Baxter

CASE STUDY

GYNAECOLOGICAL SURGERY

ADHESIOLYSIS FOLLOWING OPEN UTERINE MYOMECTOMY

Case Study: **Adhesiolysis Following Open Uterine Myomectomy**

PRESENTATION, HISTORY, DIAGNOSIS AND INITIAL SURGERY

Bernadette, a 39-year-old African-American female, presented to her gynaecologist with chronic pelvic pain, dysmenorrhoea and heavy menstrual bleeding with previous anaemia. She reported that her symptoms severely impacted her daily life, and made it difficult for her to work and enjoy quality time with her spouse and friends.[1] She has no children and no previous pregnancies, but was planning to try to conceive within the next year. She also wanted to discuss her symptoms and concerns regarding fertility. Her gynaecologist performed a pelvic examination and suspected the presence of fibroids due to an enlarged uterus. She ordered a full blood count (FBC), and confirmed that Bernadette was again anaemic. She referred her to a gynaecologic surgeon for specialist care.

Bernadette's gynaecologic surgeon performed a transvaginal ultrasound and ordered magnetic resonance imaging (MRI) that identified numerous uterine leiomyoma.[1]

Following an open uterine myomectomy, Bernadette's symptoms improved and she no longer experienced pelvic pain, dysmenorrhoea or heavy menstrual bleeding.[1] However, Bernadette was unable to conceive over a period of two years. Despite no other obvious symptoms, Bernadette returned to her gynaecologist to discuss her concerns. Once again, Bernadette was referred to a specialist for investigation, where she underwent a pelvic examination and transvaginal ultrasound and was subsequently diagnosed with post-surgical adnexal adhesions that were potentially impacting her fertility.

OVERVIEW OF PATIENT'S ADHESIOLYSIS SURGERY

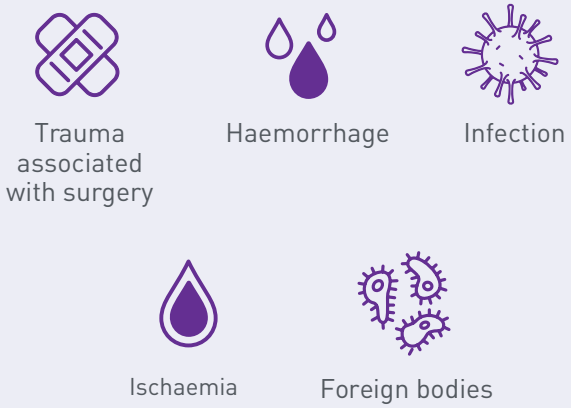
Following her diagnosis of adnexal adhesions, Bernadette's specialist recommended adhesiolysis to prevent infertility and increase her chances of conception. Her surgeon performed a laparoscopic adhesiolysis procedure to minimise pain, recovery time and formation of future adhesions.[2] Her surgeon was meticulous in his approach and technique to ensure minimal blood loss, and haemostasis was achieved prior to completion of the procedure.[3] He did not use an anti-adhesive barrier or solution prior to closure.

WHAT ARE THE MAJOR RISK FACTORS FOR ADHESIONS?

Post-surgical adhesions affect 60–90% of patients undergoing major gynaecologic surgery.[4] Despite advances in surgical techniques, the burden of adhesion-related complications has not changed. Moreover, while it was previously thought laparoscopic surgeries were less adhesiogenic, the risk of adhesion-related complications is comparable for open and laparoscopic operations across many procedures.[4]

Bernadette is one of the high proportion of patients who develop adhesions following gynaecologic surgery.[6] Approximately a third of patients undergoing initial gynaecologic surgery are readmitted due to adhesion-related complications or require further surgery within ten years.[6]

Risk factors that contribute to adhesion development following surgery include[5]:



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

Adhesions are the most frequent complication of abdominal surgery.[7] And yet, the significant consequences of adhesions for patients and their quality of life are often overlooked.[7] Patients may also experience a myriad of complications and symptoms associated with post-surgical adhesions, such as[8]:

- **Chronic post-surgical pain**
- **Intestinal obstruction**
- **Sexual dysfunction**
- **Organ malfunction**
- **Secondary infertility**

Case Study: **Adhesiolysis Following Open Uterine Myomectomy**

As a surgeon, you may face several challenges in the diagnosis and treatment of post-surgical adhesions and adhesion-related complications, including[4]:

- **Adhesion-related complications occur unpredictably and often several years after a procedure**
- **Complications are often treated by a surgeon or specialist other than the initial operating surgeon**
- **Aetiology of adhesion formation is not fully understood**
- **There is a long track record of failure or underuse of traditional adhesion-prevention methods, until recent introductions of newer agents**
- **Adhesions may be asymptomatic and therefore remain undiagnosed in many cases**

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

In patients like Bernadette who are seeking to preserve their fertility, a key aspect of surgery and follow-up therapy must include steps to reduce adhesion formation. Here are a few other features of patientswhere adhesion prevention measures should be considered[9]:

- **Any patient requiring surgery of the adnexa**
- **Patients who will require a secondary procedure**
- **Patients undergoing laparoscopic gynaecologic surgeries**

The medical community recognises the importance of meticulous surgical technique and use of anticoagulants, fibrinolytics, anti-inflammatory and anti-fibrotic agents in the prevention of post-surgical adhesions. However, despite good surgical technique, the risk of adhesion formation cannot be completely eliminated due to the routine tissue trauma that occurs with any surgery which can be a factor in the development of adhesions.[7] In addition, surgical adhesiolysis causes further disruption and adhesion reformation in around 85% of patients.[10] 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.[7]

Additional methods that have demonstrated clinical benefit in adhesion prevention, and therefore could have improved Bernadette's clinical outcome, include:

Barrier films – SEPRAFILM Adhesion Barrier* is a sodium hyaluronate/ carboxymethylcellulose bioresorbable film that acts as a barrier during healing following abdominal surgery.[11] In patients undergoing open myomectomy, the incidence, severity, extent, area of the uterus associated with adhesions and portion of patients with adnexal adhesions were all reduced in patients treated with **Seprafilm** Adhesion Barrier versus control.[11]

Adhesion Reduction Solution – ADEPT*
contains 4% icodextrin that also acts as an irrigant during surgery. In patients undergoing laparascopic gynaecologic surgery involving adhesiolysis, significantly more patients achieved clinical success with **Adept** Adhesion Reduction Solution compared with lactated Ringer's solution (49% versus 38%).[12]

Adhesion Reduction Surgical Sealant – COSEAL* is indicated for patients undergoing laparotomic or laparoscopic gynaecological surgery as an adjunct to good surgical technique to reduce the incidence, severity and extent of post-surgical adhesion formation.[13] In a multicentre, randomised single blind study nearly twice as many **Coseal** Surgical Sealant patients were adhesion free at second look laparoscopy.[14]

Based on clinical evidence, it is possible that in this case, an adjunctive adhesion barrier may have improved Bernadette's chances of remaining adhesion-free after her initial surgery.[11] Although her operating surgeon who performed her adhesiolysis did not use an anti-adhesion strategy, the use of an adhesion reduction product like **Adept** Adhesion Reduction Solution during laparoscopic gynaecologic adhesiolysis may also provide clinical benefit in preventing subsequent adhesion formation.[12]

SUMMARY: WHY IS ADHESION REDUCTION SO IMPORTANT IN GYNAECOLOGIC SURGERY?

In patients like Bernadette, adhesiolysis may be necessary to help prevent infertility and chronic pelvic pain.[4] However, subsequent operations increase the risk of adhesion formation, creating a vicious circle for patients and healthcare professionals.[4] A frequent adhesion-related complication is secondary infertility in women. 20-40% of cases are caused by adhesions. Many of these women develop long term chronic pain.[4] An understanding of the risk and causes of adhesions can help inform prevention for patients like Bernadette.

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

Adept

ADHESION REDUCTION SOLUTION (4% ICODEXTRIN)

INDICATIONS

Adept Adhesion Reduction Solution is intended for use as an intraperitoneal instillate for the reduction of adhesions following gynaecological laparoscopic surgery, and should be used as the irrigant during the course of that surgery. **Adept** Adhesion Reduction Solution is indicated to be used in gynaecological laparoscopic surgery of the abdominal-pelvic cavity in adults.

Adept is contraindicated: In patients with known or suspected allergy to cornstarch based polymers, icodextrin, maltose or isomaltose intolerance, or in patients with glycogen storage disease. In the presence of frank infection (e.g. peritonitis) in the abdomino-pelvic cavity. In procedures with laparotomy incision. Serious post-operative wound complications including dehiscence and cutaneous fistula formation have been reported from clinical experience when **Adept** was used in surgical cases with laparotomy incision. In procedures involving bowel resection or repair, or appendectomy. Anastomotic failure, ileus, peritonitis and rare cases of serosal fibrosis following procedures involving bowel resection and instillation of **Adept** have been reported from clinical experience. There are rare reports of pleural effusion from clinical experience with **Adept**. As a possible relationship to the use of **Adept**, in conjunction with inappropriate fluid monitoring during surgical procedure cannot be ruled out, the volume of **Adept** instilled should always follow the recommendations of the Instructions for Use. Self-limited vulvar swelling is a known side-effect of instilling large volumes of fluid into the abdomino-pelvic cavity. Most cases resolve within one week of surgery. When swelling is associated with urinary retention, catheterisation may be necessary effects. Maltose metabolites of icodextrin may interfere with blood glucose measurement in diabetic patients who use rapid blood glucose systems that are not glucose specific.

For safe and proper use of this device, please refer to full Instructions For Use.

Seprafilm

ADHESION BARRIER

INDICATIONS

Seprafilm Adhesion Barrier is a sterile, bioresorbable, translucent membrane composed of two chemically modified anionic polysaccharides, sodium hyaluronate and carboxymethylcellulose. **Seprafilm** is intended as an adjunct in abdominal and pelvic surgery for reducing the incidence, extent and severity of postoperative adhesions at the site to placement and to reduce adhesive small bowel obstruction when placed in the abdomen.

WARNINGS AND PRECAUTIONS

Read instruction for use prior to using **Seprafilm** Adhesion Barrier. For single use only. Do not resterilise. **Seprafilm** should not be wrapped directly around a fresh anastomotic suture or staple line of the intestine. Clinical trial data on **Seprafilm** indicate that such use may result in an increased risk of anastomotic leak-related events (fistula, abscess, leak, sepsis and peritonitis). The incidence of these events was not affected when **Seprafilm** was placed elsewhere in the abdomen. **Seprafilm** is not recommended for use in women undergoing surgery for ovarian, fallopian tube or peritoneal malignancies.

Some clinical literature has associated this use of **Seprafilm** with an increased incidence of fluid collection and/or abscess requiring intervention. No controlled clinical studies have been conducted in patients with active infections or abdominopelvic malignancy. Foreign body reaction may occur as with most surgical adjuncts but have been rarely reported during clinical use. No pre-clinical reproductive studies have been conducted. No clinical studies have been conducted in women who become pregnant in the first month after application of **Seprafilm**. Therefore, avoiding pregnancy during the first complete menstrual cycle after the use of **Seprafilm** Adhesion Barrier should be considered. 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.

Coseal

SURGICAL SEALANT

INDICATIONS

Coseal Surgical Sealant is indicated for sealing suture lines along arterial and venous reconstructions; and enforcement of suture and staple lines in lung resection procedures. Patients undergoing cardiac surgery to prevent or reduce the incidence, severity and extent of post surgical adhesion formation. Patients undergoing laparotomic or laparoscopic gynaecological surgery as an adjunct to good surgical technique intended to reduce the incidence, severity and extent of post-surgical adhesion formation.

CONTRAINDICATIONS

Do not use **Coseal** Surgical Sealant as a bronchial stump sealant, during bronchial sleeve resections, or for sealing decorticated lung areas. Do not use **Coseal** in procedures in which pleural adhesions are desired.

WARNINGS

Application involving the use of pressurised gas may be associated with potential risks of air embolism, tissue rupture, or gas entrapment with compression, that may be life-threatening. To minimise these risks control the maximum pressure as indicated in the applicator instructions for use. Do not inject **Coseal** into vessels. Do not use in place of sutures, staples or mechanical closure. To prevent any compressive effects, in compression-sensitive cavities or in patients with an increased risk of compression (e.g. neonatal cardiac procedures), application of a thin layer of product is recommended (1 mL per 10 cm^2). **Coseal** should be used with caution in contaminated areas of the body. Specifically, do not use **Coseal** in contaminated or "dirty" pulmonary resection cases. **Coseal** swells up to four times its volume within 24 hours of application and additional swelling occurs as the gel resorbs. Therefore, surgeons should consider the maximum swell volume and its possible effect on surrounding anatomic structures potentially sensitive to compression.

For safe and proper use of this device, please refer to full Instructions For Use.

1 Donnez J, Dolmans MM. Hum Reprod Update 2016;22(6):665–686. **2** Adhesiolysis. E-Book. Published by NCBI (Statpearls). Available at:https://www.ncbi.nlm.nih.gov/books/NBK563219/ **3** Monk BJ, et al. Am J Obstet Gynecol 1994;170:1396–1403. **4** DeWilde RL, Trew G. Gynecol Surg 2007;4:161–168. **5** Fortin CN, et al. Hum Reprod Update 2015;21(4):536–551. **6** Lower AM, et al. BJOG 2000;107(7):855–862. **7** DeWilde RL, Trew G. Gynecol Surg 2007;4:243–253. **8** Jeong JJ, et al. PLOS One 2019; 14(2):e0212583. **9** DeWilde RL, et al. Gynecol Surg 2012;9:365–368. **10** Diamond MP, Freeman ML. Hum Reprod Update 2001;7(6):567–576. **11** SEPRAFILM Adhesion Barrier Instructions for Use. **12** ADEPT Adhesion Reduction Solution Instructions for Use. **13** COSEAL Surgical Sealant Instructions for Use. **14** L. Mettler, et al. A safety and efficacy study of a resorbable hydrogel for reduction of post-operative adhesions following myomectomy. Human Reproduction Vol.23, No.5 pp. 1093-1100, 2008.

Baxter Healthcare Pty Ltd
1 Baxter Drive, Old Toongabbie NSW 2146, Australia. Tel: 1800 BAXTER (1899 229 837)

baxterhealthcare.com.au

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