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SurgiWrap® MAST Bioresorbable Sheet Use for the Prevention of Soft Tissue Attachment; A Two Year Experience.

Introduction

Soft tissue attachments are a form of uncontrolled healing that can develop in response to trauma to the peritoneum either from surgery or inflammation. During surgery ischemia, abrasion, dessication, heat, electrocautery and suturing can cause uncontrolled healing and may lead to undesired soft tissue attachments. Injury to the mesothelial layer of the peritoneum leads to leakage of the plasma proteins leading to protein deposits at the injury site. Mesothelial regeneration is delayed by factors such as electrocautery.^{1,2} Simultaneous release of histamine and kinins increase the level of vascular permeability leading to inflammation and exudation with fibrin deposition on the peritoneal surface. A fibrin mesh forms, which can either be lysed by plasmin derived from plasminogen (a blood derived protein) resulting in a scarless repair or not lysed resulting in soft tissue attachments. Uncontrolled healing and subsequent soft tissue attachments begin within one to three days after surgery, maturing into fibrous bands within one to two months, often with calcification and its own blood supply.² Complications can strike months or years after the initial surgery. The goal of surgeons is to minimize postoperative soft tissue attachments since it may complicate future surgery by increasing the risk of perforations of the viscera, extends operating time, and increases pain in the immediate postoperative period as well as in the future.^{3,4,5,6,7} It can also lead to infertility, pelvic pain, bowel obstruction and increase operating room costs.^{8,9,10,11,12} For example, a recent study from the University of Kansas Medical Center demonstrated significant uncontrolled healing and soft tissue attachments in the abdominopelvic region at a rate of twenty-one percent of the time at Repeat Cesarean Section.¹³

Material / Methods

The SurgiWrap Bioresorbable Sheet is cleared by the FDA to reinforce soft tissue and minimize tissue attachment to the device in case of direct contact with the viscera. The device is indicated for open and laparoscopic procedures. Between September 2003 and September 2005, SurgiWrap was placed in one-hundred and eighty patients to support the soft tissues and minimize the attachment of surrounding tissues. The size of the sheet most commonly used was 0.05mm. The 0.02mm sheet was used rarely. The SurgiWrap sheets were placed intra-operatively during Cesarean Sections after the uterine incisions were closed. The sheets were either sutured with two interrupted sutures of Vicryl on to the uterine incision or sutured below the rectus muscle after it had been placed on top of the uterus and bladder flap. The 0.02mm sheet was used for laparoscopic cases. In these cases after resection of endometriosis or lysis of adhesions the sheet was wrapped around a blunt probe, introduced through the 5mm trocar sites and placed in the posterior cul-de-sac. SurgiWrap was also used after Hysterectomies when the ovaries were left behind. In these cases, the sheet was wrapped around the ovary and sutured in place.

Results

In the past two years, eleven re-looks have been performed. Five re-looks were for Repeat Cesarean Sections. One re-look was several months after lysis of adhesions for an ovarian cystectomy. Two re-looks were done during Laparoscopic Tubal Ligations several weeks after a Cesarean Section. The sixth re-look had bilateral endometriomas. Both endometriomas were resected through the laparoscope. During the Laparoscopy, multiple adhesions were noted. The 0.02mm sheets were

wrapped around each ovary after the ovarian cystectomies. This same patient later had an Abdominal Hysterectomy for complex endometrial hyperplasia. Healing was controlled and no soft tissue attachments were visualized at that time. The next re-look was done during a Hysterectomy after removal of bilateral endometriomas and lysis of adhesions. The most recent re-look was on a patient who had an Abdominal Hysterectomy with a Left Salpingo-Oophorectomy. Her right ovary had been wrapped with SurgiWrap. She recently had her right ovary removed through the laparoscope. In all of the above cases, the healing process was controlled and no soft tissue attachments were found in the areas where the SurgiWrap had been placed. In one of the Laparoscopic Tubal Ligations, which was done seven weeks after the Cesarean Section, fragments of the SurgiWrap were found opposing the bladder and uterus as a thin filmy layer.

Safety Profile

Adverse events possibly related to SurgiWrap have been observed in four out of one-hundred and eighty patients (2.2%). The patients presented with abdominal pain several weeks after their Cesarean Sections not directly associated with SurgiWrap. Upon examination some fluid could be detected between the rectus muscle and the uterus. The Radiologists called them abscesses. The patients were afebrile with a normal white blood count. They were sent home and explained that what appeared to be an abscess, was actually the SurgiWrap sheet undergoing hydrolysis. All patients had complete resolution of their pain. In one patient who had an Abdominal Hysterectomy, a resorbing remnant piece of SurgiWrap protruded through the vaginal cuff. It was not determined if the patient followed post surgical instructions as to why the cuff had opened. The patient transferred care, and had a Laparotomy in which resorbing SurgiWrap remnants were removed.

Discussion

Uncontrolled healing can be managed and soft tissue attachments can be minimized by creating a temporary barrier between healing tissues. Currently, there are several such barriers present in the market. However, in our practice we used several of these but we prefer SurgiWrap because of its performance in reinforcing soft tissues, minimizing soft tissue attachments and excellent handling characteristics. SurgiWrap is a polylactide Polymer which retains its strength for 8-12 weeks

and then gradually degrades by hydrolysis within 24 weeks. It is easy to use in both open and laparoscopic procedures

In the eleven re-looks that we have had, SurgiWrap seems extremely effective reinforcing soft tissue and subsequently in minimizing soft tissue attachments to the device. Several more patients will have re-looks in the future given the increasing rate of Cesarean Sections thus providing us with a better idea of SurgiWrap's usefulness.

As mentioned before, soft tissue attachments have severe implications for both the patients as well as the surgeons. It goes without saying that attempts at minimizing soft tissue attachments start with good surgical technique but often this is not enough. SurgiWrap holds great promise for the future as a means to minimize soft tissue attachments.

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