Surgical Hemostasis in Knee Replacement Surgery—A Physician’s Perspective

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Abstract
Total knee arthroplasty (TKA) is one of the most successful operations in orthopaedic surgery and commonly provides significant improvements in the quality of life of patients. Tissue-sparing and minimally invasive techniques have made recovery from this surgery much easier for patients. Paradoxically, peri-operative bleeding with these techniques is often increased, counteracting some of the short-term benefits. It can also increase the risk for infection and may compromise the long-term outcome. This article reviews the evolution of surgical and peri-operative hemostasis techniques in the clinical experience of the author. It also provides a rationale for abandoning some of the techniques that are popular in the literature, and describes some techniques that appear successful.

Keywords
Knee replacement, minimally invasive surgery, blood loss, hemostatic matrix

Minimally Invasive Techniques in Knee Replacement Surgery
Minimally invasive techniques for total knee arthroplasty (TKA) have evolved over the past 20 years and have been an opportunity to improve outcomes and patient satisfaction, with at least no increase in complications. The term ‘minimally invasive’ is not well defined. To most surgeons, the term is better translated as ‘minimal-incision surgery.’ This effectively means performing the same operation through a keyhole instead of sizeable incisions around the affected joint. With the adoption of minimally invasive procedures by many surgeons within the past decade, patient satisfaction has generally been high, but an increased rate of complications has begun to be reported. It is recognized that relatively small increases in complications can be problematic, as dissatisfied patients are four to five times more likely to complain about their treatment than satisfied ones are to tell their friends; therefore, potential complications require urgent attention.

It was apparent after the adoption of minimally invasive techniques for both hip and knee replacements that patients mobilized more rapidly after their surgery than after surgery by traditional techniques (see Figure 1 for a comparison of the arthrotomies made using the two methods). This was accompanied by no increase in complications other than bleeding, which still represented a significant advance for this type of technique compared with the traditional approach. Minimally invasive techniques are more effective at enabling patients to mobilize rapidly, reducing the need for pain medication, reducing the need for support devices, and allowing patients to return to normal life much more quickly. However, as tissue-sparing techniques improved and the early activity level of patients increased, so did the proportion of patients with post-operative bleeding into the knee during seven to 14 days after surgery. In the author’s clinic, patients often describe themselves initially as a ‘poster child’ (an ideal patient) for the procedure and then, after the bleed, as a ‘cripple.’

Further complicating the matter are some advances in the tissue-sparing technique. When first described, the originators of the minimally invasive total knee replacement indicated that interference with the supra-patellar pouch should be minimized in order to facilitate faster recovery. Subsequent experience has contradicted this assertion. Using such an approach may retain an inflamed synovium, and a post-operative sensation of ‘ground glass’ when moving the joint may be experienced. It can also result in an audible soft-tissue crepitus. This clinical problem has been almost eliminated in the experience of the author and others by performing an extensive intra-operative synovectomy. However, even if performed with a Bovie electrocautery, this procedure opens up a large surface area for potential bleeding. One method for addressing this concern may be to adjust the peri-operative chemoprophylaxis for venous thromboembolic events.

Balancing Thromboembolism Prophylaxis and Blood Loss from the Surgical Site
A major problem following TKA is managing venous thromboembolism and maintaining large groups of patients in a very narrow range of international
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Methods to Limit Blood Loss Following Surgery

Blood loss after TKA can be significant. Various orthopaedic surgeons have reported that this can be reduced by eliminating the operation-site drain. However, this action has been shown to considerably increase pain, stiffness, and swelling post-surgery and substantially reduces patient satisfaction. For these reasons the drain should be retained. Irrigation and extensive cauterizing of the surgical site can result in a reduction of peri-operative draining of about 25%, but this is not sufficient to eliminate the need for drains. In order to reduce these problems following TKA surgery, it is necessary to adopt surgical practices that may protect orthopaedic patients from developing bleeding complications at a later stage. Manual application of thrombin, injecting thrombin into the knee, applying Surgicel, or using many other hemostatic agents often fails to reduce this problem of post-surgical bleeds.

An alternative approach is to use the Aquamantys™ system, which is designed to markedly reduce blood loss. Aquamantys permanently seals blood vessels through a biomechanical process that transforms fibrous collagen in vessel walls. The system contains a pump generator for delivery of radiofrequency (RF) energy and saline for hemostatic sealing and coagulation of soft tissue and bone at the operative site. However, in the author’s experience this device tended to increase the variability of the volume of blood drained from the surgical site. While there were modest decreases in the average accumulated drainage, the number of knees with accumulated drainage between 1,500 and 2,000ml (described as ‘wet knees’) increased. Use of the Aquamantys system can be problematic in other ways as well. Significant pain reaction has been observed when it is used on the posterior capsule. The use of local anesthetics can diminish this response, but not eliminate it. As minimally invasive surgery is intended to minimize peri-operative pain, this system may not be useful for this type of surgery.

FLOSEAL Hemostatic Matrix

Recently, use of adjunctive products has increased, such as topical hemostatic agents, sealants, and glue in surgery to provide more effective means of reducing blood loss. These have been valuable in minimally invasive procedures where access into parts of the wound to reduce blood loss is limited. As control of bleeding by sutures or cautery is not always effective or practical, a variety of products have been developed to try to achieve bleeding control by alternative means; these include:

- hemostatic agents, which are used to halt bleeding, are applied directly to a bleeding site, and work in the presence of actively flowing blood;
- glues/adhesives, which are used to attach organs, structures, or tissues; and
- sealants, which are used to prevent the leakage of liquids, gases, and solids from surgical sites, or applied to dry or clamped tissue surfaces to create a barrier.

The limitations of some hemostatic and sealant agents include variable efficacy, difficulty in application, particularly when bleeding is aggressive or the bleeding site is difficult to reach, and lack of efficacy in heparinized patients.

A product that activates the clotting cascade while maintaining a hemostatic plug that is not readily displaced could help to overcome these shortcomings. This realization led to the development of a gelatin matrix–thrombin composite product. FLOSEAL Hemostatic Matrix is indicated in surgical procedures (other than ophthalmic) as an adjunct to hemostasis when the control of bleeding by ligature or conventional procedures is ineffective or impractical. FLOSEAL consists of a patented bovine-derived gelatin matrix coated in human-derived thrombin, which...
works in combination with human thrombin to form a stable clot at the bleeding site: as the unique gelatin granules swell to produce a tamponade effect. High localized concentrations of thrombin convert fibrinogen into fibrin monomers, accelerating clot formation.

FLOSEAL Hemostatic Matrix is applied to the tissue surface at the base of the lesion, and conforms to the irregular shape of the wound. FLOSEAL expands by approximately 20% within about 10 minutes, giving predictable control during and after surgery. Blood percolating through the matrix encounters high concentrations of thrombin. This rapidly reduces bleeding and provides support assisting the formation of a clot and subsequent healing. FLOSEAL is resorbed by the body within six to eight weeks, consistent with the time-frame of normal wound healing. This product must be in contact with blood at the administration site to allow activation.

To date, FLOSEAL Hemostatic Matrix has been successfully used in multiple surgical specialties, including urology, gynecology, trauma, ear, nose, and throat (ENT), nephrolithotomy, adenectomy, spine, thyroid, general, vascular, and cardiac surgery. Regulatory approval for the product was based on data from randomized clinical trials on cardiovascular, vascular, and spinal/orthopaedic surgery in multiple treatment centers. FLOSEAL administration has a possible risk for thrombosis and infection, although in practice these risks are small.

There have been few reports in the literature on the use of FLOSEAL Hemostatic Matrix following orthopaedic surgery. One case report documented the limitation of iatrogenic injury during mandibular joint replacement. A randomized study in the US including 127 patients undergoing spinal surgery showed that FLOSEAL stopped bleeding within 10 minutes in a significantly greater proportion of patients compared with standard GELFOAM® thrombin treatment. Successful hemostasis was achieved in 97% of the FLOSEAL-treated patients compared with 71% of the control group (p<0.0001). FLOSEAL has also been successfully used in vascular surgery. One study in 89 patients undergoing various types of vascular operation, including arterial repair and bypass procedures, showed that FLOSEAL provided more rapid hemostasis than GELFOAM® plus thrombin. In another study on 93 patients undergoing cardiac surgery in whom standard bleeding control measures had failed, FLOSEAL stopped the bleeding within 10 minutes in 94% of patients (compared with 60% in the control group). These studies showed that FLOSEAL had a similar safety profile to GELFOAM® with thrombin. A retrospective chart analysis on the effective use of FLOSEAL following post-operative total knee or total hip replacement surgery has begun (NCT00958945), which is designed to record efficacy in terms of hemoglobin and hematocrit levels and red blood cell counts in a planned population of 500 patients who have received FLOSEAL treatment. The findings should provide a better assessment of the technique and may provide data supporting its use from a wider cross-section of patients than were seen in the author’s clinic.

Using FLOSEAL Hemostatic Matrix on a regular basis in the author’s clinic has resulted in improved control of peri-operative bleeding compared with other methods. The average drain output remains higher than desirable at about 400ml, but the range is reduced: the upper limit is about 800ml, while the lowest output for a functioning drain is 65ml. Prior to using FLOSEAL Hemostatic Matrix, patients were often prevented from discharge on the first or second post-operative day due to the volume of output in their site drains. This resulted in a significant number of patients needing to remain hospitalized for a third post-operative day, at which point drain removal would be mandated. Using the FLOSEAL method, the proportion of patients requiring extended hospital stays due to drain output is markedly diminished. In addition, the percentage of patients who consider themselves one day as poster children and the next day as cripples is less than 1%.

Application of FLOSEAL Hemostatic Matrix

FLOSEAL offers flexible preparation time that can be as little as two minutes. After mixing the thrombin and the gelatin matrix components, it is recommended to wait at least 30 seconds to obtain optimal product consistency before applying FLOSEAL to the wound. FLOSEAL matrix should be used within two hours of mixing with the thrombin solution. The method for application of FLOSEAL to active bleeding sites is as follows:

- identify the source of bleeding;
- apply a small ‘mound’ of FLOSEAL Hemostatic Matrix to the bleeding site with the applicator tip;
- gently apply light pressure with a damp lap pad for approximately two minutes;
- in cases of tissue defects (‘divots’ or ‘craters’), apply FLOSEAL to the deepest part of the lesion and release as the applicator is withdrawn from the lesion; and
- after bleeding has ceased, gently irrigate with sterile saline to remove excess FLOSEAL.

In knee replacement surgery, electrocautery remains useful at a site likely to bleed, such as the medial and lateral middle geniculate and superior lateral geniculate blood vessels. FLOSEAL Hemostatic Matrix is best used after the components are in place and the cement is setting, the last irrigation has been completed, and all excess cement has been removed, but before the tibial spacer has been inserted. The procedure is as follows:

- 10–15ml of FLOSEAL is used, with the volume depending on both the size of the knee and the amount of bleeding occurring when the tourniquet is deflated;
- FLOSEAL is applied to the bleeding surfaces—small quantities of FLOSEAL can also be applied to the bleeding bone;
- if there has been a release of the posterior capsule, FLOSEAL can also be applied proximal to the condyles and posterior to the femur;
- gauze pads or moistened lap sponges are gently applied to the entire knee, the knee is moved into full extension, and the moistened lap pads are held in place for approximately four to five minutes;
- after this time the lap sponges are removed, and excess FLOSEAL is gently irrigated from the knee with a bulb syringe;
- if bleeding persists, insert the applicator tip through the center of the previous application site and deliver additional material to the tissue surface; and
- the definitive tibial spacer is placed, a drain is also placed, and the site is closed.

FLOSEAL Hemostatic Matrix has also provided improvements for total hip arthroplasty using the direct anterior approach originally described by Judet in 1947–1948 and more recently popularized by Matta. Relatively
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early in the procedure, one particular step can result in moderate bleeding in an area that is mostly inaccessible. Regardless of visible bleeding, an application of approximately 5ml of FLOSEAL should be made over the area and then packed with a lap sponge. The sponge can then remain in situ for the next 20–30 minutes; following sponge removal and gentle irrigation of the application site to remove excess FLOSEAL, there is rarely any visible bleeding from the area.

The net result of these modifications, in the author’s practice, is that the rates of peri-operative bleeding, transfusion, and post-operative complications following TKA are reduced and patient satisfaction is increased. When the results of the ongoing retrospective chart analysis study become available there is likely to be more evidence supporting the use of surgical sealants as an adjunct to minimally invasive TKA surgery, greater interest in their development, and more widespread use. This could result in generally decreased blood loss following knee replacement surgery, which has been a significant cause of patient morbidity and peri-operative expense.

Trademark Statement

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42. Summary of safety and effectiveness: Floseal matrix hemostatic sealant, United States Food and Drug Administration, PMA, 2000;P990009.


