood loss during spinal surgery and that should be used as an adjunct to conventional procedures, which can often be ineffective or impractical.