Baxter

CASE STUDY

COLORECTAL SURGERY

ADHESIVE SMALL BOWEL OBSTRUCTION FOLLOWING SURGERY FOR ACUTE DIVERTICULITIS

Case Study: **Adhesive Small Bowel Obstruction Following Surgery for Acute Diverticulitis**

PRESENTATION, HISTORY, DIAGNOSIS AND INITIAL SURGERY

Frank, an overweight, 50-year-old Caucasian man, presented to his primary care physician with a fever and severe, persistent cramping on the left side of his abdomen, which had previously eased after passing flatus or stool. In addition, he had experienced constipation, diarrhoea and general abdominal pain over the last two weeks.[1] Frank's social history was also significant for a sedentary lifestyle and smoking (approximately 20 cigarettes [1 pack] per day).

Frank's physician performed a physical examination of his abdomen and ran blood, urine and stool evaluations. Based on initial findings, including leukocytosis (white blood count [WBC] of 14,400 cells/μL), Frank was referred to the emergency department for further evaluation, including C-reactive protein (CRP) levels, as well as a computed tomography (CT scan).[2] Based on the WBC, CRP and CT scan results, Frank was diagnosed with Hinchey Class III acute diverticulitis (generalised purulent peritonitis).[3] Frank was subsequently referred to a colorectal surgeon for an emergent procedure, and underwent a sigmoidectomy with a primary anastomosis and a diverting loop ileostomy.[2,4-6] Frank then underwent a loop ileostomy closure approximately 3 months after the initial procedure.[2,6,7]

Following sigmoidectomy and ileostomy reversal, Frank's symptoms improved for approximately 1 year. Frank then began to experience intermittent abdominal pain, swelling of the abdomen and vomiting. When he was unable to have a bowel movement or pass flatus, Frank was advised by his primary care physician to go to the emergency department for assessment. Following a CT scan of the abdomen, Frank was subsequently diagnosed with a small bowel obstruction (SBO) that was most likely due to intestinal adhesions based on distortion of bowel loops visualised on the CT scan.[8]

OVERVIEW OF PATIENT'S ADHESIOLYSIS SURGERY

After receiving his diagnosis, Frank was referred for an urgent exploratory laparotomy and adhesiolysis to address his SBO and prevent life-threatening complications.[9-11] Surgeons should be aware that adhesive SBOs are often the result of previous abdominal surgical procedures or disease.[11] Sodium hyaluronate carboxymethylcellulose [**SEPRAFILM** Adhesion Barrier12]* reduces adhesion formation and the risk of subsequent reoperations of adhesive SBO, and has been shown to be cost-effective in open colorectal surgery.[11,12-15] Therefore, **SEPRAFILM** was utilised for adhesion reduction prior to closing.

WHAT ARE THE MAJOR RISK FACTORS FOR ADHESIONS?

Adhesion development is the most common complication following laparotomy and occurs in over 93% of patients.[16,17] Adhesions are the most common aetiology for SBO in developed world countries and account for approximately 60% of all episodes.[10] In addition, SBO is one of the most severe of adhesion-related complications, with a 30-day mortality rate of up to 10%.[18]

Risk factors that contribute to adhesion development following abdominal surgery include[19]:

Frank was one of a high proportion of patients who developed adhesions following abdominal surgery. Approximately 16% of patients undergoing adhesiolysis for SBO develop recurring adhesions,[20] and approximately 20% require subsequent admission and surgery.[21] The consequences of post-surgical abdominal adhesions for patients like Frank are significant. In addition to the high 30-day mortality rate,[18] the incidence of bowel injuries during adhesiolysis for SBO is as high as 10-20%.[22,23]

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WHAT ARE THE CHALLENGES RELATED TO THE DIAGNOSIS AND TREATMENT OF ADHESIONS AFTER ABDOMINAL SURGERY?

There are several challenges in the diagnosis and treatment of post-surgical adhesions and adhesion-related complications following abdominal surgery, including:

- Adhesion-related complications occur unpredictably and often several years after a procedure.[24]
- Symptoms attributable to adhesive disease are non-specific and, with the paucity of sensitive/accurate diagnostic tests, patients are often undiagnosed.[24]
- Complications are often treated by a surgeon or specialist other than the initial operating surgeon.[25]
- Adhesion-related complication are underestimated by surgeons.[25]
- Despite the burden of post-surgical adhesions, and the proven benefit of adhesion barriers, they are seldom applied.[26]

WHAT COULD HAVE BEEN DONE DIFFERENTLY TO PREVENT FRANK'S ADHESIONS?

The medical community recognises the importance of meticulous surgical technique in the prevention of post-surgical adhesions.[27] However, even the most experienced surgeons are unable to completely eliminate the risk of adhesion formation, as the trauma that causes adhesions are a routine part of any surgery.[27,28] In addition, surgical adhesiolysis causes further disruption and adhesion reformation in approximately 97% of patients.[28] To further compound this issue, adhesive tissue contains higher levels of growth factors than unaffected peritoneal tissue, suggesting a greater proclivity for adhesion reformation, thus creating a vicious cycle of adhesion formation for patients.[29]
The guidelines for diagnosis and management of adhesive small bowel obstruction recommend (Level 1A evidence) the use of **SEPRAFILM*** to reduce adhesion formation and subsequent reoperations of adhesive SBO.[11] Based on clinical evidence, it is possible that in this case, a barrier method such as **SEPRAFILM** may have improved Frank's chances of reducing or eliminating adhesions after his initial surgery as well as adhesive SBO requiring reoperation.[13,30] **SEPRAFILM** is a sodium hyaluronate/carboxymethylcellulose bioresorbable film that acts as a barrier during healing following abdominal or pelvic laparotomy.[12] In Frank's initial surgery, **SEPRAFILM** could have been utilised for adhesion reduction.[12] In patients undergoing abdominal surgery, 51% of patients who received **SEPRAFILM** before closing were adhesion-free, compared with 6% of the control group ($p<0.0001$).[12]

SUMMARY: WHY IS ADHESION REDUCTION SO IMPORTANT IN COLORECTAL/ ABDOMINAL SURGERY?

In patients like Frank, adhesiolysis to rectify SBO is a necessary emergency procedure to avoid life-threatening complications.[11,30] However, subsequent operations increase the risk of adhesion formation,[20] creating a vicious circle for patients and healthcare professionals. Approximately 16% of patients undergoing adhesiolysis for small bowel obstruction develop recurring adhesions,[20] and approximately 20% require subsequent admission and surgery.[21] Therefore, an understanding of the causes and risks of adhesions, and specific interventions for adhesion reduction, can potentially improve long-term results.

*Please see the Indications and Important Risk Information on the next page.

Seprafilm

ADHESION BARRIER

SEPRAFILM indications and important safety information indications for use

SEPRAFILM Adhesion Barrier is indicated for use in patients undergoing abdominal or pelvic laparotomy as an adjunct intended to reduce the incidence, extent and severity of postoperative adhesions between the abdominal wall and the under-lying viscera such as omentum, small bowel, bladder, and stomach, and between the uterus and surrounding structures such as tubes and ovaries, large bowel, and bladder.

Important Risk Information

SEPRAFILM Adhesion Barrier is contraindicated in patients with a history of hypersensitivity to Seprafilm and/or to any component of **SEPRAFILM. SEPRAFILM** Adhesion Barrier is contraindicated for use wrapped directly around a fresh anastomotic suture or staple line; as such use increases the risk of anastomotic leak and related events (fistula, abscess, leak, sepsis, peritonitis).

SEPRAFILM Adhesion Barrier must be used according to the instructions for use. **SEPRAFILM** Adhesion Barrier is for single use only, supplied sterile and must not be re-sterilised. Every opened and unused **SEPRAFILM** pouch must be discarded. Do not use product if pouch is damaged or opened. The number of sheets used should be just adequate to cover the under surface of the abdominal wall or uterine incision in a single layer.

In patients who have ovarian, primary peritoneal or fallopian tube malignancies, **SEPRAFILM** use has been reported to have an increased risk of intra-abdominal fluid collection and/or abscess, particularly when extensive debulking surgery was required. The safety and effectiveness of **SEPRAFILM** Adhesion Barrier has not been evaluated in clinical studies for the following: Patients with frank infections in the abdominopelvic cavity; patients with abdominopelvic malignancy; device placement in locations other than directly beneath an abdominal wall incision following laparotomy, or directly on the uterus following open myomectomy (not laparoscopic); patients with ongoing local and/or systemic inflammatory cell responses; device use in the presence of other implants, e.g. surgical mesh; patients requiring re-operation within four weeks of SEPRAFILM placement – during anticipated time of peak adhesion formation. Foreign body reactions have occurred with **SEPRAFILM** Adhesion Barrier.

The safety and effectiveness of **SEPRAFILM** Adhesion Barrier in combination with other adhesion prevention products and/or in other surgical procedures not within the abdominopelvic cavity have not been established in clinical studies.

The safe and effective use of **SEPRAFILM** Adhesion Barrier in pregnancy and Cesarean section has not been evaluated. No clinical studies have been conducted in pregnant women or women who have become pregnant within the first month after exposure to **SEPRAFILM** Adhesion Barrier. Therefore, this product is not recommended for use during pregnancy and avoidance of conception should be considered during the first complete menstrual cycle after use of **SEPRAFILM** Adhesion Barrier. Long term clinical outcomes such as chronic pain and infertility have not been determined in clinical studies.

Serious incidents and adverse events should be reported to Baxter Healthcare Pty Ltd by calling 1800 BAXTER (1800 229 837) or sending an email to ANZ_Product_Safety@baxter.com and to the Therapeutic Goods Administration on the following site: www.tga gov.au

For safe and proper use of this device refer to the complete Instructions for Use.

References

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