Clinical Evaluation of Oxidized Cellulose Powder and Endoscopic Applicator in Multicenter Trial

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ABSTRACT

Purpose: Oxidized cellulose-based haemostatic agents are widely used for managing bleeding in various surgical procedures. This study evaluates the efficacy and safety of oxidized cellulose powder and an endoscopic applicator across a broad spectrum of surgical settings.
Methods: This was a prospective, multicentre study involving 99 evaluable patients undergoing surgeries with varying bleeding severities and surgical approaches (open, laparoscopic, or thoracoscopic). The primary endpoint was achieving haemostasis within 3 minutes and avoiding revision surgery within 12 hours. The time to haemostasis (TTH) and complications were recorded, and statistical comparisons were made using a paired and unpaired t-test, with a significance threshold of $P < 0.05$. Data from this study were compared to historical results from fibrillar haemostats.
Results: Haemostasis was achieved within 3 minutes in 61.6% (95% CI [52.0, 71.2]) of patients and within 5 minutes in 99.0% (95% CI [97.0, 100.0]) of patients. The overall mean TTH was 153.8 seconds (95% CI: 141.5–166.1), with shorter TTH observed in minimally invasive procedures using the endoscopic applicator. Subgroup analysis revealed higher success rates for patients with mild bleeding (78%) compared to moderate bleeding (50%).
Conclusion: Oxidized cellulose powder demonstrates reliable haemostatic performance across diverse surgical applications. The endoscopic applicator enhances precision and applicability, particularly in minimally invasive settings, making it a valuable tool in modern surgical practice.

KEYWORDS

oxidized cellulose; haemostasis; endoscopic applicator; haemostatic powder; Traumastem

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INTRODUCTION

The ability to achieve effective haemostasis during surgical procedures is critical for minimizing blood loss, ensuring clear surgical fields, and reducing postoperative complications. Despite advancements in surgical techniques, capillary and diffuse bleeding remain common challenges that may be in procedures involving parenchymal organs, vascular anastomoses, or delicate tissue handling. Conventional methods, such as sutures, ligatures, and electrocautery, often provide effective control but may fail in cases of diffuse oozing from capillary beds or in hard-to-reach anatomical locations. Local haemostatic agents have emerged as indispensable tools for addressing these challenges (1, 2). Among these, oxidized cellulose-based products offer unique advantages. Oxidized cellulose is a naturally derived polysaccharide that has been widely utilized in medical applications, particularly as a haemostatic agent that is biodegradable, bioresorbable, and biocompatible, making it an ideal choice for surgical interventions (3). The secondary effect is bactericidal and antifungal, driven by a low pH, which eliminates microorganisms and prevents their growth and proliferation (2). Oxidized cellulose-based haemostatic agents have a history spanning nearly ninety years. Initially developed in the United States to advance surgical techniques in both military and civilian medicine, their method of preparation was first documented in 1945 (3).

Traumacel PULVIS, (other names: Traumastem POWDER, EMOXICEL EMIPOL, Resorcell) developed in the 1970s in Czechoslovakia, has been extensively used in surgical practice for decades. Its broad applicability includes use in open surgeries, minimally invasive procedures, and even outpatient settings for minor injuries (4). This powder containing a hydrogen calcium salt of oxidized cellulose, is a specialized haemostatic agent that leverages the synergistic effects of oxidized cellulose and calcium ions to enhance haemostasis and promote wound healing. Oxidized cellulose stops bleeding through a combination of physical absorption, gel formation, platelet activation, and stabilization of the clot. Studies have shown that the activation of blood platelets by oxidized cellulose, depends on the availability of calcium ions in its dispersion (5).

Beyond its role in coagulation, the hydrogen calcium salt of oxidized cellulose has demonstrated significant healing properties due to the combined action of oxidized cellulose (OC) and calcium ions. This combination has been shown to enhance fibroblast proliferation, as evidenced by an in-vitro study conducted by Hughes. This property accelerates the formation of granulation tissue, leading to faster wound healing (6). Another research highlights the unique healing effects of the hydrogen calcium salt of OC (7). The combination of OC and calcium ions not only facilitates haemostasis but also actively supports the biological processes involved in tissue repair and regeneration.

The synergistic effects of OC and calcium ions are well-documented in numerous publications. However, the number of publications on the effectiveness of OC-based haemostatic powder remains limited compared to the extensive research on haemostatic gauze and fibrillar forms.

METHODS

OBJECTIVES

The primary objective of the study was to confirm the safety and effectiveness of the haemostatic agent Traumacel PULVIS, (OC powder) and the endoscopic applicator Traumacel ENDO Applicator in real-world surgical settings. By evaluating these devices across a diverse patient population, this research aims to provide robust data supporting their continued use in modern surgical practice. The results were compared with primary data from a published clinical study of a similar design that evaluated OC fibrillar haemostats (8).

STUDY DESIGN

This prospective, multicentre clinical study was conducted as part of post-market clinical follow-up (PMCF), ensuring rigorous scientific and ethical oversight. The single-arm design included patients undergoing various surgical procedures across four centres in the Czech Republic. The study centres represented a range of surgical disciplines, including thoracic, cardiovascular, general, and urologic surgery, ensuring a broad evaluation of the devices.

An achievement of haemostasis within three minutes and avoidance of revision surgery within 12 hours were set as primary endpoint. Time to Haemostasis (TTH), degree of bleeding at the application site and incidence of adverse events (AEs) and postoperative complications were observed.

Data were collected using a standardized Case Report Form (CRF), which captured detailed intraoperative and postoperative observations.

ETHICAL ISSUES

This study was conducted in accordance with the Declaration of Helsinki (52nd WMA General Assembly, Edinburgh, Scotland, October 2000) and was approved by the Ethics Committee of the University Hospital Hradec Králové, Czech Republic. Written informed consent was obtained from all participants, who were also given the option to withdraw from the study at any time without obligation or penalty.

PATIENT POPULATION

A total of 100 patients were screened for inclusion, with 99 ultimately enrolled in the per-protocol set (PPS) after exclusions. The study population consisted of adult patients undergoing open, laparoscopic, thoracoscopic, or robotic surgeries. Demographics, including age, gender, and comorbid conditions, were recorded to provide context for efficacy and safety outcomes. Inclusion criteria were age above 18 years or older and capillary or diffuse bleeding unmanageable by conventional methods. Exclusion Criteria were known hypersensitivity to oxidized cellulose, pregnancy or severe medical conditions compromising safety. If another local haemostatic agent was used, patients were excluded from the effectiveness assessment (PPS) but were included in the Safety Set (SS).

USED HAEMOSTATS

Traumacel PULVIS (other names: Traumastem POWDER, EMOXICEL EMIPOL, Resorcell; BIOSTER, a. s., Veverská Bítýška, Czech Republic) is a sterile, bioresorbable powder designed to achieve haemostasis across various surgical fields. It is packaged in 1, 2, 3, and 5 g doses, with the 2 g package utilized in this study. An applicator Traumacel ENDO Applicator, (other names: Traumastem ENDO Applicator, EMOXICEL ENDO Applicator; BIOSTER, a. s., Veverská Bítýška, Czech Republic) was used for endoscopic procedures or in hard-to-reach areas. This applicator specifically designed for laparoscopic and thoracoscopic surgeries, allows precise application in minimally invasive settings, extending the versatility of the product.

STATISTICAL ANALYSIS

The safety analysis included all patients who received the tested haemostat (Safety set – SS), while the efficacy analysis was conducted on patients who adhered to the study protocol without deviations. (Per Protocol Set – PPS) The proportion of patients meeting the primary endpoint and the mean time to haemostasis (TTH), both with 95% confidence intervals, were evaluated. In addition, subgroup analyses were performed based on bleeding severity and surgical approach. Mean TTH across the total groups was compared using an unpaired t-test, with statistical significance defined as $P < 0.05$.

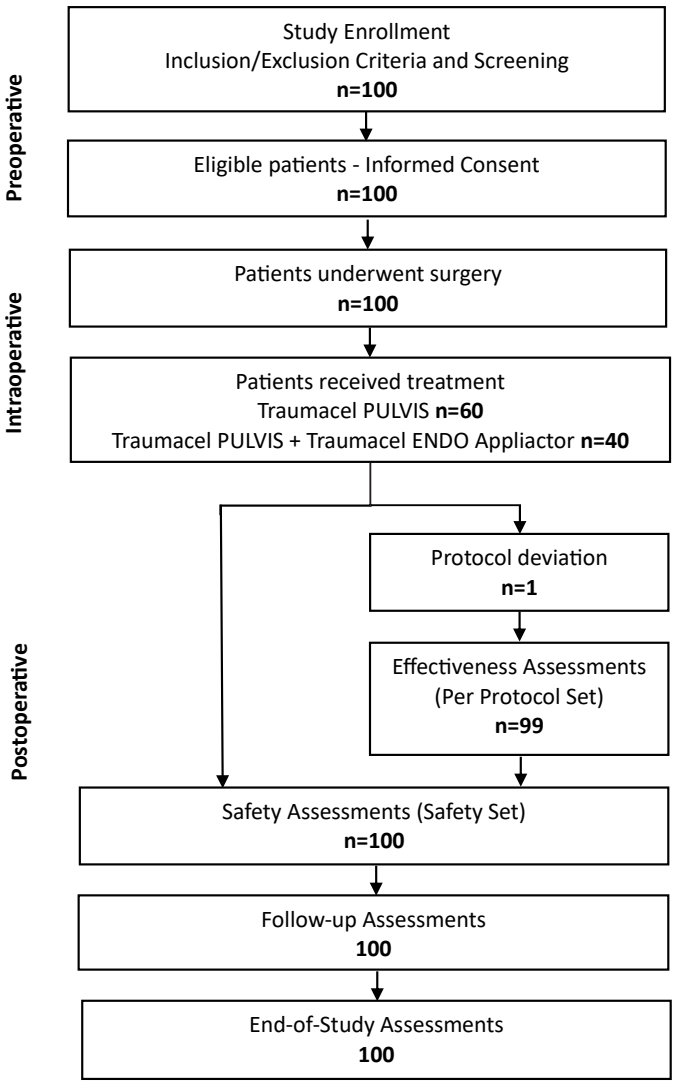

Fig. 1 Study Flowchart.

RESULTS

DEMOGRAPHICS AND PATIENT CHARACTERISTICS

The study enrolled a total of 100 patients across four surgical centres, with 99 included in the per-protocol set (PPS) after one exclusion due to protocol deviation.

The mean age of patients was 60.8 years, with 60.6% male and 39.4% female participants.

A substantial portion of the study population (42.4%) had significant comorbidities, including diabetes mellitus, ischemic heart disease, and oncologic conditions, which could potentially influence surgical outcomes.

The inclusion of patients with diverse comorbidities ensured that the results reflected real-world clinical scenarios.

The thoracic region was the most frequent target bleeding site (TBS), representing 50% of cases, followed by retroperitoneal/abdominal (21.0%) and cutaneous/subcutaneous sites (10.0%). Notably, in 55% of the cases, no additional methods were required to control bleeding beyond the application of the OC powder, with electrocoagulation being the most frequently used adjunctive technique (34%). These findings highlight the versatility and effectiveness of the OC powder across a variety of surgical procedures and bleeding scenarios.

PRIMARY OUTCOMES

A total of 61.6% (95% CI [52.0, 71.2]) of patients achieved haemostasis within three minutes after the OC powder application, meeting the primary efficacy endpoint. One patient did not meet the primary endpoint due to revision surgery within 12 hours postoperatively. However, the revision was due to a mechanical failure of a vein graft ligature, unrelated to the performance of tested product.

Tab. 1 Demographic Characteristics (PPS).

Characteristic	Traumacel PULVIS n (%) N = 60 (PPS)	Traumacel PULVIS + Traumacel ENDO Applicator n (%) N = 39 (PPS)	Total n (%) N = 99 (PPS)
Age, mean (SD)	62.0 (16.41)	58.9 (17.09)	60.8 (16.58)
Age, MIN – MAX	18–88	20–83	18–88
Sex, n (%)			
Male	35.0 (58.3)	25.0 (64.1)	60.0 (60.6)
Female	25.0 (41.7)	14.0 (35.9)	39.0 (39.4)
PHCCM, n (%)	21.0 (35.0)	21.0 (53.8)	42.0 (42.4)

SD, standard deviation; PHCCM, possible health complications, comorbidities and medications that may affect the outcome of treatment; PPS, Per Protocol Set (for more information, see Table 2).

Tab. 2 List of PHCCM and occurrence.

	Occurrence
Comorbidities	Oncologic disease (5), ischemic heart disease (4), diabetes mellitus (1), arterial hypertension (5), renal failure (3), Ischemia of lower extremities (1), hypothyroidism (1)
Medications	Acetylsalicylic acid (15), warfarin (6), heparin and its derivatives (6), apixaban (1), ticagrelor (1), corticosteroids (3), diosmin (1), dabigatran (1), clopidogrel (1), chemotherapy (2)
Other complications	smoking (5), alcohol abuse (1), obesity (2), condition after kidney transplantation (1), condition after kidney resection (1), immobility (1), warfarin discontinued (1), anopyrin discontinued (3), dialysis (1)

PHCCM, possible health complications, comorbidities and medications that may affect the outcome of treatment.

Tab. 3 Operative procedures (SS).

Parametr	Traumacel PULVIS n (%) N = 60	Traumacel PULVIS + Traumacel ENDO Applicator n (%) N = 40	Total n (%) N = 100
Number of Patients Screened	60 (60.0)	40 (40.0)	100 (100)
Did Not Meet Preoperative Eligibility	0 (0.0)	0 (0.0)	0 (0.0)
Did Not Meet Intraoperative Eligibility	0 (0.0)	1 (1.0)	1 (1.0)
Type of intervention			
Classic	60 (100.0)	11(27.5)	71 (71.0)
Laparoscopic	0 (0.0)	13 (32.5)	13 (13.0)
Thoracoscopic	0 (0.0)	16 (40.0)	16 (16.0)
Robotic	0	0	0
Endoscopic	0	0	0
Anatomic location of TBS, n (%)			
Thoracic	27 (45.0)	23 (57.5)	50 (50.0)
Retroperitoneal / Abdominal	10 (16.7)	11 (27.5)	21 (21.0)
Pelvic	5 (8.3)	2 (5.0)	7 (7.0)
Cutaneous / Subcutaneous	9 (15.0)	1 (2.5)	10 (10.0)
Extremities	7 (11.7)	0 (0.0)	7 (7.0)
Spinal canal	2 (3.3)	3 (7.5)	5 (5.0)
Other methods used to stop bleeding from TBS, n			
Electrocoagulation only	21 (35.0)	13 (32.5)	34 (34.0)
Mechanical methods only	5 (8.3)	0 (0.0)	5 (5.0)
Pharmacological methods only	2 (3.3)	0 (0.0)	2 (2.0)
Electrocoagulation + mechanical methods	2 (3.3)	1 (2.5)	3 (3.0)
Electrocoagulation + pharmacological methods	1 (1.7)	0 (0.0)	1 (1.0)
None	29 (48.4)	26 (65.0)	55 (55.0)

SS, Safety set.

The other patients achieved haemostasis within 5 minutes. The proportion of patients with haemostasis within 5 minutes without surgical revisions in 12 hours was 99.0% (95% CI [97.0, 100.0]).

The primary outcomes of the study were analysed across different subgroups, categorized by bleeding severity (mild, moderate, or severe) and type of surgery (open or endoscopic). Among patients with mild bleeding 78% (95% CI [66.5, 89.5]) achieved the primary outcome. In the group of patients with moderate bleeding 50% (95% CI [35.6, 64.5]) of patients met the primary outcome. None of the patients with severe bleeding achieved the primary outcome. In terms of surgical approach, 59.2% (95% CI [47.7, 70.6]) of patients undergoing open surgery achieved the primary outcome. For endoscopic procedures, the success rate was higher, at 67.9% (95% CI [50.6, 85.2]). These findings indicate variability in outcomes depending on the severity of bleeding and the type of surgical intervention, highlighting the importance of patient-specific factors in achieving effective results.

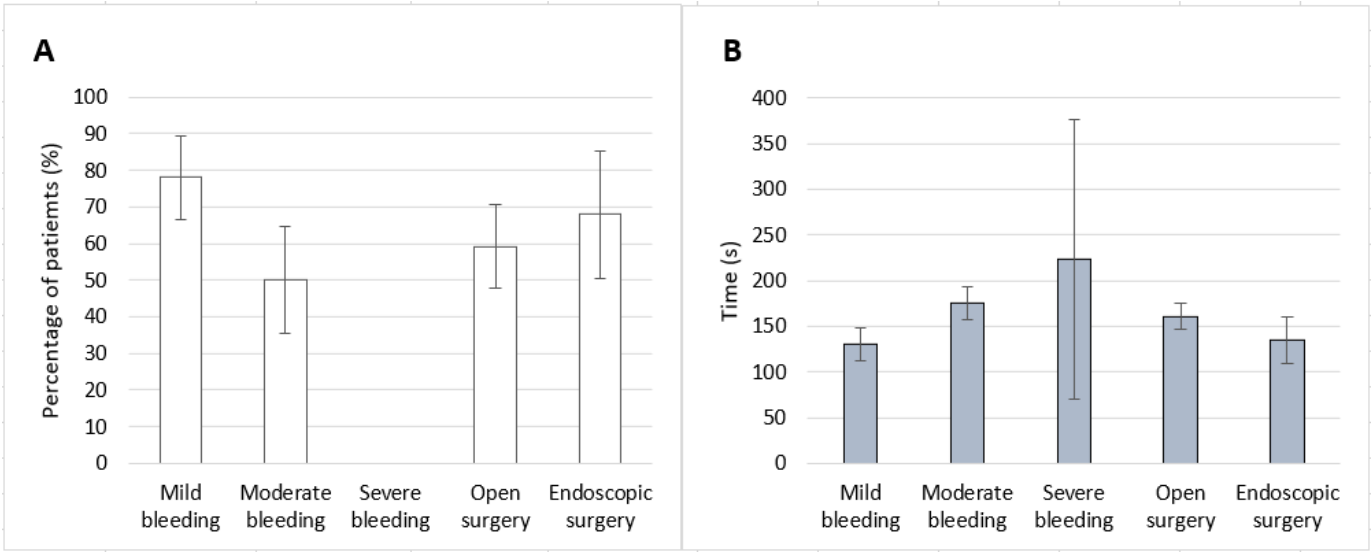

Fig. 2 (A) Primary endpoint success rate as percentage with 95% CI in subgroups according to bleeding severity and type of surgery; (B) Mean time to haemostasis in seconds with 95% CI in subgroups according to bleeding severity and type of surgery; PPS, Per Protocol Set.

OTHER PRIMARY OUTCOME MEASURES

To provide a clearer understanding of the average time required to achieve haemostasis, the graph displays the mean TTH for individual subgroups, along with their 95% confidence intervals (Fig. 2). Across the entire study population, the overall mean TTH was 153.8 seconds (95% CI: 141.5–166.1), with the shortest recorded time being 30 seconds.

The total number of patients who achieved haemostasis within 3 minutes without requiring revision surgery within 12 hours was compared to the total number of patients who achieved haemostasis within 5 minutes without requiring revision surgery within 12 hours.

Regarding the degree of bleeding, patients in minimally invasive procedures, where the endoscopic applicator was used, had predominantly mild bleeding (61.5%). In contrast, moderate bleeding was more common in open surgeries (53.3%).

Tab. 4 Proportion of patients with the same degree of bleeding PPS.

Clinical parameter	Traumacel PULVIS n (%) N = 60	Traumacel PULVIS + Traumacel ENDO Applicator n (%) N = 39	Total n (%) N = 99 (PPS)
Degree of bleeding, n			
1 = mild bleeding	26 (43.3)	24 (61.5)	50 (50.5)
2 = moderate bleeding	32 (53.3)	14 (35.9)	46 (46.5)
3 = severe bleeding	2 (3.4)	1 (2.6)	3 (3.0)
4 = life-threatening bleeding	0	0	0
Degree of bleeding, mean (SD)	1.60 (0.56)	1.41 (0.55)	1.53 (0.56)

SD, standard deviation; TTH, time to haemostasis.

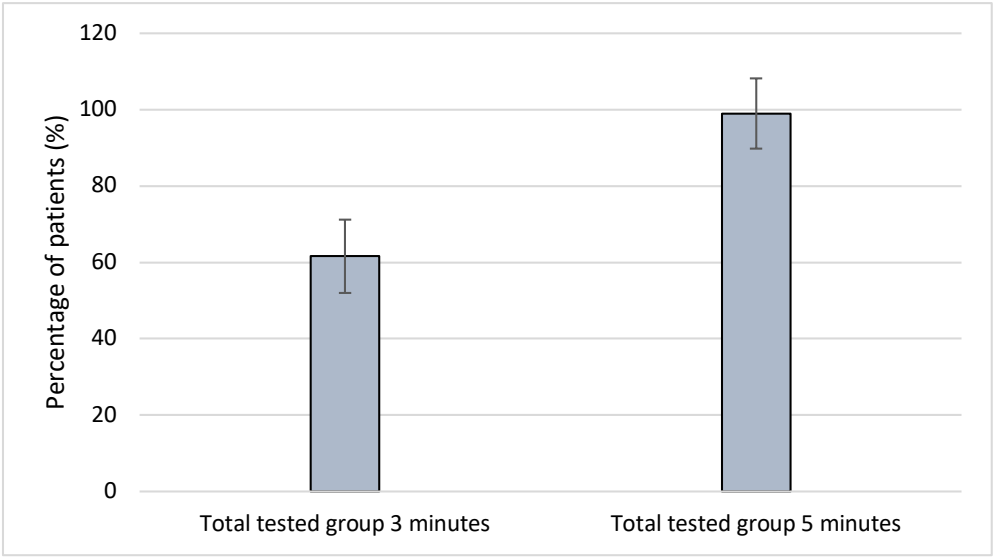

Fig. 3 Proportions of patients in total tested group with bleeding control within 3 and 5 minutes and no need for revision within 12 hours after surgery (with 95% CI); PPS, Per Protocol Set.

This appears to be due to the generally higher tissue bleeding in open surgery than in mini-invasive procedures.

The success rates of 61.6% (95% CI: [52.0, 71.2]) for achieving haemostasis within 3 minutes and 99.0% (95% CI: [97.0, 100.0]) within 5 minutes, without the need for surgical revisions within 12 hours, align closely with data from a similar study (7) on OC fibrillar haemostatic agents. That study reported a success rate of 68.4% (95% CI: [59.2, 77.6]) for achieving haemostasis within 3 minutes and 95.0% (95% CI: [90.5, 99.25]) within 5 minutes, also without revision surgery in 12 hours. Additionally, a comparison of average TTH showed similar results, with this study reporting a mean TTH of 153.8 seconds (95% CI: [141.5, 166.1]) versus 155.94 seconds (95% CI: [141.28, 170.72]) in the fibrillar OC haemostat study. A paired t-test found no statistically significant difference between the mean TTH values ($p = 0.39$). Similarly, when comparing the average degree of bleeding across all PPS patients in this study (1.53) with the average degree of bleeding in the fibrillar haemostat study (1.58), no significant difference was observed ($p = 0.26$). These findings indicate that the degree of bleeding likely does not influence the measured TTH data.

SAFETY OUTCOMES

No device-related adverse events were reported during the study. Postoperative complications were minimal, occurring in 2% of cases, and were unrelated to the haemostatic agent or applicator.

Tab. 5 Safety outcome measures.

Clinical parameter	Traumacel PULVIS n (%) N = 60	Traumacel PULVIS + Traumacel ENDO Applicator n (%) N = 40	Total n (%) N = 100
Complications, n (%)	2 (3.3)	0 (0)	2 (2.0)
AEs, n (%)	0 (0)	0 (0)	0 (0)
AEs at 1-month follow-up, n (%)	0 (0)	0 (0)	0 (0)
Unscheduled visits, n (%)	0 (0)	0 (0)	0 (0)

AEs, adverse events

These postoperative complications occurred: a vein graft ligature failure resulting in rebleeding one-hour post-surgery and bleeding from the chest wall following pleural removal, occurring 13 hours postoperatively. The low number of complications observed aligns with the results of a comparable study involving OC fibrillar haemostats, which reported two complications (2%) unrelated to the haemostatic agent. This consistency supports the strong safety profile of oxidized cellulose-based haemostats, as demonstrated in the efficacy comparisons.

USING THE ENDOSCOPIC APPLICATOR

Endoscopic applicator was used in 40% of cases, predominantly in laparoscopic and thoracoscopic procedures. Its precision delivery of the OC powder contributed to faster haemostasis, particularly in anatomically challenging areas.

The applicator was typically passed through the port and positioned near the target bleeding site (TBS) using a laparoscopic dissector; however, in some instances, the dissector was not required. The data indicate that tools were not necessary for every application of the device, with tools being used in a total of 24 recorded cases.

Tab. 6 Overview of used tools.

Area of surgery	Number of usages of Traumacel ENDO Applicator n (%) N = 40 (SS)	Used Tools N = 24
Thoracic surgery	16 (40.0)	trocar of the brand Storz (6) mediastinoscope of the brand Wolf (3)
Cardiovascular surgery	7 (17.5)	tweezer (1)
General surgery	9 (22.5)	trocar without the specified brand with laparoscopic dissector (8) trocar without the specified brand only (2)
Vascular surgery	0 (0.0)	–
Plastic surgery	0 (0.0)	–
Neurosurgery	3 (7.5)	–
Urology	5 (12.5)	trocar of the brand Storz (3) trocar of the brand Olympus (1) trocar without the specified brand (1)
Department of Anesthesiology, Resuscitation	0 (0)	

DISCUSSION

The findings of this study confirm the efficacy and safety of oxidized cellulose (OC) powder as a versatile haemostatic agent across a variety of surgical scenarios. The use of the endoscopic applicator further enhances the precision and applicability of OC powder, particularly in minimally invasive procedures, where the challenges of accessibility and bleeding control are heightened.

By achieving haemostasis in 61.6% of patients within three minutes and 99.0% within five minutes without revision surgery, the OC powder demonstrates results that are consistent with, and in some cases comparable to, historical data from studies on various OC haemostats.

When comparing the 5-minute success rate of 99% from this study with similar published data, a study comparing knitted non-regenerated OC and regenerated OC haemostats reported a 71.1% success rate for regenerated OC and 89.2% for non-regenerated OC in achieving haemostasis within 5 minutes [11]. Additionally, another

post-market clinical study evaluating a haemostatic powder based on regenerated OC reported a 5-minute haemostatic success rate of 87.5% (9).

A closer look at the subgroup analysis reveals that outcomes vary based on the severity of bleeding and the type of surgery. Patients with mild bleeding demonstrated a higher rate of achieving the primary endpoint (78%) compared to those with moderate bleeding (50%) and severe bleeding (0%), highlighting the importance of bleeding severity as a determining factor for haemostatic efficacy. Although the primary endpoint was not achieved in patients with severe bleeding, suggesting that the OC powder may not be suitable for such cases, haemostasis was nonetheless achieved within 4 minutes in these individuals, and no complications were reported. Common efficacy parameters were chosen, studies on haemostatic agents often compare the proportion of patients achieving haemostasis within a specific time frame (9–11) or analyse the average TTH (11–13). Additionally, other methods are employed, such as calculating blood loss based on haematocrit and haemoglobin levels (14) or measuring the volume of blood collected in surgical drains (15).

Given the absence of device-related AEs, no further statistical tests were done for safety outcomes. The low complication rate aligns with historical safety data for oxidized cellulose-based haemostats (8). However, in rare cases, complications may arise. Several published studies have reported instances of foreign body reactions or hypersensitivity responses (16, 17).

The single-arm design, while practical, limits direct comparisons with alternative haemostatic agents. Future randomized controlled trials could provide more robust evidence. Additionally, exploring the use of these devices in specialized procedures, such as paediatric or robotic surgeries, could expand their applicability.

CONCLUSION

The results of this study highlight the consistent performance of OC powder and its endoscopic applicator across diverse surgical settings and confirm their role as indispensable tools for modern surgical practice. These findings support their continued use across a wide range of surgical disciplines, ensuring effective bleeding control and improved patient outcomes. The absence of device-related adverse events further underscores the safety profile of these products.

CONFLICT OF INTEREST

V. Sívková is an employee of BIOSTER, a. s. Other authors confirm that there are no conflicts of interest associated with this publication.

ABBREVIATIONS

OC	oxidized cellulose
OC powder	the oxidized cellulose hydrogen calcium salt powder
TTH	time to haemostasis
CI	confidence interval
SS	safety set
PPS	per protocol set

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