Original Article

The novel use and feasibility of hemostatic oxidized regenerated cellulose agent (SurgiGuard®): multicenter retrospective study

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Background: SurgiGuard® is an absorbent hemostatic agent based on oxidized regenerated cellulose. The efficacy, effects and safety of SurgiGuard® are equivalent to existing hemostatic agents in animal experiments. This study was designed to confirm that the use of SurgiGuard® alone is effective, safe and feasible compared to combination with other hemostatic methods.

Methods: We retrospectively reviewed clinical data from 12 surgery departments in seven tertiary centers in South Korea nationwide. All surgeries were performed between January and December 2018.

Results: A total of 807 patients were enrolled; 447 patients (55.4%) had comorbidities. The rate of major surgery (operative time ≥4 hours) was 44% (n=355 patients). Regarding the type of SurgiGuard® used in surgery, more than 70% of minor surgeries used non-woven types. In major surgery, more than five SurgiGuards® were used in 7.3% (26 patients), and the proportion of co-usage (with four other hemostatic products) was 19.7% (70 patients). The effectiveness score was higher when SurgiGuard® was used alone in both major (5.3±0.5 *vs.* 5.1±0.6, P=0.048) and minor surgery (5.4±0.6 *vs.* 5.2±0.4, P<0.001). Seven patients had immediate re-bleeding, and all of them used SurgiGuard® and other products together. Nine patients reported adverse effects, such as abscess, bleeding, or leg swelling, but we found no direct correlation with SurgiGuard®.

Conclusions: SurgiGuard® exhibited greater effectiveness when used alone. No direct adverse effects associated with SurgiGuard® use were reported, and SurgiGuard® had stable feasibility. Prospective comparative studies are needed in the future.

Keywords: SurgiGuard®; hemostasis; hemostatic agent; oxidized regenerated cellulose (ORC)

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Introduction

Perioperative bleeding is a major concern for surgeons, and efforts have been made by numerous surgeons and researchers to prevent perioperative bleeding (1). The reported prevalence of postoperative bleeding is 0.9–10% in various major surgeries, such as hepatectomy (2), pancreatic surgery (3), gastrointestinal tract surgery (4,5), cardiovascular surgery (6,7), nephrectomy (8), and liver transplantation (9). On a closer look, various recent studies have reported that the prevalence of capillary, venous and small artery bleeding is in the range of 3.3–30% (10-12). The evolution of hemostasis during the last few centuries of surgical history has resulted from the development of hemostatic agents and devices, as well as surgical skills and principles (1). Moreover, different types of bleeding occur, and appropriate methods should be applied in each situation. Several materials have been devised to control bleeding by understanding the mechanisms of the hemostatic process (13,14).

Several commercial hemostatic products assist with the hemostatic process. Polysaccharides are biologically derived polymers composed of sugar building blocks. Polysaccharide-based materials can be prepared and modified by chemical or physical methods (15). Since Frantz reported the potential for clinical application of oxidized cellulose as a topical hemostatic agent in 1943 (16), oxidized regenerated cellulose (ORC) has been developed and achieved notable clinical results (17).

Highlight box

Key findings

- SurgiGuard® showed stable feasibility and effectiveness with no direct adverse effect.

What is known and what is new?

- Oxidized regenerated cellulose is effective for hemostasis with various surgeries
- Among oxidized regenerated cellulose products, SurgiGuard® is effective and feasible.

What is the implication, and what should change now?

- Prospective comparative studies are needed in the future with this product.

SurgiGuard® (Samyang Biopharmaceuticals Corp., Seoul, Korea) is an absorbent hemostatic agent based on ORC. It is a hemostatic supplement used when other methods, such as the ligation of capillaries, veins, and arterial bleeding, are ineffective during surgery (18). The carboxyl group of oxidized cellulose has a low pH (acidity) through an oxidation reaction to promote hemostatic action and inhibit bacterial growth. In the case of *in vitro*, the product is suspended in water, and no appreciable solvation occurs; however, a drop in pH lower than 2.5 is observed. In *in vivo* studies (including previous papers reported by our group), after 24 h post-implantation, it has been noted that the product becomes completely gelatinous, and within 48 h, only small fragments remain. A rapid decrease in the pH (~2.5) of the fluid surrounding the site of implantation of the ORC has also been observed (19-22). The effectiveness of SurgiGuard® has been demonstrated to be equivalent to existing hemostatic agents in several animal studies, and the safety of the product has been demonstrated through biocompatibility tests and antimicrobial tests by NAMSA (Medical Research Organization, Toledo, OH, USA) (23).

To confirm that sustained use of this hemostatic material is feasible, it is important to clinically determine that the use of SurgiGuard® is effective compared to combination use with other hemostatic methods. Therefore, this study retrospectively reviewed data collected from patients who used SurgiGuard® to assess its effectiveness, safety and feasibility. We present this article in accordance with the STROBE reporting checklist (available at https://gs.amegroups.com/article/view/10.21037/gs-22-675/rc).

Methods

Study population and study design

We collected the clinical data of patients who underwent surgery at seven different tertiary medical centers between January 2018 and December 2018. A total of 22 surgeons from 12 different departments participated in this study. To eliminate bias, all types of surgeries using a full anticoagulation agent or medication during surgery, such as cardiopulmonary surgery, were excluded from the study. Patients who underwent minor vascular surgery and

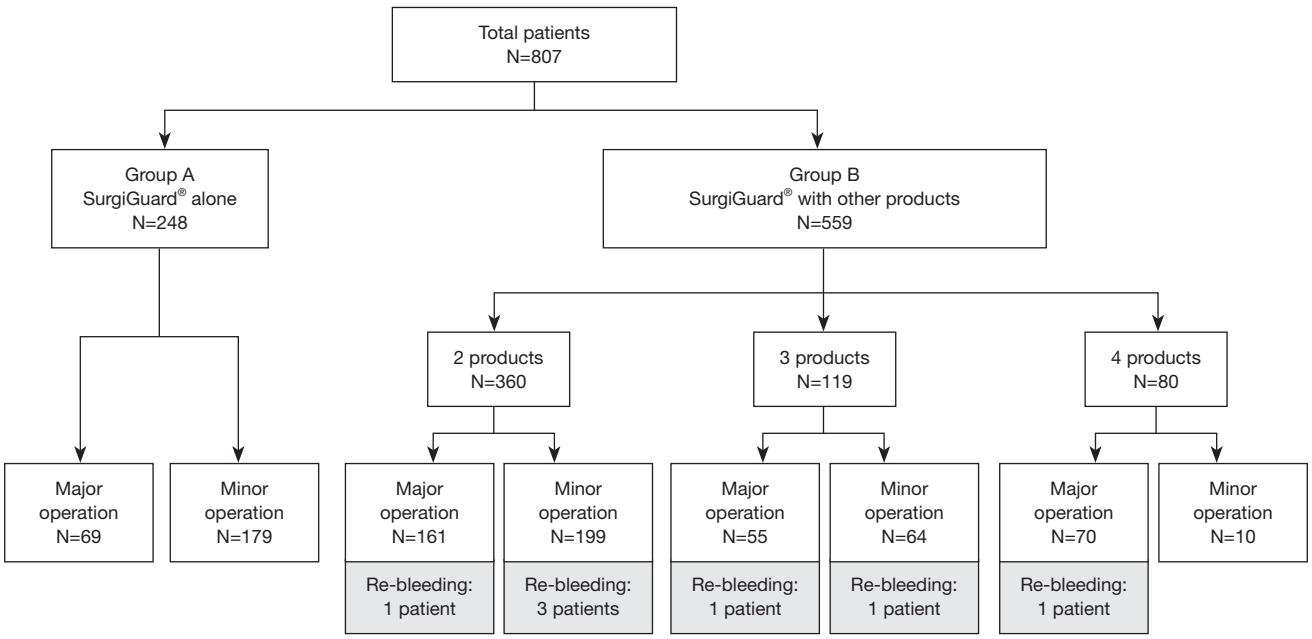

Figure 1 Patient enrollment flow chart.

kidney/liver transplantation with limited-dose heparin were included. We retrospectively investigated sex, diagnosis, surgical department, co-morbidities, medications, and perioperative findings (surgery, estimated blood loss, transfusion, serum hemoglobin level, time to hemostasis, drain usage). "Hemostasis" was defined as any type of oozing or pulsatile bleeding that was not observed at the bleeding site after application of SurgiGuard®. In cases of rebleeding even after the application of SurgiGuard®, the time until rebleeding occurred was also recorded. As the total patient cohort was heterogeneous, we divided it into two groups to assess the SurgiGuard® product: group A, who used SurgiGuard® alone (n=248), and group B, who used SurgiGuard® with other hemostatic products (n=559). All surgery types were categorized as major (total operative time ≥4 hours) or minor surgery (total operative time <4 hours; *Figure 1*).

To assess the hemostatic effectiveness and user satisfaction of handling SurgiGuard® as a hemostasis supplement, we used a questionnaire containing a numeric 6-point scale. The hemostatic effectiveness score was given up to the first decimal place. From the surgeon's point of view, 6 points indicated that the surgeon was very satisfied with the hemostatic effect, and 1 point indicated they were very dissatisfied. Regarding the satisfaction score, 6 points indicated that surgical handling was very satisfactory as a hemostatic supplement, and 1 point indicated it was very unsatisfactory (Appendix 1). In addition, we described adverse effects as more than grade 3 according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTC-AE). The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Institutional Review Board of Severance Hospital (Approval No. 4-2019-0576) and informed consent was taken from all the patients.

SurgiGuard®

SurgiGuard® is a type of ORC capable of assisting in managing small vessel bleeding. It is designed to achieve hemostasis when conventional surgical techniques are not available or are impractical. Indication for use is as follows: "During the operation, this product assists the hemostasis for capillary and venous, small artery bleeding". Thus, this product is generally applied in a situation corresponding to the VIBe scale grade 1 or 2. Four types of SurgiGuard® products were used in this study (*Figure 2*). SurgiGuard Original® is the most common and has long and widely been used in a variety of surgeries. It offers good visibility of the surgical site due to the sheer knit structure. SurgiGuard Fabric® is denser than SurgiGuard Original® and made

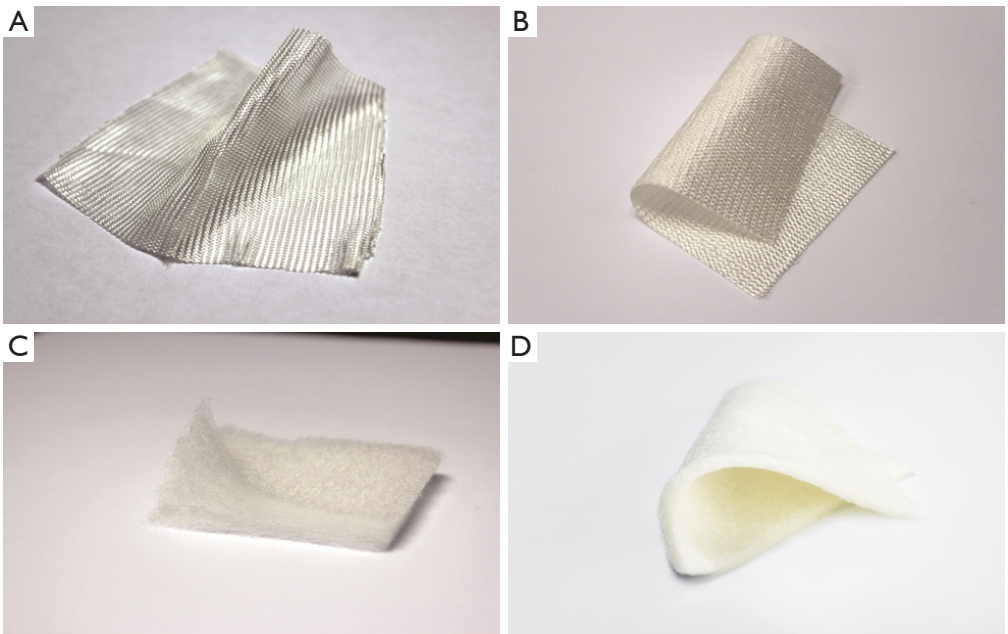

Figure 2 Types of SurgiGuard®. (A) SurgiGuard Original®. (B) SurgiGuard Fabric®. (C) SurgiGuard Fibrillar®. (D) SurgiGuard Non-Woven®.

for heavier bleeding with faster hemostasis. In contrast, SurgiGuard Fibrillar® can be shaped or molded to various shapes for optimal adherence or used in multiple sites. Finally, SurgiGuard Non-woven® is an advanced product for maximized effect and superior handling. The non-woven structure increases surface contact with the bleeding site and can be applied not only in open surgery, but also minimally invasive surgery.

Statistical analysis

Continuous variables were analyzed using the independent samples *t*-test, and categorical variables were analyzed using Pearson's chi-squared test or Fisher's exact test. All results are expressed as mean and standard deviation or frequency and percentage. P<0.05 indicates significance. All statistical analyses were performed using SPSS® for Windows version 22.0 (IBM Corp., Armonk, NY, USA) and R version 3.3.1 (The R Project, Vienna, Austria).

Results

Clinical characteristics and use of products

A total of 807 patients were enrolled in this study, 29% of which underwent hepato-biliary-pancreas surgeries. The Obstetrics and Gynecology Department and Neurosurgery Department had 155 (19.2%) and 150 (18.6%) patients, respectively (*Figure 3*). The mean age was 53.0±18.5 years, and female patients were 54.5% of the cohort (n=440). A total of 360 (44.6%) patients who had no comorbidities, and 266 (33.0%) had hypertension, the most common comorbid disease. Regarding the type of surgery, 355 (44.0%) patients underwent major surgery and 452 (56.0%) patients underwent minor surgery (*Table 1*).

SurgiGuard Non-woven® was the most commonly used product in both types of surgery. More than 70% of minor surgeries used the non-woven product, and solitary use occurred in more than 83% of minor surgeries. In contrast, in major surgery, 26 (7.3%) patients used more than five products (*Figure 4*).

Perioperative findings

Regarding the type of surgery, we found a significant difference between the two groups. Minor surgery was the most common in group A (72.2%) and major surgery was the most common in group B (51.2%; P<0.001).

We found no significant differences between groups A and B concerning preoperative and postoperative hemoglobin levels. In group B, 503 patients (90.0%) had

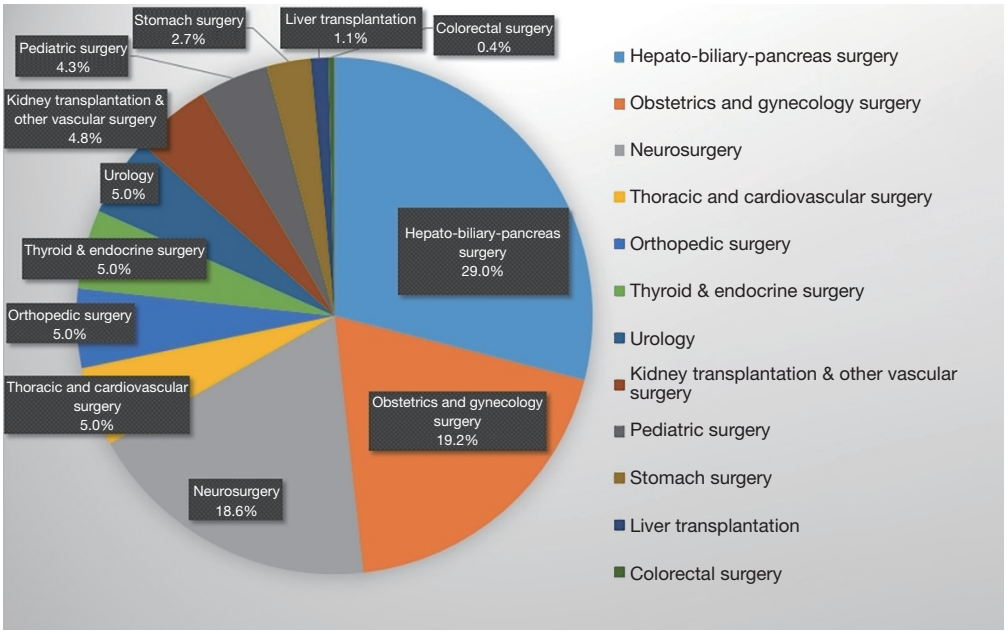

Figure 3 Proportion of surgical departments.

an indwelling postoperative surgical drain, and the amount on postoperative day 1 was 198.7±299.2 mL. In contrast, in group A, 136 patients (54.8%) had an inserted drain, and the amount was 128.2±136.9 mL (P<0.001).

The estimated blood loss was significantly higher in group B than group A (mean 261.6 *vs.* 506.7 mL, P=0.001). Similarly, the postoperative transfusion rate was higher in group B than group A (7.7% *vs.* 23.8%, P<0.001). The mean time to hemostasis was 4.0±2.7 minutes in group A and 6.3±9.8 minutes in group B.

We found no significant differences regarding the mean time to hemostasis between the two groups (P=0.685). Intraoperative re-bleeding after SurgiGuard® application occurred in 7 patients (group B only), but we found no significant differences between the two groups (P=0.174). The mean time to re-bleeding was 6.3±11.6 min (*Table 2*).

Effectiveness and satisfaction grade

In major surgery, we found no significant differences in the hemostatic effectiveness grade or the handling satisfaction grade between the two groups. In minor surgery, the proportion of patients with the most satisfying scale (≥ grade 5) was small in group A compared to group B (hemostatic effectiveness grade ≥5: 94.4% *vs.* 97.8%, user handling satisfaction grade ≥5: 95.6% *vs.* 97.4%; *Figure 5*).

Effectiveness score and reasons for ineffective cases

In both major and minor surgery, the effectiveness score was higher with SurgiGuard® used alone (major surgery, 5.3±0.5 *vs.* 5.1±0.6, P=0.048; minor surgery, 5.4±0.6 *vs.* 5.2±0.4, P<0.001). We identified three cases of 'very dissatisfied' responses, the reasons for which were comorbidities, concomitant drug use, and vascular injury (*Table 3*).

Adverse effect

A total of nine postoperative adverse effects were reported: bleeding, postoperative intestinal obstruction, abscess, fever, leg swelling, and respiratory dysfunction. There were no general dysfunctions such as liver/renal dysfunction, postoperative fever or localized wound infection. The most common adverse effect was bleeding or leakage from the treated site (3 patients, 33.3%), and one patient required an intraoperative transfusion. Postoperative intestinal obstruction occurred in 2 patients (22.2%). However, these complications did not directly correlate with SurgiGuard® use (*Table 4*).

Discussion

A topical hemostatic agent should not only have a certain

Table 1 Clinical characteristics of the entire patient cohort

Variable	Patients (N=807)
Age, years, mean ± SD	53.0±18.5
Sex, n (%)	
Female	440 (54.5)
Male	367 (45.5)
Number of comorbidities, n (%)	
None	360 (44.6)
1	255 (31.6)
2	135 (16.7)
3	43 (5.3)
4	14 (1.7)
Liver disease, n (%)	
No	727 (90.1)
Yes	80 (9.9)
Renal disease, n (%)	
No	772 (95.7)
Yes	35 (4.3)
Hypertension, n (%)	
No	541 (67.0)
Yes	266 (33.0)
Diabetes, n (%)	
No	681 (84.4)
Yes	126 (15.6)
Other disease, n (%)	
No	604 (74.8)
Yes	203 (25.2)
Operation type, n (%)	
Major (≥4 hours)	355 (44.0)
Minor (<4 hours)	452 (56.0)

SD, standard deviation.

ability to achieve hemostasis, but also minimum tissue reactivity. Given these characteristics, polysaccharide-based materials are a good source for topical hemostatic agents. Polysaccharides are naturally derived polymers with advantages such as abundant sources, biodegradability, compatibility, and no immune responses (15,24). Polysaccharide-based hemostatic materials have evolved with the development of technology and requirements in the clinic, and many researchers and clinicians have used these devices as topical hemostatic agents, tissue adhesives, and sealants (25,26). Due to biocompatibility, biodegradability, low toxicity, and relatively low cost, ORC has been widely used in medical products, such as hemostatic agents, wound dressings, and drug carriers (27). In the 1960s, Surgicel® (Johnson and Johnson, New Brunswick, NJ, USA) was introduced to the clinical market as the first ORC-derived hemostatic agent. Since then, ORC has evolved into a globally used topical hemostatic agents (28).

A recently developed and advanced form of ORC can aid in hemostasis through calcium and sodium ion interactions, acid-induced small vessel contraction, and sealant properties. In addition, ORC acts as a support matrix for the initiation and formation of the clot. These material-derived products can be molded into different shapes and sizes, and are compressible without loss of hemostatic ability (29). ORC has great potential with minimum cost, low rate of thrombotic complications, and low disease transmission risk. Moreover, it provides the benefit of a long shelf-life (13). ORC has also been applied for dressings, which are versatile and do not require wounds to be of a certain duration before application (30). Furthermore, the ORC not only shows an excellent hemostatic effect but has also emerged as an effective adhesion barrier over the past several years. In various abdominal surgeries, ORC and its derived products have proven to be effective and feasible for preventing postoperative adhesion events (31-33). According to a large cohort meta-analysis, ORC significantly reduced the incidence of adhesions, and no trials have reported data on reoperation for adhesive small bowel obstruction (34). When the sheet form of the ORC is placed to cover the surgical site, it changes into a gel form within 24 days, and the ORC is degraded by phagocytosis by macrophages. During tissue repair, fibroblasts, epithelial cells, and endothelial cells are stimulated to increase tissue-reinforcing efficacy, which is thought to act as an adhesion barrier (19,35).

In this study, we assessed the hemostatic effectiveness and satisfaction with user handling of SurgiGuard® from the perspective of a surgeon who confronted the surgical field. We previously reported the effectiveness and non-toxicity of this product in the porcine spleen and liver resection models. It was then important to verify the surgeon-oriented effectiveness for application in the real surgical field based on clinical data. The results of the current study confirmed that the surgeon's preferred material type (SurgiGuard

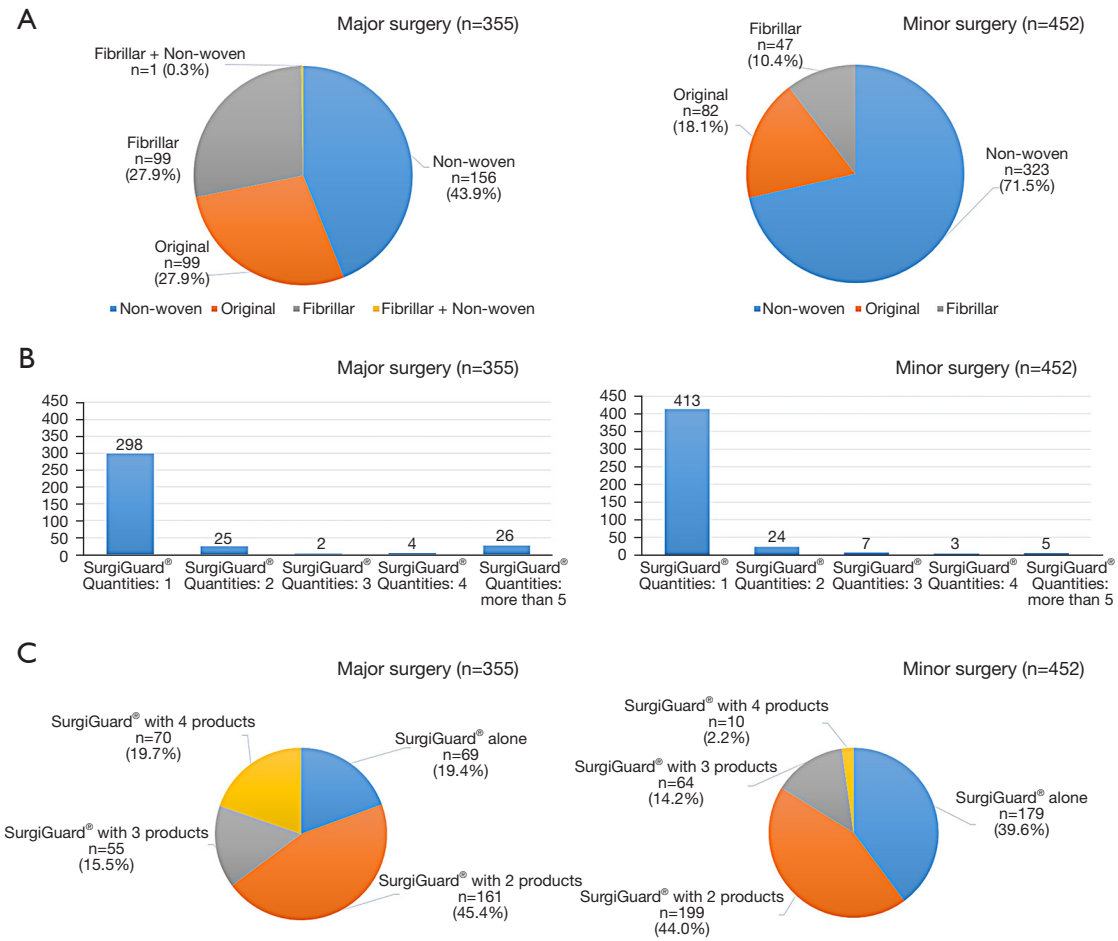

Figure 4 Distribution of SurgiGuard® and combination use according to surgery type. (A) SurgiGuard® product types. (B) Quantities of SurgiGuard® used. (C) SurgiGuard® used with other products.

Non-woven®) regardless of surgery type. This result reflects the importance of ease of handling of the topical agent and how well it works on the treated site. Regardless of major or minor surgery, the effectiveness score was defined as how much the hemostatic effect of the SurgiGuard® satisfied the surgeon, which was higher in group A. In minor surgery, the most satisfied proportion (≥ grade 5) was smaller in group A than group B. However, the 'extremely satisfied' category (grade 6) in both effectiveness and satisfaction more frequently had patients in group A compared to group B. For the effectiveness grade, six patients in group B and one patient in group A were 'somewhat/very dissatisfied'. Overall, no SurgiGuard®-related adverse effects were reported, but nine patients had postoperative complications.

Although randomized controlled trials have investigated the efficacy and safety of ORC as a topical hemostatic agent (36), the present study was based on a large cohort focusing on the clinical effectiveness of ORC-derived material in multiple clinical surgery departments. In previous studies, the SurgiGuard® shown to be effective and safe in porcine models (18,23). Based on these favorable results, a large-cohort multicenter collaborative study was designed and conducted. These results evaluated and reported from the perspective of surgeons who used topical hemostasis agents themselves may be a milestone for more surgeons who will use these materials in the future.

However, ORC hemostatic agents have several side effects. ORC has been reported to dissolve promptly at various sites in an animal experiment within 6 weeks (37). In contrast to the animal model, several case reports have

Table 2 Perioperative findings and characteristics

Variable	Group A (N=248)	Group B (N=559)	P
Preoperative hemoglobin, g/dL, mean ± SD	12.7±1.7	12.8±2.0	0.663
Postoperative day 1 hemoglobin, g/dL, mean ± SD	11.5±1.7	11.5±1.8	0.802
Postoperative drain, n (%)			<0.001
No	112 (45.2)	56 (10.0)	
Yes	136 (54.8)	503 (90.0)	
Postoperative day 1 drainage amount, mL, mean ± SD	128.2±136.9	198.7±299.2	<0.001
Operation type, n (%)			<0.001
Major	69 (27.8)	286 (51.2)	
Minor	179 (72.2)	273 (48.8)	
Estimated blood loss (mL), mean ± SD	261.6±452.4	506.7±1,403.2	0.001
Postoperative transfusion, n (%)			<0.001
No	229 (92.3)	426 (76.2)	
Yes	19 (7.7)	133 (23.8)	
Time to hemostasis, min, mean ± SD			0.685
No postoperative bleeding	4.0±2.7	6.3±9.8	
Re-bleeding after SurgiGuard®	N/A	6.3±11.6	
Intra-operative re-bleeding, n (%)			0.174
No	248 (100.0)	552 (98.7)	
Yes	0 (0.0)	7 (1.3)	
Additional treatment, n (%)			N/A
SurgiGuard® + thrombin	0 (0.0)	1 (0.2)	
SurgiGuard® + Floseal	0 (0.0)	2 (0.4)	
Surgicel + TachoSil	0 (0.0)	1 (0.2)	
Surgicel + Tisseel + Fibrillar + Gelfoam	0 (0.0)	1 (0.2)	
Surgicel + Greenplast + Fibrillar	0 (0.0)	1 (0.2)	
Floseal	0 (0.0)	1 (0.2)	

Group A: used SurgiGuard® alone; Group B: used SurgiGuard® with other hemostatic products. SD, standard deviation; N/A, not available.

presented that the residue of ORC could easily be mistaken for an abscess or granuloma on postoperative imaging (38). For this reason, some clinicians have suggested that ORC should be used in extreme care for rigid non-extensive anatomical structures and be removed after hemostasis as soon as possible (39).

Despite encouraging results, this study has certain limitations. First, this study was based on a survey that received responses from a surgeon who performed various surgeries. Thus, one of the main challenges of this study is that the results reflect subjective points of view and experiences. Second, due to the heterogeneity of the analyzed study group, we did not sufficiently investigate the unique characteristics of each surgery. In the same context, the degree of bleeding was not accurately assessed using the confirmed bleeding scale VIBe SCALE (validated intraoperative bleeding scale) (40). Third, this study was focused on a short-term outcome survey, and it was not

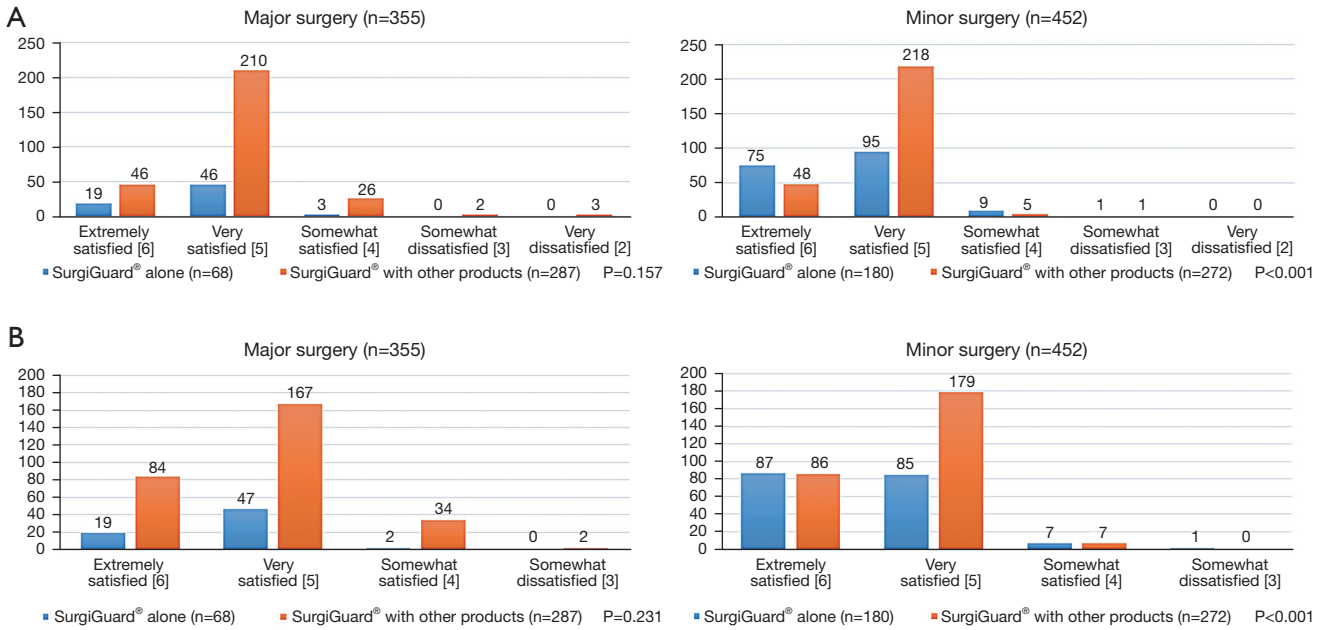

Figure 5 Effects of SurgiGuard® alone and SurgiGuard® with other hemostatic products according to the type of surgery. (A) Distribution of the hemostatic effectiveness grade and (B) user handling satisfaction grade.

Table 3 Effectiveness comparison and reasons for ineffectiveness with SurgiGuard® alone or SurgiGuard® and other hemostatic products according to the type of surgery

SurgiGuard® use	Major			Minor		
	Group A (N=68)	Group B (N=287)	P	Group A (N=180)	Group B (N=272)	P
Effectiveness score, mean ± SD	5.3±0.5	5.1±0.6	0.048	5.4±0.6	5.2±0.4	<0.001
Reason for not-effective, n (%)			N/A			N/A
Comorbidities (liver, renal, sepsis, etc.)	0 (0.0)	1 (33.3)		0 (0.0)	0 (0.0)	
Concomitant drug (aspirin, warfarin, etc.)	0 (0.0)	1 (33.3)		0 (0.0)	0 (0.0)	
Vascular injury	0 (0.0)	1 (33.3)		0 (0.0)	0 (0.0)	

Group A: used SurgiGuard® alone; Group B: used SurgiGuard® with other hemostatic products. SD, standard deviation; N/A, not available.

possible to investigate long-term complications, such as abscess or mass-like foreign body, the most common complication of ORC-derived hemostatic agents. As various surgeries and divisions were included, the endpoint of this study was unclear. Further studies, such as head-to-head, randomized controlled cohorts, are required to investigate not only short-term but also long-term complications, taking into account the characteristics of each surgery. Moreover, research on which type of SurgiGuard® is useful and effective under what circumstances should be accompanied.

Conclusions

In conclusion, SurgiGuard® had a higher effectiveness score when SurgiGuard® is used alone, and no direct adverse effects associated with SurgiGuard® use were reported. A prospective comparative study will be needed in the near future.

Table 4 Adverse effects with SurgiGuard® alone or SurgiGuard® and other hemostatic products

Variable	Group A (N=248)	Group B (N=559)	P
Adverse effect, n (%)			<0.001
No	248 (100.0)	550 (98.4)	
Yes	0 (0.0)	9 (1.6)	
Specific adverse effect, n (%)			
Bleeding/leakage from treated site	0 (0.0)	3 (33.3)†	
Postoperative intestinal obstruction	0 (0.0)	2 (22.2)	
Abscess	0 (0.0)	1 (11.1)	
Fever	0 (0.0)	1 (11.1)	
Leg swelling	0 (0.0)	1 (11.1)	
Respiratory dysfunction	0 (0.0)	1 (11.1)	
Correlation with SurgiGuard®, n (%)			
No relation	0 (0.0)	9 (100.0)	

†, including one patient who required intraoperative transfusion. Group A: used SurgiGuard® alone; Group B: used SurgiGuard® with other hemostatic products.

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Footnote

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://gs.amegroups.com/article/view/10.21037/gs-22-675/coif). MJ is current employee of Samyang Biopharmaceuticals Corp. The other authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Institutional Review Board of Severance Hospital (Approval No. 4-2019-0576) and informed consent was taken from all the patients.

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Supplementary

Appendix 1

Case Report Form (CRF)

Site _____ Department _____ Investigator _____

1. **Subject information**
   - Initial:
   - Date of birth:
   - Gender:
   - Diagnosis:
   - Surgery (☐Emergency ☐Regular):
   - Surgery date (Date of SurgiGuard® Use):
   - Comorbidity: ☐Hypertension ☐Diabetes ☐Liver disease ☐Renal disease ☐other
   - Concomitant drug ☐Antihypertensive ☐Hypoglycemic agent ☐Liver disorder ☐Anticoagulant ☐Hormone ☐Immunosuppressant ☐other

2. **Usage of SurgiGuard®**

2.1 SurgiGuard® Product name

☐ SurgiGuard® Original	☐5 cm x 7.5 cm (2inch x 3inch) ☐5 cm x 35 cm (2inch x 14inch) ☐10 cm x 20 cm (4inch x 8inch) ☐1.25 cm x 5 cm (0.5inch x 2inch)
☐ SurgiGuard® Fabric	☐5 cm x 7.5 cm (2inch x 3inch) ☐7.5 cm x 10 cm (3inch x 4inch) ☐15.2 cm x 22.9 cm (6inch x 9inch) ☐2.5 cm x 2.5 cm (1inch x 1inch) ☐2.5 cm x 7.5 cm (1inch x 3inch)
☐ SurgiGuard® Fibrillar	☐2.5 cm x 5.1 cm (1inch x 2inch) ☐5.1 cm x 10.2 cm (2inch x 4inch) ☐10.2 cm x 10.2 cm (4inch x 4inch)
☐ SurgiGuard® Non-woven	☐2.5 cm x 5.1 cm (1inch x 2inch) ☐5.1 cm x 10.2 cm (2inch x 4inch) ☐10.2 cm x 10.2 cm (4inch x 4inch)

2.2 Number of SurgiGuard® used in surgery

☐ 1
☐ 2
☐ 3

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☐ 4

☐ More than 5

2.3 Whether you use SurgiGuard® alone or in combination with other products?(When using combination, please select a duplicate)

☐ SURGIGUARD (ORC)

☐ SURGICEL (ORC)

☐ EVICEL (Fibrin)

☐ TACHOSIL (Fibrin)

☐ TISSEEL (Fibrin)

☐ GREENPLAST (Fibrin)

☐ BERIPLAST (Fibrin)

☐ FLOSEAL (Fibrin)

☐ COSEAL (Synthetic Sealant)

☐ DURASEAL (Synthetic Sealant)

☐ BIOGLUE (Albumin Sealant)

☐ AVITENE (Collagen)

☐ COLLAPAD (Collagen)

☐ BLEESTOP (Collagen)

☐ other ( )

2.4 Removal of SurgiGard® after hemostasis

☐ Removed

☐ Not removed

☐ other ( )

3. SurgiGard® Hemostatic effect

3.1 Hemostasis effect of SurgiGuard® as hemostasis supplement(6 point scale)

: _____._____ points (Please, display the first decimal place)

Extremely satisfied (6)	Very satisfied (5)	Somewhat satisfied (4)	Somewhat dissatisfied (3)	Very dissatisfied (2)	Extremely dissatisfied (1)

3.2 User Satisfaction with SurgiGuard® Surgical Handling as hemostasis supplement

Extremely satisfied (6)	Very satisfied (5)	Somewhat satisfied (4)	Somewhat dissatisfied (3)	Very dissatisfied (2)	Extremely dissatisfied (1)

3.3 If there was no hemostatic effects (1-2 point), why?

☐ Comorbidity (Liver disease, Renal disease, Sepsis, etc)

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☐ Extensive bleeding
☐ Vascular injury
☐ Concomitant drug (Aspirin, Wafarin, Platelet aggregation inhibtor, etc)
☐ Lack of SurgiGuard® usage (Use less than the right amount or the right size)
☐ other ( )

4. Operative characteristics

- Intraoperative blood loss (ml):_____ml
- Intraoperative blood transfusion: ☐ Yes ☐ No
- Pre/Post-operative hemoglobin level

  ① Pre-operative Hemoglobin:_____

  ② Post-operative day-1 Hemoglobin:_____
- Postoperative drain tube insertion: ☐ Yes ☐ No

  ① If yes, drainage volume within 1 day after operation:_____ml
- Re-bleeding after using SurgiGuard®: ☐ Yes ☐ No

  ① If there **was no re-bleeding**, the time until the complete hemostasis was confirmed after the surge guard was applied: ( ) min

  ② If there **was re-bleeding**, the time from to re-bleeding after SurgiGuard® application: ( ) min

  ③ Treatment for re-bleeding: **(When using the combination, please select a duplicate)**

  ☐ SURGIGUARD (ORC)
  ☐ SURGICEL (ORC)
  ☐ EVICEL (Fibrin)
  ☐ TACHOSIL (Fibrin)
  ☐ TISSEEL (Fibrin)
  ☐ GREENPLAST (Fibrin)
  ☐ BERIPLAST (Fibrin)
  ☐ FLOSEAL (Fibrin)
  ☐ COSEAL (Synthetic Sealant)
  ☐ DURASEAL (Synthetic Sealant)
  ☐ BIOGLUE (Albumin Sealant)
  ☐ AVITENE (Collagen)
  ☐ COLLAPAD (Collagen)
  ☐ BLEESTOP (Collagen)
  ☐ other ( )

  ④ Reoperation due to bleeding after the operation: ☐ Yes ☐ No

5. Adverse events after using SurgiGuard® (Side effects)

5.1 Adverse events occurred within 24 hours after surgery

☐ Yes ☐ No

5.2 If there was an adverse events

☐ Requiring transfusion blood products
☐ Bleeding/leakage from treated site

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☐ Hemorrhage
☐ Allergic Reaction
☐ Abscess
☐ Granuloma
☐ Obstruction
☐ Stroke
☐ Ischemia
☐ Sepsis
☐ Infection
☐ Deep Vein Thrombosis
☐ Cellulitis
☐ Ischemia
☐ Pericardial Effusion
☐ Respiratory dysfunction
☐ other ( )

5.3 Relationship between Adverse Events and SurgiGard®

☐ Related ☐ Not related ☐ Not evaluable

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