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# Collagen-Based Peritoneal Reconstruction Following Peritonectomy in Cytoreductive Surgery: A Multicenter Randomized Trial with 6-Month Outcomes

**Ravi Krishnappa[1], Naveen Narayan[2]*, Ashwini Narasimha Murthy[3], Rajesh Kunigal Nanjundaiah[4], Sumith S Deep[1]**

## Abstract

**Background:** Peritonectomy during cytoreductive surgery (CRS) for peritoneal surface malignancies disrupts the native mesothelial barrier and predisposes to adhesion-related morbidity and delayed recovery. High-purity type I collagen (HPTC) biomaterials may function as regenerative peritoneal substitutes that modulate healing and reduce postoperative complications. This study evaluated the safety and efficacy of a collagen-based peritoneal reconstruction following peritonectomy in patients undergoing CRS.

**Methods:** In this prospective, multicenter, randomized controlled trial, 60 patients undergoing CRS with peritonectomy for peritoneal malignancies were randomized (1:1) to collagen (HPTC/Surgicoll-Mesh®) peritoneal reconstruction (n = 30) or standard care without peritoneal reconstruction (n = 30). The primary endpoint was major intra-abdominal complications within 2 months. Secondary endpoints included adhesion-related events, bowel function recovery, ICU and hospital stay, radiologic adhesions, device safety, and quality of life (EORTC QLQ-C30).

**Results:** Baseline oncologic and operative characteristics were comparable between groups. Major intra-abdominal complications occurred in 13.3% of patients receiving HPTC compared with 36.7% in the control group (RR 0.36, 95% CI 0.13–0.99, p=0.049). Reoperation was required in 0% vs 20% of patients respectively (p=0.024). Severe complications (Clavien-Dindo ≥III) were reduced in the HPTC group (6.7% vs 23.3%). Adhesive small bowel obstruction occurred in 3.3% vs 26.7% of patients (RR 0.13, p=0.028). MRI-detected dense adhesions were significantly lower with HPTC (10% vs 40%, RR 0.25, p=0.018). Median time to bowel recovery was shorter (4.2 vs 6.1 days; p = 0.002), with reduced ICU stay (1.9 ± 1.1 vs 3.1 ± 1.4 days; p = 0.001) and hospital stay (9.8 ± 2.6 vs 13.4 ± 3.1 days; p < 0.001). At 6 months, adhesion-related complications remained significantly lower in the HPTC group (6.7% vs 30.0%), with sustained improvement in quality-of-life scores and no late device-related complications. No device-related adverse events occurred. Quality-of-life improvement at 2 months was greater with collagen reconstruction across global health and functional domains (all p ≤ 0.002).

**Conclusions:** Collagen-based peritoneal reconstruction following peritonectomy during CRS was associated with a reduction in postoperative intra-abdominal morbidity, adhesion formation, and recovery time without added safety risk. HPTC-based peritoneal reconstruction was associated with lower postoperative morbidity and faster recovery in this trial. These preliminary findings require confirmation in larger trials with longer follow-up. However, these findings should be interpreted in light of the modest sample size and short follow-up duration.

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## Introduction

Peritoneal surface malignancies (PSMs), arising from primary tumors such as colorectal carcinoma, ovarian cancer, appendiceal neoplasms, malignant peritoneal mesothelioma, and pseudomyxoma peritonei, represent a challenging oncologic condition associated with significant morbidity and historically poor survival outcomes. Over the last two decades, cytoreductive surgery (CRS), with or without hyperthermic intraperitoneal chemotherapy (HIPEC), has emerged as a standard-of-care strategy in selected patients, demonstrating improved overall and disease-free survival when complete cytoreduction is achieved [1-3].

CRS frequently necessitates extensive peritonectomy to remove macroscopic tumor deposits. While oncologically effective, peritonectomy disrupts the native peritoneal lining, a specialized mesothelial surface responsible for frictionless visceral movement, immunologic defense, fluid homeostasis, and rapid tissue repair [4]. Loss of this biological barrier predisposes patients to a spectrum of postoperative complications, including dense intra-abdominal adhesions, adhesive small bowel obstruction, prolonged postoperative ileus, enterocutaneous fistula formation, surgical site infection, incisional hernia, and the need for reoperation [5-7]. These complications significantly prolong hospital stay, delay adjuvant oncologic therapies, impair quality of life, and increase overall healthcare utilization.

At present, there is no universally accepted standard for peritoneal reconstruction following peritonectomy. Conventional surgical practice typically involves leaving the peritoneal defect untreated, allowing secondary healing through fibrosis. However, this process is often disorganized and pro-inflammatory, promoting excessive fibrin deposition and adhesion formation rather than structured regeneration of a functional mesothelial layer [8]. Consequently, there has been increasing interest in biologic materials that can serve as temporary peritoneal substitutes, restoring anatomic continuity while modulating the wound-healing response.

High-purity Type I collagen (HPTC)–based biomaterials with intrinsic phosphorylation have demonstrated favorable biological and mechanical properties across a range of reconstructive and regenerative surgical applications. Collagen, the principal structural protein of the extracellular matrix, plays a critical role in cellular adhesion, angiogenesis, and tissue remodeling. When processed through stringent purification protocols, HPTC scaffolds are biocompatible, minimally immunogenic, and bioresorbable, providing a three-dimensional framework that supports orderly tissue regeneration rather than scar-driven fibrosis [9-11].

In abdominal and reconstructive surgery, collagen-based matrices have been shown to reduce infection rates, improve integration in contaminated fields, and promote functional tissue repair. Prior studies evaluating biological meshes in the context of complex abdominal wall reconstruction during CRS have demonstrated acceptable safety profiles and encouraging clinical outcomes [12]. Additionally, emerging clinical evidence from wound care and soft tissue reconstruction has shown that HPTC-based scaffolds can significantly reduce complication rates and enhance healing outcomes when compared with alternative biological substitutes [13-16].

The HPTC, used in this study, Surgicoll-Mesh®, is a sterile, resorbable, high-purity Type I collagen–based biomaterial designed to function as a temporary regenerative scaffold [17]. When used as a peritoneal substitute following peritonectomy, it is hypothesized to provide a protective barrier between visceral surfaces, reduce fibrin-mediated adhesion formation, and facilitate organized neo-peritoneal regeneration during the critical early postoperative period. Despite strong biological plausibility and supportive evidence from related surgical domains, high-quality prospective randomized data evaluating collagen-based peritoneal substitutes in patients undergoing CRS for intraperitoneal malignancy remain limited.

Given the substantial morbidity associated with post-peritonectomy complications and the absence of standardized reconstructive strategies, there exists a clear unmet clinical need for interventions that enhance intra-abdominal healing without compromising oncologic safety. This need is particularly relevant in resource-conscious healthcare systems, where reducing postoperative complications has direct implications for patient outcomes and system sustainability.

Accordingly, this prospective, multicenter, randomized controlled trial was designed to evaluate the safety and efficacy of HPTC as a peritoneal substitute following peritonectomy in patients undergoing CRS for intraperitoneal malignancies. The primary objective was to determine whether the use of an HPTC scaffold reduces the incidence of major postoperative intra-abdominal complications compared with standard care without peritoneal reconstruction. Secondary objectives included assessment of individual complication rates, bowel function recovery, length of hospital and intensive care stay, device-related adverse events, radiologic evidence of adhesions, and patient-reported quality of life outcomes using a validated instrument.

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## Materials and Methods

### Study Design and Setting

This study was designed as a prospective, multicenter, open-label, randomized controlled clinical trial evaluating the safety and efficacy of a high-purity Type I collagen–based biomaterial (HPTC) as a peritoneal substitute following peritonectomy in patients undergoing cytoreductive surgery (CRS) for intraperitoneal malignancies. The trial was conducted at two tertiary referral centers specializing in oncologic and reconstructive surgery.

The trial was conducted at two tertiary oncology referral centers – JSS Academy of Higher Education and Research, Mysuru and Adichunchanagiri Institute of Medical Sciences, B G Nagara. The trial was registered prospectively prior to initiation of patient recruitment at ClinicalTrials.gov (Identifier: NCT07241091) (url: https://clinicaltrials.gov/study/NCT07241091) and approved by the Institutional Ethics Committee (Approval No.: AIMS/IEC/266/2025). The authors confirm that all ongoing and related clinical trials involving this intervention are registered.

Patient recruitment was conducted between 02/11/2025 and 21/02/2026. Clinical follow-up continued until 30/10/2026 following protocol-approved extension of follow-up duration to 6 months. Written informed consent was obtained from all participants prior to enrollment and surgery. The study was conducted in accordance with the principles of the Declaration of Helsinki, Good Clinical Practice (GCP) guidelines, and Consolidated Standards of Reporting Trials (CONSORT) recommendations [18]. Institutional Ethics Committee approval was obtained at all participating centers prior to patient enrollment. Written informed consent was obtained from all participants prior to enrollment.

### Study Population

Patients were consecutively screened for eligibility during multidisciplinary tumor board evaluation at participating centers. Adults aged 18–75 years with histologically confirmed peritoneal surface malignancy (including colorectal, ovarian, appendiceal, pseudomyxoma peritonei, or malignant peritoneal mesothelioma) scheduled to undergo cytoreductive surgery with anticipated peritonectomy, with or without hyperthermic intraperitoneal chemotherapy, were considered eligible. Additional inclusion criteria included Eastern Cooperative Oncology Group (ECOG) performance status 0–2 [19], adequate hematologic, renal, and hepatic function, and ability to provide written informed consent.

Exclusion criteria comprised known hypersensitivity to collagen-based products, active intra-abdominal infection or uncontrolled sepsis, chronic immunosuppression or long-term systemic corticosteroid therapy, pregnancy or lactation, extensive small-bowel resection precluding safe reconstruction, and emergency surgery or bowel perforation at presentation. (Figure 1)

### Randomization and Allocation

Eligible patients were randomized in a 1:1 ratio to either the intervention group (HPTC peritoneal reconstruction) or the control group (standard care without peritoneal reconstruction). Randomization was performed using a computer-generated block randomization sequence with variable block sizes to ensure balanced group allocation across participating centers.

Allocation concealment was achieved using sealed, opaque envelopes opened intraoperatively after completion of cytoreduction and confirmation of peritoneal defect suitability. Due to the nature of the surgical intervention, blinding of the operating surgeon was not feasible. However, outcome assessors, radiologists evaluating imaging studies, and statisticians were blinded to treatment allocation wherever applicable. Quality-of-life assessments were administered using standardized validated questionnaires and were collected independently of the operating surgical team.

## Surgical Procedure and Intervention

### Cytoreductive Surgery and Peritonectomy

All patients underwent CRS performed by experienced surgical oncologists following standardized institutional protocols. The goal of CRS was complete or near-complete macroscopic tumor clearance (CC-0 or CC-1 resection). Peritonectomy procedures were carried out as required based on disease distribution and included parietal and/or visceral peritoneal stripping.

The use of HIPEC was permitted and performed according to tumor-specific protocols but was evenly distributed between study arms.

### Intervention Group: HPTC Peritoneal Reconstruction

In patients randomized to the intervention arm, peritoneal defects created following peritonectomy were reconstructed using HPTC (Surgicoll-Mesh®), a sterile, resorbable HPTC scaffold. The mesh was tailored intraoperatively to match the dimensions of the peritoneal defect and secured using interrupted absorbable sutures to adjacent tissue margins prior to abdominal closure. The biomaterial was applied without tension and without overlap onto visceral organs. The scaffold was applied selectively to parietal and accessible visceral peritoneal defects created during peritonectomy (Figure 2). The additional operative time required for scaffold application was approximately 10–15 minutes per patient, depending on the extent of peritoneal defects.

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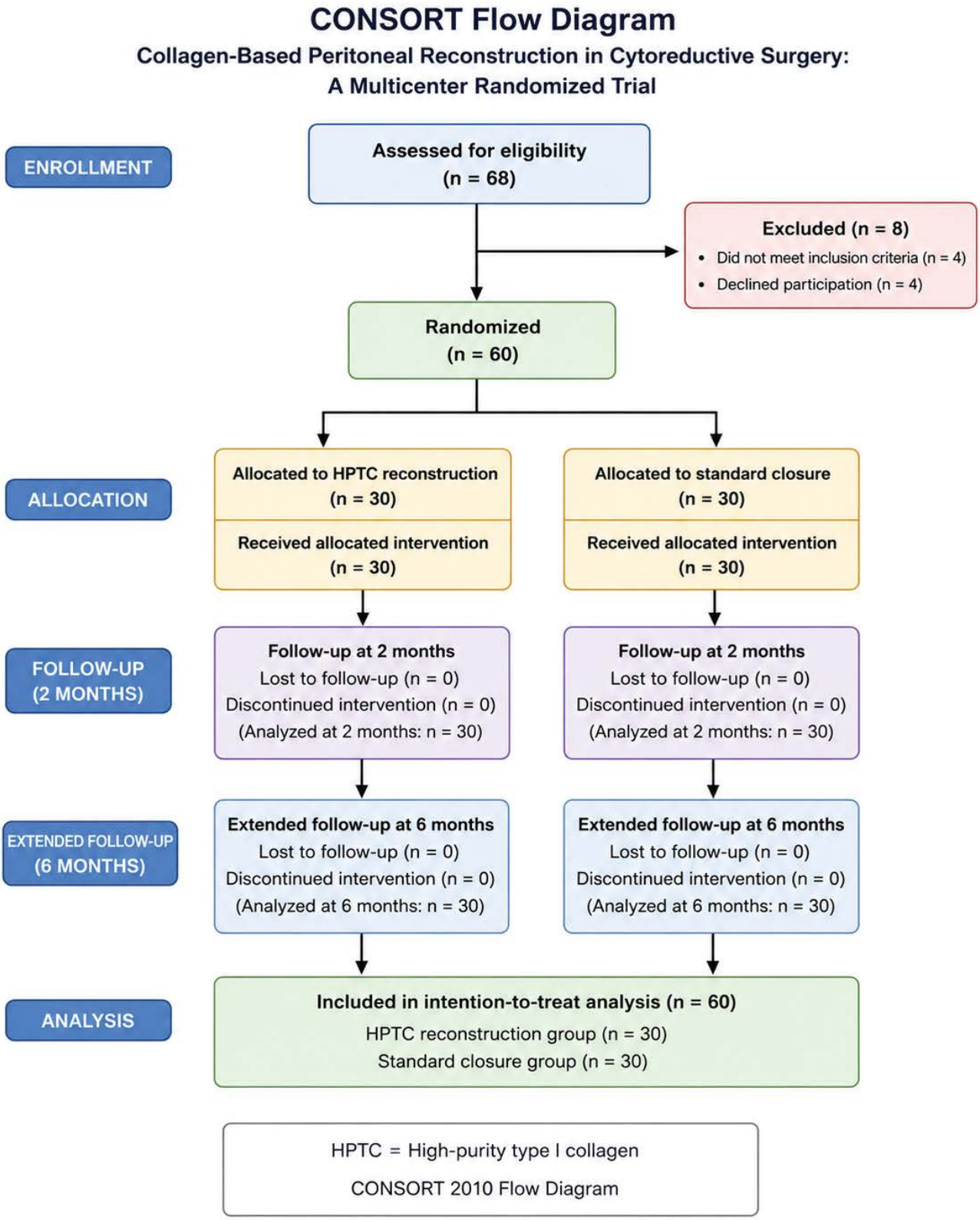


CRS = Cytoreductive Surgery; HIPEC = Hyperthermic Intraperitoneal Chemotherapy; ITT = Intention-to-Treat analysis; n = number of patients; PSM = Peritoneal Surface Malignancy.

**Figure 1:** CONSORT flow diagram illustrating patient enrollment, randomization, allocation, follow-up, and analysis.

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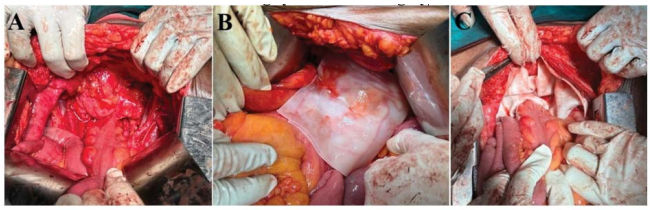


**Figure Figure 12:** Intraoperative application of high-purity type I collagen - peritoneal substitute during cytoreductive surgery.

The mesh was intended to function as a biologic barrier and regenerative scaffold, facilitating organized tissue remodeling during the early postoperative period [9-11].

Exposure following cytoreductive surgery and peritonectomy demonstrating the peritoneal defect and exposed visceral surfaces prior to reconstruction (A); Placement of the high-purity type I collagen scaffold over the peritoneal defect (B); Final positioning of the collagen scaffold over the peritonectomy area prior to abdominal closure, ensuring adequate coverage of the denuded peritoneal surfaces (C).

## Control Group: Standard care without peritoneal reconstruction

Patients allocated to the control arm underwent standard care without peritoneal reconstruction, with no peritoneal substitute or biomaterial used. Peritoneal defects were left untreated, allowing secondary healing according to standard institutional practice.

## Postoperative Care and Follow-Up

Postoperative management protocols, including analgesia, antibiotic prophylaxis, early mobilization, and nutritional advancement, were standardized across centers. Nasogastric decompression was discontinued at the discretion of the treating team based on bowel function recovery.

Patients were followed for a minimum of two months postoperatively, with scheduled clinical assessments at discharge, 30 days, and 60 days. Imaging studies and quality-of-life assessments were performed according to protocol-defined timelines.

## Extended Follow-Up and Longitudinal Outcome Assessment

To evaluate durability of the intervention, follow-up was extended to 4 months and 6 months postoperatively. Additional outcomes assessed included:

- Late adhesive small bowel obstruction
- Incisional hernia
- Persistent or recurrent adhesions on imaging
- Longitudinal quality-of-life outcomes (EORTC QLQ-C30)
- Late complications and reinterventions

Follow-up data were collected through scheduled outpatient visits and structured telephonic interviews when necessary.

## Outcome Measures

Primary Outcome

The primary outcome was the incidence of major intra-abdominal complications within two months following surgery. Major complications were predefined as:

- Adhesive small bowel obstruction requiring intervention
- Enterocutaneous fistula
- Reoperation for intra-abdominal complication
- Grade ≥3 wound complications based on the Clavien–Dindo classification

## Secondary Outcomes

Secondary outcomes included:

- Individual complication rates, including intraperitoneal adhesions, small bowel obstruction (SBO), surgical site infection, incisional hernia, and fistula formation
- Time to bowel function recovery, defined as the time to first flatus and tolerance of oral diet
- Length of intensive care unit (ICU) stay and total hospital stay
- Device-related adverse events, including infection, inflammatory reaction, or mesh-related complications
- Radiologic assessment of adhesions or obstruction using magnetic resonance imaging (MRI) at baseline, one month, and two months
- Quality of life assessment using the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30), a validated cancer-specific instrument [20]
- Extended Follow-Up - Late SBO (>2 months), Adhesion persistence (MRI at 6 months), Incisional hernia (mid-term), QoL trajectory (longitudinal), Time to event (complication-free survival)

MRI-based adhesion assessment was performed using predefined radiologic criteria, including bowel tethering, restricted visceral movement, and presence of soft tissue bridging. Imaging was independently evaluated by blinded radiologists. Given the absence of a universally accepted scoring system, a standardized qualitative assessment approach was used across centers.

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### Sample Size Calculation

Based on prior literature reporting overall postoperative complication rates of approximately 40–45% following extensive peritonectomy, and in the absence of robust data specifically for major intra-abdominal complications, an effect size reflecting a clinically meaningful reduction in significant postoperative morbidity was assumed for sample size estimation. The required sample size for comparing two independent proportions was estimated using the formula:

$$n = ((Z1-\alpha/2 + Z1-\beta)^2 \times [p1(1-p1) + p2(1-p2)]) / (p1-p2)^2$$

where p1 represents the expected complication rate in the control group and p2 the expected rate in the intervention group, $Z_{1-\alpha/2}$ corresponds to the two-sided significance level $\alpha$=0.05, and $Z_{1-\beta}$ to the desired power (80%). Assuming p1=0.40 and p2=0.20, the calculated minimum sample size was 26 patients per group. To account for potential dropouts and protocol deviations, 30 patients were enrolled in each arm, yielding a total sample size of 60 participants.

### Statistical Analysis Plan

Statistical analyses were performed using SPSS version 29.0 (IBM Corp., Armonk, NY, USA). Continuous variables were assessed for normality using the Shapiro–Wilk test and are presented as mean ± standard deviation for normally distributed data or median with interquartile range for non-normally distributed data. Between-group comparisons were conducted using the independent t-test or Mann–Whitney U test for continuous variables and the chi-square test or Fisher's exact test for categorical variables, as appropriate. Effect estimates for the primary and key secondary binary outcomes were expressed as relative risks with 95% confidence intervals. Time-to-event outcomes, including time to bowel function recovery, were analyzed using Kaplan–Meier survival curves with log-rank testing. Multivariable logistic regression analysis was performed to adjust for potential confounders, including age, primary tumor type, peritoneal cancer index score, and use of hyperthermic intraperitoneal chemotherapy. All statistical tests were two-sided, and a p-value < 0.05 was considered statistically significant. Analyses were conducted on an intention-to-treat basis. Confidence intervals were reported for all primary and key secondary outcomes. Exploratory analyses, including ROC and correlation analyses, were conducted for hypothesis-generating purposes and should be interpreted cautiously.

### Data Management and Ethical Considerations

All data were prospectively collected using standardized case report forms and anonymized prior to analysis. Data integrity was ensured through regular monitoring and cross-verification. The study included a predefined plan for de-identified individual participant data (IPD) sharing upon reasonable request following publication.

## Results

### Study Population and Patient Flow

A total of 68 patients were assessed for eligibility during the study period. Eight patients were excluded (four did not meet inclusion criteria, four declined participation). The remaining 60 patients were randomized in a 1:1 ratio to the HPTC group (n = 30) or the standard care without peritoneal reconstruction group (n = 30). All randomized patients completed the planned intervention and were included in the intention-to-treat analysis. No patients were lost to follow-up at the two-month assessment.

### Baseline Demographic and Clinical Characteristics

Baseline demographic, oncologic, and operative characteristics were comparable between the two groups, with no statistically significant differences observed, confirming successful randomization (Table 1).

**Table 1:** Baseline demographic and operative characteristics

| Variable | HPTC (n = 30) | Control (n = 30) | p-value |
|---|---|---|---|
| Age, years (mean ± SD) | 54.6 ± 9.8 | 56.1 ± 10.2 | 0.54 |
| Male sex, n (%) | 17 (56.7) | 16 (53.3) | 0.79 |
| ECOG performance status 0–1, n (%) | 26 (86.7) | 25 (83.3) | 0.71 |
| Primary malignancy – colorectal, n (%) | 12 (40.0) | 11 (36.7) | 0.79 |
| Ovarian malignancy, n (%) | 9 (30.0) | 10 (33.3) | 0.78 |
| Other PSMs*, n (%) | 9 (30.0) | 9 (30.0) | 1.00 |
| Peritoneal Cancer Index (PCI), mean ± SD | 17.8 ± 4.9 | 18.3 ± 5.2 | 0.68 |
| HIPEC performed, n (%) | 21 (70.0) | 22 (73.3) | 0.78 |
| CC-0/CC-1 cytoreduction, n (%) | 28 (93.3) | 27 (90.0) | 0.64 |

*Includes appendiceal neoplasms, pseudomyxoma peritonei, and mesothelioma.

The extent and type of surgical procedures, including bowel resections and multi-visceral resections, were comparable between groups, with no statistically significant differences observed, supporting procedural balance between study arms.

The proportion of patients achieving optimal cytoreduction (CC-0/CC-1) exceeded 90% in both groups, with no significant intergroup difference, minimizing potential confounding due to completeness of cytoreduction. Although most patients achieved optimal cytoreduction (CC-0/CC-1), a small proportion of higher CC scores may introduce minor heterogeneity.

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### Primary Outcome: Major Intra-Abdominal Complications

Major postoperative complications occurred in 4 patients (13.3%) in the HPTC group compared with 11 patients (36.7%) in the control group. This corresponds to Relative Risk (RR) of 0.36 with 95% CI equaling 0.13–0.99 and statistically significant p = 0.049, representing a 64% relative reduction in major postoperative morbidity.

**Table 2:** Primary outcome – major intra-abdominal complications

| Outcome | HPTC (n=30) | Control (n=30) | RR | p-value |
|---|---|---|---|---|
| Major complication | 4 (13.3%) | 11 (36.7%) | 0.36 | 0.049 |
| Reoperation | 0 (0%) | 6 (20%) | — | 0.024 |
| Clavien ≥III | 2 (6.7%) | 7 (23.3%) | 0.29 | 0.15 |

Reoperation for intra-abdominal complications occurred in 6 patients (20%) in the control group, while no patient in the HPTC group required reoperation (p=0.024).

Severe complications defined as Clavien–Dindo grade ≥III occurred in 2 patients (6.7%) in the HPTC group and 7 patients (23.3%) in the control group, with RR = 0.29. (Table 2)

In cases where multiple complications occurred in a single patient, events were classified according to the most severe complication to avoid duplication within the composite endpoint.

## Secondary Outcomes

### Individual Postoperative Complications

Evaluation of individual postoperative complications demonstrated consistently lower event rates in patients undergoing peritoneal reconstruction with HPTC compared with standard care without peritoneal reconstruction. Adhesive small bowel obstruction occurred in 1 patient (3.3%) in the HPTC group compared with 8 patients (26.7%) in the control group, corresponding to an 87% relative reduction in risk (RR 0.13; p = 0.028).

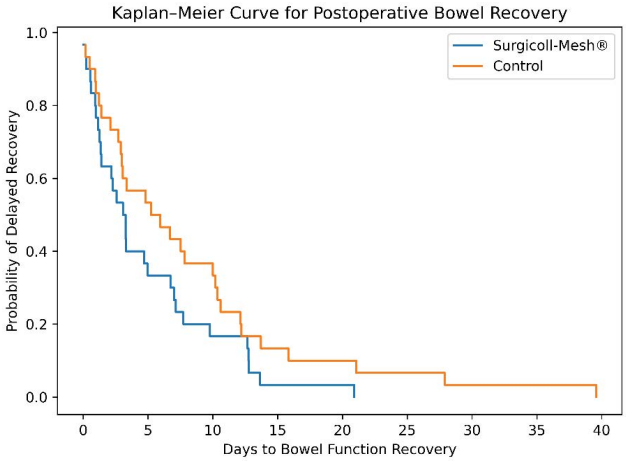
Enterocutaneous fistula formation was observed in three patients (10.0%) in the control group, whereas no cases were recorded in the HPTC group. Surgical site infections were also less frequent in the HPTC group, occurring in one patient (3.3%) compared with three patients (10.0%) in the control arm. Similarly, early incisional hernia was documented in two patients (6.7%) in the control group but was not observed in any patient receiving HPTC reconstruction.

MRI assessment performed during follow-up demonstrated dense intra-abdominal adhesions in 3 patients (10.0%) in the HPTC group compared with 12 patients (40.0%) in the control group, representing a 75% relative reduction in adhesion formation (RR 0.25; p = 0.018). (Table 3)

**Table 3:** Individual postoperative complication rates

| Complication | HPTC | Control | RR | p-value |
|---|---|---|---|---|
| Adhesive small bowel obstruction | 1 (3.3%) | 8 (26.7%) | 0.13 | 0.028 |
| Enterocutaneous fistula | 0 | 3 (10%) | — | 0.24 |
| Surgical site infection | 1 (3.3%) | 3 (10%) | 0.33 | 0.61 |
| Incisional hernia (early) | 0 | 2 (6.67%) | — | 0.49 |
| MRI-detected dense adhesions | 3 (10%) | 12 (40%) | 0.25 | 0.018 |

All cases of enterocutaneous fistula occurred in patients who had undergone bowel resection. Adhesive bowel obstruction was diagnosed based on combined clinical and radiologic criteria; not all cases required surgical intervention, and selected patients were managed conservatively without reoperation.




Kaplan–Meier analysis comparing time to bowel function recovery between patients receiving HPTC peritoneal reconstruction and those undergoing standard care without peritoneal reconstruction. The HPTC group demonstrates earlier recovery of bowel function, indicating faster postoperative gastrointestinal recovery.

**Figure 3:** Kaplan–Meier Curve for Time to Postoperative Bowel Function Recovery.

### Time to Bowel Function Recovery

Patients in the HPTC group experienced significantly faster bowel recovery, with earlier return of flatus and oral intake. Kaplan–Meier analysis demonstrated a shorter median time to bowel function recovery (4.2 days vs 6.1 days; log-rank p = 0.002) (Figure 3).

### Length of ICU and Hospital Stay

Use of HPTC was associated with significantly reduced ICU and total hospital stay. (Table 4)

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**Table 4:** Postoperative recovery parameters.

| Parameter | HPTC | Control | Mean difference | p-value |
|---|---|---|---|---|
| ICU stay, days (mean ± SD) | 1.9 ± 1.1 | 3.1 ± 1.4 | −1.2 days | 0.001 |
| Hospital stay, days (mean ± SD) | 9.8 ± 2.6 | 13.4 ± 3.1 | −3.6 days | <0.001 |

## Device-Related Adverse Events

No device-related infections, inflammatory reactions, or foreign-body responses were observed in the HPTC group. There were no instances of device explantation. Device safety was therefore deemed excellent within the study follow-up period.

## Radiologic Outcomes (MRI Assessment)

Magnetic resonance imaging performed at one and two months postoperatively demonstrated a substantially lower incidence of dense intra-abdominal adhesions and bowel tethering in patients receiving HPTC reconstruction compared with standard care without peritoneal reconstruction. Dense adhesions were identified in 3 patients (10.0%) in the HPTC group compared with 12 patients (40.0%) in the control group, corresponding to a 75% relative risk reduction (RR 0.25, 95% CI 0.08–0.74, p = 0.018).

Patients with MRI-detected dense adhesions were significantly more likely to develop postoperative bowel obstruction. Correlation analysis demonstrated a strong positive relationship between radiologic adhesions and bowel obstruction events (Spearman's $\rho = 0.64$, $p < 0.001$).

The presence of dense adhesions on MRI was associated with a markedly increased likelihood of adhesive bowel obstruction, with an estimated odds ratio (OR) of approximately 4.0 compared with patients without radiologic adhesions.

Diagnostic performance analysis demonstrated that MRI-detected dense adhesions had a sensitivity of approximately 89% and specificity of approximately 60% for predicting adhesive bowel obstruction in this cohort. The negative predictive value exceeded 90%, indicating that patients without radiologic adhesions were highly unlikely to develop clinically significant bowel obstruction during follow-up.

ROC analysis demonstrated good predictive ability of MRI-detected adhesions for postoperative bowel obstruction (AUC ≈ 0.88) (Figure 4). Forest plot analysis demonstrated consistent reductions in postoperative complication risk in the HPTC group (Figure 5).

Receiver operating characteristic (ROC) curve showing the predictive value of postoperative MRI-detected dense adhesions for adhesive small bowel obstruction following cytoreductive surgery. The model demonstrated good diagnostic performance (AUC ≈ 0.88) with high sensitivity and specificity, indicating strong correlation between radiologic adhesions and clinical obstruction.

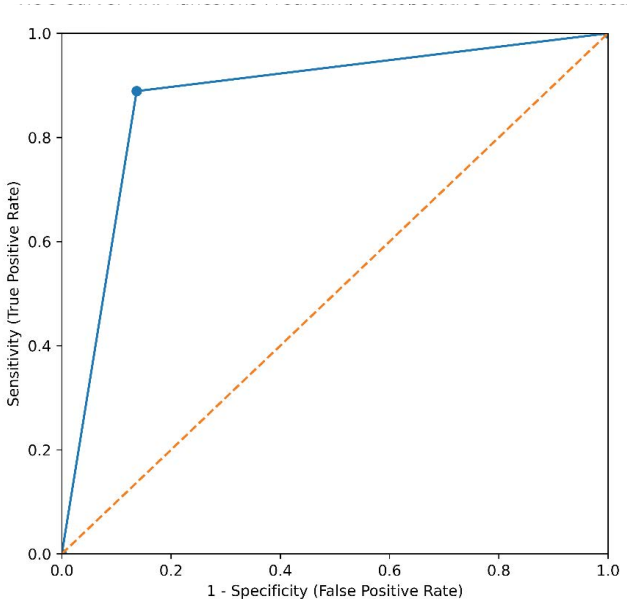


**Figure 4:** ROC Curve for Prediction of Adhesive Small Bowel Obstruction AUC = 0.88 (95% CI 0.79-0.96) Using MRI-Detected Dense Adhesions.

Forest plot illustrating the relative risk (RR) with 95% confidence intervals for major complications and secondary outcomes comparing HPTC reconstruction with standard care without peritoneal reconstruction. Most estimates favor HPTC, particularly for adhesion-related outcomes.

## Quality of Life Outcomes

Baseline EORTC QLQ-C30 scores were comparable between groups [20]. At two months, the HPTC group demonstrated significantly greater improvement in global health status and functional domains. (Table 5)

To provide a consolidated overview of treatment effects across multiple postoperative outcomes, a forest plot analysis was performed comparing the relative risk of complications between the HPTC and control groups. The

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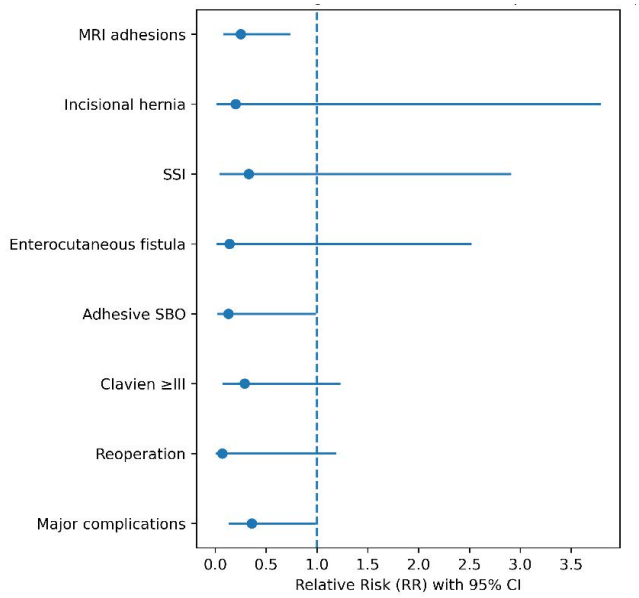


Forest plot illustrating the relative risk (RR) with 95% confidence intervals for major complications and secondary outcomes comparing HPTC reconstruction with standard care without peritoneal reconstruction. Most estimates favor HPTC, particularly for adhesion-related outcomes.

**Figure 5:** Forest Plot of Relative Risk for Postoperative Complications

analysis demonstrated a consistent trend toward reduced postoperative morbidity with HPTC, with the greatest relative risk reductions observed for adhesion-related outcomes, particularly adhesive small bowel obstruction and MRI-detected dense adhesions.

## Extended follow-up analysis

Extended follow-up analysis demonstrated sustained reduction in adhesion-related morbidity and persistent radiologic benefit in patients undergoing HPTC reconstruction. Comparison of late adhesion-related complications, persistent radiologic adhesions, incisional hernia, and reintervention rates between the HPTC and control groups during extended follow-up after cytoreductive surgery.

Quality-of-life outcomes were assessed using the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30). Quality-of-life improvements observed at 2 months remained sustained throughout extended follow-up. Comparison of changes in global health status and functional recovery between patients undergoing HPTC peritoneal reconstruction and standard care without peritoneal reconstruction at serial postoperative time points.

**Table 5:** Quality of life outcomes (EORTC QLQ-C30).

| Domain | HPTC (mean change) | Control (mean change) | p-value |
|---|---|---|---|
| Global health status | +18.6 ± 7.4 | +9.2 ± 6.8 | <0.001 |
| Physical functioning | +15.1 ± 6.9 | +8.3 ± 7.1 | 0.002 |
| Pain (symptom scale) * | −21.4 ± 8.1 | −11.7 ± 7.9 | <0.001 |

*Lower scores indicate improvement.

**Table 6:** Extended Outcomes at 4 and 6 Months.

| Outcome | HPTC | Control | p-value |
|---|---|---|---|
| Late SBO | 1 (3.3%) | 5 (16.7%) | 0.08 |
| Incisional hernia | 1 (3.3%) | 4 (13.3%) | 0.16 |
| Persistent adhesions (MRI) | 4 (13.3%) | 14 (46.7%) | 0.01 |
| Reintervention | 0 | 3 (10%) | 0.07 |

Values are presented as number (%) unless otherwise specified. Persistent adhesions were assessed using MRI-based predefined radiologic criteria. Late adhesive small bowel obstruction was defined as bowel obstruction occurring beyond the initial 2-month postoperative period. Reintervention included any procedure performed for postoperative intra-abdominal complications during follow-up.

**Table 7:** Longitudinal Quality-of-Life Outcomes.

| Time | HPTC | Control | p-value |
|---|---|---|---|
| Baseline | similar | similar | — |
| 2 months | ↑↑ | ↑ | <0.001 |
| 4 months | sustained | moderate | <0.001 |
| 6 months | stable high | plateau | <0.001 |

Values represent mean change from baseline scores. Higher functional and global health scores indicate improvement. Longitudinal analysis was performed using repeated measures ANOVA.

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**Table 8:** Subgroup Outcomes.

| Subgroup | Outcome | HPTC | Control |
|---|---|---|---|
| High PCI | Major complications | 18% | 45% |
| HIPEC | Adhesions | 12% | 38% |
| Bowel resection | SBO | 5% | 28% |

High PCI was defined as PCI >20. Adhesion-related outcomes included adhesive small bowel obstruction and MRI-detected dense adhesions. Percentages represent within-subgroup event rates. Subgroup analyses were exploratory and not powered for definitive statistical inference.

Exploratory subgroup analyses demonstrated consistent benefit of HPTC across varying operative complexity and oncologic burden. Subgroup comparison of major postoperative complications and adhesion-related outcomes stratified by Peritoneal Cancer Index (PCI), use of HIPEC, and bowel resection status.

## Discussion

The present prospective, multicenter randomized controlled trial suggests that peritoneal reconstruction using a high-purity Type I collagen (HPTC)–based biomaterial following peritonectomy during cytoreductive surgery (CRS) may reduce postoperative intra-abdominal morbidity compared with standard care without peritoneal reconstruction. Across both primary and secondary endpoints, the use of HPTC was associated with lower rates of major complications (64% reduction), reduced adhesion-related sequelae, faster gastrointestinal recovery, shorter ICU and hospital stay, and superior patient-reported quality-of-life outcomes, without an increase in device-related adverse events.

### Interpretation of Primary Outcome

Major complications following CRS remain a major clinical challenge, with reported rates ranging from 30–50% in large series [21-24]. In the present study, the complication rate in the control group (36.7%) is consistent with these reports.

The observed major-complication rate was lower in the HPTC group (13.3%) than in the control group (36.7%). No reoperations occurred in the HPTC group, compared with six (20%) in the control group.

Reoperation following CRS is associated with increased mortality, prolonged hospitalization, and delayed adjuvant therapy [25]. The absence of reoperations in the HPTC group is a potentially important finding. Given the small sample size, this result should be interpreted cautiously and confirmed in larger studies.

### Adhesion Prevention and Bowel Recovery

Adhesion formation is a major contributor to postoperative complications following peritonectomy. Peritoneal injury leads to fibrin deposition, inflammatory cell recruitment, and fibrotic bridging between visceral surfaces [26].

The observed reduction in enterocutaneous fistula formation may be explained by indirect mechanisms. By restoring a protective peritoneal interface and reducing adhesion-related inflammation, the collagen scaffold may decrease abnormal bowel tethering, localized ischemia, and mechanical stress on anastomotic sites. This more favorable intra-abdominal environment may contribute to improved anastomotic integrity despite the scaffold not being applied directly over bowel segments.

In the present study, HPTC reduced radiologic adhesion formation by 75%, with MRI demonstrating dense adhesions in only 10% of treated patients compared with 40% of controls.

These findings are consistent with the proposed biological mechanism of collagen scaffolds as temporary barriers that facilitate organized mesothelial regeneration while preventing fibrin-mediated adhesion formation.

### Extended Follow-Up

A key strength of this study is the extension of follow-up to 6 months, allowing evaluation of early durability of peritoneal reconstruction. Lower rates of adhesion-related outcomes and improved quality-of-life scores were observed through six months. Longer follow-up is needed to determine whether these differences persist and reflect durable peritoneal healing.

### Biological Rationale for HPTC

The favorable outcomes observed in this trial are biologically plausible and consistent with the known properties of HPTC scaffolds. HPTC serves as a native extracellular matrix component providing a three-dimensional framework that supports cellular migration, angiogenesis, and tissue remodeling while modulating the inflammatory response [9–11]. HPTC scaffolds are bioresorbable and integrate gradually into host tissue, minimizing chronic foreign-body reactions.

The stringent purification process and the Type-I collagen phosphorylation used in Surgicoll-Mesh® production are particularly relevant, as it reduces immunogenicity and variability while preserving the structural integrity necessary for regenerative support [17]. This distinction may explain the absence of device-related complications in the present study, even in a high-risk surgical environment involving extensive tissue dissection and, in many cases, HIPEC.

Importantly, the oncologic safety of collagen-based biomaterials remains a critical consideration in cancer surgery. Available preclinical and clinical evidence suggests

that HPTC scaffolds are biologically inert with respect to tumor promotion and do not stimulate malignant proliferation. These biomaterials have been widely used in oncologic and reconstructive settings without evidence of increased recurrence risk. In the present study, no early signals of tumor progression or adverse oncologic behavior were observed; however, longer-term follow-up is required to definitively establish oncologic safety in this setting.

### Comparison With Existing Literature

Data evaluating peritoneal substitutes following CRS are limited. Most prior investigations have focused on abdominal wall reconstruction rather than peritoneal regeneration. Tzivanakis et al. reported that biological meshes could be safely used for abdominal wall reconstruction during CRS without increased infectious complications [12]. While informative, their study did not specifically address peritoneal healing or adhesion-related outcomes.

In contrast, the current trial extends the application of biological scaffolds to true peritoneal substitution, demonstrating safety along with encouraging signals of efficacy in reducing postoperative morbidity. Furthermore, the results align with accumulating evidence from other surgical domains in which HPTC-based biomaterials have shown superior outcomes compared with alternative biological substitutes, particularly in contaminated or high-inflammatory environments [13–16, 27-29].

The observed improvement in quality-of-life outcomes, as measured by the EORTC QLQ-C30, is also noteworthy. While many surgical studies focus primarily on complication rates, patient-reported outcomes are increasingly recognized as essential indicators of treatment success. The greater improvement in global health status, physical functioning, and pain scores in the HPTC group suggests that anatomical and physiological benefits translated into meaningful patient-perceived recovery.

### Clinical and Economic Implications

These results may inform future evaluations of HPTC-based peritoneal reconstruction in cytoreductive surgery. Larger studies should establish its effectiveness, safety, and cost implications before routine use is considered. Reduced complication rates, faster bowel recovery, and shorter hospital stays may facilitate earlier initiation of adjuvant therapies and improve overall treatment timelines.

Economically, although biologic materials entail an upfront cost, the reduction in ICU utilization, hospital length of stay, reoperations, and adhesion-related readmissions may offset these expenses. This consideration is particularly relevant in resource-constrained healthcare settings, where preventing postoperative complications can have a disproportionate impact on system sustainability [30, 31].

### Strengths of the Study

This study's key strength lies in its prospective, randomized controlled design, providing high-level evidence for evaluating a surgical regenerative intervention. The multicenter setting enhances generalizability while maintaining standardized operative and postoperative protocols. The trial uniquely addresses an unmet clinical need by evaluating a true peritoneal substitute following peritonectomy rather than indirect reconstructive strategies. Use of objective clinical endpoints, supplemented by MRI-based adhesion assessment and validated patient-reported outcomes (EORTC QLQ-C30), allowed comprehensive evaluation of anatomical, functional, and quality-of-life benefits. Finally, the consistent improvement across multiple clinically meaningful outcomes, coupled with good safety profile, strengthens the translational relevance of the findings.

## Limitations

Several limitations of this study warrant consideration. First, although randomized and multicenter, the sample size was modest and powered primarily for short-term postoperative outcomes. The sample size calculation was based on overall postoperative complication rates due to limited available data specifically for major intra-abdominal complications, which may represent a methodological limitation. Hence, the above exploratory analyses should be interpreted cautiously given the limited sample size. Larger trials with longer follow-up are necessary to evaluate late adhesion-related complications and long-term oncologic outcomes. Second, the open-label design may introduce performance bias; however, objective endpoints and blinded outcome assessment were employed to mitigate this risk. Third, while MRI provided valuable radiologic insight into adhesion formation, laparoscopy remains the gold standard for adhesion assessment and was not ethically justifiable in this context. Fourth, the inclusion of heterogeneous tumor types and variability in HIPEC use may influence outcomes and limit subgroup-specific interpretation.

While follow-up was extended to 6 months, longer-term outcomes including late adhesive complications and oncologic safety require further evaluation.

These findings should therefore be interpreted as preliminary. Longer-term follow-up will be required to assess durability of the regenerative effect and potential late sequelae.

## Future Directions

Future studies should explore the role of HPTC-based peritoneal substitutes in larger cohorts, with stratification by tumor type, PCI score, and HIPEC protocols. Comparative effectiveness studies against other anti-adhesion strategies

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and cost-effectiveness analyses would further strengthen the evidence base. Additionally, translational research examining mesothelial regeneration at the cellular level may provide mechanistic insights into the observed clinical benefits.

In summary, this randomized controlled trial provides prospective clinical evidence suggesting that HPTC-based biomaterial may be a safe and effective peritoneal substitute following peritonectomy in patients undergoing cytoreductive surgery for intraperitoneal malignancies [32]. By significantly reducing postoperative complications, accelerating recovery, and improving quality of life, HPTC-based peritoneal reconstruction represents a promising regenerative strategy with the potential to improve both surgical and patient-centered outcomes [33, 34].

## Conclusion

This multicenter randomized trial found that HPTC-based peritoneal reconstruction was associated with lower postoperative morbidity and faster recovery than standard peritonectomy closure. No device-related adverse events were observed during the six-month follow-up. Given the modest sample size and short follow-up, these findings should be considered preliminary. Larger trials with longer follow-up are needed before routine use can be recommended.

## Ethics approval and consent to participate

The study was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines. Ethical approval was obtained from the Institutional Ethics Committee of Adichunchanagiri Institute of Medical Sciences (Approval No.: AIMS/IEC/266/2025) and from the Institutional Ethics Committees of the participating centers. The trial was prospectively registered at ClinicalTrials.gov (Identifier: NCT07241091). Written informed consent was obtained from all participants prior to enrolment.

## Consent for publication

Written informed consent for publication of anonymized clinical data and intraoperative images was obtained from all participants. No identifiable personal information is included in this manuscript.

## Availability of data and materials

The datasets generated and analysed during the current study are available from the corresponding author on reasonable request. Data are stored in a secure institutional research database with coded participant identifiers to ensure confidentiality.

## Competing interests

The authors declare that they have no competing financial or non-financial interests related to this study. The investigators had full control of study design, data collection, analysis, interpretation, and manuscript preparation. The manufacturer of the collagen matrix had no role in the conduct or reporting of the study.

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## Authors' contributions

RK - performed surgeries, patient recruitment, clinical assessments and drafted the manuscript

NN - conceived the study, supervised data collection, and drafted the manuscript.

ANM - contributed to surgical procedures, and clinical assessments.

RKN and SSD participated in patient recruitment, contributed to surgical procedures, data acquisition, follow-up evaluations, and database management.

All authors contributed to study design, critically revised the manuscript for intellectual content, and approved the final version.

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