Safety and effectiveness of Merizelle oxidised regenerated cellulose in achieving haemostasis in surgical procedures: a surveillance study

Objective: Topical haemostatic materials applied to bleeding sites during surgery play an important role in intraoperative haemostasis. This study aimed to evaluate the clinical safety and efficacy of Merizelle oxidised regenerated cellulose (ORC) (Meril Life Sciences Pvt. Ltd., India) in achieving haemostasis across various surgical procedures.
Method: This was a prospective, multicentre, single-arm, observational, post-marketing surveillance study. The primary endpoint was the proportion of patients achieving haemostasis within 10 minutes of application of ORC at target bleeding sites. The secondary endpoints were the absence of proven infection and the absence of bleeding-related adverse events (AEs) until six months after surgery. Patients were followed up at discharge, two weeks, one month, three months and six months after the index procedure.
Results: In all, 189 patients were screened and enrolled, and 188 patients completed the study. The mean±standard deviation (SD) age of patients was 43.00±12.79 years and 59.79% were female. Neurological surgeries, nephrectomy and lower segment caesarean section were the most common surgeries performed. The mean±SD length of hospital stay was 6.28±4.08 days and the mean±SD coagulation time was 2.57±1.12 minutes. Haemostasis was achieved in all patients with the use of Merizelle ORC, with 94.68% of patients achieving it within 10 minutes. Almost 80% of patients had mild-to-moderate bleeding. There were no cases of bleeding-related AEs, proven infection or death at the end of all follow-ups.
Conclusion: The ORC demonstrated excellent safety with no occurrence of bleeding-related AEs, proven infections or postoperative death.
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coagulation • haemostasis • oxidised regenerated cellulose • wound • wound care • wound dressing • wound healing

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Annually, about 313 million surgical procedures are performed worldwide.[1] Data have shown approximately 4.2 million post-surgical deaths within 30 days of surgery each year, amounting to 7.7% of annual global deaths.[2] A study[3] found that severe bleeding during non-cardiac surgery was associated with a significant increase in mortality. According to this study, approximately 17.3% of patients who experienced severe bleeding during surgery died, highlighting the critical impact of uncontrolled bleeding on patient outcomes.

Additionally, Corral et al.[4] reported that severe, excessive or uncontrolled bleeding during surgery can raise mortality rates to as high as 20%. Perioperative bleeding is a major cause of perioperative morbidity, mortality and resource use.[3] Uncontrolled haemorrhage can lead to various complications, including hypothermia, coagulopathy, infection, acidosis and multiple organ failure.[5] Moreover, reopening of the surgical wound, systemic procoagulant administration and transfusion of blood products are associated with high risks of adverse outcomes; hence, control of intraoperative and postoperative bleeding is important.[6] Topical haemostatic materials applied locally to bleeding sites during surgery play an important role in intraoperative haemostasis.[5]

Various options and procedures are available for intraoperative haemostasis.[7] The ideal haemostat should be able to stop bleeding promptly, be biodegradable and bioabsorbable, safe, easy to use and affordable.[8] Haemostatic materials can be classified, based on the material source, as inorganic haemostatic, polysaccharide haemostatic, biological haemostatic and synthetic haemostatic.[5] Haemostats based on inorganic materials are not bioabsorbable and need to be removed after application.[5] While biological haemostatic agents directly increase coagulation factors at the bleeding site, they can lead to immune reactions and postoperative complications, and might be associated with the risk of transmitting blood-borne pathogens.[5] Polysaccharide-based haemostatic materials do not contain clotting factors.[6] A commonly used

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polysaccharide-based haemostatic material is oxidised regenerated cellulose (ORC). Cellulose is a carbohydrate forming the skeleton of most plant structures and plant cells. It is also a source of dietary fibre. Oxidised cellulose is an absorbable oxidation product of cellulose and can be regenerated to form organised fibres.[5] Since their introduction in 1943, several ORC products have been developed and are often used in surgeries.[9] ORC provides a milieu for clot initiation, and promotes platelet activation and adherence without directly enhancing coagulation mechanisms.[10] It has an acidic pH, which causes a reaction with blood to form an artificial clot. This clot provides a platform on which platelets can start adhering and aggregating, leading to coagulation, without interfering with the physiological clotting mechanism.[6] The acidic pH of ORC leads to coagulative necrosis and causes a tamponade effect.[11] It also has additional effects. The low pH makes the local environment bacteriostatic, offering antimicrobial activity against Gram-positive, Gram-negative and antibiotic-resistant organisms, including meticillin-resistant *Staphylococcus aureus* (MRSA), meticillin-resistant *Staphylococcus epidermidis* (MRSE) and vancomycin-resistant *Enterococcus* (VRE).

ORCs can also be easily adapted to various wound shapes and sizes. Absorption begins within 24 hours after application and the ORC is completely dissolved in between 2–6 weeks, depending on product volume, local vascularity and tissue.[12] ORC is also available in various fabric types and shapes; this makes it feasible to make it conform to irregular surfaces and hard-to-reach sites. It also adheres easily to bleeding surfaces.[7]

Merizelle ORC (Meril Life Sciences Pvt. Ltd., India) is an absorbable knitted fabric composed of ORC. It is designed to assist in the control of capillary, venous and small arterial haemorrhage, and can be used effectively when control of small vessel bleeding by pressure, ligature and other conventional procedures are ineffective. This study aimed to evaluate the clinical safety and efficacy of Merizelle ORC in achieving haemostasis across various surgical procedures.

Methods

Study design

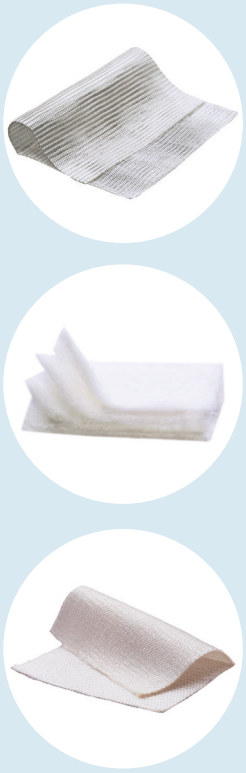
This was a prospective, multicentre, single-arm, observational, post-marketing surveillance study to evaluate the clinical safety and efficacy of the ORC in achieving haemostasis across various surgical procedures, including: general surgery; gastric resection; ears, nose and throat surgery; gynaecological operations; neurosurgery; implantation of vascular prostheses; biopsies; lung operations; surgery to face and jaw; liver and gall bladder operations; thoracic and abdominal sympathectomies; thyroid operations; skin transplantations; and treatment of superficial injuries.

Ethical approval and patient consent

The study was conducted across four centres in India and was carried out according to the International Council for Harmonization (ICH) standards for clinical research including: ICH E6 (Good Clinical Practice) and ICH E3 (Study Reporting) standards for conduct of the study. The Institutional Review Board (IRB)/Independent Ethics Committee (IEC) of the participating sites provided approval for the study. The study was registered on the Clinical Trials Registry – India (CTRI) (National Institute of Medical Statistics portal of the Indian Council of Medical Research) (CTRI number: CTRI/2017/01/007710). Patients were recruited from 24 February 2017 to 19 April 2021.

Written informed consent was obtained from every participant before enrolment in the study.

Fig 1. Merizelle oxidised regenerated cellulose (ORC) (Meril Life Sciences Pvt. Ltd., India) product images



Standard
Fine weave ORC
2×3 inches | 4×8 inches | 2×14 inches

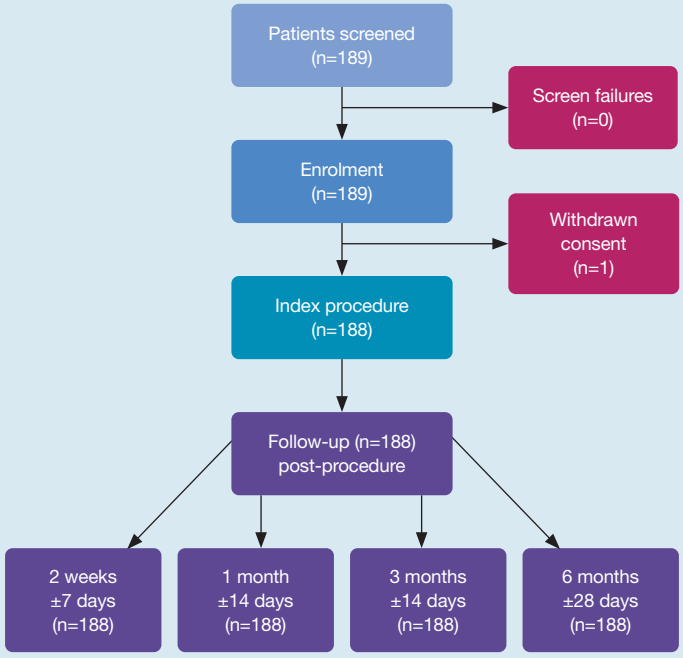
Fiber
Tufts of soft, lightweight ORC
1×2 inches | 2×4 inches | 4×4 inches

Woven
Denser weave of ORC for heavier bleeding
1×1 inches | 1×3.5 inches | 3×4 inches | 6×9 inches

Study product

The product used in the study was Merizelle ORC (Fig 1). It is stable at room temperature and usable as packaged, requiring no mixing or other preparation. A slight discolouration can occur over time; however, this does not affect its properties. The three different types of the ORC—Standard, Fiber and Woven—are manufactured with the same ORC. 'Standard' is a finely woven structured material of ORC and is indicated for use in nephrological, neurological and general surgical procedures to assist in the control of capillary, venous and small arterial haemorrhages when ligation or other conventional methods of control are impractical or

Fig 2. Study flow and patient disposition



ineffective. 'Fiber' has tufts of soft lightweight ORC. It can be peeled off as desired. It can be used in any size, shape or thickness for hard-to-reach sites or irregularly shaped bleeding sites, and is most suitable for neurosurgical procedures. 'Woven' is a densely woven structured ORC material that is indicated for use in general surgical procedures when ligation or other conventional methods of control are impractical or ineffective.

Inclusion criteria

The inclusion criteria were as follows:

- Patients aged ≥18 years scheduled for a surgical procedure
- Willingness to provide written informed consent by signing and dating the IRB or IEC approved informed consent form
- Willingness to return for scheduled follow-up visits
- Haemoglobin level ≥8.0g/dl at baseline (within 24 hours before the surgical procedure)
- Identified target bleeding site with moderate bleeding during surgery according to the investigator's discretion.

All consecutive patients who met all eligibility criteria were included to avoid selection bias.

The exclusion criteria were:

- Known sensitivity to device materials
- History of drug or alcohol misuse or psychological disorders that could affect follow-up care or treatment outcomes
- Unwillingness or inability to sign the informed consent form
- Non-suitability for follow-up adherence according to the investigator
- Female patient with a ruptured ectopic pregnancy
- Medical history of abnormal coagulopathy or uraemia
- Currently enrolled in another ongoing study
- Taking anticoagulant medication
- History of radiation therapy treatment at the surgical site
- Receiving an organ transplant during the surgical procedure
- Life expectancy <12 months
- Taking immunosuppressive therapy (>40mg of corticosteroid per day or azathioprine).

Procedure

Merizelle absorbable haemostat in dry form and appropriate size was laid on the bleeding site or against the tissue until haemostasis was achieved, as per the instructions for use.

Performance endpoints

Primary endpoint

The proportion of patients achieving haemostasis at target bleeding sites up to 10 minutes after application. Haemostasis was defined as no detectable bleeding at the target bleeding site.

Secondary endpoints

- Absence of proven infection (no positive results on blood culture, indicative of infection) up to 30 days after index surgery

Table 1. Follow-up plan

Study activity	Index procedure	Discharge	2 weeks	1 month	3 months	6 months
Type of follow-up	Clinical	Clinical	Telephone	Clinical	Clinical	Clinical
Physical examination	X	X		X	X	X
Vital signs	X	X		X	X*	X*
Laboratory assessment (CBC)				X**	X**	X**
Coagulation time	X					
Bleeding events	X	X	X	X	X	
Tissue/blood culture	X***	X***	X***	X***	X***	X***
Adverse event/serious adverse event	X	X	X	X	X	X

*Vital signs were optional at 3-month and 6-month follow-up; **Laboratory assessments were optional at 1-month, 3-month and 6-month follow-up; ***Tissue/blood cultures were optional at index procedure, 2-week, 1-month, 3-month and 6-month follow-up visits. CBC—complete blood count

- Absence of specifically bleeding-related adverse events (AEs) up to three months after index surgery.

Safety endpoint
Postoperative mortality up to 30 days after index surgery.

Follow-up plan
Patients were followed-up at: discharge; two weeks; one month; three months; and six months after the index procedure. The detailed follow-up plan is shown in Table 1.

Sample size calculation
Reliable data on the usage pattern of the ORC for achieving haemostasis across several surgical procedures were collected. Previous studies have reported that the proportion of patients who achieved haemostasis with the use of an absorbable haemostat (ORC) within 10 minutes was 73.3%.[13] Assuming the proportion of patients likely to achieve haemostasis with ORC was 73.3%, a sample size of 166 patients was required to produce a two-sided confidence interval (CI) with a half-width equal to 0.07 based on the exact method. Accounting for a dropout rate of approximately 10%, a total of 185 patients were planned to be enrolled in this study.

Statistical analysis
No potential confounders or effect modifiers were identified. All endpoints and analyses were predefined and were not changed during the study. All statistical analysis was performed on an intent-to-treat basis. All patients lost to follow-up after one month were considered for efficacy evaluation based on Last Observation Carried Forward data. All drop-outs and lost-to-follow-up patients were excluded from the safety analysis. The proportion of patients achieving haemostasis was summarised as frequency (percent) and analysed by constructing 95% binomial CIs using the exact method (Clopper–Pearson). The demographic and baseline characteristics were summarised using descriptive statistics.

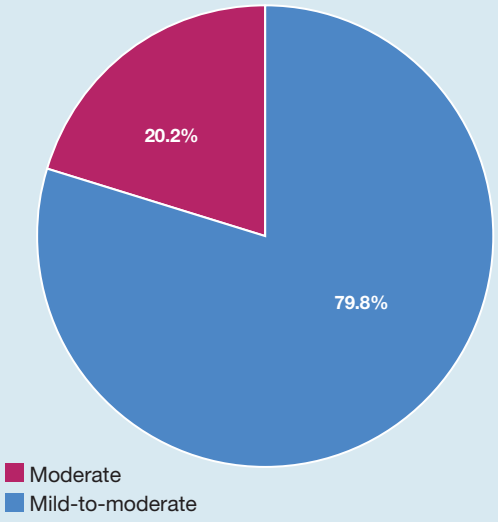
Data are presented using descriptive statistics, such as mean±standard deviation (SD) for continuous variables, and frequencies with percentages for categorical variables. No subgroup analysis was planned. Procedural success was defined as having no occurrence of bleeding-related AEs and is presented as frequency and percentage.

All statistical analyses were performed using Microsoft Excel (Microsoft Corp., US).

Results
A total of 189 patients were screened and enrolled. A single patient withdrew from the study prior to the index procedure; thus, a total of 188 patients completed the study. The patient disposition is shown in Fig 2.

The mean age of patients was 43.0±12.79 years and 59.79% were female. The baseline characteristics of patients are shown in Table 2. The overall prevalence of comorbidities in the cohort was low: diabetes 3.17%; hypertension 8.47%; anaemia 1.06%; and bleeding disorder 0.53%.

Fig 3. Distribution of bleeding severity



Central nervous system, nephrectomy and lower segment caesarean section were the commonest surgeries performed, and Merizelle Standard was used in 76.06% of patients (Table 3).

Almost 80% of patients had mild-to-moderate bleeding (Fig 3), and the commonest target bleeding locations were the uterus, head and renal fossa (Table 2).

Study outcomes are presented in Table 4. The mean length of hospital stay was 6.28±4.08 days and the mean coagulation time was 2.57±1.12 minutes. Haemostasis was achieved in all patients with the use of ORC, with 94.68% of patients achieving it within 10 minutes.

In all, 52 non-serious AEs were reported up to the 6-month follow-up in the study and were resolved through medication (Table 5).

Discussion
The study outcomes show that haemostasis was achieved in all patients with the use of ORC, with 94.68% of patients achieving it within 10 minutes of application. Merizelle ORC demonstrated excellent safety up to 3-months postoperative follow-up with no occurrence of bleeding-related AEs, proven infections or postoperative death. Moreover, almost 80% of patients had only mild-to-moderate bleeding and Merizelle Standard was able to control bleeding in 76.06% of patients.

Cellulose-based haemostatic agents swell on contact with blood, eventually leading to the formation of a fibrin plug at the bleeding site.[14] Moreover, bioabsorbable haemostats, such as ORCs, are preferred over non-absorbable haemostats because they do not need to be removed from the wound, which can often lead to re-bleeding. This is even more important intraoperatively, because the consequences of

Table 2. Baseline and demographic characteristics

Variables	n=189
Age, years, mean±SD	43.00±12.79
Age groups, years, n (%)	
21–30	38 (20.11)
31–40	45 (23.81)
41–50	48 (25.40)
51–60	38 (20.11)
61–70	16 (8.47)
≥71	4 (2.12)
Sex, n (%)	
Male	76 (40.21)
Female	113 (59.79)
Body mass index, kg/m^2, mean±SD	26.71±4.96
Heart rate, beats per minute, mean±SD	78.3±7.41
Systolic blood pressure, mmHg, mean±SD	122.74±13.64
Diastolic blood pressure, mmHg, mean±SD	78.58±8.79
Medical history, n (%)	
Diabetes	6 (3.17)
Bleeding disorder	1 (0.53)
Anaemia	2 (1.06)
Hypertension	16 (8.47)
Other illness	16 (8.47)
Smoker	4 (2.12)
Alcoholic	1 (0.53)
Target bleeding location, n (%), n=188	
Renal bed (fossa)	52 (27.65)
Uterus	59 (31.38)
Neck	6 (3.19)
Head	55 (29.26)
Spinal cord	7 (3.72)
Other	9 (4.79)

SD—standard deviation

Table 3. Surgeries performed and Merizelle oxidised regenerated cellulose (ORC) (Meril Life Sciences Pvt. Ltd., India) type used

Types of surgery, n (%), (n=188)	
Merizelle Standard (n=143)	
Lower segment caesarean section	12 (8.39)
Hysterectomy	6 (4.19)
Robotic-assisted radical prostatectomy	10 (6.99)
Nephrectomy	40 (30.76)
Central nervous system	66 (46.15)
Others	9 (6.29)
Merizelle Woven (n=41)	
Lower segment caesarean section	25 (60.97)
Myomectomy	4 (9.75)
Hysterectomy	4 (9.75)
Digital laparoscopy	2 (4.87)
Others	6 (14.63)
Merizelle Fiber (n=4)	
Central nervous system	4 (100)

re-bleeding caused by topical haemostat removal can be more severe. Hence, it is much safer to leave the haemostat on the wound where it can be eventually absorbed by the body.[9]

Previous studies have reported the beneficial use of ORC in controlling bleeding in various surgeries, including hepatectomy, neurosurgery, gynaecological surgery, nephrectomy, cardiovascular surgery and others.[15–24] In patients who underwent on-pump coronary artery bypass grafting, evaluation of postoperative haemorrhage showed that the amount of drainage fluid was least in the ORC+electrocauterisation (EC) group, compared to the EC alone, and the bone wax+EC groups at all timepoints considered. Furthermore, requirements for fresh frozen plasma and erythrocyte suspensions were also lowest in the ORC+EC group.[23]

A review of several studies showed that effective haemostasis is usually achieved within 2–8 minutes of

Table 4. Study outcomes (n=188)

Outcome measures		
Length of hospital stay, days, mean±SD	6.28±4.08	
Coagulation time, minutes, mean±SD	2.57±1.12	
Patients who achieved haemostasis with Merizelle ORC, n (%)	188 (100)	
Time to haemostasis, n (%)		
<10 minutes	178 (94.68)	
>10 minutes	10 (5.32)	
Follow-up after discharge, n (%)		
	1-month follow-up (n=188)	**3-month follow-up (n=188)**
Absence of bleeding-related adverse events	188 (100)	188 (100)
Absence of proven infection	188 (100)	188 (100)
Postoperative mortality	0	0

ORC—oxidised regenerated cellulose (Merizelle, Meril Life Sciences Pvt. Ltd., India); SD—standard deviation

ORC application in patients undergoing neurosurgeries such as dissections in the region of the cavernous sinus, extreme lateral inferior transcondylar-transtubular exposure, and lateral suboccipital craniotomy.[15] In another study among patients undergoing neurosurgery, the overall time to haemostasis was significantly less (2.43±0.75 minutes; p<0.05) in the ORC group compared to the gelatin sponge group (4.23±0.89 minutes). ORC was significantly faster than gelatin sponge (p<0.05) in achieving haemostasis when used in surgeries for cerebral contusions, brain tumours and cerebral vascular malformations.[25] In patients undergoing laparoscopic cholecystectomy, application of ORC at the port-site just prior to closure quickly controlled bleeding from small abdominal incisions.[26]

ORC has also been used for the management of postpartum haemorrhage in patients undergoing caesarean section. In a study,[27] 80% of patients in the non-ORC group needed haemoderivatives transfusion versus 20% in the ORC group. The proportion of hysterectomies was 5% versus 66% in the ORC and the non-ORC groups, respectively. A decrease in the mean days of hospitalisation and proportion of patients admitted to the intensive care unit was observed in the ORC group versus the non-ORC group.[27]

In patients undergoing partial nephrectomy, it took only 5–10 minutes to fix the ORC. No additional haemostatic agent was used and there were no significant changes in preoperative and postoperative haematocrit values.[28] In a cost-effectiveness analysis in 2015, total haemostat costs were 28–56% lower, and mean haemostat units per discharge were 16–41% lower, with the use of ORCs than with the use of other adjunctive haemostats in patients undergoing cardiovascular procedures, carotid endarterectomy, cholecystectomy or hysterectomy. A shorter length of hospital stay observed with ORC use was associated with significantly lower (p<0.001) total procedure costs. Use of ORCs in carotid endarterectomy and cholecystectomy also led to significantly decreased (p<0.001) transfusion rates when compared with other adjunctive haemostats used.[29]

Table 5. Post-procedural adverse events reported during the study period

Adverse events, n	Discharge	2 weeks	1 month	3 months	6 months
Incisional site pain	9	3	0	0	0
Vomiting	2	4	4	2	2
Fever	0	1	1	3	0
Cold	2	1	3	0	2
Dyspnea	0	1	1	1	0
Abdominal pain	0	3	4	3	0

Among more recent studies, haemostasis was achieved within 10 minutes with the use of ORC in 94.9% of patients undergoing abdominal, thoracic and vascular surgeries.[9] In another study, among patients who underwent laparoscopic cholecystectomy, the application of ORC rapidly controlled bleeding in all patients, with the average time to haemostasis ranging from 3–7 minutes. Patients were discharged after a mean duration of 2.2 days.[7]

Our outcomes are in line with those of previous studies on the use of ORC for intraoperative haemostasis.

Limitations

There are certain limitations to our study. This was a single-arm study; thus, there was no comparison of Merizelle with other ORCs or other topical haemostatic agents. Further, the sample size was small. Hence, no meaningful subgroup analysis by type of surgery and type of Merizelle used could be performed. More prospective studies in various types of surgeries with larger sample sizes are necessary to validate our findings.

Conclusion

Merizelle ORC demonstrated excellent safety up to the 3-month follow-up in this study, with no occurrence of bleeding-related AEs, proven infections or postoperative death. Merizelle ORC's outcomes have been found to be comparable with contemporary ORC devices with successful haemostasis within a short time. JWC

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Reflective questions

- What is the impact of bioabsorbable haemostats such as oxidised regenerated cellulose (ORC) on controlling moderate or severe intraoperative bleeding?
- When should ORC be used for intraoperative haemostasis?
- What is the impact of ORC on haemostasis in other types of surgeries?

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