Original Article

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Surgery Section

# Effectiveness of Seprafilm in Reducing Postoperative Adhesions after Abdominopelvic Surgery: A Prospective Interventional Study

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## ABSTRACT

**Introduction:** Postoperative adhesions are indeed a significant concern following abdominopelvic surgeries. These fibrous bands of tissue can form between abdominal or pelvic organs and tissues, leading to various complications. Postoperative Peritoneal Adhesions (PPAs) barriers are safer and better because they lower the risk of illness and the need for repeated interventions. Various agents and techniques have been studied to prevent PPAs, including activating fibrinolysis, interrupting blood coagulation, inhibiting collagen synthesis, reducing cellular inflammatory responses, and creating a physical barrier between the wound and surrounding tissue or organ. Seprafilm acts as a physical barrier on wounded tissue surfaces, minimising tissue adhesions during wound healing.

**Aim:** To compare the outcomes of patients undergoing abdominopelvic surgery with and without Seprafilm application, in terms of adhesion formation and complication rates.

**Materials and Methods:** The present prospective interventional study was conducted at SRM Medical College Hospital and Research Centre, Chennai, Tamil Nadu, India, from July 2023 to December 2024. In this study, group A, 50 patients underwent surgery with the use of Seprafilm, while group B (50 patients) underwent surgery without the use of Seprafilm. The outcomes measured were: postoperative complications, 20th day adhesions as seen in CT abdomen, postoperative pain, and intraoperative blood loss. Blood loss was estimated using a Gauze Visual Analogue (GVA), and pain was estimated using a visual pain analogue.

**Results:** Among the 100 patients, the mean age was 44 years in group A and 45 years in group B, and among the gender distribution, group A had 21 males and 29 female patients, group B had 23 males and 27 female patients. A total of 42 patients (42%) belonged to the age group of <40 years, of which 22 patients (44%) belonged to group A and 20 patients (40%) belonged to group B. In the present study, 10 patients developed postoperative complications in group A and 22 patients developed postoperative complications in group B (p-value=0.010). A total of 34 patients had developed adhesions, among which 8 (23.5%) patients belonged to group A and 26 (76.5%) belonged to group B (p-value=0.001).

**Conclusion:** In this study, the group that used seprafilm as an adhesion barrier following abdominopelvic surgeries had a significant reduction in the incidence of postoperative adhesions compared to the group in which an adhesion barrier was not used.

**Keywords:** Bowel obstruction, Incisional hernia, Peritoneal adhesions, Physical barrier

## INTRODUCTION

Postoperative adhesions are indeed a significant concern following abdominopelvic surgeries. These fibrous bands of tissue can form between abdominal or pelvic organs and tissues, leading to various complications such as severe chronic pain, organ dysfunction and increased requirement for repeated surgeries [1]. Some of the most common complications associated with adhesions included large bowel obstruction, female infertility, adhesive small bowel obstruction, and pelvic pain syndrome [2]. PPAs were formed through the interaction of damaged peritoneum, mesothelium, and inflammatory processes. During the healing and clotting phases, growth factors, cytokines, neuropeptides, cell adhesion molecules, and other bioactive substances were released, resulting in the formation of a fibrinous mass that bound the injured surfaces together [2]. Various growth agents promoted the vascularisation of fibrous tissue, ultimately forming a fibrous band of adhesion [2]. Because adhesions tend to recur after successive procedures, adhesiolysis remains a temporary staple treatment for adhesion removal [1]. The development of barriers to prevent PPAs was considered a safer and more effective approach, as it reduced the risk of complications and minimised the need for repeated surgical interventions. Pharmacologically active agents such as Non Steroidal Anti-inflammatory Drugs (NSAIDs), dexamethasone, and heparin were employed to inhibit PPAs by targeting specific cytokines and reducing vascular permeability [2]. Several types of barriers were employed to prevent postoperative adhesions. These included solution-based agents such as icodextrin, carboxymethyl dextrin, and polyethylene glycol; natural polymers like chitin, chitosan, cellulose, carboxymethyl cellulose, hyaluronic acid, alginate, and gelatine and synthetic polymers such as polyethylene glycol and polyvinyl alcohol [3]. Seprafilm, a globally available mechanical bioresorbable adhesion barrier approved by the Food and Drug Administration (FDA) in 1996, was used to protect adhesiogenic tissues during surgery. It functioned as a physical barrier on injured tissue surfaces, effectively minimising the formation of adhesions throughout the wound healing process [4]. The body absorbs seprafilm gel, After 24-48 hours, the gel forms and lasts up to seven days during tissue repair. Seprafilm disappears on day 28 [5]. Seprafilm is commonly used in gynaecological procedures. In this study, Seprafilm was used for all abdominopelvic surgeries to find the ability to form a physical barrier and thus reduce postoperative adhesions.

## MATERIALS AND METHODS

The present prospective interventional study was conducted at SRM Medical College Hospital and Research Centre, Chennai, Tamil

Nadu, India, from July 2023 to December 2024. Ethical committee approval was obtained (SRMIEC-ST0523-710).

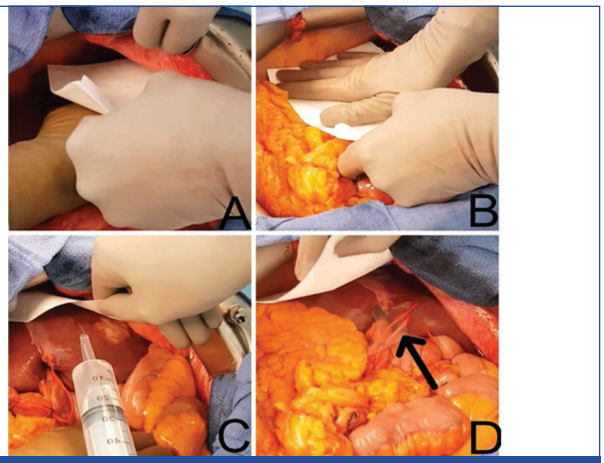
**Inclusion criteria:** Patients aged between 18 and 75 years, planned for a clean elective/emergency laparotomy, and patients who gave informed consent were included.

**Exclusion criteria:** Patients who were scheduled for/undergoing intestinal anastomosis, immunocompromised patients, and patients undergoing laparoscopic surgeries were excluded.

No formal sample size calculation was performed; the sample size of 100 was based on the number of eligible patients recruited during the study period, and they were divided into two groups, with each group consisting of 50 patients, using a simple randomisation method.

### Study Procedure

In the study, group A underwent elective abdominopelvic surgery with the use of Seprafilm as an adhesion barrier. In contrast, group B underwent elective abdominopelvic surgery without the use of Seprafilm. [Table/Fig-1] shows seprafilm placement.




**[Table/Fig-1]:** Seprafilm placement A and B show the fashioning of SepraFilm over bowel loops. C shows separating Seprafilm from its cover using normal saline as lubricant. D- black arrow shows Seprafilm placement.

The outcomes measured were: Postoperative complications, CT 20th day adhesions, postoperative pain, and intraoperative blood loss. Postoperative adhesions were assessed by Computed Tomography (CT) abdomen scan on the 20th postoperative day. Intraoperative blood loss was estimated using GVA; less than 300 mL was considered as minimal blood loss, 300-500 mL was considered as moderate blood loss, and more than 500 mL was considered as severe blood loss [6]. Postoperative pain was assessed using VAS, as no pain (score 0), mild pain (score 1-3), moderate pain (score 4-6), severe pain (score 7-9), very severe pain (score 10) [7].

## STATISTICAL ANALYSIS

Statistical Package for Social Sciences (SPSS) statistical software version 21 and Microsoft Excel were utilised for data computation. Data were analysed using appropriate statistical tests based on the type and distribution of variables. Continuous variables (mean age between group A and group B) were compared using the independent samples t-test, and categorical variables were compared between the two groups using the Chi-square test of independence. A p-value of less than 0.05 was considered statistically significant.

## RESULTS

The most common procedure done in the study was open meshplasty, in 68 patients, out of which 33 (48.5%) belonged to group A and 35 (51.5%) belonged to group B [Table/Fig-2]. Among the 100 patients the mean age was 44 years in group A and 45 years in group B which showed a p-value of 0.975 (not significant) and among the gender distribution group A had 21 male and 29 female patients, group B had 23 male and 27 female patients which showed a p-value of 0.687 (not significant) Out of the 100 patients included in the study, 25 had a previous history of abdominal surgery. Among these, 12 patients (24%) were in group A, and 13 patients (26%) were in group B [Table/Fig-3].Out of the 100 patients enrolled in the study, 10 patients from group A and 22 patients from group B experienced postoperative complications. Among these, 10 patients developed fever, with 3 (30%) belonging to group A and 7 (70%) to group B [Table/Fig-4]. On the 20th postoperative day, patients were followed up with a CT abdomen to assess for adhesions. Among the 100 patients, 34 developed adhesions, of whom 8 (23.5%) were in group A and 26 (76.5%) in group B [Table/Fig-5].

When comparing the postoperative pain, 42 patients experienced minor pain, with 29 (69%) falling into group A and 13 (31%) into category B. Three patients (25%) and 9 (75%) of the 12 patients who experienced significant pain fell into categories A and B, respectively [Table/Fig-6]. Among the patients studied, 23 individuals experienced blood loss between 300-500 mL, of whom 10 (43.4%) were in group A and 13 (56.6%) in group B. Additionally, four patients lost more than 500 mL of blood, with one (25%) belonging to group A and three (75%) to group B. A total of 73 patients had blood loss of less than 300 mL, including 39 (53.4%) from group A and 34 (46.6%) from group B [Table/Fig-7].

| Groups | | Procedure | | | | Total |
|---|---|---|---|---|---|---|
| | | Exploratory Laparotomy | Open cholecystectomy | Open meshplasty | Open splenectomy | |
| Group A | Count | 6 | 7 | 33 | 4 | 50 |
| | % within Group A | 12.0% | 14.0% | 66.0% | 8.0% | 100.0% |
| | % within Procedure | 66.7% | 41.2% | 48.5% | 66.7% | 50.0% |
| Group B | Count | 3 | 10 | 35 | 2 | 50 |
| | % within Group B | 6.0% | 20.0% | 70.0% | 4.0% | 100.0% |
| | % within Procedure | 33.3% | 58.8% | 51.5% | 33.3% | 50.0% |
| Total | Count | 9 | 17 | 68 | 6 | 100 |
| | % within Group | 9.0% | 17.0% | 68.0% | 6.0% | 100.0% |
| | % within Procedure | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |

**[Table/Fig-2]:** Distribution of both the procedures performed in both the group.

| Groups | | Previous Surgery | | Total |
|---|---|---|---|---|
| | | No | Yes | |
| Group A | Count | 38 | 12 | 50 |
| | % within Group A | 76.0% | 24.0% | 100.0% |
| | % within previous surgery | 50.7% | 48.0% | 50.0% |

| | | | | |
|---|---|---|---|---|
| Group B | Count | 37 | 13 | 50 |
| | % within Group B | 74.0% | 26.0% | 100.0% |
| | % within previous surgery | 49.3% | 52.0% | 50.0% |
| | Count | 75 | 25 | 100 |
| | % within Group | 75.0% | 25.0% | 100.0% |
| | % within Previous Surgery | 100.0% | 100.0% | 100.0% |

**[Table/Fig-3]:** Data showing the frequency distribution of previous surgeries performed.

| Groups | | Postoperative complications | | | | | Total |
|---|---|---|---|---|---|---|---|
| | | Fever | Haematoma | Nil | Wound Gaping | Wound infection | |
| Group A | Count | 3 | 2 | 40 | 3 | 2 | 50 |
| | % within group A | 6.0% | 4.0% | 80.0% | 6.0% | 4.0% | 100.0% |
| | % within Post Operative complications | 30.0% | 33.3% | 58.8% | 33.3% | 28.6% | 50.0% |
| Group B | Count | 7 | 4 | 28 | 6 | 5 | 50 |
| | % within group B | 14.0% | 8.0% | 56.0% | 12.0% | 10.0% | 100.0% |
| | % within Post Operative complications | 70.0% | 66.7% | 41.2% | 66.7% | 71.4% | 50.0% |
| Total | Count | 10 | 6 | 68 | 9 | 7 | 100 |
| | % within group | 10.0% | 6.0% | 68.0% | 9.0% | 7.0% | 100.0% |
| | % within Post Operative complications | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |

**[Table/Fig:4]:** Postoperative complications between study groups.
*Chi-square value : 14.439a; p-value: 0.001

| Seprafilm | | CT 20th day adhesions | | Total |
|---|---|---|---|---|
| | | No | Yes | |
| Group A | Count | 42 | 8 | 50 |
| | % within group A | 84.0% | 16.0% | 100.0% |
| | % within CT 20th day Adhesions | 63.6% | 23.5% | 50.0% |
| Group B | Count | 24 | 26 | 50 |
| | % within group B | 48.0% | 52.0% | 100.0% |
| | % within CT 20th day Adhesions | 36.4% | 76.5% | 50.0% |
| Total | Count | 66 | 34 | 100 |
| | % within group | 66.0% | 34.0% | 100.0% |
| | % within CT 20th day Adhesions | 100.0% | 100.0% | 100.0% |

**[Table/Fig-5]:** CT 20th Day Adhesions among study groups.
*Chi-square value : 12.243a; p-value: 0.007

| Seprafilm | | Postoperative pain scale | | | | Total |
|---|---|---|---|---|---|---|
| | | Mild | Moderate | No Pain | Severe | |
| Group A | Count | 29 | 16 | 2 | 3 | 50 |
| | % within group A | 58.0% | 32.0% | 4.0% | 6.0% | 100.0% |
| | % within Postoperative pain scale | 69.0% | 37.2% | 66.7% | 25.0% | 50.0% |
| Group B | Count | 13 | 27 | 1 | 9 | 50 |
| | % within group B | 26.0% | 54.0% | 2.0% | 18.0% | 100.0% |
| | % within Postoperative pain scale | 31.0% | 62.8% | 33.3% | 75.0% | 50.0% |
| Total | Count | 42 | 43 | 3 | 12 | 100 |
| | % within group | 42.0% | 43.0% | 3.0% | 12.0% | 100.0% |
| | % within Postoperative Pain Scale | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |

**[Table/Fig-6]:** Postoperative Pain Scale comparison among the study groups.
*Chi-square value : 12.243a; p-value: 0.007

| Groups | | Intraoperative blood loss | | | Total |
|---|---|---|---|---|---|
| | | <300 mL | >500 mL | 300-500 mL | |
| Group A | Count | 39 | 1 | 10 | 50 |
| | % within group A | 78.0% | 2.0% | 20.0% | 100.0% |
| | % within Intraoperative blood loss | 53.4% | 25.0% | 43.5% | 50.0% |
| Group B | Count | 34 | 3 | 13 | 50 |
| | % within group B | 68.0% | 6.0% | 26.0% | 100.0% |
| | % within Intraoperative blood loss | 46.6% | 75.0% | 56.5% | 50.0% |

| | | | | | |
|---|---|---|---|---|---|
| Total | Count | 73 | 4 | 23 | 100 |
| | % within Group | 73.0% | 4.0% | 23.0% | 100.0% |
| | % within Intraoperative blood loss | 100.0% | 100.0% | 100.0% | 100.0% |

**[Table/Fig-7]:** Crosstabulation for intraoperative blood loss comparisons among study groups.
*Chi-square value: 1.734a; p-value: 0.420

## DISCUSSION

Postoperative adhesions were recognised as the most frequent complication following surgical procedures. According to research conducted by Lauder CIW et al., adhesions were observed in approximately 95% of cases after surgery, regardless of the type or location of the procedure, including pelvic, peritoneal, and thoracic surgeries [8]. In another study by Ouaïssi M et al., peritoneal adhesions were reported to account for 65-75% of all small bowel obstructions and 32% of acute intestinal obstructions [9]. Furthermore, it was found that peritoneal adhesions formed in 93-100% of upper abdominal surgeries and 67-93% of lower abdominal surgeries, although only 15-18% of these cases necessitated surgical reintervention [9]. In this study, the mean age of the subject was 50 years. In a survey conducted by Latha D et al, the most prevalent age group was also under 40 years, accounting for approximately 36.5% of the population [10]. A study conducted by Krielen P et al, reported a male-to-female ratio of 1:2 suggesting that abdominal surgeries were more commonly performed in females than in males [11].

According to findings reported by Latha D et al, ventral hernias represented the most frequent diagnosis (66.6%) [10]. In a study by Diamond MP et al., small bowel obstruction (9% in the Seprafilm group and 10% in the control group), abscess formation (8% and 2%), gastrointestinal symptoms such as nausea, vomiting, and diarrhoea (4% and 5%), pulmonary embolism (4% and 0%), deep vein thrombosis (2% and 1%), ileus (2% and 1%), fever (2% and 0%), and adrenal insufficiency (2% and 0%) were identified as the most frequently observed postoperative side-effects [12].

In this study, patients were followed up postoperatively, and a CT abdomen was performed on the 20$^{th}$ postoperative day. A total of 34 patients developed adhesions, of whom 8 (23.5%) belonged to group A and 26 (76.5%) to group B. A study by Nakashima M et al., reported a lower rate of follow-up surgeries within two years: 8.2% in the barrier group and 4.7% in the no-barrier group [13], aligning with the present study's findings that highlighted Seprafilm efficacy in reducing intra-abdominal adhesions. Study by Hajibandeh S et al., estimated a significant reduction in the risk of small bowel obstruction with the use of Seprafilm [14]. However, research conducted by Choy KT et al., Lima SROS et al., van der Wal JB et al., demonstrated that while Seprafilm reduced postoperative adhesions, it did not significantly decrease the incidence of bowel obstruction [5,15,16]. Moreover, Choy KT et al., noted a higher risk of anastomotic leakage despite the adhesion-reducing effect [5]. Additionally, both Choy KT et al., and Tyler J et al, reported that a foreign body reaction to Seprafilm could lead to sterile intra-abdominal fluid collections [5,17].

The incorporation of Seprafilm into routine surgical practice may serve as a valuable strategy to enhance postoperative outcomes and minimise adhesion-related complications. Seprafilm is found to decrease the incidence of postoperative adhesions and decreasing the morbidity of the patients but still the cost of seprafilm is reasonably high and availability is limited. Larger sample size and inclusion of immunocompromised patients were considered for future studies.

### Limitation(s)

Potential confounders (e.g., surgical technique, operative duration, surgeon experience, underlying pathology) may influence outcomes and are difficult to control. Adhesion severity is often graded visually or semi-quantitatively during reoperation, which is inherently subjective. Small sample size or single-center design. Short follow-up period. Compliance and application technique.

## CONCLUSION(S)

The incidence of postoperative adhesions was significantly lower in the group that received Seprafilm as an adhesion barrier following abdominopelvic surgeries, compared to the group that did not receive it. Hereby, we suggest the use of seprafilm in all abdominopelvic surgeries, which prevents postoperative adhesions and has a better outcome following the surgery, reducing the morbidity for the patients.

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