Comparative Analysis of Surgical Hemostatic Technologies and the Clinical Differentiation of WoundClot® Surgical (NONRCS)

Abstract

Topical surgical hemostatic agents are widely used when conventional surgical techniques (suture, ligature, cautery, pressure) are ineffective or impractical. Despite broad adoption, many legacy technologies have endemic limitations, including dependence on an intact coagulation cascade, restricted performance to mild bleeding, swelling/mass effect in confined spaces, immunogenicity (animal- or plasma-derived products), and technique-sensitive risks (e.g., spray-related gas embolism). This paper contrasts principal hemostatic technology classes—oxidized regenerated cellulose (ORC), gelatin-based, collagen-based, polysaccharide-based powders, thrombin-based agents, and fibrin sealants—against WoundClot® Surgical, a non-oxidized, non-regenerated cellulose (NONRCS) hemostatic gauze with cascade-independent, mechanically dominant gel formation.

Introduction

Surgical bleeding contributes to prolonged operative time, transfusion requirements, and downstream morbidity. Topical hemostatics are commonly positioned as adjuncts, primarily for capillary, venous, and small arteriolar bleeding. However, many products' indications and contraindications explicitly restrict use in brisk arterial/venous hemorrhage, intravascular application, and confined anatomic spaces where swelling can create unwanted pressure. [5–7,9–12]. In contrast, WoundClot® Surgical is designed as an implantable, water-soluble, absorbable, gel-forming hemostatic gauze intended for hemostasis at the site of active bleeding and absorption of blood and physiologic fluids[3].

Oxidized Regenerated Cellulose (ORC)

ORC hemostatics (e.g., SURGICEL® family) are manufactured by oxidation of raw cotton and wood fibers. They function by providing a local matrix for clot formation. In practice, product labeling and essential product information include limitations such as: avoidance in large artery/vein hemorrhage; prohibition of intravascular placement; and the requirement for removal after hemostasis when used near confined structures due to swelling and risk of unwanted pressure[5]. In vitro viscoelastic testing across multiple hemostat classes showed ORC (Surgicel®) forming clots in citrated blood only under conditions where blood contact remains necessary and exhibiting less favorable longer-term material behavior relative to NONRCS (e.g., stiffening over time)[1,2].

Additionally, ORC materials are inherently acidic (low pH) as a result of the oxidation process. While this acidity contributes to bacteriostatic properties, it has been associated with local tissue irritation, delayed fibroblast activity, and impaired wound healing, particularly when material is left in situ. The acidic microenvironment may also interfere with normal resorption, leading to prolonged inflammatory response, foreign-body reaction, or granuloma formation, which has been documented to mimic abscesses or tumor recurrence on postoperative imaging[13-19].

Gelatin-Based Hemostatics

Gelatin hemostatic agents are made from animal-derived gelatin, which is produced by hydrolyzing collagen from bovine or porcine skin. Gelatin sponges/matrices provide a physical scaffold and absorb blood to support clot formation. Package inserts commonly restrict use in intravascular compartments due to embolization risk and emphasize using only the minimum amount required, with removal of excess material after hemostasis. Additional limitations include cautions in infection/contaminated fields and contraindications in patients with porcine collagen allergies[6,7].

Collagen-Based Hemostatics

These products are manufactured from purified animal collagen, most commonly sourced from bovine (cow) or porcine (pig) tissue. Collagen hemostatics promote platelet adhesion/aggregation and provide a matrix to support clot formation. Contraindications and warnings for representative products (e.g., AVITENE™) include avoidance in closure of skin incisions, avoidance on bone surfaces where methylmethacrylate adhesives are used, and restrictions against injection/intravascular use[8].

Polysaccharide-Based Powders

Polysaccharide hemostatics are made from plant-derived polysaccharides**,** most commonly purified starch extracted from potatoes or corn**.** Polysaccharide powders (e.g., ARISTA™ AH) act by absorbing fluid and concentrating formed elements. IFU limitations include the prohibition of intravascular placement/injection due to embolization risk and warnings that the device is not a substitute for meticulous surgical technique [9].

Thrombin-Based Agents

Thrombin hemostatic agents are made from biologically derived thrombin, sourced either from human plasma or animal plasma (bovine), or produced as recombinant human thrombin using cell-culture technology. Topical thrombin accelerates the conversion of fibrinogen to fibrin and is generally indicated for oozing/minor bleeding accessible to topical application. Representative labeling (bovine thrombin) includes boxed warnings describing severe bleeding and thrombosis complications related to immunogenicity (e.g., antibody development) and contraindications against intravascular administration and use for severe/brisk arterial bleeding [10].

Fibrin Sealants

Fibrin hemostatic agents are made from human blood–derived proteins, specifically fibrinogen and thrombin, which are combined at the point of use to form a fibrin clot. Fibrin sealants supply components of the terminal coagulation pathway and are commonly indicated as adjuncts when standard techniques are ineffective or impractical. Key IFU limitations across products include: contraindication for intravascular injection; non-indication for severe/brisk arterial bleeding; and technique-dependent constraints for spray application due to risk of air/gas embolism and the need to maintain minimum distance/pressure specifications [11,12].

WoundClot® Surgical (NONRCS): Mechanism and Comparative Performance

WoundClot® is manufactured using a unique, multi-patented process that converts plant-derived cellulose into a non-oxidized, non-regenerated cellulose structure. This proprietary process creates a highly absorbent matrix that rapidly gels on contact with blood and utilizes multiple mechanisms to form an effective clot, without the use of animal or human-derived components.

WoundClot® Surgical is an implantable, water-soluble, absorbable, gel-forming hemostatic gauze intended for hemostasis at the site of active bleeding and absorption of blood and physiological fluids [3]. In a head-to-head in-vitro evaluation using contactless real-time viscoelastic testing, WoundClot® (NONRCS) demonstrated cascade-independent performance and was the only gauze-based agent reported as consistently effective across recalcified blood, citrated blood (impaired cascade), and PBS (non-blood fluid), supporting a mechanically dominant mode of action [1,2].

Clinical Performance and Safety

In the prospective, multi-center, single arm investigation[1,3], clinically successful hemostasis within 5 minutes was achieved in **97.18%** of subjects, with a mean time to hemostasis of **92.648 seconds** [3,4]. Serious adverse device effects (SADEs) did not occur, and the study did not identify safety concerns that apply to the use of WoundClot® Surgical [3,4].

Conclusion

Across legacy hemostatic categories, labeling-based limitations repeatedly constrain use to adjunctive roles (oozing/capillary/small-vessel bleeding), restrict intravascular exposure, caution against confined-space swelling, and—where biologics are involved—add immunogenicity or technique-dependent risks [5-12]. In contrast, WoundClot® Surgical's NONRCS platform demonstrates cascade-independent clot/gel formation in vitro and rapid hemostasis with a strong safety profile in prospective clinical evaluation, supporting differentiation for broader primary hemostatic utility within its labeled use conditions [1-4].

Table 1. Comparative Adverse Events Across Surgical Hemostatic Technologies
Events listed reflect recurring clinically significant risks described in product labeling and/or evaluated clinical evidence.

Technology class	Commonly reported adverse events / safety concerns	Typical risk drivers	Data sources
ORC (oxidized regenerated cellulose)	Swelling with risk of unwanted pressure near confined structures; limitations for large artery/vein hemorrhage; intravascular placement prohibited[5].	Material swelling in confined anatomy; use beyond indicated bleeding types; intravascular exposure.	SURGICEL™ essential product information[5, 13-19].
Gelatin-based (sponges/matrices)	Embolization risk if used intravascularly; allergy restrictions (porcine collagen/gelatin); cautions in infection/contaminated fields; remove excess after hemostasis[6,7].	Swelling/expansion; retention; animal-derived antigenicity; misuse in vascular compartments.	GELFOAM PI; SURGIFOAM essential info[6,7].
Collagen-based	Contraindicated for closure of skin incisions; restrictions with methylmethacrylate adhesives; not for injection/intravascular use[8].	Mechanical interposition; interaction with adhesives; foreign-body risk if misapplied.	AVITENE™ contraindications/warnings[8].
Polysaccharide powder	Do not inject/place into blood vessels due to embolization risk; adjunctive only (not substitute for meticulous technique)[9].	Powder migration; intravascular exposure; swelling upon contact with fluids.	ARISTA™ AH product labeling summary[9].
Thrombin (topical)	Boxed warning: severe bleeding/thrombosis complications related to immunogenicity; contraindicated for intravascular administration; not for severe/brisk arterial bleeding[10].	Antibody development; systemic exposure/misuse; dependence on fibrinogen availability.	THROMBIN-JMI FDA PI[10].
Fibrin sealants	Contraindicated intravascularly; not for severe/brisk arterial bleeding; spray application constraints due to life-threatening air/gas embolism risk[11,12].	Technique sensitivity (pressure/distance); intravascular exposure; biologic component risks.	TISSEEL FDA PI; EVICEL FDA PI[11,12].
WoundClot® Surgical (NONRCS)	No serious adverse device effects (SADEs) occurred in WCS-1; no safety concerns identified applying to use; strong benefit–risk conclusion[3,4].	Absorbable, gel-forming mechanical hemostasis; cascade-independent performance shown in vitro[1,2].	WCS-1 report; Clinical performance summary; in-vitro viscoelastic evaluation[1-4].

Table 2. IFU / Package-Insert Limitations by Technology
Limitations are summarized directly from representative product IFU/package insert language for each technology class.

Technology class	Representative IFU / package-insert limitations (examples)	Data Reference
ORC (SURGICEL™ ORC representative)	Not for hemorrhage from large arteries/veins; not for intraluminal/intravascular placement; swelling-related restrictions near foramina/bony confines/spinal cord/optic structures; not for implantation in bone defects; not for non-hemorrhagic serous oozing surfaces; not an adhesion prevention product[5, 13-19].	SURGICEL™ essential product information[5, 13-19].
Gelatin sponge (GELFOAM® / SURGIFOAM® representatives)	Not for intravascular compartments (embolization); allergy restrictions to porcine collagen (product-specific); not recommended in presence of infection/contaminated areas (product-specific); not for closure of skin incisions (product-specific)[6,7].	GELFOAM PI; SURGIFOAM essential info[6,7].
Collagen hemostat (AVITENE™ representative)	Should not be used in closure of skin incisions; should not be used on bone surfaces where methylmethacrylate adhesives are planned; not for injection/intravascular use (product labeling)[8].	AVITENE™ contraindications/warnings[8].
Polysaccharide powder (ARISTA™ AH representative)	Do not inject or place into blood vessels (embolization/death risk); not intended as a substitute for meticulous surgical technique and conventional hemostasis methods[9].	ARISTA™ AH product labeling summary[9].
Thrombin topical (THROMBIN-JMI® representative)	Do not inject into circulatory system; contraindicated for patients with hypersensitivity to bovine components; not for severe or brisk arterial bleeding; limitations related to re-exposure if antibodies suspected[10].	THROMBIN-JMI FDA PI[10].
Fibrin sealant (TISSEEL® / EVICEL® representatives)	Do not inject intravascularly; not for severe/brisk arterial bleeding; spray application only under specified conditions (distance/pressure) due to risk of air/gas embolism; additional biologic limitations (e.g., hypersensitivity; potential infectious agent transmission warnings depending on product)[11,12].	TISSEEL FDA PI; EVICEL FDA PI[11,12].
WoundClot® Surgical (WCS-1 documentation / labeled-use framing)	Clinical study objectives and population framing describe use for mild-to-moderate bleeding in the operating field; investigational definition of target bleeding site required conventional techniques to be ineffective or impractical[3].	WCS-1 report; Clinical performance summary; in-vitro viscoelastic evaluation[3].

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