

A Compendium of **Scientific Literature**

Evidence Supporting the **Efficacy and Safety** of the SURGICEL® Family
of **Absorbable Hemostats**



Surgicel® Family of Absorbable Hemostats



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Snow™

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Nu-Knit®

Strength

High tensile strength and thickness allows it to hold suture

Table of Contents

Cardiovascular/Cardiothoracic Surgery

- Predictors of neck bleeding after eversion carotid endarterectomy (Baracchini) 7
- The use of oxidized regenerated cellulose for video-assisted thoracic surgery (Tanaka) 8
- SURGICEL® Nu-Knit® hemostat for bleeding control of fragile sternum (Mair) 9
- A novel treatment for pulmonary hemorrhage during thromboendarterectomy surgery (Shetty) 10
- Comparison of sternal intramedullary bleeding prevention strategies in cardiac surgery (Tavlasoglu) 11

Neurosurgery

- Clinical experience with the SURGICEL® family of absorbable hemostats (oxidized regenerated cellulose) in neurosurgical applications: A review (Keshavarzi) 14
- A hemostatic agent delivery system for endoscopic neurosurgical procedures (Waran) 16
- Management of meningiomas invading the major dural venous sinuses: Operative technique, results, and potential benefit for higher grade tumors (Mantovani) 17
- Clinical hemostasis effect of a novel hemostatic material SURGICEL® versus gelatin sponge in neurosurgery (Lei) 18
- Rapid closure technique in decompressive craniectomy (Guresir) 20

General Surgery

- Co-suturing SURGICEL® and colonic fat to achieve hemostasis in presacral hemorrhage (Liu) 22
- A simplified approach to techniques of splenic salvage (Trooskin) 23
- Spleen hydatidosis treated by hemi-splenectomy: A low-morbidity, cost-effective management by a recently improved surgical technique (Costi) 24
- Surgical treatment of recurrent prolapse after stapled haemorrhoidopexy (Selvaggi) 25
- Oxidized cellulose (SURGICEL®) as a surgical hemostat in liver injury: A case report and literature review (Hamzah) 26
- Successful treatment of active hemorrhage from a duodenal diverticulum using SURGICEL® (absorbable hemostat): A case report (Muguti) 27
- Control of port-site bleeding from smaller incisions after laparoscopic cholecystectomy surgery (Rastogi) 28

Obstetric/Gynecologic Surgery

- A local hemostatic agent for the management of postpartum hemorrhage due to placenta previa and placenta accreta: A cross-sectional study (Portilla) 30
- Ovarian salvage in bilaterally complicated severe ovarian hyperstimulation syndrome (Al Omari) 31
- Effects of oxidized regenerated methylcellulose on lymphocyst formation and peritoneum in gynecologic cancer patients (Ayhan) 32

• Laparoscopic management of primary hepatic pregnancy (Chin)	33
• Use of oxidized regenerated cellulose (SURGICEL® Nu-Knit®) as a hemostat in laparoscopic endometriotic cystectomy: A case report (Sharma)	34
• Successful management of uterine incision hemorrhage in cesarean section with topical oxidized regenerated cellulose (SURGICEL® Nu-Knit®): A case report (Sharma)	35
• Repaired uterine rupture at mid gestation (Patricío)	36
• Laparoscopic oxidized cellulose (SURGICEL®) application for small uterine perforations (Sharma)	37

Urologic Surgery

• Robotic surgery and hemostatic agents in partial nephrectomy: A high rate of success without vascular clamping (Morelli)	39
• Use of oxidized cellulose hemostats (SURGICEL®) to support parenchymal closure and achieve hemostasis following partial nephrectomy (Abou-Elela)	40
• Use of hemostatic agents and glues during laparoscopic partial nephrectomy: A multi-institutional survey from the United States and Europe of 1347 cases (Breda)	41

Orthopedic Surgery

• The use of local agents: SURGICEL® and SURGIFOAM® (Sabel)	43
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Plastic Surgery

• Use of oxidized regenerated cellulose to stop bleeding after a facelift procedure (Bassetto)	46
--	----

ENT Surgery

• Using NU-KNIT® for hemostasis around recurrent laryngeal nerve during transthoracic esophagectomy with lymphadenectomy for esophageal cancer (Rino)	48
---	----

Health Economics and Outcomes Research

• Reduction in hospital costs and resource consumption associated with the use of advanced topical hemostats during inpatient procedures (Martyn)	50
• Variation in hospital resource use and cost among surgical procedures using topical absorbable hemostats (Martyn)	52

In Vivo Studies

• Hemostatic efficacy and tissue reaction of oxidized regenerated cellulose hemostats (Hutchinson)	55
• Effects of absorbable hemostats on intraabdominal sepsis (Kuchta)	56
• The effect of oxidized regenerated cellulose on experimental infected splenotomies (Dineen)	57
• The effect of oxidized regenerated cellulose on experimental intravascular infection (Dineen)	59

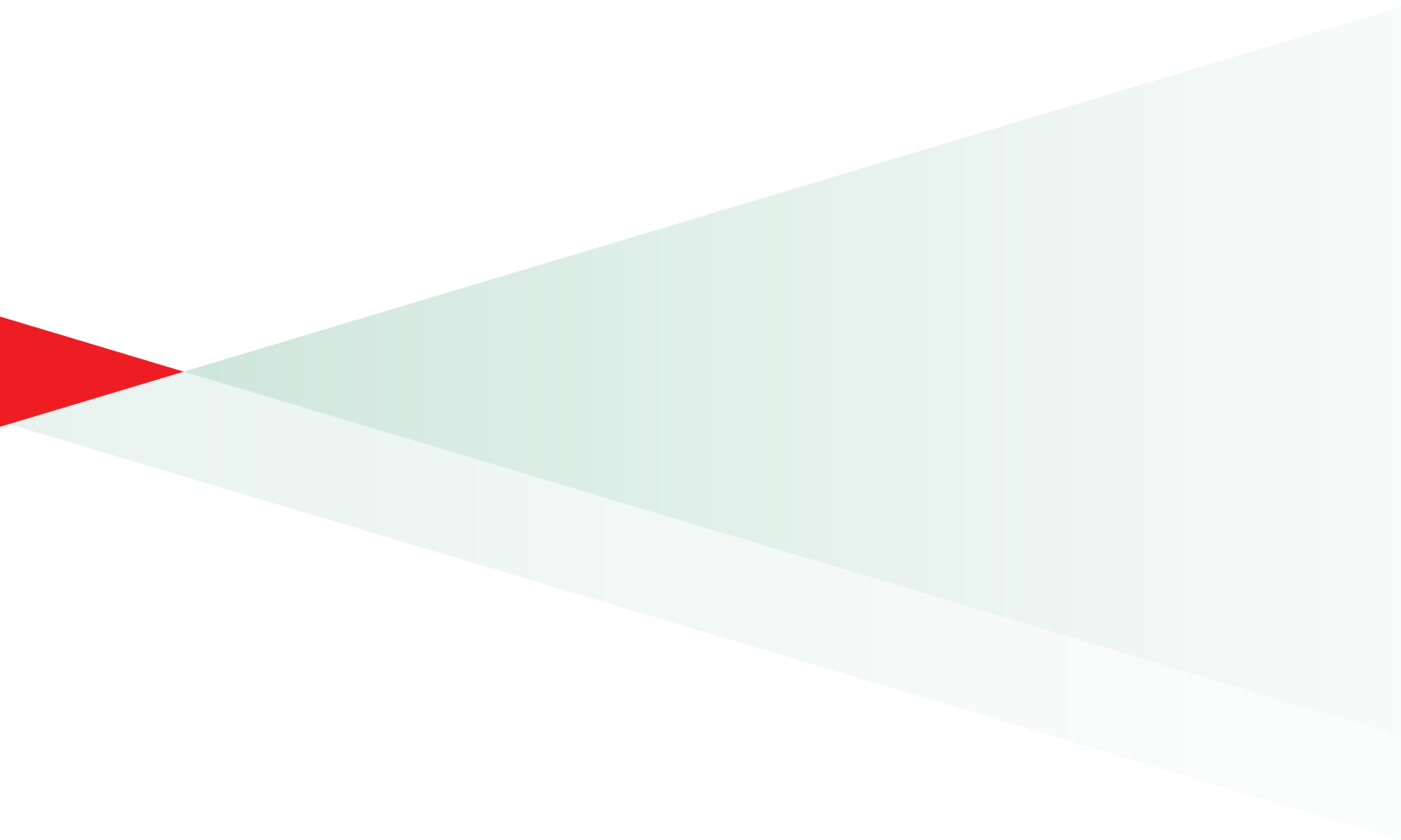
In Vitro Studies

- In vitro antimicrobial activity of oxidized regenerated cellulose against antibiotic-resistant microorganisms (Spangler) 61
- Antibacterial activity of oxidized regenerated cellulose (Dineen) 63

Bibliography64

Full Prescribing Information66

Cardiovascular/ Cardiothoracic Surgery



Predictors of neck bleeding after eversion carotid endarterectomy

Baracchini C, Gruppo M, Mazzalai F, et al.

Journal of Vascular Surgery 2011; 54: 699-705.

Objective

This paper aimed at identifying predictors for neck bleeding after eversion carotid endarterectomy (eCEA).

Methods

A prospectively compiled computerized database of all primary eCEAs, performed by the same surgeon, was analyzed. The end point was any neck bleeding after eCEA. SURGICEL® FIBRILLAR™ Absorbable Hemostat was routinely used on the suture line after the internal carotid artery was reimplanted in the common carotid artery. The study end points were any clinical signs of neck bleeding after CEA, warranting or not warranting surgical re-exploration.

Results

Neck bleeding after eCEA occurred in 120 cases (8.2%), of which 69 (4.7%) needed re-exploration. Using univariate analysis (odds ratio [95% confidence interval]) preoperative antiplatelet treatment with clopidogrel (1.77 [1.20-2.62], $P = 0.004$), particularly when continued to the day before CEA (3.84 [2.01-7.33], $P < 0.001$), and postoperative hypertension (9.44 [6.34-14.06], $P < 0.001$) were identified as risk factors for neck bleeding in general and for neck bleeding requiring re-exploration (4.50 [1.85-10.89], $P = 0.001$; 15.27 [2.08-104.43], $P = 0.006$, and 2.44 [1.12-5.30], $P = 0.02$, respectively). Use of clopidogrel plus acetylsalicylic acid (12.00 [2.59-56.78], $P = 0.005$), acetylsalicylic acid alone (4.37 [1.99-9.57], $P < 0.001$), and ticlopidine (2.49 [1.10-5.63], $P = 0.02$) were associated with an increased risk of neck bleeding only when they were continued to the day before CEA. Preoperative treatment with dipyridamole or warfarin, or use of no medication, were not associated with neck bleeding. There were no complications in patients who underwent re-exploration.

Conclusions

Neck bleeding after CEA is relatively common but is not associated with an increased risk of stroke or death.

The use of oxidized regenerated cellulose for video-assisted thoracic surgery

Tanaka Y, Tane S, Hokka D, et al.

Annals of Thoracic Surgery 2016; 101: 786-8.

Objective

This paper examined the possibility of preventing obstruction of surgical view using wound edge protector with oxidized regenerated cellulose (ORC) rings for hemostasis at wound surfaces of the access ports during video-assisted thoracic surgery (VATS).

Methods

Lobectomy and lung wedge or mediastinal tumor resection were performed by VATS. ORC sheets (SURGICEL® Nu-Knit® Absorbable Hemostat) were rolled around the narrow portion of a wound edge protector and were used to cover wound surfaces of the utility incision and access ports. After the procedure, the ORC and protectors were removed and the wound was closed.

Results

This technique was used on 57 patients. In 55/57 (96.5%) cases, there was no need for interrupting the procedure to clean the lens head of the thoracoscope; in the other 2 cases, replacement of the ORC sheet was sufficient to maintain a clear surgical view. In 53 (93%) cases, no hemostatic procedure was required for the wound surface before wound closure because the ORC sheet completely stopped wound surface bleeding. No wound complications were observed in any patient. Application of ORC did not result in delay of wound healing or wound infection. Hemostasis of the wound surface before wound closure was needed in 4 cases possibly due to insufficient contact between the wound surface and the ORC sheet. Better sheet placement maybe necessary for patients whose chest walls are thick.

Conclusions

Use of an ORC sheet rolled around a wound protector could improve surgical viewing during thoracoscopic operations.

SURGICEL® Nu-Knit® hemostat for bleeding control of fragile sternum

Mair H, Kaczmarek I, Oberhoffer M, et.al.

The Journal of Thoracic and Cardiovascular Surgery 2005; 130: 605–6.

Objective

Bone wax has been typically utilized to control bleeding from sternal bone marrow after sternotomy because of efficacy and decreased cost. However, bone wax inhibits osseous fusion and promotes infection. In this case report, the authors describe an alternative technique to control bleeding from sternal bone marrow utilizing SURGICEL® Nu-Knit® Absorbable Hemostat.

Methods

This case study describes a 73-year-old woman with a history of unstable angina, insulin-dependent diabetes, chronic obstructive lung disease, and obesity (body mass index, 32.4), who was referred for urgent surgical revascularization and mitral valve repair. The median sternotomy revealed a fragile sternum and severe osteoporosis with excessive bleeding from the bone marrow. Electrocautery was used sparingly to control bleeding. Patches of SURGICEL Nu-Knit Hemostat were placed on each side of the sternum before the sternal retractor was inserted. Full heparinization was then initiated for the extracorporeal circulation and routine coronary arterial bypass grafting (3 grafts) and mitral valve repair were performed. The sternum was closed in a standard fashion.

Results

Hemostasis was achieved within 2 to 3 minutes after application of the SURGICEL Nu-Knit. The intraoperative and postoperative course of the patient was uneventful. No enhanced bleeding, infection, or sternal wound-healing complications occurred postoperatively. Additionally, the authors report they have subsequently used this technique in 53 patients who were at high risk for unstable sternum and infection. Intraoperative blood control in all cases was reported as good or at least satisfactory. In-house mortality was not observed. No patient required reoperation because of bleeding or unstable sternum and no patient had a deep sternal wound infection.

Conclusions

Based on this case study and subsequent surgeries using this technique, the authors conclude that temporary administration of ORC patches can be a safe and effective alternative to bone wax to avoid sternal bleeding complications.

Disclaimer: If SURGICEL® Absorbable Hemostat is used temporarily to line the cavity of large open wounds, it should be placed so as not to overlap the skin edges.

A novel treatment for pulmonary hemorrhage during thromboendarterectomy surgery

Shetty DP, Nair HC, Shetty V, et al.

The Annals of Thoracic Surgery 2015; 99: e77–e8.

Objective

Pulmonary thromboendarterectomy is the definitive treatment for chronic thromboembolic pulmonary hypertension in patients at advanced stages of the illness. The authors report on techniques used to detect injury sustained to the pulmonary artery (PA) after performing the endarterectomy and its subsequent treatment using SURGICEL® Absorbable Hemostat.

Method

Patient 1 (male, 58 years) was diagnosed with grade IV dyspnea, cyanosis, and right heart failure; patient 2 (male, 41 years) was diagnosed with grade III dyspnea; and patient 3 (male, 50 years), with chronic thromboembolic pulmonary hypertension. In all 3 patients, pulmonary thromboendarterectomy was performed, following which air leaks were detected in the PA.

The following approaches were used: Injury to the PA was detected by irrigating the area with saline solution and visualizing the air bubbles streaming in from the affected ostia. The affected branch of the PA was sealed with SURGICEL using forceps to introduce a rolled up SURGICEL wick that filled the PA branch gradually. This was done because unlike a ball of SURGICEL, a long strip of it can reach the segmental or subsegmental branch and will be held in position by the forward flow of the pulmonary circulation and the wind sock-like shape of the PA radicals. This approach did not require it to be tethered in place.

Results

Patient 1 was extubated after 48 hours of elective ventilation on showing improvement in both gas exchange and PA pressures.

In patient 2, arterial partial pressure of oxygen was less than 100 mm Hg for 6 hours, but then steadily improved during the next 48 hours, enabling extubation on the postoperative day-2.

In patient 3, gas exchange improved overnight and extubation occurred after 48 hours of ventilation.

Conclusions

Left untreated, a PA breach results in massive bleeding into the bronchus when the heart starts ejecting. The authors use SURGICEL for sealing the leak because it can be fashioned into a filiform wick that can be placed deep into the PA radicals. This procedure resulted in effective bleeding control in all three patients.

Comparison of sternal intramedullary bleeding prevention strategies in cardiac surgery

Tavlasoglu M, Durukan A.B, Kurkluoglu M, et al.

Turkish Journal of Medical Sciences 2013; 43: 695-9.

Objective

Postoperative bleeding is a significant complication of open heart surgery and results in increased mortality and morbidity rates. The need for re-exploration also leads to increased health care costs. This prospective, controlled, and randomized clinical study compares the use of bone wax (Bone-wax®, Aesculap Inc., USA), oxidized regenerated cellulose (ORC) (SURGICEL® Absorbable Hemostat), and electrocauterization (EC) in the management of intramedullary bleeding control.

Methods

Patients who underwent on-pump coronary artery bypass grafting were randomized into 3 groups, chronologically. The first group received bone wax concomitant with EC, the second group received ORC concomitant with EC, and in the third group, only EC was performed. Drainage amounts were noted at the postoperative 1st, 2nd, 3rd, 6th, 12th, and 24th hours. The units of blood utilized and its products used were recorded.

Results

Overall, 142 patients (mean age \pm SD, 64.23 ± 5.81 years) were included in the study with no statistically significant differences in pre-operative demographic characteristics between the three groups.

Evaluation of postoperative hemorrhage showed that the drainage amount was the lowest in the ORC + EC group, during all time points considered (Table 1). The number of fresh frozen plasma and erythrocyte suspensions used was also lowest in the second group, with no statistically significant differences between the groups using bone wax and EC together and EC alone. In the 30-day postoperative follow-up period, no superficial wound infections were detected. Re-exploration for hemorrhage due to sternal bleeding sites was required only in the EC alone group.

Table 1. Comparison of experimental groups by postoperative variables

	Bone wax + EC	ORC + EC	EC	P-value*
Drainage amount (mL)				
1 hour	138.83 ± 77.99	99.25 ± 36.45	194.79 ± 51.98	<0.001
2 hours	213.30 ± 103.76	131.04 ± 39.41	307.17 ± 151.97	<0.001
3 hours	252.34 ± 57.93	191.06 ± 39.84	293.86 ± 91.52	<0.001
6 hours	352.94 ± 67.71	243.92 ± 42.26	375.71 ± 113.46	<0.001
12 hours	477.36 ± 83.71	287.43 ± 40.26	472.17 ± 139.72	<0.001
24 hours	622.15 ± 102.71	353.00 ± 49.48	695.88 ± 199.98	<0.001
FFP used	1.87 ± 0.76	1.60 ± 0.49	2.52 ± 0.55	<0.001
ES used	2.62 ± 0.61	1.62 ± 0.59	2.83 ± 0.49	<0.001
Patient, n (%)	47 (100.0)	53 (100.0)	42 (100.0)	
Re-exploration for hemorrhage, n (%)	-	-	3 (7.1)	0.026**

Data are mean ± standard deviation unless specified otherwise.

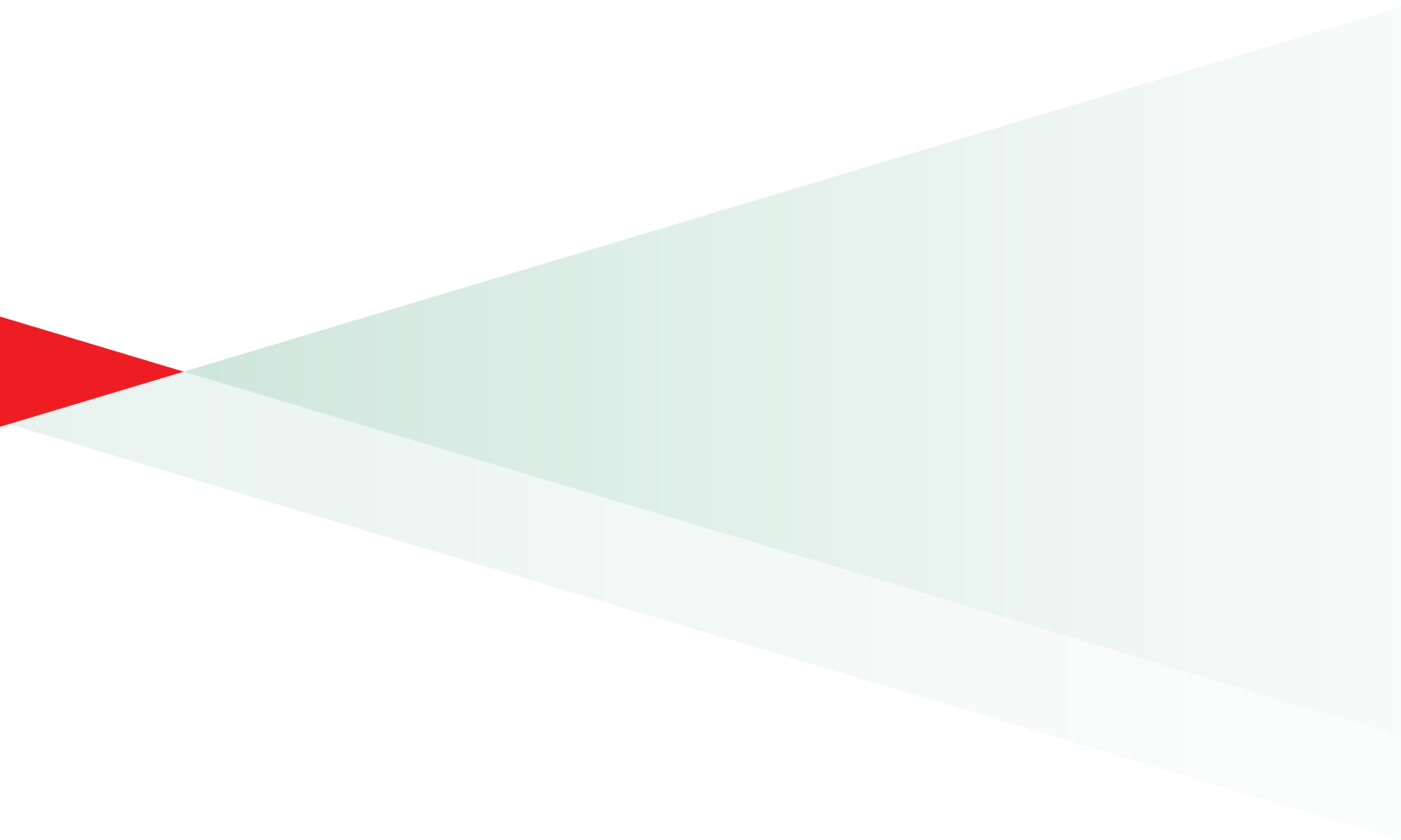
* Kruskal Wallis test; ** chi-square test

EC, electrocauterization; ORC, oxidized regenerated cellulose; FFP, fresh frozen plasma; ES, erythrocyte suspension

Conclusions

Compared to bone wax, ORC is absorbable, expands to the sternal corpus, and demonstrates antimicrobial properties against a wide range of pathogenic organisms. The present study clearly demonstrates that ORC decreases sternal intramedullary bleeding with low risk of infection. Requirements for fresh frozen plasma and erythrocyte suspensions were also lowest in the group using ORC along with electrocauterization. Results of this study show that ORC concomitant with electrocauterization is safe and effective in the control of intramedullary bleeding.

Neurosurgery



Clinical experience with the SURGICEL® family of absorbable hemostats (oxidized regenerated cellulose) in neurosurgical applications: A review

Keshavarzi S, MacDougall M, Lulic D, et al.

Wounds 2013; 25: 160–7.

Objective

This paper discusses the neurosurgical applications of SURGICEL® Original and SURGICEL® FIBRILLAR™ Absorbable Hemostats.

Methods

The authors reviewed PubMed literature (search string: (oxidized[Title/Abstract] AND cellulose[Title/Abstract] AND surgery[Title/Abstract]) AND ("humans"[MeSH Terms] AND English[lang]) 83 relevant articles) and described their clinical experience with SURGICEL hemostatic products.

Results

Hemostatic and bactericidal activity of ORCs

Effective hemostasis is typically achieved between 2–8 minutes following ORC application. SURGICEL Original has broad spectrum bactericidal properties, making it effective against antibiotic resistant organisms such as *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Staphylococcus epidermidis*, and *Pseudomonas aeruginosa*.

Neurosurgical applications

During intracranial surgeries, SURGICEL Original is used to decrease oozing from the epidural space and to slow epidural hematoma formation. The authors especially recommend the use of SURGICEL FIBRILLAR for operative interventions in the cerebrum as it allows placement around the resection cavity with rapid adherence to the cavity wall; for instance, it can be used for controlling venous bleeding and oozing from cortical surfaces after lobectomies or tumor resection.

For surgeries involving the ventricular system, SURGICEL Original is recommended for use along with glue to seal the cerebral ventricle and to avoid complications of subdural hygroma following transcortical approaches.

In spinal surgery, SURGICEL FIBRILLAR is an effective control for epidural oozing. Intraosseous implantation of ORCs, controls bleeding and may also promote lamellar bone formation. Further, the bactericidal activity of SURGICEL Original against several organisms commonly implicated in osteomyelitis infections can be beneficial against infectious organisms.

ORCs can offer safe and meticulous hemostasis in skull base approaches, such as during dissections in the region of the cavernous sinus, during extreme lateral inferior transcondylar-transtubular exposure, and during lateral suboccipital craniotomy. In such approaches, SURGICEL Original creates an effective hemostatic environment

Safety

ORCs are generally safe and well tolerated. In accordance with its labeling instructions, SURGICEL Original is suited for use as an adjunct to other conventional methods to control capillary, venous, and small arterial hemorrhage. It is not recommended for the control of large arterial hematomas.

Further, since ORCs are plant-derived, there is no risk of viral disease (e.g. human immunodeficiency virus).

Conclusions

The physical, hemostatic, and bactericidal characteristics of both SURGICEL Original and SURGICEL FIBRILLAR make them a safe and effective adjunct to conventional hemostasis during neurosurgery. Risks can be minimized by using the products according to label instructions.

A hemostatic agent delivery system for endoscopic neurosurgical procedures

Waran V, Sek K, Bahuri N.F, et al.

Minimally Invasive Neurosurgery 2011; 54: 279–81.

Objective

Due to poor access in endoscopic neurosurgery, hemostasis can be challenging. The authors report development of a device using tube systems which allows the delivery of a variety of hemostatic agents in a more efficacious manner. They report its use in endoscopic skull base surgery and endoscopic surgery within the parenchyma of the brain.

Methods

This system comprised 2 tubes, an internal tube connected to the suction, and an external tube with a larger diameter. A hemostatic agent, such as SURGICEL® FIBRILLAR™, was inserted or injected into the distal end of the external tube. To control bleeding, the inner tube was pushed forward like a piston, driving the hemostatic agent out, thereby compressing the hemostatic agent over the bleeding area. The external tube also protected the hemostatic agent, preventing it from being washed away in the event of brisk bleeding.

Results

This system was successfully tested in a variety of cases where brisk bleeding was encountered from the sinus or artery during endoscopic pituitary and other anterior skull base surgeries and from intraparenchymal arteries during excision of intraparenchymal lesions using an expandable port in conjunction with an endoscope. However, this device is not recommended for conventional channel-based endoscopic neurosurgery. For sinus hemorrhages, bleeding was easily stopped by delivering SURGICEL or FloSeal®.

Conclusions

This system allowed the delivery of the SURGICEL or other hemostatic material, accurately over the site of hemorrhage whilst maintaining simultaneous compression and suction, for rapid coagulation of sinus hemorrhages. Use of this device may, therefore, allow delivery of SURGICEL in a variety of endoscopic procedures more effectively.

Management of meningiomas invading the major dural venous sinuses: Operative technique, results, and potential benefit for higher grade tumors

Mantovani A, Di Maio S, Ferreira MJ, et al.

World Neurosurgery 2014; 82: 455-67.

Objective

This article analyzed results from consecutive surgical series of meningiomas involving the major venous sinuses, with emphasis on various technical options for sinus reconstruction, and on preoperative and perioperative patient management.

Methods

This retrospective review analyzed surgeries (N = 304) of consecutive meningiomas invading the dural venous sinuses that were operated upon at a single center. The surgical technique involved removal of tumor outside the sinus area first and then re-evaluating the surgical plan for each patient. Venous bleeding from normal sinus was controlled with 2-3 pieces of SURGICEL® Absorbable Hemostat. The sutures near the terminal ends were left loose, and tied after the SURGICEL pieces occluding the sinus were removed.

Results

Meningiomas involved the superior sagittal sinus (26 patients), torcular Herophili (5 patients), transverse (5 patients), or sigmoid sinus (2 patients). A gross total resection was achieved in 86.9% of patients, and sinus reconstruction followed in 21 cases. No deaths and 1 major postoperative complication occurred, and the mean postoperative Karnofsky performance status score was 88.9 ± 15.3 . Two recurrences (5.3%) occurred during a mean follow-up of 26.05 months. In 1 of the cases, considerable leakage of blood around the shunt tube was observed despite placement of the balloon shunt, requiring SURGICEL packing and blood transfusion.

Conclusions

The surgical strategies presented in this paper support the practice of aggressive removal of tumors invading the sinus, particularly in the case of higher grade meningiomas.

Clinical hemostasis effect of a novel hemostatic material SURGICEL® versus gelatin sponge in neurosurgery

Lei H, Wen-Hua R, Zhi-Liang D, et al.

Chinese Journal of Tissue Engineering Research 2012; 16: 551-3.

Objective

This prospective randomized controlled study compares the efficacy of SURGICEL® Absorbable Hemostat and gelatin sponge in the management of active and local bleeding in neurosurgery.

Methods

Data from patients undergoing cranial neurosurgery at the Suzhou Municipal Hospital, Jiangsu Province, China between April 2008 and December 2010 was collected. The SURGICEL group included patients in whom SURGICEL was used after hematocoe removal on the tissue surface by using a suction. In the gelatin sponge group, gelatin sponge was used to stop bleeding after hematocoe removal on the tissue surface. In both groups, a piece of wet cerebral cotton sheet was used for covering and pressing after the application of the hemostatic material.

The time when the hemostatic material was stuck to the surface of the brain tissue (point 1) was recorded. Hemostasis was considered achieved when no bleeding was observed when the cotton sheet opened (point 2). The time to hemostasis was from point 1 to point 2. If the bleeding persisted, the time to hemostasis was recorded until there was no bleeding. Types of bleeding were recorded, including small venous bleeding, errhysis, small venous bleeding + errhysis, small venous bleeding and/or errhysis + small arterial bleeding). If the time taken to achieve hemostasis was >5 minutes, it was considered as a failure to control bleeding.

Results

Overall, 60 patients (mean \pm standard deviation, 39.7 ± 8.2 years) were enrolled; 58.3% were male. There was no significant difference ($P > 0.05$) in the bleeding types between the two groups. However, the failure rate of hemostasis was 10% (3/30) in the gelatin sponge group, compared with 3% (1/30) in the SURGICEL group.

The overall time to hemostasis was significantly lesser ($P < 0.05$) (2.43 ± 0.75 minutes) in the SURGICEL group compared to the gelatin sponge group (4.23 ± 0.89 minutes). A sub-analysis of hemostasis time in various types of brain surgeries showed that SURGICEL was significantly faster than that of gelatin sponge ($P < 0.05$; Table 1) in achieving hemostasis when used in operations for cerebral contusions, brain tumors, and cerebral vascular malformation.

Table 1. Comparison of hemostasis time (in minutes) between SURGICEL and gelatin sponge groups in different types of brain surgeries (mean ± standard deviation)

	Cerebral contusion	Brain tumor	Cerebral vascular malformation
SURGICEL (n = 29)	2.26 ± 0.54	2.58 ± 0.52	2.56 ± 0.89
Gelatin sponge (n = 27)	4.12 ± 0.96	4.31 ± 0.85	4.52 ± 0.59

Conclusions

SURGICEL showed faster and more effective hemostatic effects than the gelatin sponge, even across multiple kinds of brain surgeries. The results of this study indicate that the routine use SURGICEL in neurosurgery may help improve clinical outcomes.

Rapid closure technique in decompressive craniectomy

Guresir E, Vatter H, Schuss P, et al.

Journal of Neurosurgery 2011; 114: 954-60.

Objective

Decompressive craniectomy is performed in patients suffering from intractable elevation of intracranial pressure following traumatic brain injury, and typically involves a duraplasty, which is associated with postoperative complications. This study describes the use of rapid closure decompressive craniectomy (RCDC) technique without duraplasty in a large cohort of consecutive patients.

Methods

From October 1999 to October 2008, RCDC was performed 341 times in 318 patients. Instead of a duraplasty involving watertight suturing, the dura and exposed brain tissue was covered by the loosely replaced remaining dura and SURGICEL® Absorbable Hemostat. Surgical time and complications encountered including those during the follow-up (>6 months) were recorded.

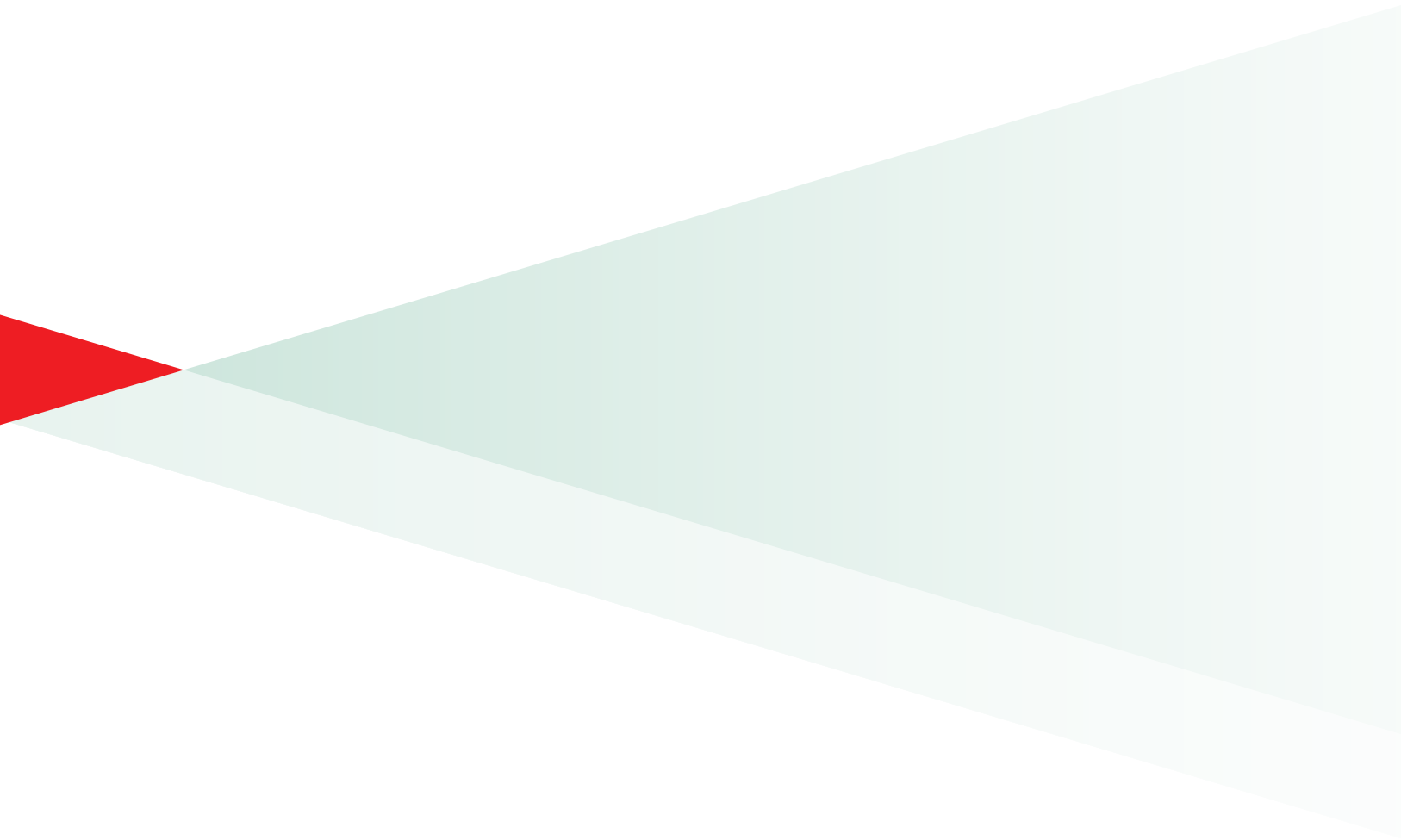
Results

The mean (\pm SD) surgical time for RCDC was 69 ± 20 minutes and the procedure was successfully performed in all 341 cases. Complications encountered included superficial wound healing disturbance (3.5% of procedures), abscess (2.6%), and cerebrospinal fluid fistula (0.6%). Compared with the results reported in the literature for decompressive craniectomy with duraplasty, there were no significant differences in the frequency of complications. However, surgical time for RCDC was significantly shorter (69 ± 20 vs 129 ± 43 minutes, $P < 0.0001$).

Conclusions

The use of SURGICEL to cover the dura instead of a duraplasty contributes to reduction in total surgical time in RCDC and is not associated with a higher complication rate. The results of this study suggest that RCDC is a safe, feasible, efficacious, and time-sparing procedure.

General Surgery



Co-suturing SURGICEL® and colonic fat to achieve hemostasis in presacral hemorrhage

Liu Z, Ju H, Zhu Y, Li D, et al.

Techniques in Coloproctology 2015; 19: 365-6.

Objective

This case series describes a technique for managing presacral hemorrhage during total mesorectal excision (TME) with the use of sutured SURGICEL® FIBRILLAR™ Absorbable Hemostat and colonic fat.

Methods

In this technique, when presacral bleeding occurred, immediate direct pressure was applied upon the bleeding site using a small tampon of gauze. Effective suction was maintained to keep the plane as dry as possible. The SURGICEL patch was folded so that it was 1 inch × 1 inch in size, and a piece of colonic fat was prepared. The SURGICEL with the fat was pressed directly over the bleeding site with forceps. Then, 4/0 Prolene was used to suture the presacral tissue to the SURGICEL patch (a figure-of-eight suture). Thus, continuous pressure was maintained upon the bleeding site, achieving the hemostasis.

Results

The technique was used successfully in six patients with life threatening presacral bleeding after the resection of rectal carcinoma. No postoperative bleeding was noticed in the drainage tube in these patients. After a mean follow-up time of 20 months (range 4-38 months), all patients recovered uneventfully without other serious complications.

Conclusions

This alternative technique involving co-suturing SURGICEL and colonic fat onto the bleeding site is a simple, effective, and safe option for controlling presacral hemorrhage.

A simplified approach to techniques of splenic salvage

Trooskin SZ, Flancbaum L, Boyarsky AH, et al.

Surgery, Gynecology and Obstetrics 1989; 168: 546-48.

Objective

This paper describes a simple method for controlling splenic parenchymal hemorrhage after splenic trauma or during partial splenectomy utilizing oxidized regenerated cellulose (ORC) as a suture bolster.

Methods

A sharp dissection of the splenic attachments to the diaphragm, colon, and left kidney was performed to mobilize the spleen from the left upper quadrant, leaving the spleen suspended by the splenic hilar and short gastric vessels. This allowed for easy visual inspection of splenic surface and avoidance of capsular tears caused by traction.

For partial splenectomy, the spleen was mobilized in the standard fashion, taking care to ligate the short gastric vessels and control the splenic hilum. Ischemic tissue was readily identified by its deep blue color and sharply excised. Bleeding was minimized by placing a non-crushing clamp at the junction of the viable and nonviable splenic tissue, and the nonviable tissue was excised using a scalpel. Suturing the splenic parenchyma was simplified by passing the suture through bolsters consisting of pledgets of folded sheets of oxidized cellulose (SURGICEL® Absorbable Hemostat or SURGICEL® Nu-Knit® Absorbable Hemostat). 2-0 absorbable suture was placed as a horizontal mattress through the bolsters to compress the raw or oozing splenic surface and prevent the suture from tearing or cutting through the splenic capsule.

For splenic salvage after trauma, nonviable splenic tissue was sharply debrided. Bleeding from lacerations deep into the splenic parenchyma were controlled by compression of splenic tissue between bolsters of folded sheets of oxidized cellulose placed parallel to the laceration and sutured. Sutures were placed through the spleen in the manner of a horizontal mattress and tied snugly.

Results

The approach described was successfully used in 14 patients, 11 of whom underwent extensive splenic repair, and 3 of whom had partial splenectomies. There were no episodes of postoperative bleeding.

Conclusions

The technique of placing mattress sutures through absorbable pledgets of oxidized cellulose was effective in controlling parenchymal bleeding during partial splenectomy or splenic salvage.

Spleen hydatidosis treated by hemi-splenectomy: A low-morbidity, cost-effective management by a recently improved surgical technique

Costi R, Castro Ruiz C, Zarzavadjian le Bian A, et al.

International Journal of Surgery 2015; 20: 41-5.

Objective

A total splenectomy is typically carried out for the management of spleen hydatidosis. Partial splenectomy is less commonly performed because of technical difficulties associated with the procedure and the risk of potentially life threatening intraoperative complications. The authors report on an improved technique for hemi-splenectomy, associated with comparatively fewer complications.

Methods

From 2003 to 2011, a total of 4 patients (1 female, 3 males; mean age, 30 years) with splenic hydatid cysts were treated. One of the patients had both splenic and hepatic hydatidosis. The first three patients (including the patient with spleen and liver localizations) were treated by laparotomy, the fourth required a laparoscopy. The hemi-splenectomy procedure involved a selective vascular ligation, a mechanical stapler-assisted section, and SURGICEL® Absorbable Hemostat application on the cutting surface.

Results

Mean operative time was 74.6 minutes, excluding the patient undergoing splenic and hepatic resection (290 minutes). Mean blood loss related to surgery was 8.3 mL (range 5-10 mL) when the patient undergoing the additional right hepatectomy procedure was excluded. Average hospital stay was 7.5 days (range 5-13 days) overall, and 5.6 days (range 5-7 days) excluding the hepatectomy patient. All patients survived and recovered from surgery uneventfully.

Conclusions

Results show that the application of SURGICEL allows for effective hemostasis, as indicated by low blood loss in all patients treated. This technique may, therefore, reduce intra- and postoperative hemorrhage and lower risk of postoperative splenic infarction. The authors state that the availability of SURGICEL at a reasonable price may facilitate its use in developing countries, where such parasitic cysts are highly prevalent.

Surgical treatment of recurrent prolapse after stapled haemorrhoidopexy

Selvaggi F, Pellino G, Sciaudone G

Techniques in Coloproctology 2014; 18: 847-50.

Objective

The paper describe a method to manage patients with recurrent prolapsing hemorrhoids after stapled hemorrhoidopexy (SH) by means of a modified technique used for circumferential piles.

Methods

A total of 11 patients (4 males; mean age, 32 ± 11.3 years) presented with recurrent large circumferential prolapse after SH. An excisional hemorrhoidectomy of left-lateral, right-anterior, and right-posterior piles was carried out. Previous staples were removed. After hemorrhoidectomy, a transverse incision was performed on the proximal part of 1-2 residual mucocutaneous bridges, and a flap of anal mucosa was gently raised by means of scissors and LigaSure™ Precise (Covidien, Mansfield MA, USA). Staples noticed after raising the flap were removed. The hemorrhoidal tissue inside the flap was preserved. Monofilament absorbable stitches were passed through the free edge of the flap and sutured above the proximal divided edge of the rectal mucosa. Anal retractor was removed, sutures were tied and an absorbable haemostatic gauze (TABOTAMP®) was placed on the wound.

Results

Postoperative recovery was uneventful in 9 patients. One patient (9%) suffered from bleeding during the night before being discharged, but this was controlled with conservative measures. One patient (9 %) had urinary retention requiring catheterization. No other complications were observed. At a mean follow-up of 4 ± 1.8 years, neither symptomatic nor asymptomatic recurrences were observed.

Conclusions

This technique achieved a low recurrence rate, regression of chronic pain, amelioration of preoperative urgency and excellent patient satisfaction. The minimal morbidity and long-term effectiveness indicate that the technique is an effective option for the management of this condition.

Oxidized cellulose (SURGICEL®) as a surgical hemostat in liver injury: A case report and literature review

Hamzah AA, Adnan AS, Rahman MNG

International Journal of Surgical Research 2013; 2: 21-3.

Objective

Most low grade liver injury is managed conservatively with minimal invasive methods, especially in pediatric patients; however, an open surgical approach using liver packing may be required in some cases. This paper presents a case report of a patient undergoing such a surgery.

Methods

A 15 year-old boy in a motor vehicle accident sustained a blunt abdominal injury and fractured left clavicle with no loss of consciousness. A computed tomography (CT) scan revealed grade IV splenic injury and lacerations to the liver. A splenectomy was done along with SURGICEL® Absorbable Hemostat packing of the liver.

Results

The estimated blood loss during surgery was 4 liters. The patient's postoperative recovery was uneventful and took over six weeks. The in-situ liver bed drain was kept in the likelihood of clot lysis, which is known to occur within the first 72 hours; however, it remained empty from postoperative day-1 to day-5 when it was removed.

Conclusions

Use of SURGICEL in the current patient was a relatively simple and effective technique for perihepatic packing. The authors suggest that effective liver packing for grade IV liver injury using SURGICEL may be significant for the management of such injuries.

Disclaimer: SURGICEL® Absorbable Hemostat may be left in situ, though it is advisable to remove the excess once hemostasis is achieved.

Successful treatment of active hemorrhage from a duodenal diverticulum using SURGICEL® (absorbable hemostat): A case report

Muguti G, Gandhi H, Ridgeway D

The Central African Journal of Medicine 2007; 53: 18-21.

Objective

Upper gastrointestinal (GI) hemorrhage is a serious complication of duodenal diverticulum that is commonly fatal. This report describes the use of SURGICEL® Absorbable Hemostat in the successful management of active hemorrhage from a duodenal diverticulum.

Methods

An oesophago-gastro-duodenoscopy was carried out in a 61-year-old male patient, suspected of upper GI bleeding. The procedure confirmed bleeding from a duodenal diverticulum in the second part of the duodenum. The large volume of blood in the duodenum prevented endoscopic treatment and a laparotomy was performed. A duodenotomy revealed blood clots in the lumen and evidence of active hemorrhaging in the duodenal diverticulum. The diverticulum was packed gently with SURGICEL. In order to retain the SURGICEL pack in place, the ostium of the diverticulum was narrowed with a VICRYL™ stitch, such that adequate room was left for drainage from the diverticulum.

Results

Using SURGICEL, adequate hemostasis was achieved and the operation was completed successfully. The patient recovered well and was discharged on postoperative-day 11. During the 3-year follow-up period, the patient had no recurrent bleeding.

Conclusions

In the case of active hemorrhage of duodenal diverticulum, gentle packing of the bleeding diverticulum with SURGICEL was effective in controlling bleeding. The authors suggest that this procedure may be used when more established procedures are either ineffective or inapplicable as timely surgical intervention before the development of coagulopathies increases the likelihood of a successful clinical outcome.

Control of port-site bleeding from smaller incisions after laparoscopic cholecystectomy surgery

Rastogi V, Dy V

Surgical Laparoscopy, Endoscopy & Percutaneous Techniques. 2002; 12: 224-6.

Objective

The authors describe a technique to rapidly control bleeding from difficult to approach small port-site incisions from the inside, utilizing SURGICEL® Absorbable Hemostat (endoscopic size, 2.54 cm × 8.89 cm) as a plug.

Methods

Of 207 patients undergoing laparoscopic cholecystectomy between July 1998 and June 2000, 20 patients experienced bleeding from one or more small (5 mm) port-sites at the conclusion of the procedure. These 20 comprised the study group.

Once the laparoscopic procedure was completed, the 5 mm ports were removed. When bleeding was noted along the port-site, the port was reintroduced through the same incision. A grasper was introduced from the 10 mm subxiphoid port along with SURGICEL. A second grasper was introduced through the 5 mm port at the port-site that was bleeding. Through this site, the ORC was grasped in the middle and pulled through the port incision, thereby snugly fitting through the hole to provide occlusion. The port and grasper were removed and excess SURGICEL cut so that it was flush with the skin incision. The skin incision was approximated with interrupted subcuticular 4.0 Coated VICRYL™ (polyglactin 910) suture and ¼-inch steristrips. Patients were followed 7 days after the procedure by the surgeon during office visits.

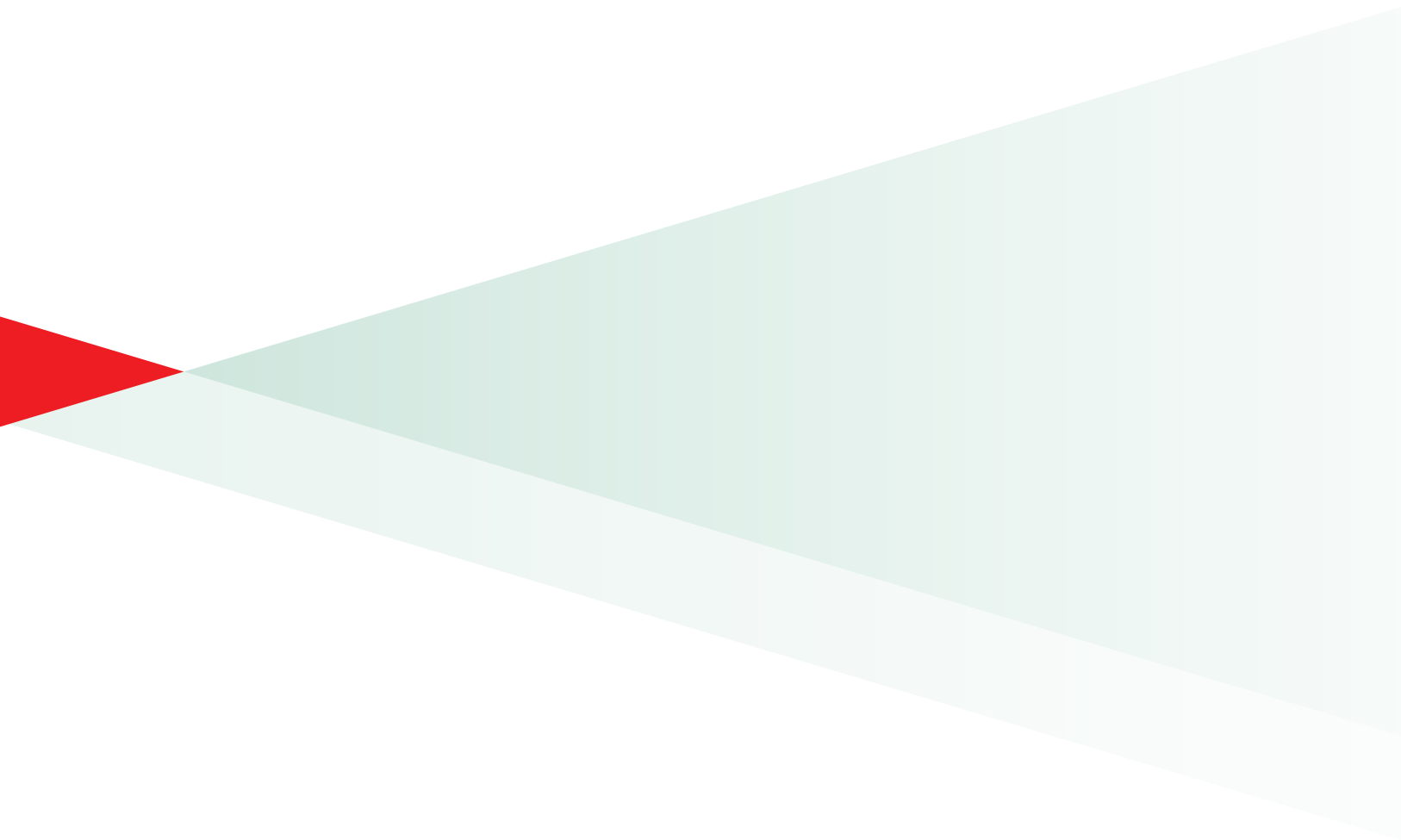
Results

The authors report cessation of bleeding in all patients who were treated with this technique. No visible wound hematomas or port-site infections were noted during follow-up.

Conclusions

Although not a blinded or comparative trial, and involving a small number of patients, the authors concluded that this technique, utilizing SURGICEL at the port-site just prior to closure, was a simple and time-saving technique to control bleeding from small abdominal incisions.

Obstetric/Gynecologic Surgery



A local hemostatic agent for the management of postpartum hemorrhage due to placenta previa and placenta accreta: A cross-sectional study

Portilla D, Hernández-Giraldo C, Moreno B, et al.

Archives of Gynecology and Obstetrics 2013; 288: 543–9.

Objective

This study describes the use of a SURGICEL® FIBRILLAR™, a local hemostatic agent (LHA), for the management of postpartum hemorrhage (PPH) due to bleeding of the placental bed in patients taken to caesarean section.

Methods

This cross-sectional study analyzed cases of PPH during caesarean section in patients with placenta previa or accreta. Primary outcome was emergency hysterectomy during PPH. In the group that used the LHA, if the initial management of PPH (volume resuscitation, use of uterotonics, uterine massage) due to bleeding of the placental bed secondary to placenta accreta or previa was unsuccessful and bleeding continued, the LHA (generally 2–3 gauzes) was applied directly to the bleeding surface. If bleeding was severe, no more than 3 minutes were waited in order to evaluate the effectiveness of the LHA, whereas if there was oozing or mild to moderate bleeding, up to 10 minutes were waited.

Results

The proportion of hysterectomies was 5% vs 66% for the LHA and the no-LHA groups, respectively (Prevalence Ratio [PR], 0.07; 95%Confidence Interval [CI], 0.01–0.51; $P < 0.01$). For the group managed without LHA, 80% of patients needed hemoderivatives transfusion vs 20% in the group managed with a LHA (PR, 0.24; 95%CI, 0.1–0.6; $P < 0.01$). A reduction in the mean days of hospitalization in addition to a decrease in the proportion of patients admitted to the intensive care unit was noticed when comparing the group that received a LHA vs the one that did not.

Conclusions

There was an inverse correlation between the use of a LHA in patients with PPH due to bleeding of the placental bed and the need to perform an emergency obstetric hysterectomy.

Ovarian salvage in bilaterally complicated severe ovarian hyperstimulation syndrome

Al Omari W, Ghazal-Aswad S, Sidky IH, et al.

Fertility and Sterility 2011; 96: e77-9.

Objective

The study presents 2 cases of complicated severe ovarian hyperstimulation syndrome (OHSS) in which the patients' safety was compromised and the ovarian integrity was in jeopardy.

Methods

In case 1, a 20-year old woman had ovulation induction and was admitted 4 days later with severe OHSS. An ultrasound showed enlarged ovaries with multiple big follicles with excessive fluid in the abdomen and pelvic area. Both ovaries were meticulously repaired by laparotomy; all active bleeding points were initially sutured with a 4/0 VICRYL™ suture, and the oozing cracked surfaces were joined together and covered with Tachocomb. Finally, SURGICEL® FIBRILLAR™ Absorbable Hemostat was used to fill the oozing spaces in the ovarian tissue. In case 2, a 30-year-old woman presented at 10 weeks, with severe left-sided lower abdominal pain. Examination revealed a tender mass at the left iliac fossa with rebound tenderness. Laparotomy was performed but 3 days later, the patient complained of abdominal pain. Diagnostic laparoscopy revealed that the right ovary was enlarged with a 180 degrees twist at its pedicle without any active bleeding. A manipulator was used for ovarian detortion and conservation.

Results

Timely diagnosis and constructive ovarian repair resulted in bilateral ovarian complete preservation. Hemostasis with sutures or electrocautery may not be easy in such cases owing to the soft friable nature of the enlarged edematous ovary. In this case, SURGICEL and Tachocomb were used to pack and join the bleeding fissures. The aforementioned combination was successful in conserving both ovaries.

Conclusions

The authors present 2 cases where ovarian mutilation or castration was probably imminent, but ovarian salvage was achieved through early diagnosis using innovative and conservative surgery.

Disclaimer: SURGICEL® Absorbable Hemostat may be left in situ, though it is advisable to remove the excess once hemostasis is achieved.

Effects of oxidized regenerated methylcellulose on lymphocyst formation and peritoneum in gynecologic cancer patients

Ayhan A, Basaran A, Güler TO

International Journal of Gynecological Cancer 2010; 20: 23-7

Objective

This study evaluated the role of oxidized regenerated methylcellulose (ORC) (SURGICEL® FIBRILLAR™ Absorbable Hemostat) in the lymphocyst formation and effects on peritoneum after systematic lymphadenectomy.

Methods

This retrospective case-control study enrolled patients with gynecologic cancer who underwent systematic lymphadenectomy. Two groups were identified according to ORC use. The lymphocysts were evaluated via ultrasonography/computed tomography/magnetic resonance imaging between the 3rd and 6th months after surgery. In all patients, retroperitoneal “no closure” method was applied. All patients were operated on by the same surgeon, and decision to use ORC was the surgeon's preference.

Results

Lymphocyst incidence in the ORC and control groups was 45/150 (30%) and 30/102 (29.4%), respectively. The mean (SD) total number of extracted lymph nodes in the ORC group was 27.5 (10.6), which was significantly higher than that in the control group (22.1 [10.8]; $P = 0.001$). Duration of drain was significantly longer in the ORC group ($P = 0.028$). However, when confounding variables were included into the binary logistic regression analysis for the prediction of the duration of drains, only the stage of disease predicted the duration of drains.

Conclusions

Utilization of ORC for hemostasis during systematic lymphadenectomy neither affects lymphocyst formation nor seems to pose a stimulatory effect on the peritoneum.

Laparoscopic management of primary hepatic pregnancy

Chin PS, Wee HY, Chern BS

The Australian and New Zealand Journal of Obstetrics and Gynaecology 2010; 50: 95–8.

Objective

This case study describes the management of a rare hepatic ectopic pregnancy.

Methods

A 30-year-old, gravida 2 para 1 woman presented 4 weeks after her last menstrual period with one-day history of pain over the epigastrium and right flank. Transvaginal pelvic ultrasound scan revealed marked echogenic fluid in the pouch of Douglas with no definite intrauterine gestational sac. The patient experienced an episode of syncope 48 hours after admission. Her clinical condition then deteriorated with the development of right shoulder tip pain and worsening epigastric pain. Diagnostic laparoscopy revealed a ruptured ectopic pregnancy at the liver hilum surrounded by clots. This was removed by laparoscopic suctioning and pressure was applied using SURGICEL® FIBRILLAR™ Absorbable Hemostat to achieve hemostasis while avoiding surgical intervention to the liver and hepatic vessels.

Results

Ultrasound scans of the pelvis and the abdomen 3 days later revealed absence of intrauterine gestational sac, normal adnexae and no evidence of residual ectopic tissue. Intramuscular methotrexate was administered to promote degeneration of residual products of conception. The patient was discharged well 24 hours after methotrexate administration.

Conclusions

This was the first reported case of a primary hepatic ectopic pregnancy in Singapore. It is also the first reported case worldwide that was successfully surgically managed by laparoscopy alone without conversion to laparotomy.

Use of oxidized regenerated cellulose (SURGICEL® Nu-Knit®) as a hemostat in laparoscopic endometriotic cystectomy: A case report

Sharma JB, Zangmo R, Kumar S, et al.

International Journal of Reproduction, Contraception, Obstetrics, and Gynecology 2015; 4: 283-5.

Objective

This case study describes the use of SURGICEL® Nu-Knit® Absorbable Hemostat to achieve hemostasis in a patient undergoing laparoscopic endometriotic cystectomy under general anesthesia.

Methods

A 33 year old patient presented to the gynecology outpatient department with the chief complaints of inability to conceive and severe dysmenorrhea for the last 2 years. An endometriotic cyst measuring 4 × 4 cm was present in right ovary. Right ovary was enlarged and was adherent to the posterior surface of the uterus and the right uterosacral ligament. Endometriotic cystectomy was performed and the adhesions around the right ovary were removed. Minor oozing from the posterior surface of the uterus was controlled with bipolar cauterization. Cauterization was not attempted at the ovarian surface and at the uterosacral ligament keeping risk of ureteric injury in mind. SURGICEL Nu-Knit was then placed on the oozing points on the right ovary and uterosacral ligament. Bleeding site was observed for 5 minutes. Laparoscopic ports were removed after ensuring hemostasis, pneumoperitoneum was released and port sites closed. Vitals were monitored in the postoperative period.

Results

Postoperative course of the patient was uneventful, and the patient was discharged in stable condition after 7 hours of surgery.

Conclusions

The use of oxidized regenerated cellulose as a hemostatic agent in the described scenario was simple and very effective. Additionally, the risk of compromising ovarian reserve was also minimized.

Successful management of uterine incision hemorrhage in cesarean section with topical oxidized regenerated cellulose (SURGICEL® Nu-Knit®): A case report

Sharma JB, Malhotra M

Archives of Gynecology and Obstetrics 2006; 274: 115–6.

Objective

The objective of this paper was to describe and document the use of SURGICEL® Absorbable Hemostat to treat excessive hemorrhage from a uterine incision site at the time of cesarean section, when traditional treatments were unsuccessful.

Methods

In this case report, surgeons attempted to treat constant oozing of blood from the uterine C-section incision in a 28-year-old female at 38 weeks of her second pregnancy. Despite good approximation, an oxytocin drip, intravenous ergometrine, and prostaglandin F2 alpha, bleeding persisted. A 15.2 × 22.9 cm² piece of SURGICEL® Nu-Knit® Hemostat was placed on the incision. It was stitched on the bleeding site with 2 interrupted VICRYL™ (polyglactin 910) sutures and local pressure was applied. The site was observed for 10 minutes, and then the abdomen was closed in layers.

Results

The observed bleeding stopped with the use of SURGICEL Nu-Knit. There was no post-partum hemorrhage. The patient's postoperative period was uneventful, and she and her baby were discharged on day 5. Both were doing well at a 1-month follow-up visit. No adverse events were reported.

Conclusions

Oxidized cellulose appears to be a safe and effective in the treatment of uterine incision hemorrhage.

Repaired uterine rupture at mid gestation

Patrício L, Martins D, Henriques A, et al.

Archives of Gynecology and Obstetrics 2013; 288: 457-8.

Objective

This case report describes the successful repair and management of a mid-gestation uterine rupture.

Methods

A 36-year-old gravida 3, para 1, presented, in her 20th week of gestation, at the emergency department of her local hospital with abdominal pain and rebound abdominal tenderness. Exploratory laparotomy revealed hemoperitoneum and a 2.5 cm uterine fundus rupture (near the right fallopian tube isthmus). The rupture was first repaired with a double-layer suture and then covered with SURGICEL® Absorbable Hemostat.

Results

Postoperatively, the patient remained asymptomatic and hospitalized. Ultrasound scans were performed on a monthly basis, revealing normal fetal growth and amniotic fluid production, a posterior fundal placenta and a thin fundal myometrium. At 34 weeks, cesarean section was performed under general anesthesia with the delivery of a healthy 2,120 g female newborn (Apgar scores of 5 and 8 at minutes 1 and 5, respectively). The placenta was easily removed and the macroscopic uterine examination confirmed that the fundal myometrium was thin and covered by an epiploon adhesion.

Conclusions

This is one of the few cases of successful mid gestation uterine rupture repair with preservation of pregnancy.

Laparoscopic oxidized cellulose (SURGICEL®) application for small uterine perforations

Sharma JB, Malhotra M, Pundir P

International Journal of Gynecology and Obstetrics 2003; 83: 271-5.

Objective

This prospective study was conducted to evaluate the efficacy and safety of laparoscopic oxidized cellulose application at the site of uterine perforation.

Methods

Thirty cases of 1786 women requesting concurrent surgical termination of pregnancy and laparoscopic sterilization, all with iatrogenic uterine perforations, were enrolled in this prospective study between January 1999 and July 2002. Surgical termination was offered in the first trimester only, up to 12 weeks from last menstrual period. Patients were eligible for study inclusion if the perforation was <10 mm with moderate bleeding and no injury to intestines or any other organ as seen by laparoscopy. Oxidized regenerated cellulose (SURGICEL® Absorbable Hemostat), was applied to the perforation site, pressure was applied for approximately 2 minutes, then checked again for hemostasis. In the event that hemostasis was not achieved with local SURGICEL application, polyglactin 910 sutures (VICRYL™) were placed. Patients were hospitalized for at least 24 hours to observe hemodynamic stability and abdominal distension. Patients who required laparotomy were kept for 5 days as per hospital protocol.

Results

Laparoscopic application of oxidized cellulose was successful in achieving hemostasis in all cases of perforation in the fundal, anterior and posterior wall, and upper lateral uterine wall. Two cases of lower lateral uterine wall perforation did not respond to laparoscopic oxidized cellulose application despite being only 3 mm and 4 mm in size. The uterine artery had given way with excessive bleeding in one case and the oxidized cellulose fell off. A broad ligament hematoma in the second case extending from the lower lateral uterine wall perforation occurred with no place to apply oxidized cellulose. Laparotomy was performed in these cases and hemostasis was achieved utilizing sutures. All 28 women in which oxidized cellulose application was successful were discharged in good condition on the next day with no postoperative complications. No patient in this group required laparotomy.

Conclusions

Oxidized cellulose was applied to bleeding uterine perforations with excellent results. Only two cases of lower lateral uterine wall perforations were not controlled by application of oxidized cellulose. The present study also confirms that location of perforation is at least as important as size in assessing risk of serious sequelae from uterine perforation. Failed cases had only 3 mm and 4 mm perforations; however, their lateral position in proximity to the vascular injuries and excessive hemorrhage precluded success of topical treatment with oxidized cellulose. Laparoscopic application of oxidized cellulose appears to be safe and effective for treating small uterine perforations with moderate bleeding and in the absence of injury to intraperitoneal organs.

Urologic Surgery



Robotic surgery and hemostatic agents in partial nephrectomy: A high rate of success without vascular clamping

Morelli L, Morelli J, Palmeri M, et al.

Journal of Robotic Surgery 2015; 9: 215-22.

Objective

This prospective analysis describes the experience of 31 patients who underwent robotic partial nephrectomy with or without vascular clamping with systematic use of hemostatic agents.

Methods

The robot was docked perpendicular to the patient at the level of 12th rib. The renal surface was exposed by colonic mobilization and opening of Gerota's fat. Subsequent steps varied depending on tumor size. After tumor removal, primary hemostasis at the resection bed was managed by application of a fibrin sealant (FloSeal® Hemostatic Matrix, Baxter, Healthcare) and by compression with a surgical sponge. The defect was finally covered with a sheet of oxidized regenerate cellulose (TABOTAMP® FIBRILLAR™). If there was further bleeding or urine leak, Prolene stitches with or without Dacron pledget were used to improve hemostasis.

Results

Thirty-three renal tumors were treated in 31 patients. There were no conversions to open surgery, intraoperative complications, or blood transfusions. The mean size of the resected tumors was 27 mm (median 20 mm, range 5-40 mm). A total of 27/33 (82 %) lesions did not require vascular clamping and therefore were treated in the absence of ischemia. In these patients, hemostasis was achieved through the bipolar coagulation device and the use of hemostatic agents in 20/27 (74 %) patients.

Conclusions

Robot-assisted partial nephrectomy appears to be a safe and effective technique for the surgical management of localized renal malignancy while preserving oncological and clinical goals.

Use of oxidized cellulose hemostats (SURGICEL®) to support parenchymal closure and achieve hemostasis following partial nephrectomy

Abou-Elela A, Morsy A, Badawy H, et al.

Surgical Technology International 2009; 18: 75–9.

Objective

The authors describe their experience with absorbable oxidized cellulose hemostats in optimizing the outcomes in nephron-sparing surgery.

Methods

Twenty-five patients with renal masses underwent tumor resection by open partial nephrectomy. The median age was 56 years (range 24–71 years). The median tumor diameter was 3.5 cm (range 1.8–9.0 cm) and in 19 of the 25 patients, the tumor was at least 50% exophytic on preoperative CT scan.

During surgery, the renal capsule around the tumor was incised with a safety margin around the tumor and the tumor was bluntly dissected and excised with a margin of normal tissue. In situ hypothermia was performed in cases with central or large tumors where the anticipated time of warm ischemia could exceed 30 minutes. Following tumor resection, visible blood vessels within the renal defect were ligated or closed with interrupted 5-0 polypropylene vascular sutures. The collecting system was closed with running absorbable sutures. Absorbable oxidized cellulose hemostats (SURGICEL® Absorbable Hemostat) were transferred into the defect and tightened with a running suture. The renal capsule was slightly approximated with interrupted sutures. A percutaneous drain was placed to monitor bleeding and urinary leakage.

Results

The mean time of cold perfusion and warm ischemia was 59 minutes (range 27–125 minutes) and 18 minutes (range 6–28 minutes) respectively. Median operating time was 175 minutes (range 90–230 min) and the median intraoperative blood loss was 350 cc (range 100–750 cc). Typically, it took 5 to 10 minutes to fix the SURGICEL. No additional hemostatic agent was used and there were no significant changes in preoperative and postoperative hematocrits. Postoperative bleeding occurred in one patient from a segmental renal artery following resection of an angiomyolipoma on postoperative day 2 and blood transfusion was required.

Conclusions

The intraoperative blood loss (350 cc), transfusion rate (4%), and postoperative bleeding rate (4%) in the present study were comparable to published studies with similar tumor size. Therefore, although this case series had no comparator group, the authors conclude that oxidized cellulose hemostats (SURGICEL) provide ease-of-use in nephron-sparing surgeries and are effective in controlling postoperative bleeding.

Use of hemostatic agents and glues during laparoscopic partial nephrectomy: A multi-institutional survey from the United States and Europe of 1347 cases

Breda A, Stepanian SV, Lam JS, et al.

European Urology 2007; 52: 798-803.

Objective

The authors sought to investigate the practice patterns of urologists in the US and Europe, and their acceptance of renal hemostatic agents and glues in patients undergoing laparoscopic partial nephrectomy.

Methods

An e-mail survey was sent to 26 centers in the US and Europe that perform a high volume of laparoscopic renal surgeries; 18 responded. Data requested during a retrospective review of patient charts for individuals who underwent laparoscopic partial nephrectomy (LPN) included:

- ➔ Indications for hemostatic agent and/or fibrin glue usage
- ➔ The type of hemostatic agent and/or fibrin glue used
- ➔ Use of concomitant suturing/bolstering
- ➔ Type of laparoscopic tools used to perform the tumor resection
- ➔ Total number of LPNs performed
- ➔ Tumor size and position

Results

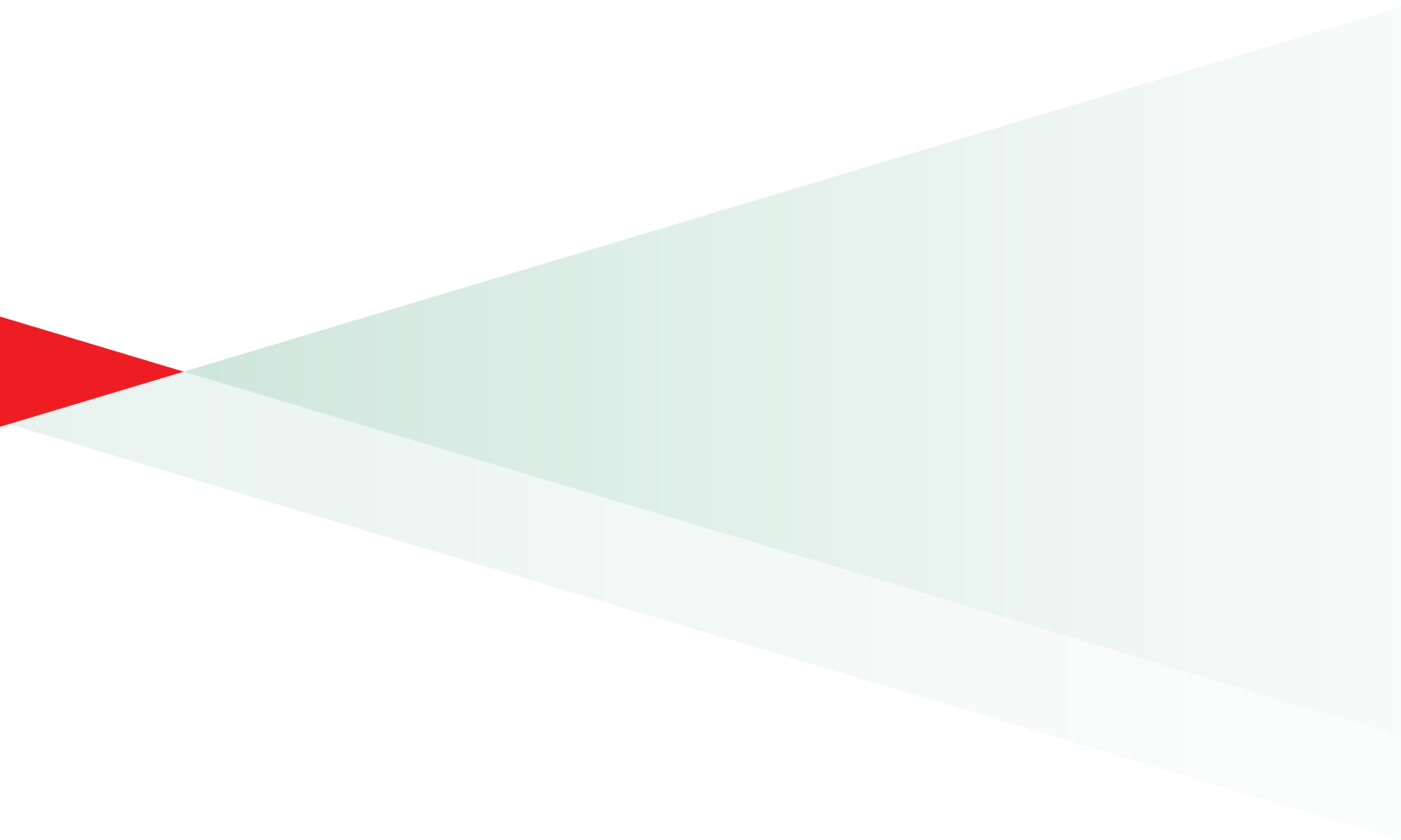
Suitable surveys from 1347 LPN cases reported from 18 major academic centers were returned. Mean tumor size was 2.8 cm (range 2 to 4 cm). Sixteen centers reported always using hemostatic agents and/or glues (n = 1042, 77%); 2 centers never used hemostatic agents and/or glues. Sixteen centers also always used parenchymal suturing over absorbable bolsters of SURGICEL® Absorbable Hemostat and/or central hemostatic suture. One center reported variable use of a bolster suture and/or central hemostatic suture depending on the depth of the lesion. One center only used sealants and never performed suturing/bolstering, 15 centers performed tumor resection with the use of cold scissor, 2 used a harmonic scalpel, and 1 used bipolar forceps.

For the 1042 cases where hemostatic agents and/or glues were used, complications included postoperative bleeding requiring transfusion in 28 patients (2.7%) and urine leakage in 20 (1.9%).

Conclusions

The authors note that use of hemostatic agents and glues is becoming increasingly standardized in most centers performing laparoscopic partial nephrectomy. Based on these self-reported survey results, the use of hemostatic agents and/or fibrin glues is routine in most centers performing laparoscopic partial nephrectomy.

Orthopedic Surgery



The use of local agents: SURGICEL® and SURGIFOAM®

Sabel M, Stummer W

European Spine Journal 2004; 13: S97-S101.

Objective

The authors review the technical aspects of the application of absorbable porcine gelatin and regenerated oxidized cellulose in spinal surgery.

Overview

In the majority of intraspinal, extradural procedures, bleeding is caused by venous vessels. Bleeding of only a few millimeters within the spinal canal may cause devastating neurological damage. In addition, continuous bleeding may impede visualization and identification of target structures. The standard methods to control hemostasis, direct pressure and ligature, are not applicable in intraspinal surgery. Complete occlusion of the vessel lumen via bipolar cautery may compromise perfusion of neural tissues and dissipation of heat may induce thermal injury to nerve roots or neural structures.

- ➔ Bone wax is commonly used to stop bleeding from oozing bone. A disadvantage of bone wax includes difficulty in molding the wax to the contours of the bleeding areas utilizing a dissector.
- ➔ Absorbable gelatin sponges tend to stick to surgical instruments. In addition, sponges do not form a tight bond with the source of bleeding and may become easily dislodged.
- ➔ Proper utilization and handling of gelatin sponges is essential to minimize the potential for engorgement and a mass effect.
- ➔ Oxidized cellulose granulomata may mimic tumor recurrence or postoperative abscess on both CT and sonography when the patient undergoes imaging early in the postoperative period. Magnetic resonance imaging may be helpful in differentiating SURGICEL® FIBRILLAR™ Hemostat from an abscess, and therefore, in preventing unnecessary attempts at re-operation.

Discussion

Chemical hemostatic agents can control bleeding without occluding the vessel lumen and cause no thermal injuries to adjacent structures. Based on the authors' experience, topical application of these agents can effectively control diffuse capillary oozing.

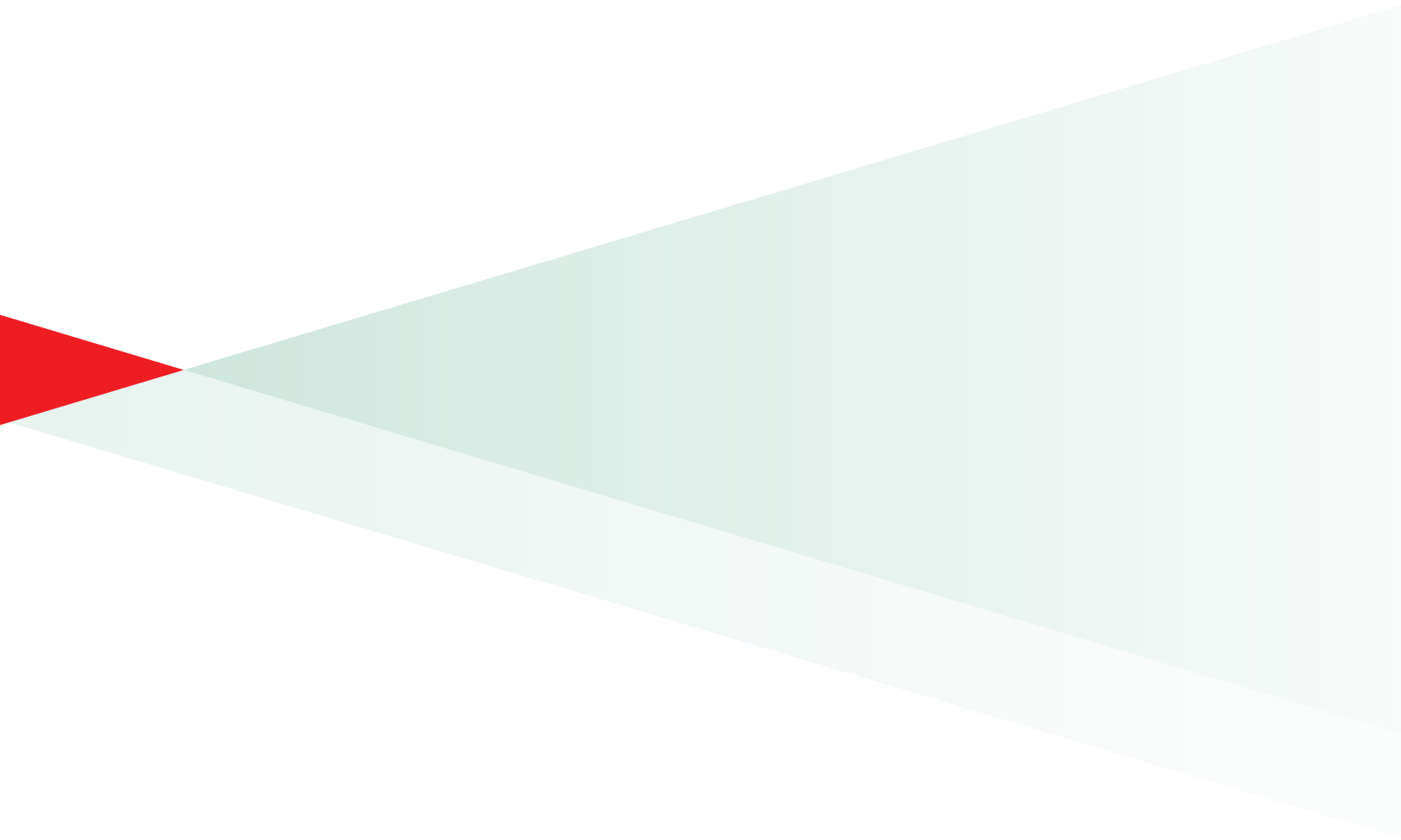
- ➔ SURGICEL FIBRILLAR Hemostat knitted strips may be easily trimmed to any size.
- ➔ SURGICEL FIBRILLAR Hemostat conforms well to shapes. It is easily manipulated and does not stick to instruments.
- ➔ SURGICEL FIBRILLAR Hemostat, a layered three-dimensional wafer resembling cotton, may be peeled off in the desired amount, facilitating placement of the customized pieces.
- ➔ Bipolar cautery can be directly applied to the SURGICEL FIBRILLAR Hemostat surface to produce more effective hemostasis.

- ➔ Direct application of suction to SURGICEL FIBRILLAR Hemostat may be performed, eliminating the need for an overlying cotton patty, which can significantly obscure visualization of the operative site.
- ➔ SURGICEL Hemostat can swell and should be removed from the site. Over-liberal use of the hemostatic agents should be avoided and excess amounts should be removed once hemostasis is achieved to prevent spinal cord compression in all intraspinal and perispinal procedures.

Conclusions

The authors state that the hemostats allow for effective control of bleeding in microsurgical procedures. These agents should be used primarily when bipolar cautery is either ineffective or dangerous. Absorbable porcine gelatin and regenerated oxidized cellulose in intraspinal surgery can be considered safe and beneficial. Their appropriate use requires an understanding of their advantages, limitations, and the nature of complications associated with application.

Plastic Surgery



Use of oxidized regenerated cellulose to stop bleeding after a facelift procedure

Bassetto F, Vindigni V, Scarpa C, et al.
Aesthetic Plastic Surgery 2008; 32: 807-9.

Objective

Hematomas and bleeding complications are typically associated with a facelift procedure (rhytidectomy). The authors describe the use of oxidized regenerated cellulose (SURGICEL® Absorbable Hemostat) for hemostasis during the surgery to control postoperative bleeding.

Method

This case report details the care of a 52-year-old woman who underwent a facelift using the SMAS technique for soft tissue laxity after a 67 kg weight loss. The deep plane facelift was performed under local anesthesia with mepivacaine plus 1:300,000 epinephrine supplemented by sedation. Three hours post-procedure taut, painful hematomas in the pre- and retro-auricular areas were noted. At reoperation, diffuse bleeding not attributable to any specific vessels was found. After local hemostasis where possible with electrocautery, oxidized regenerated cellulose (TABOTAMP®) was placed and then left in situ.

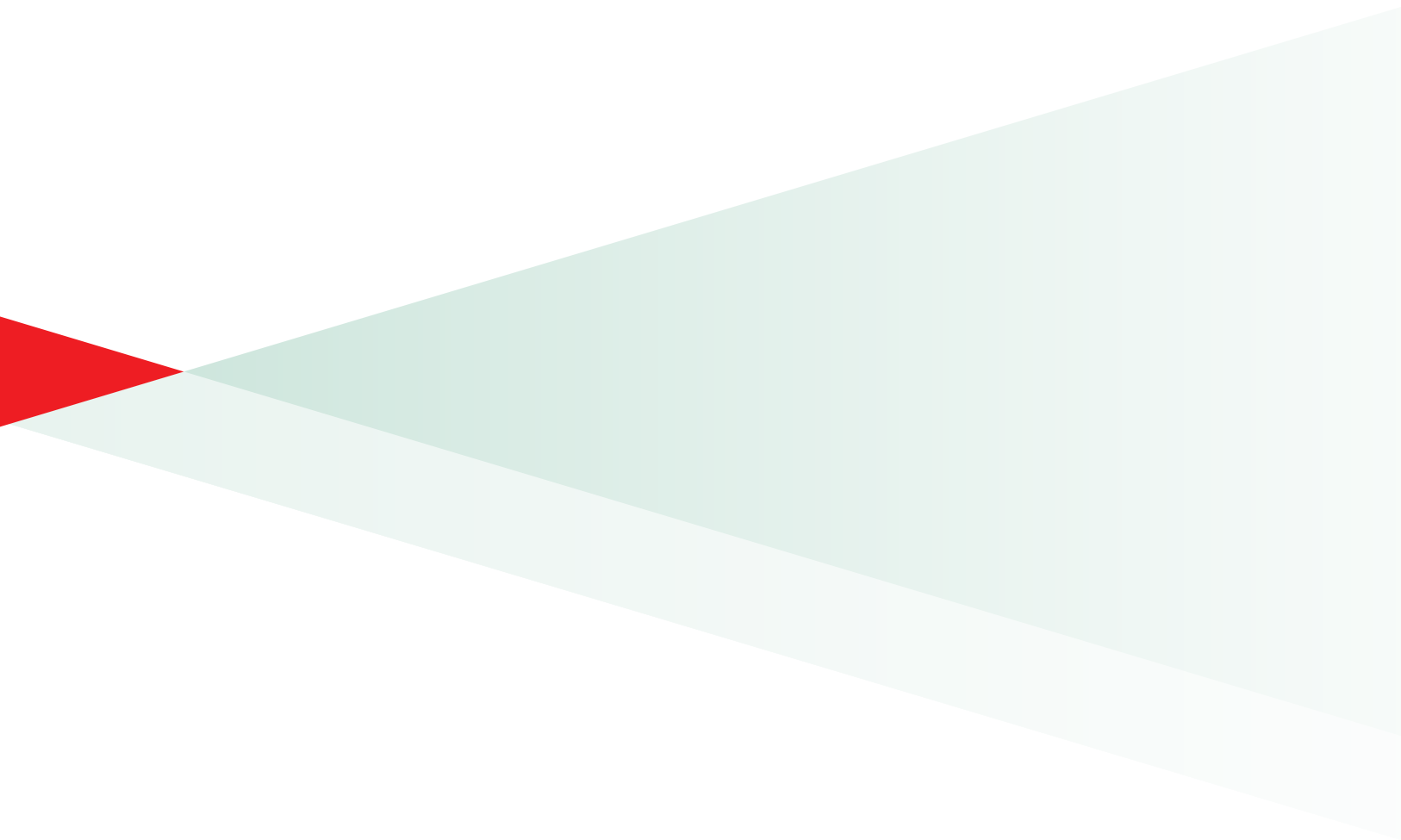
Results

Hemostasis was complete. No rebleeding was noted. Small seromas were evacuated with pressure. No local pain or skin damage was present at a 2-week follow-up visit.

Conclusions

Hematoma is the most frequent complication after rhytidectomy. The authors report that oxidized regenerated cellulose could be a good ancillary therapy for controlling local bleeding associated with this type of surgery.

ENT Surgery



Using NU-KNIT® for hemostasis around recurrent laryngeal nerve during transthoracic esophagectomy with lymphadenectomy for esophageal cancer

Rino Y, Yukawa N, Sato T, et al.

BMC Research Notes 2014; 7: 127

Objective

This retrospective study assessed if using SURGICEL® Nu-Knit® Absorbable Hemostat prevents postoperative recurrent laryngeal nerve palsy during lymphadenectomy along recurrent laryngeal nerve palsy and compared the results to electrocautery hemostasis.

Methods

Patients were candidates for esophagectomy with lymphadenectomy, and all surgeries were performed by same surgeon. Nu-Knit was used to achieve hemostasis in group N (mean age: 67.6 years; age range: 56–76 years; 18 men, 1 woman) and electrocautery was used in group E (mean age: 65.2 years; age range: 49–75 years; 8 men, 1 woman). Endpoints included rate of recurrent laryngeal nerve palsy, operation time, and blood loss.

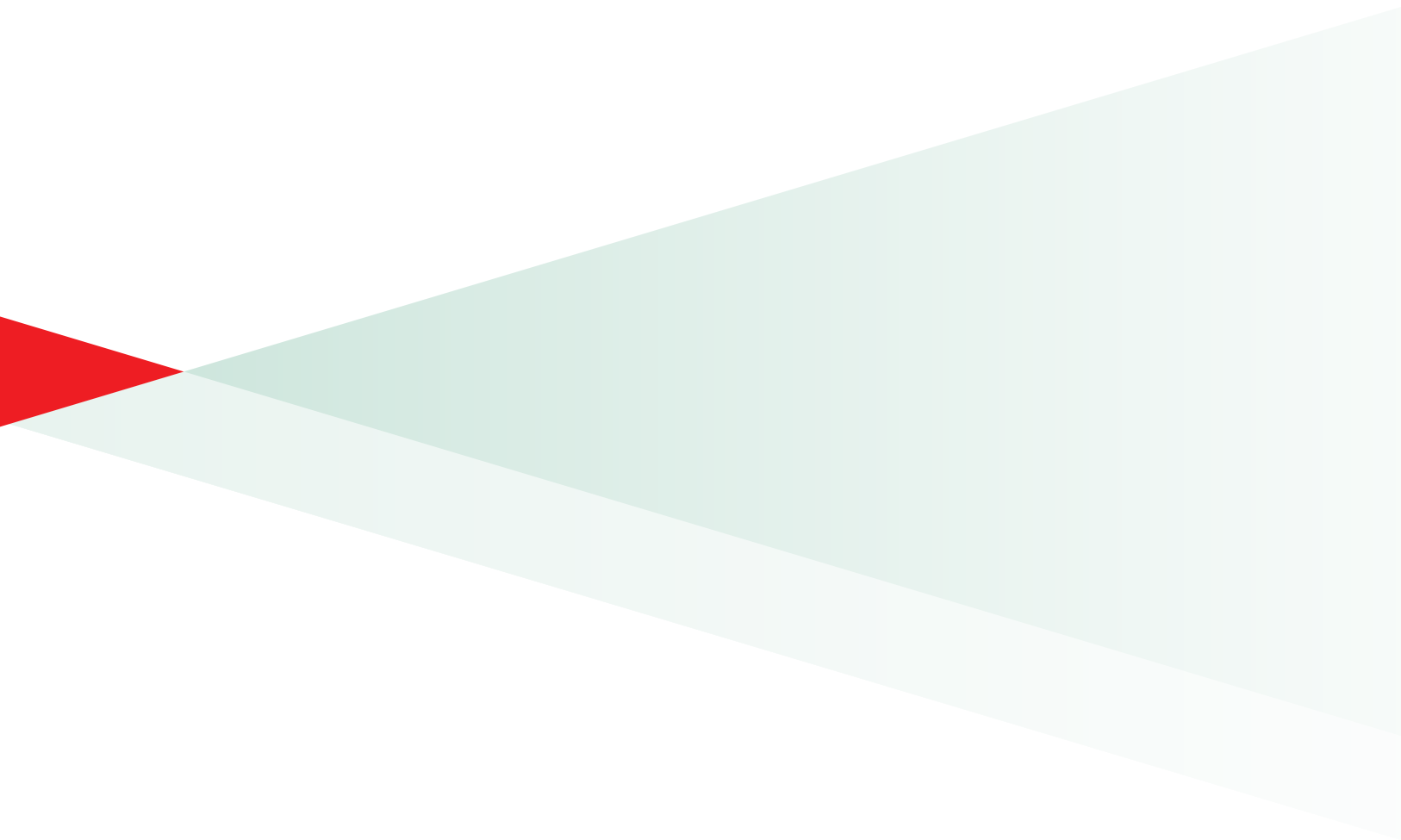
Results

In group E, there were 5/9 (55.6%; 2 bilateral) cases of complicated recurrent laryngeal nerve palsy compared to 1/19 (5.3%; 0 bilateral) cases in the N group. There was no significant difference between the 2 groups in blood loss and operation time. Incidence of recurrent laryngeal nerve palsy was significantly higher in group E (55.6%) than group N (5.3%) ($P=0.007$). No postoperative bleeding occurred and the follow-up course was satisfactory.

Conclusions

Hemostasis using Nu-Knit can be a good strategy to assess if hemostasis prevents recurrent laryngeal nerve palsy in transthoracic esophagectomy. Authors noted that Nu-Knit is 3 times more dense than SURGICEL Original and provides >36% faster time to hemostasis.

Health Economics and Outcomes Research



Reduction in hospital costs and resource consumption associated with the use of advanced topical hemostats during inpatient procedures

Martyn D, Kocharian R, Lim S, et al.

Journal of Medical Economics 2015; 18; 474-81.

Objective

This study compared SURGICEL® FIBRILLAR™ and SURGICEL® SNoW™ (collectively called SURGICEL advanced products [SAP]) to SURGICEL® Original (SO) with regard to healthcare resource use and costs.

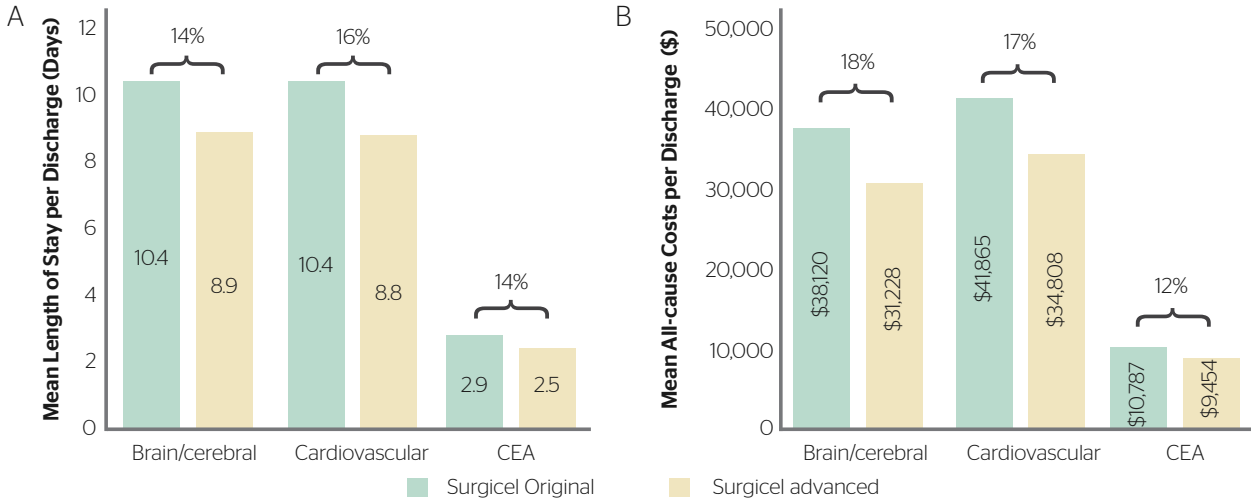
Methods

This retrospective observational analysis used the Premier Hospital Database to evaluate the clinical and economic outcomes of adults who underwent brain/cerebral (BC), cardiovascular ([CV] valve surgery and coronary artery bypass graft) and carotid endarterectomy (CEA) and whose discharge data included the use of SO or SAPs. Primary outcomes were length of stay (LOS), all-cause total cost, number of intensive care unit (ICU cost), transfusion costs and units, hospital mortality, and SO/SAP product units per discharge.

Results

Overall, SAP group had a 14-16% lower LOS for each procedure compared to SO, and 12-18% lower total mean cost per discharge for each procedure ($P < 0.02$ for all) (Figure 1). There was a significant reduction in LOS with SAP compared to SO for BC procedure ($P = 0.013$), CV procedure ($P < 0.001$) and CEA procedure ($P < 0.001$). Mean cost decreased significantly ($P < 0.001$) for all procedures with SAP instead of SO. Mean ICU costs for SAPs were lower, with a reduction of 20% for BC and 19% for CV compared to SO ($P < 0.01$). The ICU days of BC patients with SAPs was significantly lower compared to SO ($P = 0.017$). Mean transfused blood product use was 23% lower in the SAP group than SO group (3.95 vs 5.15 units per discharge, $P = 0.639$). The difference in associated costs, however, was significantly different (SAP, \$678; SO, \$1102; $P = 0.029$). Only in the CEA group, SAP patients had a significantly lower mortality (SAP, 0.1%; SO, 0.7%; $P = 0.007$). Significantly lower SURGICEL units per discharge were used in the SAP group compared to SO for CV and CEA procedures ($P < 0.001$).

Figure 1. A) Mean length of stay per discharge and B) Mean all-cause costs per discharge, for SURGICEL Original and advanced cohorts by procedure type.



Conclusions

SAPs are associated with a lower healthcare resource utilization and cost compared to SO in three common procedure groupings.

Variation in hospital resource use and cost among surgical procedures using topical absorbable hemostats

Martyn D, Meckley LM, Miyasato G, et al.

ClinicoEconomics and Outcomes Research 2015; 7: 567-74

Objective

This study compared the healthcare resource utilization (HRU), costs, and other outcomes associated with using SURGICEL®-brand oxidized regenerated cellulose (ORC) compared to other adjunctive hemostats (OAHs), for surgical procedures performed in US inpatient settings using both types of adjunctive hemostats.

Method

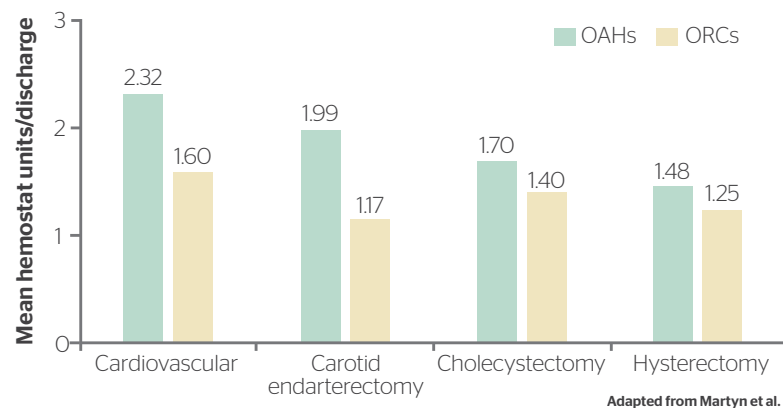
This retrospective, US-based cohort study used data from the Premier Healthcare Database, that consisted of hospital discharges for adult patients (aged ≥ 18 years) undergoing inpatient cardiovascular procedures, carotid endarterectomy, cholecystectomy, or hysterectomy from 2011 to 2012, during which adjunctive hemostats (ORCs and OAHs [flowables, gelatin, or topical thrombin]) were used.

Clinical, economic, and HRU outcomes were compared between ORCs and OAHs.

Results

In all procedures, total hemostat costs were 28%–56% lower, and mean hemostat units per discharge were 16%–41% lower, for ORCs compared to OAHs (Figure 1). Mortality rates for all procedures were low ($<4\%$) with no statistically significant difference between ORCs and OAHs. A shorter length of stay seen with ORC use was typically associated with significantly lower ($P < 0.001$) total procedure costs (Table 1). Use of ORCs in carotid endarterectomy and cholecystectomy also led to significantly decreased ($P < 0.001$) transfusion rates compared to when OAHs were used.

Figure 1. Hemostat units per discharge and total hemostat cost.



Total hemostat cost (\$)	OAH	247	186	274	265
	ORC	177	98	118	116

All differences between OAHs and ORCs for mean units/discharge total hemostat costs (US\$) were considered statistically significant at the $P < 0.001$ level. Costs for hemostatic agent classes included all hemostats used.

ORCs, oxidized regenerated celluloses; OAHs, other adjunctive hemostats

Table 1. Length of stay, total procedure cost, mortality, and transfusion rate: ORCs compared to OAHs

	Cardiovascular procedures	Carotid endarterectomy	Cholecystectomy	Hysterectomy
LOS (days)				
OAHs	9.3	3.0	8.1	3.1
ORCs	9.5	2.7	7.1	3.4
P-value	0.948	<0.001	<0.001	<0.001
Total procedure cost (US\$)				
OAH	37,784	11,282	23,656	11,033
ORCs	39,019	10,580	20,309	10,898
P-value	0.003	<0.001	<0.001	0.542
Transfusion rate during hospital stay (%)				
OAHs	43	5	19	14
ORCs	44	4	16	13
P-value	0.124	<0.001	<0.001	0.303

LOS, Length of stay; ORCs, oxidized regenerated celluloses; OAHs, other adjunctive hemostats

Conclusions

Adjunctive hemostat costs were lower when ORCs were used in patients undergoing cardiovascular procedures, carotid endarterectomy, cholecystectomy, or hysterectomy. Total procedure costs were lower when ORCs were used in carotid endarterectomy and cholecystectomy patients. ORC use also resulted in shorter inpatient length of stay in endarterectomy, cholecystectomy, and hysterectomy procedures. Overall, while clinical outcomes were similar, ORC use was associated with lower HRU and costs than OAH.

In Vivo Studies

The background features a minimalist design with a white background. A red triangle is positioned on the left side, pointing towards the center. A light green trapezoid is located below the red triangle, extending from the left edge towards the right. The trapezoid's top edge is slightly higher than its bottom edge, and its right side is a vertical line. The overall composition is clean and modern.

Hemostatic efficacy and tissue reaction of oxidized regenerated cellulose hemostats

Hutchinson RW, George K, Johns D, et al.

Cellulose 2013; 20: 537-45.

Objective

To determine the hemostasis time in swine spleen incision model by comparing non-woven (SURGICEL® FIBRILLAR™ and SURGICEL® SNoW™) and woven (SURGICEL® Original and Nu-Knit®) oxidized regenerated cellulose (ORC) hemostats.

Methods

After anesthesia, the spleen was located and incrementally externalized. Beginning at the distal tip of the ventral side of the spleen, proceeding proximally, 15 mm long x 3 mm deep incisions were made with a #11 scalpel that had a Kelly forceps clamped onto it, thereby limiting the incision depth to 3 mm. The ORC hemostats were applied to a freshly created wound site, followed by dry gauze, and occlusive digital pressure (tamponade) was applied for 1 minute (stage 1) or 2 minute (stage 2). Following the initial tamponade, digital pressure was discontinued, the gauze pad was removed, and the site evaluated for 30 s. If hemostasis was achieved, the time to hemostasis was noted and testing was concluded. If hemostasis was not achieved, pressure and gauze were reapplied for additional 30 s tamponade and observation periods until hemostasis was achieved, or until the testing period reached 10 minutes. At 10 minutes, the trial was aborted as a failure and recorded as “greater than 10 min”.

Results

The median hemostasis time for a single layer of SURGICEL SNoW was 51% shorter than woven ORCs ($P < 0.001$). The mean hemostasis time for non-woven ORC was not affected by the mass of hemostat applied to the wound, whereas the hemostatic efficacy of woven ORC increased with the mass (layers) of hemostat applied. Overall, the non-woven ORCs were significantly ($P < 0.001$) faster in achieving hemostasis than woven ORCs. Tissue reaction was minimal and the material was fully absorbed by 14 days. There was no evidence of hematoma, infection, wound dehiscence, immunologic response, or abnormal wound healing at any time.

Conclusions

The hemostatic performance of non-woven ORC materials does not depend on the mass of the implant, but mass may be important for knitted forms.

Effects of absorbable hemostats on intraabdominal sepsis

Kuchta N, Dineen P

Infections in Surgery 1983; 441-4.

Objective

An in vivo animal simulation model was utilized to compare the bactericidal activity of various hemostatic agents. Since the spleen has no endogenous flora, this made it possible to define the lethal inoculum size with a specific pathogen.

Methods

A total of 140 guinea pigs weighing 250 to 400 g were anesthetized and the abdomen was opened through a left subcostal incision. An injury to the spleen was created by ligation of the splenic artery, causing the spleen to infarct, creating a necrotic organ similar to a large blood clot. The spleen of each animal was injected with 0.5 mL of a culture of *Klebsiella pneumoniae* in a 10⁻⁴ dilution, a common postoperative pathogen. Animals were divided into 4 groups: Group 1—Control Group: after injection, the wound was closed and the animals returned to their cages; Group 2—Absorbable gelatin sponge group: an absorbable sponge (2 × 2 cm) was tied to the anterior and posterior surfaces of the spleen. The spleen was returned to the abdomen and the wound was closed; Group 3—Microfibrillar collagen hemostatic agent group: 250 mg of powder was placed on the surface of the spleen and tapped into position to form a cast. The spleen was returned to the abdomen and the incision was closed; Group 4—Oxidized regenerated cellulose (ORC) group: ORC (1 × 3 cm) was wrapped around the spleen. The spleen was returned to the abdomen and the wound was closed. Three animals from each group were sacrificed and autopsy on postoperative days 1 and 3 was performed. Splenic tissues were cultured. The study protocol also included autopsies and cultures on postoperative days 10, 20, and 30.

Results

All animals in groups 1, 2, and 3 were dead at 5 days; 90% of the animals in the ORC group were alive at 30 days. Deaths occurring in Group 4 were believed to be related to technique. No animal from the ORC group died after 3 days. All animals in groups 1, 2, and 3 had evidence of frank peritonitis and/or abscess formation. No sign of infection was seen in the splenic bed of the animals in the ORC group. Fibrous tissue was present where the necrotic spleen had been absorbed.

Animals in groups 1, 2, and 3 with abscess had cultures positive for *Klebsiella pneumoniae*. One animal in the ORC group grew 0 to 1 *Klebsiella pneumoniae* organisms.

Conclusions

Survival results clearly demonstrate that the use of oxidized regenerated cellulose (ORC, SURGICEL® Absorbable Hemostat) is effective in preventing *Klebsiella pneumoniae* infections, fatal peritonitis, and/or abdominal abscess in this experimental model. The paper speculates as to the mechanism. ORC may reduce the size of the challenge inoculum to a manageable number secondary to a low pH, allowing host defense mechanisms to control the infection. Other absorbable hemostatic agents do not appear to prevent bacterial proliferation. The lack of effectiveness demonstrates that this phenomenon cannot be due to hemostasis alone.

The effect of oxidized regenerated cellulose on experimental infected splenotomies

Dineen P

Journal of Surgical Research 1977; 23: 114-6.

Objective

The purpose of this study was to further characterize the antibacterial activity of oxidized regenerated cellulose (ORC) in an in vivo model (canine splenic injury).

Methods

Twenty-five large mongrel dogs of either sex were anesthetized, a midline incision made, and the spleen exposed. Two splenotomies were made each measuring 2×2 cm, and a core of tissue was removed. A plug of either SURGICEL® Absorbable Hemostat ORC or an absorbable gelatin sponge was placed in the splenotomy site. The splenic capsule was reapproximated and hemostasis obtained. In 5 of the animals, a third core of splenic tissue was removed to be used as a baseline of untreated tissue.

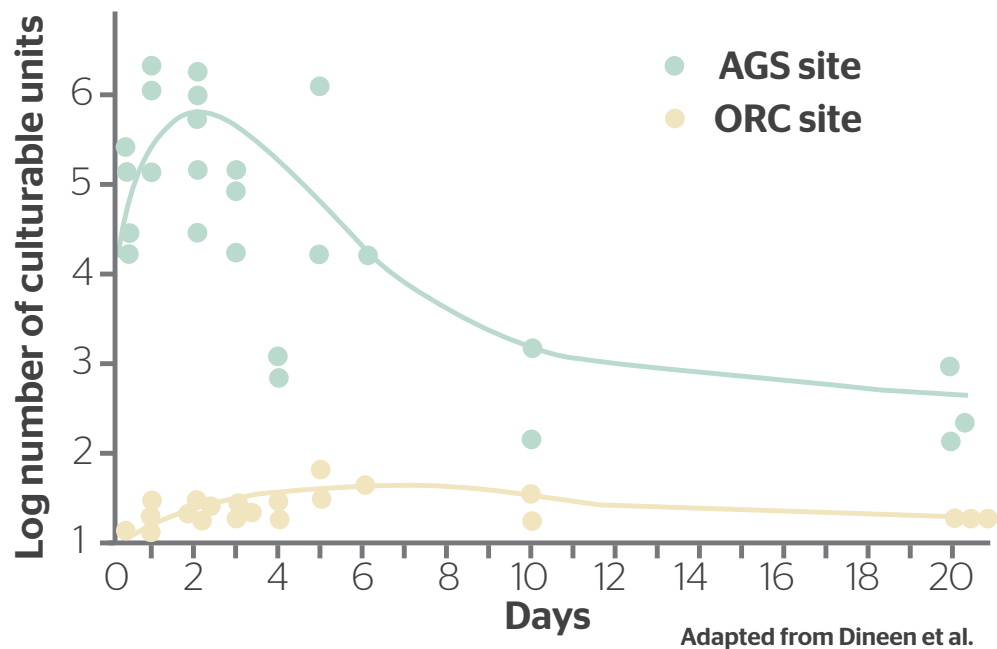
After suturing and achieving hemostasis, the animals were challenged with penicillin-resistant bacteria-contaminated normal saline (10^4 culturable units of *S. aureus* (Giorgio)/mL) intravenously. Each animal served as its own control. Evaluations were conducted immediately following closure of the abdomen (time zero) up to 20 days.

After sacrifice and under aseptic conditions, the spleen was removed. The splenotomy site and an edge of approximately 2 mm of surrounding tissue were dissected and placed in a homogenizing tube. Specimens were prepared for each of the splenotomy sites from all animals including the third untreated sample from 5. After incubation for 48 hours, the number of colonies was counted. Counts of bacterial colonies in cultured splenic tissue were measured.

Results

The number of organisms isolated from the SURGICEL Hemostat splenotomy sites remained low, while the control sites (the absorbable gelatin sponge) exhibited high (10^6 /mL) colony counts.

Figure 1. Number of culturable units of *S. aureus* from 2 splenotomy sites (containing AGS or ORC) following challenge at zero time.



AGS, absorbable gelatin sponge; ORC, oxidized regenerated cellulose

Conclusions

The use of ORC is effective in reducing the bacterial population.

The effect of oxidized regenerated cellulose on experimental intravascular infection

Dineen P

Surgery 1977; 82: 576–9.

Objective

The purpose of this study was to characterize the antibacterial activity of oxidized regenerated cellulose (SURGICEL® Absorbable Hemostat) in an in vivo model of intravascular infection.

Methods

Large mongrel dogs of either sex were anesthetized, a midline incision made, and a small ellipse of infrarenal aorta approximately 0.25 by 2.0 cm removed. A Teflon patch was then sutured in place. In the treatment group a double layer of SURGICEL Hemostat was wrapped around the aorta in tight contact with the patch area. Control animals were not wrapped. After closing the wound, 67 animals (37 treatment, 30 control) were challenged with penicillin-resistant bacteria-contaminated normal saline (10^4 culturable units of *S.aureus* (Giorgio)/mL) intravenously over 20 minutes. An additional 8 dogs were exposed to 100 mL *Klebsiella aerogenes* (10^3 /mL) in the same manner. Sacrifice was conducted immediately following closure of the abdomen (time zero) up to 30 days. Specimens were prepared from the area of the patch and 1 mm of surrounding aorta. After incubation for 48 hours, the number of colonies was counted. Outcomes measured included the number of culturable units of *S. aureus* and *Klebsiella aerogenes* isolated from Teflon aortic patches in dogs after bacterial challenge was measured, from immediately following operation up to 30 days.

Results

The animals whose patch was wrapped with SURGICEL Hemostat had significantly lower bacterial colony counts (of either strain) when the patch was removed and cultured than did those with no wrapping following a challenge. These differences were most apparent immediately following the challenge. For the *S.aureus* exposed animals, no organisms were isolated in dogs sacrificed at time zero in the SURGICEL Hemostat group. This low result continued for at least 30 days. The counts exceeded 15 colonies in only 2 dogs (sacrificed on days 7 and 10). In the untreated group, the bacterial population grew from the time of challenge and stayed high for approximately 1 week. Most of the untreated infected Teflon patches showed significant amounts of inflammatory reaction in surrounding tissues. This was not the case in the SURGICEL Hemostat wrapped aortic patches.

Conclusions

Study results indicate that in the animal model used, it was possible to reduce the bacterial contamination of an implanted Teflon patch in the aorta by wrapping the area of the patch with ORC. The authors conclude that ORC substantially reduces the number of viable organisms in the initial exposure, such that, the effective inoculum is very small.

In Vitro Studies

An abstract geometric design featuring a red triangle on the left side, which is partially overlapped by a light green trapezoid. The trapezoid extends from the left edge towards the right, creating a layered effect. The overall composition is minimalist and modern.

In vitro antimicrobial activity of oxidized regenerated cellulose against antibiotic-resistant microorganisms

Spangler D, Rothenburger S, Nguyen K, et al.

Surgical Infections (Larchmt) 2003; 4: 255–62.

Objective

The objective of this in vitro study was to examine the bactericidal activity of oxidized regenerated cellulose (ORC) products against antibiotic-resistant organisms.

Methods

This study was designed to evaluate the effect of 3 ORC product samples against a microbial challenge over a period of 24 hours. Three different ORC products were evaluated: SURGICEL® Absorbable Hemostat, SURGICEL® Nu-Knit® Absorbable Hemostat, and SURGICEL® FIBRILLAR™ Absorbable Hemostat. Microorganisms utilized included 4 clinical isolates from the Robert Wood Johnson Pharmaceutical Research Institute and 5 American Type Culture Collection strains. The samples were prepared and pour plated for the challenge. This procedure was carried out in triplicate at time 0 (immediately following inoculation), 1, 6, and 24 hours after inoculation. Positive controls of all test strains were run alongside active samples and were plated at times 0 and 24 hours. All plates were incubated at 30°C to 35°C for 24 hours. Plates were read and microorganism counts were recorded in colony forming units (CFU)/mL. Reduction in pH level in both the presence and absence of a bacterial inoculum was noted.

Results

Study results indicated antimicrobial activity of all 3 SURGICEL Hemostat products against the 9 challenge organisms. All products were significantly more antibacterial compared to the corresponding untreated controls.

Table 1. Percent kill of SURGICEL hemostat products after 24 hours exposure

Microorganism	Percentage kill (P-value) after 24 h exposure		
	SURGICEL Original	SURGICEL FIBRILLAR	SURGICEL Nu-Knit
<i>Staphylococcus aureus</i> (MRSA)	99.9999 (0.00002)	99.9999 (0.00001)	99.9999 (0.00009)
<i>Streptococcus pneumoniae</i> (PRSP)	99.9999 (0.00008)	99.9999 (0.00001)	99.9996 (0.0003)
<i>Enterococcus faecium</i> (VRE)	99.9565 (0.004)	99.9998 (0.001)	99.9413 (0.00003)
<i>Enterococcus faecalis</i> (VRE)	99.9405 (0.0003)	99.9735 (0.003)	99.9992 (0.003)
<i>Enterococcus faecium</i> (VRE)	35.15 (0.001)	63.0939 (0.001)	99.9723 (0.002)
<i>Staphylococcus epidermidis</i> (MRSE)	99.9999 (0.00007)	99.9999 (0.00004)	99.9999 (0.00004)
<i>Staphylococcus aureus</i>	99.9999 (0.00004)	99.9999 (0.00004)	99.9999 (0.00001)
<i>Staphylococcus aureus</i> (MRSA)	99.9147 (0.0001)	99.9831 (0.00007)	99.9999 (0.00007)
<i>Pseudomonas aeruginosa</i>	99.9999 (0.00007)	99.9997 (0.0003)	99.9999 (0.0003)

T-test P-values were calculated using the Student's t-test assuming unequal variances with one-tail recorded.

ATCC, American Type Culture Collection; MRSA, methicillin-resistant *S. aureus*; MRSE, methicillin-resistant *S. epidermis*; PRSP, penicillin-resistant *S. pneumoniae*; VRE, vancomycin-resistant enterococci.

All 3 SURGICEL products reduced pH levels from approximately 7.3 to a range of 3.7 to 4.5 over the 24-hour test period as compared to controls. Of the 3, SURGICEL FIBRILLAR showed the most immediate reduction in pH to a level of 4.8 at time zero, continuing to decrease and ultimately to be maintained at a level below pH 4 throughout the 24-hour testing period. Since low pH affects a relatively broad spectrum of bacteria and does not act in a mechanism specific manner, as do antibiotics, antibiotic-resistant strains of bacteria are unlikely to resist the ORC pH effect.

Conclusions

Results of this in vitro assessment support the hypothesis that the antimicrobial activity of ORC is effective against antibiotic-resistant microorganisms.

Antibacterial activity of oxidized regenerated cellulose

Dineen P

Surgery, Gynecology & Obstetrics 1976; 142: 481-6.

Objective

The objective of this study was to evaluate the antibacterial activity of oxidized regenerated cellulose (SURGICEL® Absorbable Hemostat), absorbable gelatin sponge, and topical thrombin in both in vitro and in vivo models.

Methods

For in vitro testing, test tubes were prepared with each of the test materials or control (unoxidized regenerated cellulose), 9.8 mL of trypticase soy broth, and 0.2 mL of a 10^3 dilution of an 18 hour culture of the bacterial organism to be evaluated. Ten different strains of bacterial organisms were used. At various times from 30 minutes to 48 hours, samples were removed from each tube and plated. The plates were then incubated and colonies counted after 48 hours. This test was also repeated using concentrated inoculums (1 mL). Zones of inhibition were evaluated with plates containing 2 mL of culture and either 1 cm² of SURGICEL, 1 cm² of absorbable gelatin sponge, or 0.5 mL of topical thrombin. The plates were then incubated and at 48 hours were measured.

The in vivo section of this study involved 100 male albino guinea pigs who under general anesthesia received two parallel 5 cm linear incisions on the dorsum. The incisions were carried through the fascia. After the incision, 3 mL of a concentrated 18-hour culture of 1 of 3 species of bacteria were placed in the wounds. Absorbable 5 cm strips of either gelatin sponge or SURGICEL were placed in the wounds. Control wounds had only culture inserted. The guinea pigs were divided into 2 groups. Group 1 was observed for 10 days for the development of sepsis. Wounds were inspected daily and when sepsis was noted, the time and degree was recorded. In Group 2, the wounds were opened at varying times (24h, 72h, 96h) and tissue or fluid removed and plated.

The number of bacterial colonies was counted as the primary outcome measure of both in vitro and in vivo studies.

Results

The in vitro tests demonstrated significant antibacterial activity for SURGICEL but not for the absorbable gelatin sponge or topical thrombin. When concentrated culture from any of the 10 test organisms was exposed to SURGICEL for 24 hours, no growth was apparent. Zones of inhibition around wells made in agar plates showed an average of 6 mm with SURGICEL and 0 mm with absorbable gelatin sponge and topical thrombin. Also, when pour plates were streaked with test organisms and then a strip of SURGICEL or absorbable gelatin sponge was placed on the surface, a zone of inhibition only appeared around the SURGICEL.

The in vivo test results showed that guinea pigs with SURGICEL placed in their contaminated wounds, did not develop sepsis (except in a single case). In contrast, in the control and absorbable gelatin sponge-treated wounds, sepsis was seen. Further, the bacterial counts revealed that the wound with SURGICEL had a greater than 100-fold reduction in bacterial population compared to the control and absorbable gelatin sponge-treated wounds.

Conclusions

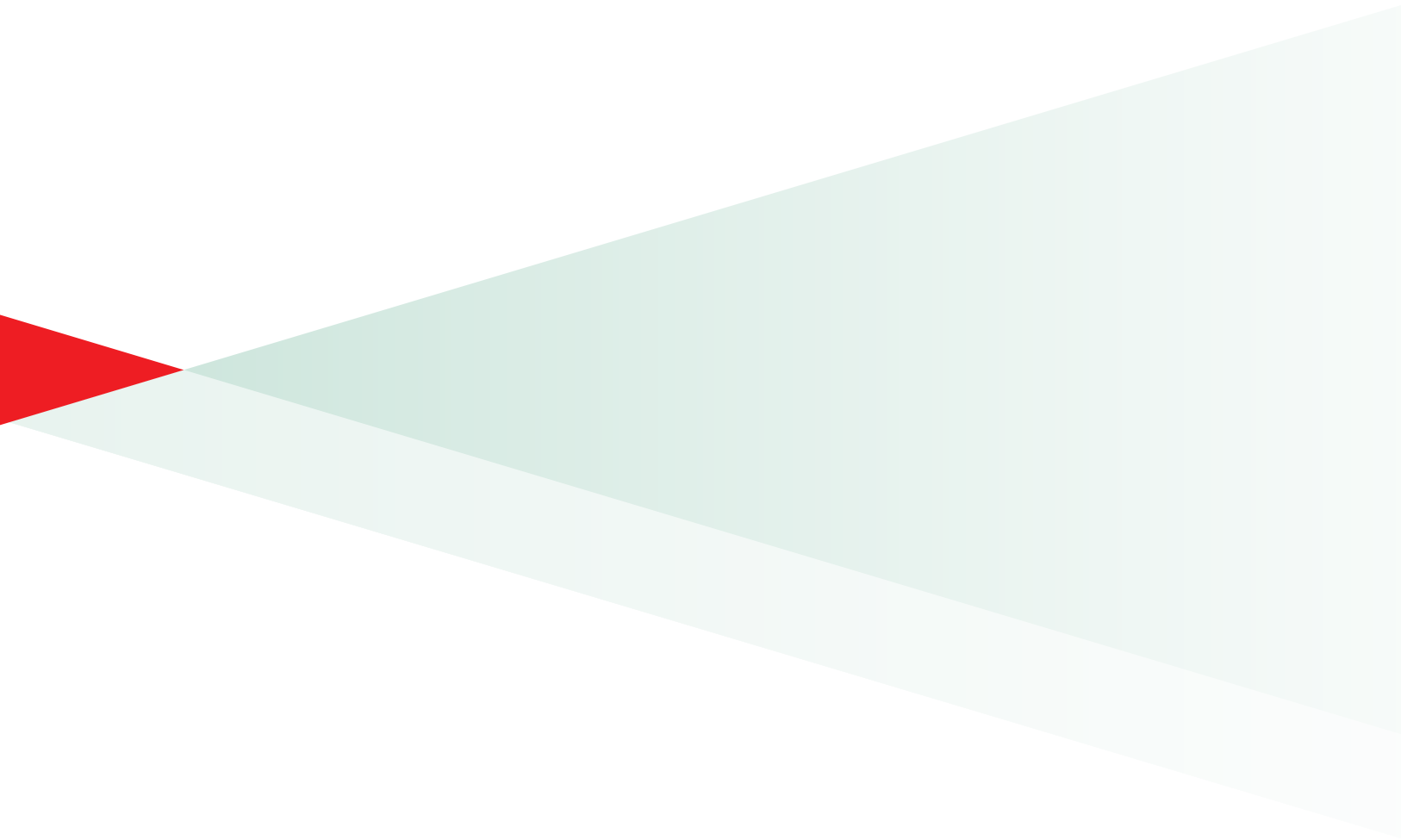
Unlike absorbable gelatin sponge and topical thrombin, oxidized regenerated cellulose substantially reduced the bacterial population of ten different strains of common pathogens when exposed to them in vitro. The in vivo results suggest that oxidized regenerated cellulose does exert an antibacterial action in the guinea pig model used.

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Full Prescribing Information



SURGICEL® ORIGINAL, SURGICEL® NU-KNIT® and
SURGICEL® FIBRILLAR™ Absorbable Hemostats
(oxidized regenerated cellulose)
FOR SURGICAL USE
(For dental application of this product, reference should
be made to the dental use section of this insert.)

DESCRIPTION

SURGICEL® Absorbable Hemostat is a sterile absorbable knitted fabric prepared by the controlled oxidation of regenerated cellulose. The fabric is white with a pale yellow cast and has a faint, caramel-like aroma. It is strong and can be sutured or cut without fraying. It is stable and should be stored at controlled room temperature. A slight discoloration may occur with age, but this does not affect performance. The SURGICEL® FIBRILLAR™ form of the product allows the surgeon to grasp with forceps any amount of SURGICEL® FIBRILLAR™ Hemostat needed to achieve hemostasis at a particular bleeding site. The SURGICEL® FIBRILLAR™ form may be more convenient than the knitted form for hard to reach or irregularly shaped bleeding sites. Although it is easy to pull the desired amount of SURGICEL® FIBRILLAR™ Hemostat from the entire supply, the group of selected fibers continue to cohere to one another and application to the bleeding site is easily controlled. Unwanted dispersal over the operative site does not occur.

ACTIONS

The mechanism of action whereby SURGICEL® Absorbable Hemostat accelerates clotting is not completely understood, but it appears to be a physical effect rather than any alteration of the normal physiologic clotting mechanism. After SURGICEL® Absorbable Hemostat has been saturated with blood, it swells into a brownish or black gelatinous mass which aids in the formation of a clot, thereby serving as a hemostatic adjunct in the control of local hemorrhage. When used properly in minimal amounts, SURGICEL® Absorbable Hemostat is absorbed from the sites of implantation with practically no tissue reaction. Absorption depends upon several factors including the amount used, degree of saturation with blood, and the tissue bed. In addition to its local hemostatic properties, SURGICEL® Absorbable Hemostat is bactericidal *in vitro* against a wide range of gram positive and gram negative organisms including aerobes and anaerobes. SURGICEL® Absorbable Hemostat is bactericidal *in vitro* against strains of species including those of:

methicillin-resistant *Staphylococcus aureus* (MRSA)
penicillin-resistant *Streptococcus pneumoniae* (PRSP)
vancomycin-resistant *Enterococcus* (VRE)
methicillin-resistant *Staphylococcus epidermidis* (MRSE)

<i>Staphylococcus aureus</i>	<i>Bacillus subtilis</i>
<i>Staphylococcus epidermidis</i>	<i>Proteus vulgaris</i>
<i>Micrococcus luteus</i>	<i>Corynebacterium xerosis</i>
<i>Streptococcus pyogenes</i> Group A	<i>Mycobacterium phlei</i>
<i>Streptococcus pyogenes</i> Group B	<i>Clostridium tetani</i>
<i>Streptococcus salivarius</i>	<i>Clostridium perfringens</i>
<i>Branhamella catarrhalis</i>	<i>Bacteroides fragilis</i>
<i>Escherichia coli</i>	<i>Enterococcus</i>
<i>Klebsiella aerogenes</i>	<i>Enterobacter cloacae</i>
<i>Lactobacillus</i> sp.	<i>Pseudomonas aeruginosa</i>
<i>Salmonella enteritidis</i>	<i>Pseudomonas stutzeri</i>
<i>Shigella dysenteriae</i>	<i>Proteus mirabilis</i>
<i>Serratia marcescens</i>	

Studies conducted in animals show that SURGICEL® Absorbable Hemostat in contrast to other hemostatic agents does not enhance experimental infection. (1-4)

INDICATIONS

SURGICEL® Absorbable Hemostat (oxidized regenerated cellulose) is used adjunctively in surgical procedures to assist in the control of capillary, venous, and small arterial hemorrhage when ligation or other conventional methods of control are impractical or ineffective. SURGICEL® ORIGINAL, SURGICEL® FIBRILLAR™ and SURGICEL® NU-KNIT® Hemostats can be cut to size for use in endoscopic procedures.

CONTRAINDICATIONS

Although packing or wadding sometimes is medically necessary, SURGICEL® Absorbable Hemostat should not be used in this manner, unless it is to be removed after hemostasis is achieved (See WARNINGS and PRECAUTIONS).

SURGICEL® Absorbable Hemostat should not be used for implantation in bone defects, such as fractures, since there is a possibility of interference with callus formation and a theoretical chance of cyst formation. When SURGICEL® Absorbable Hemostat is used to help achieve hemostasis in, around, or in proximity to foramina in bone, areas of bony confine, the spinal cord, or the optic nerve and chiasm, it must always be removed after hemostasis is achieved since it will swell and could exert unwanted pressure.

SURGICEL® Absorbable Hemostat should not be used to control hemorrhage from large arteries. SURGICEL® Absorbable Hemostat should not be used on nonhemorrhagic serous oozing surfaces, since body fluids other than whole blood, such as serum, do not react with SURGICEL® Absorbable Hemostat to produce satisfactory hemostatic effect.

SURGICEL® Absorbable Hemostat is an absorbable hemostat, and should not be used as an adhesion prevention product.

WARNINGS

SURGICEL® Absorbable Hemostat is supplied sterile and as the material is not compatible with autoclaving or ethylene oxide sterilization, SURGICEL® Absorbable Hemostat should not be resterilized.

SURGICEL® Absorbable Hemostat is not intended as a substitute for careful surgery and the proper use of sutures and ligatures.

Closing SURGICEL® Absorbable Hemostat in a contaminated wound without drainage may lead to complications and should be avoided.

The hemostatic effect of SURGICEL® Absorbable Hemostat is greater when it is applied dry; therefore it should not be moistened with water or saline.

SURGICEL® Absorbable Hemostat should not be impregnated with anti-infective agents or with other materials such as buffering or hemostatic substances. Its hemostatic effect is not enhanced by the addition of thrombin, the activity of which is destroyed by the low pH of the product.

Although SURGICEL® Absorbable Hemostat may be left *in situ* when necessary, it is advisable to remove it once hemostasis is achieved. It must ***always*** be removed from the site of application when used in, around, or in proximity to foramina in bone, areas of bony confine, the spinal cord, and/or the optic nerve and chiasm regardless of the type of surgical procedure because SURGICEL® Hemostat, by swelling, may exert pressure resulting in paralysis and/or nerve damage. Dislodgement of SURGICEL® Absorbable Hemostat could possibly occur by means such as repacking, further intraoperative manipulation, lavage, exaggerated

respiration, etc. There have been reports that in procedures such as lobectomy, laminectomy and repair of a frontal skull fracture and lacerated lobe that SURGICEL® Absorbable Hemostat, when left in the patient after closure, migrated from the site of application into foramina in bone around the spinal cord resulting in paralysis and, in another case, the left orbit of the eye, causing blindness. While these reports cannot be confirmed, special care must be taken by physicians, ***regardless of the type of surgical procedure***, to consider the advisability of removing SURGICEL® Absorbable Hemostat after hemostasis is achieved. Although SURGICEL® Absorbable Hemostat is bactericidal against a wide range of pathogenic microorganisms, it is not intended as a substitute for systemically administered therapeutic or prophylactic antimicrobial agents to control or prevent postoperative infections.

PRECAUTIONS

Use only as much SURGICEL® Absorbable Hemostat as is necessary for hemostasis, holding it firmly in place until bleeding stops. Remove any excess before surgical closure in order to facilitate absorption and minimize the possibility of foreign body reaction.

In urological procedures, minimal amounts of SURGICEL® Absorbable Hemostat should be used and care must be exercised to prevent plugging of the urethra, ureter, or a catheter by dislodged portions of the product.

Since absorption of SURGICEL® Absorbable Hemostat could be prevented in chemically cauterized areas, its use should not be preceded by application of silver nitrate or any other escharotic chemicals.

If SURGICEL® Absorbable Hemostat is used temporarily to line the cavity of large open wounds, it should be placed so as not to overlap the skin edges. It should also be removed from open wounds by forceps or by irrigation with sterile water or saline solution after bleeding has stopped.

Precautions should be taken in otorhinolaryngologic surgery to assure that none of the material is aspirated by the patient. (Examples: controlling hemorrhage after tonsillectomy and controlling epistaxis.)

Care should be taken not to apply SURGICEL® Absorbable Hemostat too tightly when it is used as a wrap during vascular surgery (see Adverse Reactions).

Endoscopic procedures should be performed only by persons having adequate training and familiarity with endoscopic techniques. Consult medical literature relative to techniques, complications and hazards prior to performance of any endoscopic procedure.

A thorough understanding of the principles and techniques involved in laparoscopic laser and electrosurgical procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Refer to appropriate electrosurgical system users manual for use indications and instructions to ensure that all safety precautions are followed. When endoscopic instruments and accessories from different manufacturers are employed together during a procedure, verify their compatibility prior to initiation of the procedure and ensure that isolation or grounding is not compromised.

ADVERSE REACTIONS

"Encapsulation" of fluid and foreign body reactions have been reported.

There have been reports of stenotic effect when SURGICEL® Absorbable Hemostat has been applied as a wrap during vascular surgery. Although it has not been established that the stenosis was directly related to the use of SURGICEL® Absorbable Hemostat, it is important to be cautious and avoid applying the material tightly as a wrapping.

Paralysis and nerve damage have been reported when SURGICEL® Absorbable Hemostat was used around, in, or in proximity to foramina in bone, areas of bony confine, the spinal cord, and/or the optic nerve and chiasm. While most of these reports have been in connection with laminectomy, reports of paralysis have also been received in connection with other procedures. Blindness has been reported in connection with surgical repair of a lacerated left frontal lobe when SURGICEL® Absorbable Hemostat was placed in the anterior cranial fossa (5) (See WARNINGS and PRECAUTIONS).

Possible prolongation of drainage in cholecystectomies and difficulty passing urine per urethra after prostatectomy have been reported. There has been one report of a blocked ureter after kidney resection, in which postoperative catheterization was required.

Occasional reports of "burning" and "stinging" sensations and sneezing when SURGICEL® Absorbable Hemostat has been used as packing in epistaxis, are believed to be due to the low pH of the product.

Burning has been reported when SURGICEL® Absorbable Hemostat was applied after nasal polyp removal and after hemorrhoidectomy. Headache, burning, stinging, and sneezing in epistaxis and other rhinological procedures, and stinging when SURGICEL® Absorbable Hemostat was applied on surface wounds (varicose ulcerations, dermabrasions, and donor sites) also have been reported.

DOSAGE AND ADMINISTRATION

Sterile technique should be observed in removing SURGICEL® Absorbable Hemostat from its sterile container. Minimal amounts of SURGICEL® Absorbable Hemostat in appropriate size are laid on the bleeding site or held firmly against the tissues until hemostasis is obtained.

Opened, unused SURGICEL® Absorbable Hemostat should be discarded, because it cannot be resterilized.

HOW SUPPLIED

Sterile SURGICEL® FIBRILLAR™ Absorbable Hemostat is supplied as staple fiber in envelopes of the following sizes.

Code No. 1961 1 in. x 2 in. (2.5 cm. x 5.1 cm.)
Code No. 1962 2 in. x 4 in. (5.1 cm. x 10.2 cm.)
Code No. 1963 4 in. x 4 in. (10.2 cm. x 10.2 cm.)

Sterile SURGICEL® ORIGINAL Absorbable Hemostat (oxidized regenerated cellulose) is supplied as knitted fabric strips in envelopes in the following sizes.

Code No. 1951 2 in. x 14 in. (5.1 cm. x 35.6 cm.)
Code No. 1952 4 in. x 8 in. (10.2 cm. x 20.3 cm.)
Code No. 1953 2 in. x 3 in. (5.1 cm. x 7.6 cm.)
Code No. 1955 0.5 in. x 2 in. (1.3 cm. x 5.1 cm.)

Sterile SURGICEL® NU-KNIT® Absorbable Hemostat

Code No. 1940 1 in. x 1 in. (2.5 cm. x 2.5 cm.)
Code No. 1941 1 in. x 3.5 in. (2.5 cm. x 8.9 cm.)
Code No. 1943 3 in. x 4 in. (7.6 cm. x 10.2 cm.)
Code No. 1946 6 in. x 9 in. (15.2 cm. x 22.9 cm.)

STORAGE

Store at controlled room temperature 15° - 30°C (59° - 86°F).

CAUTION

Federal law restricts this device to sale by or on the order of a physician.

CLINICAL STUDIES

SURGICEL® Absorbable Hemostat (oxidized regenerated cellulose) has been found useful in helping to control capillary or venous bleeding in a variety of surgical applications, including abdominal, thoracic, neurosurgical, and orthopedic, as well as in otorhinolaryngologic procedures. Examples include gallbladder surgery, partial hepatectomy, hemorrhoidectomy, resections or injuries of the pancreas, spleen, kidney, prostate, bowel, breast or thyroid, and in amputations. (6, 8)

SURGICEL® Absorbable Hemostat has been applied as a surface dressing on donor sites and superficial open wounds, controlling bleeding adequately, and causing no delay in healing or interference with epithelialization. (9, 11) It also has been applied after dermabrasion, punch biopsy, excision biopsy, curettage, finger and toenail removal, and to traumatic wounds. In the foregoing applications, bleeding was controlled and the SURGICEL® Absorbable Hemostat was absorbed from the sites where it was applied. (10)

In cardiovascular surgery, investigators have found SURGICEL® Absorbable Hemostat useful in helping to control bleeding from implanted textile grafts, including those of the abdominal aorta. (7, 12) Such grafts may leak or weep considerably, even when pre-clotted, but this seepage can be controlled by covering the graft with a layer or two of SURGICEL® Absorbable Hemostat after the graft is in place and before releasing the proximal and distal clamps. When the flow has been reestablished and all the bleeding controlled, the fabric either can be removed or left in situ, since absorption of SURGICEL® Absorbable Hemostat has been shown to occur without constriction of the graft or other untoward incidents when proper wrapping technique is employed.

Otorhinolaryngologic experience with SURGICEL® Absorbable Hemostat includes adjunctive use in controlling bleeding resulting from epistaxis, tonsillectomy, adenoidectomy, removal of nasal polyps, repair of deviated septum, tympanoplasty, Stapes surgery, surgery for sinusitis, and removal of tumors. (13, 14) SURGICEL® Absorbable Hemostat has been reported useful as a hemostatic adjunct in such gynecologic procedures as oophorectomy, hysterectomy, conization of the cervix, and repair of cystoectoceles. (6, 15)

ANIMAL PHARMACOLOGY

The effects of SURGICEL® Absorbable Hemostat, absorbable gelatin sponge, and microfibrillar collagen hemostat were compared in a standardized infection model consisting of intra-abdominal and intrahepatic abscesses in mice.

This infection mimics the common characteristics of human infection with nonspore-forming anaerobic bacteria, including a chronic and progressive course. SURGICEL® Absorbable Hemostat did not increase the infectivity of normally subinfectious inocula of mixed anaerobic species in mice. With the other hemostatic agents, microfibrillar collagen hemostat and absorbable gelatin sponge, an enhancement of infectivity of anaerobic mixtures has been shown. SURGICEL® Absorbable Hemostat, in contrast to these hemostatic agents, did not enhance or provide a site for bacterial growth.

It was also found that aerobic pathogens did not grow in the presence of SURGICEL® Absorbable Hemostat. In these studies (1), SURGICEL® Absorbable Hemostat was placed in contaminated incisions of guinea pigs and markedly reduced bacterial growth of three different strains of common pathogens. In a dog model (2), it was shown that bacterial contamination of implanted Teflon™ patches in the aorta could be reduced by wrapping the area of the patch with SURGICEL® Absorbable Hemostat prior to pathogen challenge. Also, in another study (3), SURGICEL® Absorbable Hemostat and a gelatin sponge were placed in two splenotomy sites in large mongrel dogs and the animals were then challenged intravenously and the number of organisms from the splenotomy sites were measured over a period of time. The number of organisms at the site of SURGICEL® Absorbable Hemostat were significantly lower than those in the control, or the absorbable gelatin sponge site.

DIRECTIONS FOR USING SURGICEL® ORIGINAL, SURGICEL® NU-KNIT® AND SURGICEL® FIBRILLAR™ ABSORBABLE HEMOSTAT IN ENDOSCOPIC PROCEDURES (see Figures 1-3):

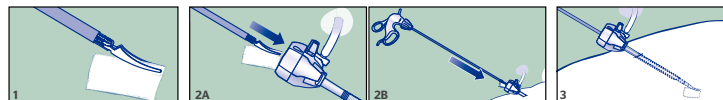


Figure 1. SURGICEL® ORIGINAL, SURGICEL® NU-KNIT® AND SURGICEL® FIBRILLAR™ Absorbable Hemostat (oxidized regenerated cellulose) should be cut to the appropriate size for endoscopic placement. Standard endoscopic procedures should be used up to the point of placement of the absorbable hemostat. Grasp the SURGICEL® ORIGINAL, SURGICEL® NU-KNIT® AND SURGICEL® FIBRILLAR™ Absorbable Hemostat at one corner.

Figure 2A and B. Slowly push the grasping instrument and material into the cavity.

Figure 3. With the use of grasping instruments in a second and/or third auxiliary site, placement can be made and the material repositioned as needed.

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SURGICEL® ORIGINAL, SURGICEL® NU-KNIT®, and SURGICEL® FIBRILLAR™ Absorbable Hemostats (oxidized regenerated cellulose) For Dental Use (For surgical applications of this product, reference should be made to the surgical use section of this insert.)

DESCRIPTION

SURGICEL® Absorbable Hemostat is an absorbable knitted fabric prepared by the controlled oxidation of regenerated cellulose. The fabric is white with a pale yellow cast and has a faint, caramel-like aroma. It is strong and can be sutured or cut without fraying. It is stable and can be stored at controlled room temperature. A slight discoloration may occur with age, but this does not affect performance. The SURGICEL® FIBRILLAR™ form of the product allows the physician to grasp with forceps any amount of SURGICEL® FIBRILLAR™ Hemostat needed to achieve hemostasis at a particular bleeding site. The fibrillar form may be more convenient than the knitted form for hard to reach or irregularly shaped bleeding sites. Although it is easy to pull the desired amount of SURGICEL® FIBRILLAR™ Hemostat from the entire supply, the group of selected fibers continue to cohere to one another and application to the bleeding site is easily controlled. Unwanted dispersal over the operative site does not occur.

ACTIONS

The mechanism of action whereby SURGICEL® Absorbable Hemostat accelerates clotting is not completely understood but it appears to be a physical effect rather than any alteration of the normal physiologic clotting mechanism. After SURGICEL® Absorbable Hemostat has been saturated with blood, it swells into a brownish or black gelatinous mass which aids in the formation of a clot, thereby serving as a hemostatic adjunct in the control of local hemorrhage. When used properly in minimal amounts, SURGICEL® Absorbable Hemostat is absorbed from the sites of implantation with practically no tissue reaction. Absorption depends upon several factors, including the amount used, degree of saturation with blood, and the tissue bed.

INDICATIONS

SURGICEL® Absorbable Hemostat (oxidized regenerated cellulose) is indicated for adjunctive use to assist in the control of bleeding in exodontia and oral surgery. It may also be used to help achieve hemostasis after single or multiple tooth extractions, alveoloplasty, gingival hemorrhage, impactions, biopsies, and other procedures in the oral cavity.

CONTRAINDICATIONS

Although packing or wadding sometimes is medically necessary, SURGICEL® Absorbable Hemostat should not be used in this manner unless it is to be removed after hemostasis is achieved.

SURGICEL® Absorbable Hemostat should not be used for implantation in bone defects, such as fractures, since there is a possibility of interference with callus formation and a theoretical chance of cyst formation.

WARNINGS

SURGICEL® Absorbable Hemostat is supplied sterile and should not be autoclaved because autoclaving causes physical breakdown of the product.

SURGICEL® Absorbable Hemostat is not intended as a substitute for careful surgery and the proper use of sutures and ligatures.

Closing SURGICEL® Absorbable Hemostat in a contaminated wound without drainage may lead to complications and should be avoided.

The hemostatic effect of SURGICEL® Absorbable Hemostat is greater when it is applied dry; therefore it should not be moistened with water or saline.

SURGICEL® Absorbable Hemostat should not be impregnated with anti-infective agents or with other materials such as buffering or hemostatic substances. Its hemostatic effect is not enhanced by the addition of thrombin, the activity of which is destroyed by the low pH of the product.

Although SURGICEL® Absorbable Hemostat may be left in situ when necessary, it is advisable to remove it once hemostasis is achieved.

PRECAUTIONS

Use only as much SURGICEL® Absorbable Hemostat as is necessary for hemostasis, holding it in place until bleeding stops. Remove any excess before surgical closure in order to facilitate absorption and minimize the possibility of foreign body reaction. SURGICEL® Absorbable Hemostat should be applied loosely against the bleeding surface. Wadding or packing should be avoided, especially within rigid cavities, where swelling may interfere with normal function or possibly cause necrosis. Precautions should be taken to assure that none of the material is aspirated by the patient.

ADVERSE REACTIONS

Encapsulation of fluid and foreign body reactions have been reported.

DOSAGE AND ADMINISTRATION

Sterile technique should be observed in removing SURGICEL® Absorbable Hemostat from its envelope. Minimal amounts of SURGICEL® Absorbable Hemostat of appropriate size are laid on the bleeding site or held firmly against the tissues until hemostasis is obtained.

Opened, unused SURGICEL® Absorbable Hemostat should be discarded, because it cannot be resterilized.

SYMBOLS USED IN LABELING

- Do not reuse
- Do not resterilize
- Do not use if package is damaged
- Use by
- Sterilized using irradiation
- Catalogue number
- Batch code
- Manufacturer
- CAUTION! See instructions for use
- Store 15-30°C (59-86°F)
- CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

