AmnioFix® SURGICAL

CASE EXAMPLES

Challenges in OB-GYN Surgical Procedures

Doctor/Practitioner Information
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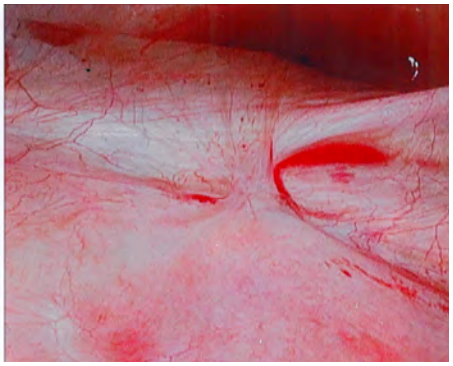
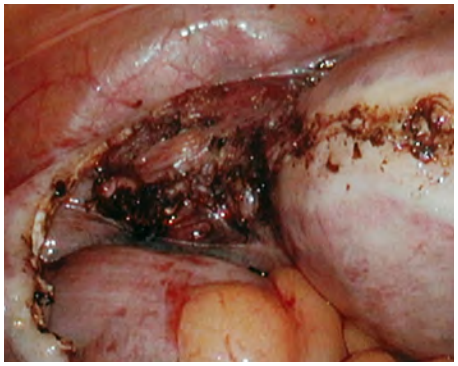
ENDOMETRIOSIS

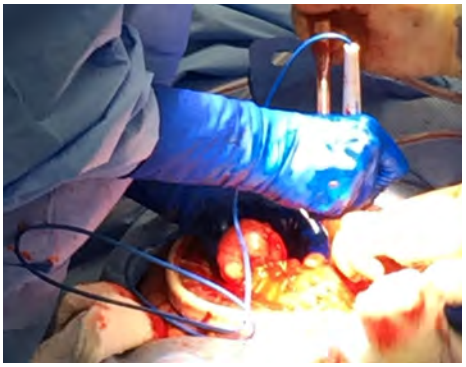


HYSTERECTOMY



CAESAREAN SECTION

MYOMECTOMY



MiMedx

PATIENT CASE EXAMPLE

AmnioFix® as a Barrier and to Enhance Healing after Endometriosis Surgery

CHALLENGE: EXPEDITE HEALING AND MINIMIZE SCAR TISSUE FORMATION ON SURGICALLY CREATED WOUNDS IN THE PELVIS

Endometriosis is a painful disorder in which the endometrium grows outside of the uterus. The endometrium thickens, breaks down, and bleeds with each menstrual cycle, leading to irritation and adhesions of the surrounding tissues and organs. Surgical intervention may be required to address severe chronic pain. Endometriosis goes deep into the layers of the uterus, so it is insufficient to only dissect the adhesions. A deeper resection of the affected area is required and often includes stripping away the peritoneal layer, as well as the adhesions. Consequently, these surgically created wounds can scar down to surrounding tissues and organs and potentially result in the recurrence of chronic pain. In this author's clinical experience, many of the commercially available barrier products applied to these areas can resorb too rapidly and do not have the ability to enhance the healing process.

CLINICAL HISTORY

38 year-old female presented with severe, chronic pelvic pain with dyspareunia. Upon examination, patient exhibited pain when the uterosacral ligaments were palpated and when the uterus was manipulated. It was determined that surgical intervention was required.

TREATMENT

The patient underwent single port, laparoscopic surgery. Endometrial lesions were present in multiple locations on the anterior and posterior peritoneum. Several of the lesions were also associated with adhesions (Figure 1). The adhesions were released and the peritoneal layer was resected in the three locations to address the depth of endometriosis (Figure 2). The three peritoneal excision sites were protected in order to heal and reperitonealize before recurring scar tissue could form.

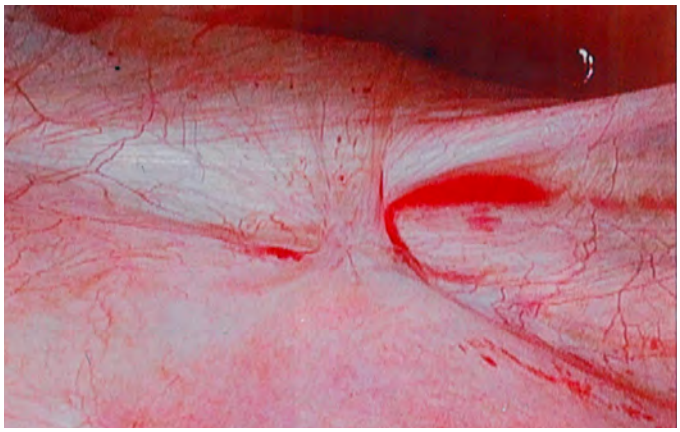


Figure 1
Endometrial lesions and adhesions (1 of 3 areas)

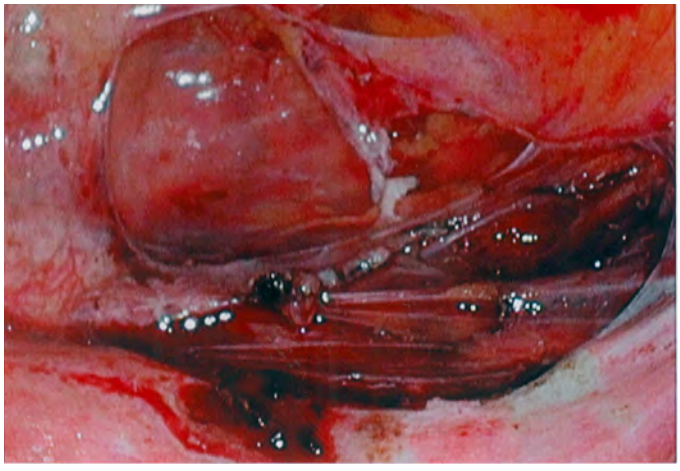


Figure 2
6 cm x 6 cm peritoneal excision

Two 4 cm x 7 cm AmnioFix grafts were used as a barrier membrane and to enhance the healing at each of the three sites of resection. Per instructions, the graft is not rehydrated prior to introduction and the trocar should be dry and clean of debris. The 4 cm x 7 cm AmnioFix grafts were cut down to smaller sizes, folded in half, and introduced separately using atraumatic graspers through the small gel port. Each graft was laid onto the surgically created wounds, arranged for maximum coverage, and allowed to rehydrate in place. No additional fixation was required as the AmnioFix grafts became "tacky" as they rehydrated and adhered to the desired locations (Figures 3-5). ***Tip***—*If graft is not rehydrating and adhering to site, gently spray a few drops of saline to expedite process.*

The patient was discharged on the same day without complications.

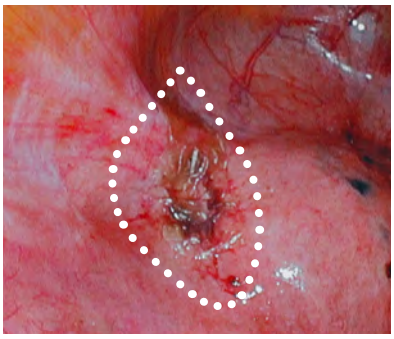


Figure 3
AmnioFix applied to site #1

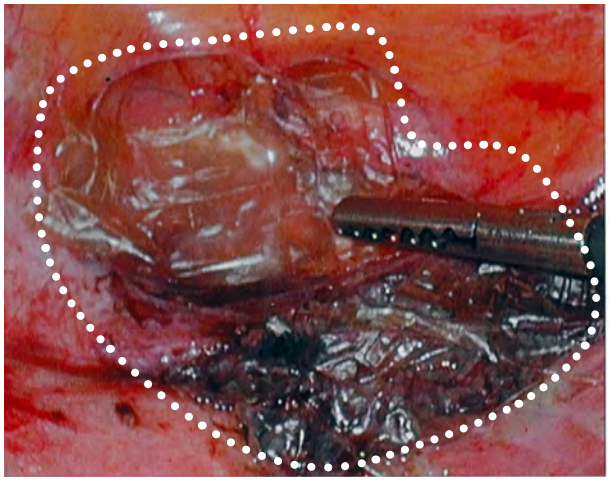


Figure 4
AmnioFix applied to site #2

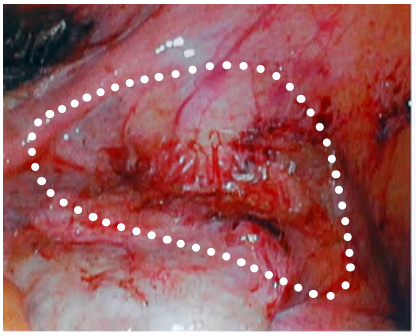


Figure 5
AmnioFix applied to site #3

FOLLOW UP

On post-op day 7, the patient called the office to request permission to return to work because she felt well. The patient was last seen 12 weeks post-op and remains free of pain and has fully recovered.

CONCLUSION

AmnioFix was a good option for this patient to provide a barrier against surrounding tissues and organs, enhance healing at the surgically created wounds, and to reduce scarring. In this case, a reduction in post-op pain and an expedited recovery process was also observed.

PATIENT CASE EXAMPLE

AmnioFix used on Vaginal Cuff after Hysterectomy in Obese Patient

CHALLENGE: RISK OF IMPAIRED HEALING IN OBESE PATIENT

The mechanisms involved in the healing process are the same throughout the entire body. However, there are many factors that can impair wound healing. For example, obesity in patients undergoing a hysterectomy can not only impair healing and recovery, but obese patients also have higher intrapelvic pressures. Either of these issues may lead to an increased risk of wound breakdown at the vaginal cuff closure or cause other post-operative complications.

CLINICAL HISTORY

A 53 year-old female with a BMI of 34 is diagnosed with endometrial hyperplasia and has a positive family history of ovarian cancer. After consultation, the patient was scheduled for a total laparoscopic hysterectomy with bilateral salpingo-oophorectomy (Figure 1).

TREATMENT

The patient underwent a single-port, laparoscopic procedure. After the uterus was resected and removed from the pelvic cavity, the vaginal cuff was closed using the Endo Stitch™ laparoscopic closure device and 2.0 resorbable sutures. Due to the patient's increased risk of impaired healing and the extra pressure on the vaginal cuff closure, AmnioFix particulate was used to help enhance healing. A 160 mg vial of AmnioFix particulate was mixed with 1.5 mL of sterile saline in order to create a flowable, "slurry-like" consistency (Figure 2).

*(**Note:** This author has used a range of 1.25 mL to 1.5 mL of sterile saline to attain the desired consistency and believes 1.25 mL is optimal.)*

The AmnioFix was then drawn into a 3 mL syringe and horizontally transferred into the laparoscopic needle aspirator (Figure 3). The 3 mL syringe was then removed and quickly replaced with an air-filled 10 mL syringe in order to add sufficient pressure to push the AmnioFix through the length of the cannula onto the intended site (Figure 4). Once the cannula was inserted into the 5 mm port, the air-filled 10 mL syringe plunger was depressed and the AmnioFix "slurry" was deposited directly onto the vaginal cuff closure where it is noted to adhere to the sutures, as well as settle down and embed in the creases of the closure (Figures 5-7).

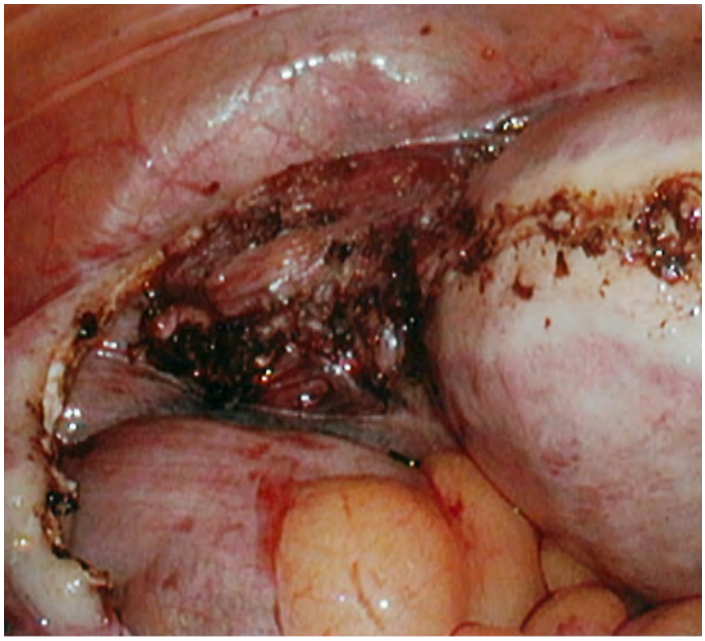


Figure 1
Total laparoscopic hysterectomy with bilateral salpingo-oophorectomy

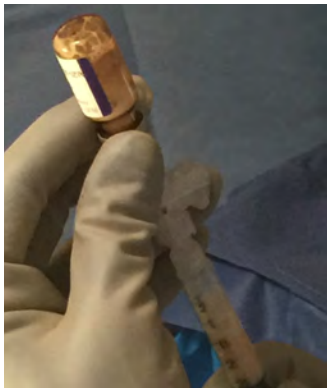
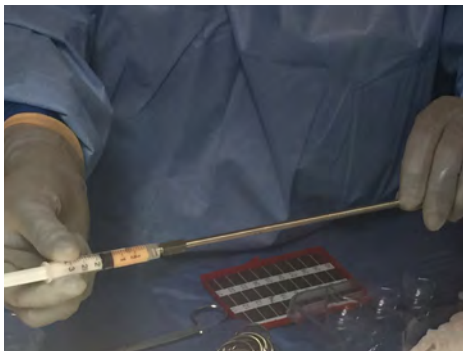
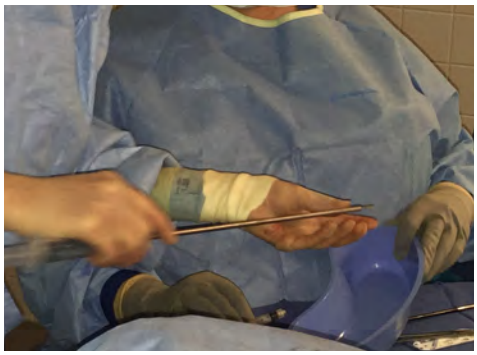


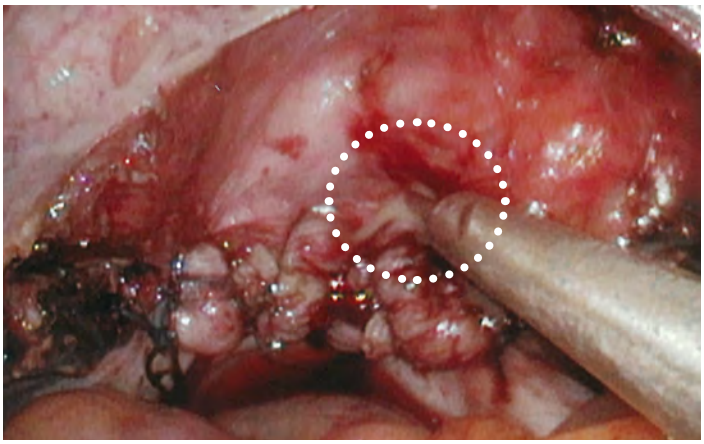
Figure 2
AmnioFix particulate mixed with saline and drawn into a 3 mL syringe (optimal saline mixture based on author's experience is 1.25 mL)

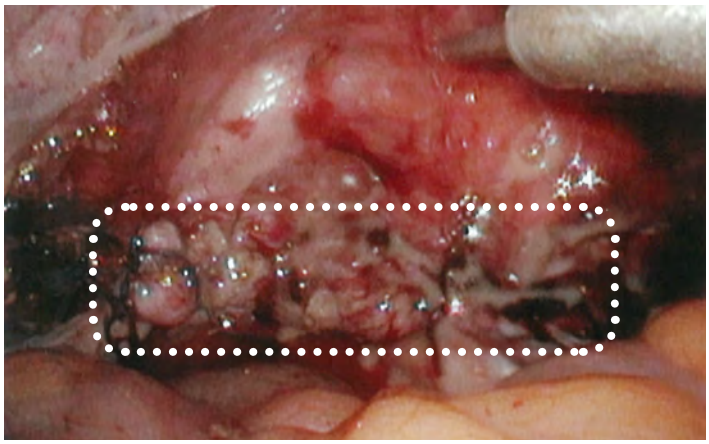




Figures 3 & 4
AmnioFix particulate is transferred to laparoscopic needle aspirator and a 10 mL air-filled syringe attached

Figure 5
10 mL air-filled syringe pressure pushes AmnioFix down the cannula





Figures 6 & 7
AmnioFix particulate mixture deposited on the suture line closure of the vaginal cuff

Migration of the AmnioFix away from the closure is not concerning because gravity will ultimately keep the AmnioFix particles in close proximity to the vaginal cuff closure. This is expected to enhance healing, even if there is some initial migration of material away from the placement site. The patient was discharged without incident the same day.

FOLLOW UP

Upon follow-up on post-op day 14, no vaginal bleeding, vaginal pain, or other complications were noted. The patient indicated that she discontinued pain medications on post-op day 4 and requested permission to return to work on post-op day 14.

CONCLUSION

As of October 2015, this author has completed more than 20 various gynecological procedures using AmnioFix grafts in both particulate and sheet configurations, including more than 10 hysterectomy procedures as described above. While additional data analysis is required, anecdotal observations to date in the prior 10 patients that received AmnioFix on the vaginal cuff closure include significant reduction in post operative pain, decreased usage of pain medication, and faster recovery and return to normal activity. Also of interest, patients receiving AmnioFix did not have any vaginal bleeding around 10-14 days post-op, as is commonly observed in this procedure when sutures degrade, which may indicate enhanced healing of the surgical wound site. No adverse events or complications secondary to the placement of AmnioFix have been observed to date.

AmnioFix is a good adjunct to enhance healing in compromised patients that undergo gynecological procedures in this author's clinical practice.

PATIENT CASE EXAMPLE

AmnioFix used to Enhance Healing after Challenging Myomectomy

CHALLENGE: DENSE ADHESIONS FROM PRIOR MYOMECTOMY PROCEDURE AND MULTIPLE LARGE FIBROID TUMORS

CLINICAL HISTORY

A 44 year-old female with a history of a prior myomectomy procedure, presents with chronic pelvic pain. MRI revealed multiple fibroids on uterus. Although the author recommended a hysterectomy, the patient elected to have a myomectomy due to desires for a future pregnancy.

TREATMENT

A pfannenstiel incision was made, and dense adhesions were observed upon entry (Figure 3). Additionally, the bladder was adhered to the anterior abdominal wall, and a fallopian tube was adhered to a posterior serosal fibroid (Figure 4). Lysis of the adhesions was performed to gain access to the uterus. Once clear, multiple large serosal and intermural fibroids were observed, more than originally identified by MRI. In total, seven serosal and eight intermural fibroid tumors were resected.

Each of the eight resected fibroids created a large and deep wound with significant bleeding, which required closure (Figures 1 & 2). The trauma during this procedure to the uterus was significant. The number and depth of wound sites and the desire for future pregnancy made this patient a good candidate for a bioactive allograft to enhanced healing. A 160 mL vial of AmnioFix particulate was deposited into several of the larger uteral wounds and closed over with resorbable sutures (Figure 5).

Additionally, the incision sites for the seven serosal fibroids would be at high risk of post-op adhesions as were seen after the prior myomectomy procedure. Two 4 cm x 6 cm AmnioFix allograft sheets were cut into appropriate sizes and placed on top of the defect suture line closures as a barrier membrane, to reduce scar tissue formation, and to enhance the healing (Figure 6).

The patient was discharged on post-op day 3 without complications.

Figure 1
Fibroid tumor excision

Figure 2
Multiple serosal and intermural fibroid tumors

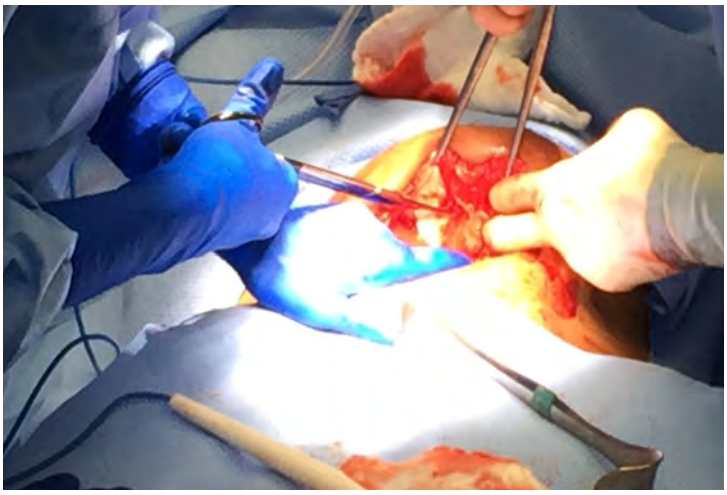


Figure 3
Dense adhesions from prior Myomectomy

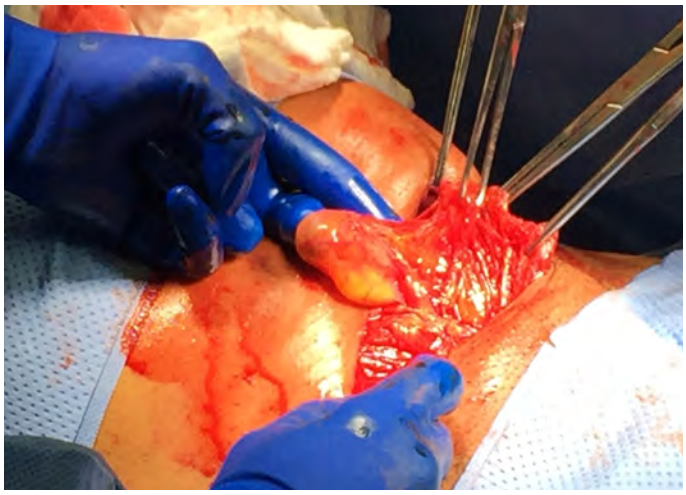


Figure 4
Fallopian tube adhered to a posterior serosal fibroid

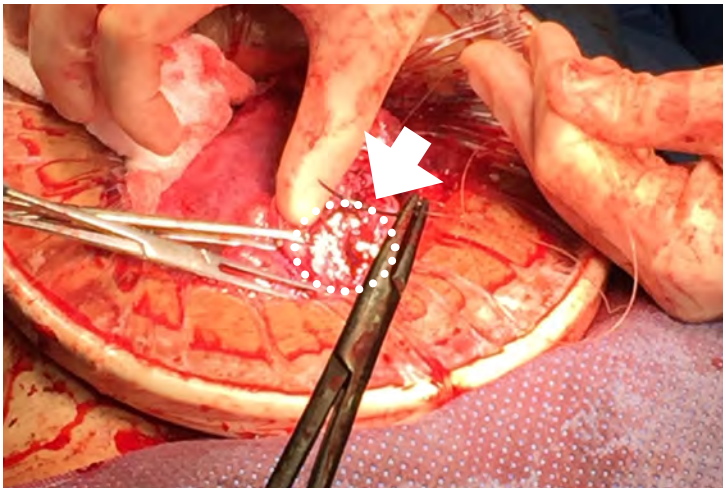


Figure 5
AmnioFix particulate sprinkled into large, deep wounds on uterus

Figure 6
AmnioFix Sheet applied to suture lines on uterus

FOLLOW UP

The patient was seen on post-op days 5 and 7 for a urinary tract infection and discontinued pain medication on post-op day 7. At follow-up examination on post-op day 13, the patient felt well and requested permission to return to work and resume sexual activity. The later was denied for several more weeks.

CONCLUSION

There are often unexpected challenges during surgical procedures. In this case, what should have been a fairly routine myomectomy procedure turned challenging due to the issues with adhesions from prior surgery and the unexpected number and size of the fibroids, which grew in only 2 years since the prior procedure. AmnioFix sheet and particulate configurations offered the versatility needed to adjust the clinical strategy to the situation, as displayed in this case, and provided this patient with a good barrier and the much needed enhanced healing.

PATIENT CASE EXAMPLE

AmnioFix as a Barrier and to Enhance Healing after Caesarean Section

CHALLENGE: OBESE PATIENT WITH TWO PRIOR CAESAREAN SECTION DELIVERIES AND LARGE PANNUS COVERING THE MONS

Adhesions are common following most surgical procedures and can increase rates of morbidity. Adhesions can also limit the mobility of pelvic tissues and organs. In OBGYN patients, morbidities caused by adhesions include acute and chronic abdominal and/or pelvic pain, bowel obstruction, urinary urgency, subfertility, and infertility. The incidence of adhesion formation after primary C-section delivery has been reported to range from 46-65% of patients[1]. Also, rates of adhesion have been shown to increase in women who had repeat C-section deliveries compared with adhesion incidence after primary C-section delivery, and the percentage of adhesion occurrence increases with each subsequent C-section delivery[2]. Patients with adhesions resulting from subsequent C-sections are often more difficult, and can lead to an increase in OR time and the possibility of injury to surrounding organs and tissue. In this patient, risk of post-operative complications is increased due to obesity. Obese patients frequently face wound complications; including skin wound infection, dehiscence, hematoma, and seroma formation[3].

CLINICAL HISTORY

The patient was a 31 year-old G4, P2012 with a BMI of 46. She was scheduled for her 3rd full-term C-section and bilateral salpingectomy (Figure 1).

TREATMENT

Adhesions were expected after two prior full-term C-section deliveries, and there were concerns for post-op wound complications due to the patient's obesity and large pannus. The plan was to utilize AmnioFix as a barrier and to enhance healing on the uterus, fallopian tube excision sites, and the dermal incision site.

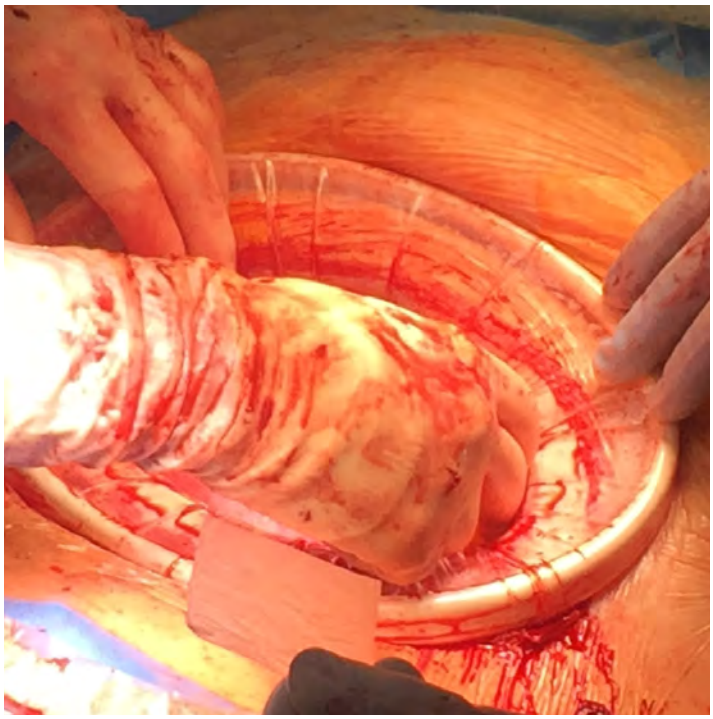


Figure 1
Caesarean section and bilateral salpingectomy

The patient's pannus was lifted and taped and Pfannenstiel incision was used to enter the abdomen. Very dense adhesions of the bladder were observed above the prior incision line on the uterus from the prior C-sections (Figures 2 & 3). Extensive lysis of adhesions of the bladder to the uterine wall was performed. The uterine wall was very thin and the uterine tissue was friable; a defect on the left lateral edge of the prior incision was noted. The baby was delivered and the uterus was sutured using a two layer closure with 2.0 Vicryl. A 2 cm x 2 cm defect still remained in the uterus from the bladder adhesion resection and was closed with 2.0 chromic sutures (Figure 4).

Next, bilateral salpingectomy was performed. Due to the high failure rate during C-section, a 4 cm x 6 cm AmnioFix sheet was cut to size and 2 cm x 2 cm squares were placed on each of the tubal excision sites in order to enhance healing, act as a barrier membrane, and to reduce scar tissue formation (Figures 5 & 6).

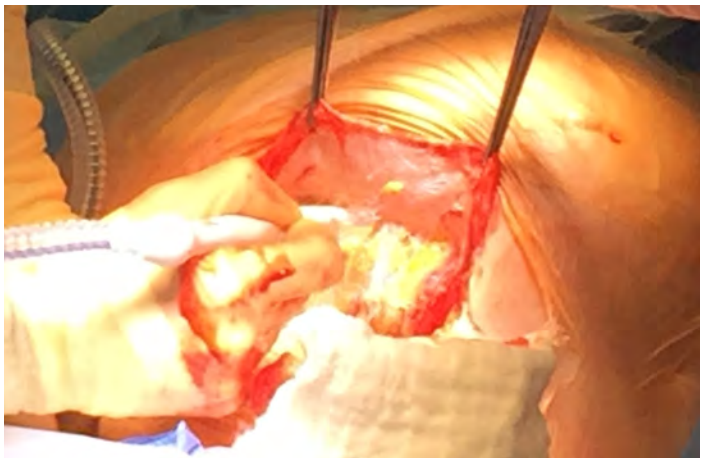


Figure 2
Dense adhesions after prior C-sections

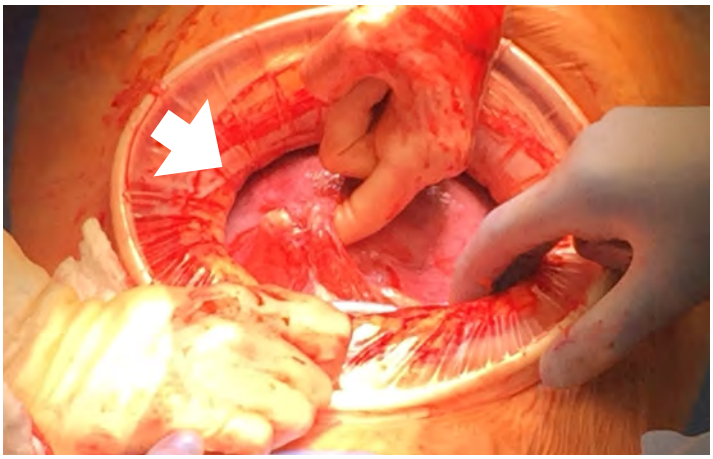


Figure 3
Bladder adhesion to uterus

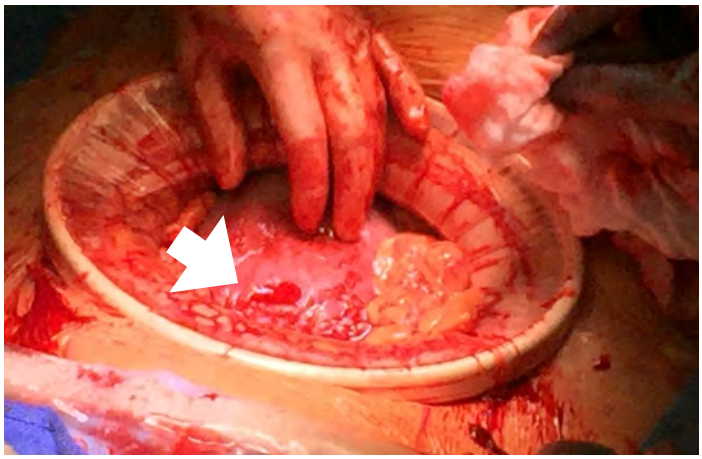


Figure 4
Defect on bladder after adhesiolysyis

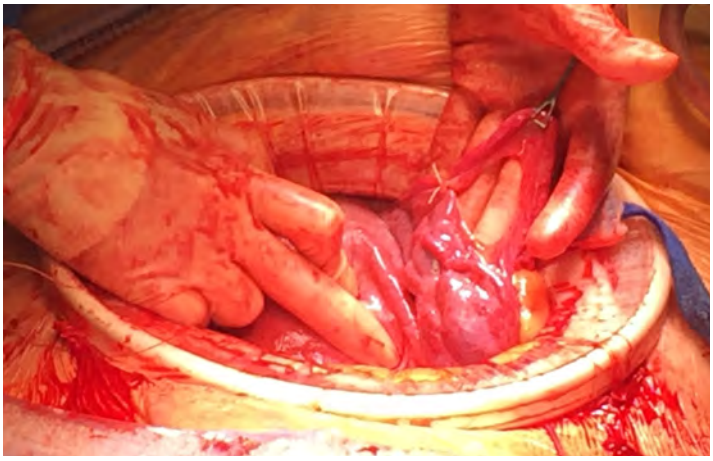


Figure 5
Salpingectomy

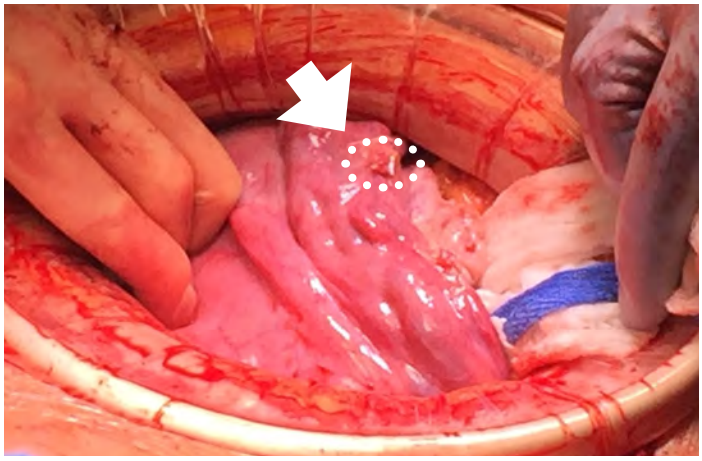


Figure 6
AmnioFix is placed on each tubal excision site

The remainder of the graft was placed on the uterus incision line in the area of the defect (Figure 7). Prior to closure, an unexpected hernia was identified with omentum protruding through the rectus muscles. The fascia was not breached or attenuated, so the defect was primarily closed. A 2 cm x 12 cm AmnioFix sheet was placed on top of the rectus defect in order to enhance healing – due to the patient's morbid obesity – before the suture would resorb (Figure 8). Normally, this author would have preferred to place AmnioFix on the entire uteral suture line. However, because the patient would not have future pregnancies and adhesions were a lesser concern, the tubal excision sites and hernia defect were more critical areas in need of enhanced healing.

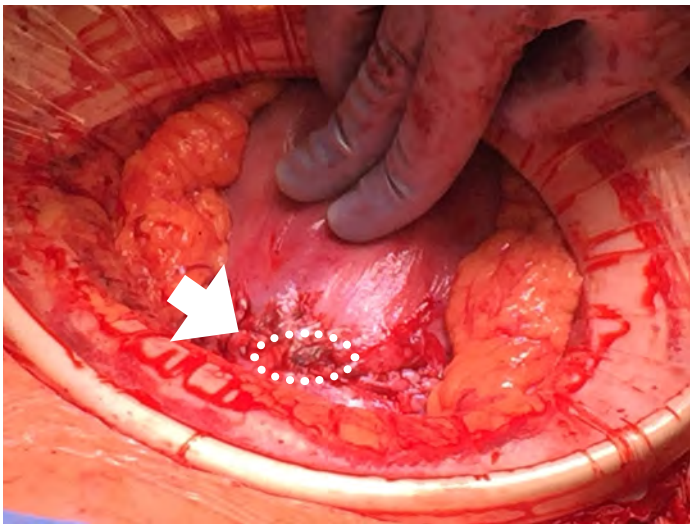


Figure 7
AmnioFix is placed on uterus defect closure

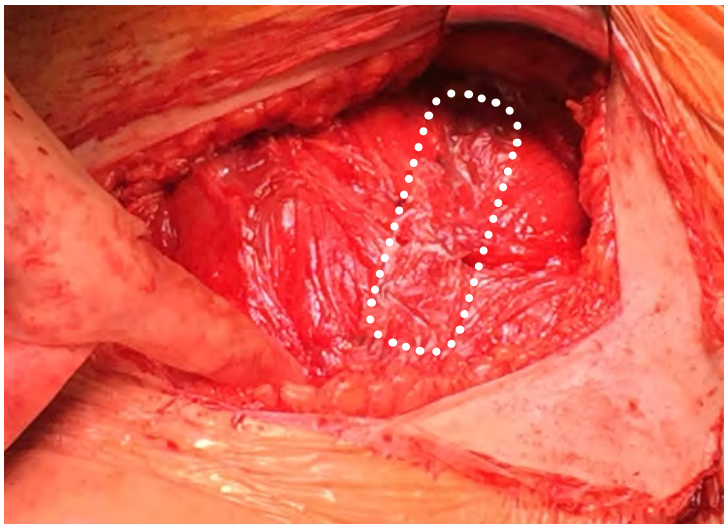


Figure 8
AmnioFix is placed on rectus defect closure

Finally, AmnioFix was also used during the two layered closure of the abdominal incision due to the multiple comorbidities and a very large pannus. The dead space was closed with 2.0 chromic sutures. A 2 cm x 12 cm AmnioFix graft was then placed into the incision site. A moist cloth was gently used to help rehydrate and position the graft in the desired location (Figure 9). The skin was then closed over top of the AmnioFix graft (Figure 10).

Examination of the incision post-op at day 3 showed no signs of infection and it was beginning to heal nicely with only a thin line visible. The patient was discharged the same day without complications.

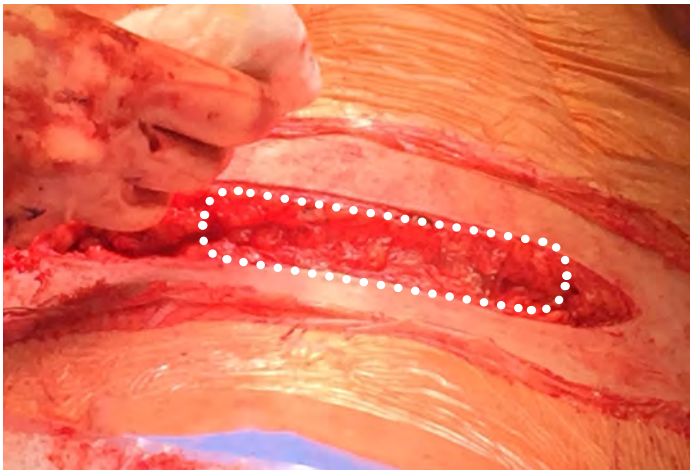


Figure 9
AmnioFix is placed into incision site and rehydratrated and positioned with damp cloth

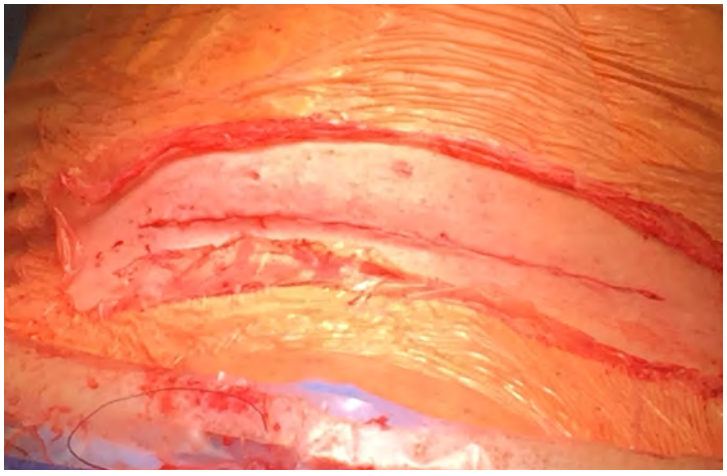


Figure 10
Skin is closed over AmnioFix

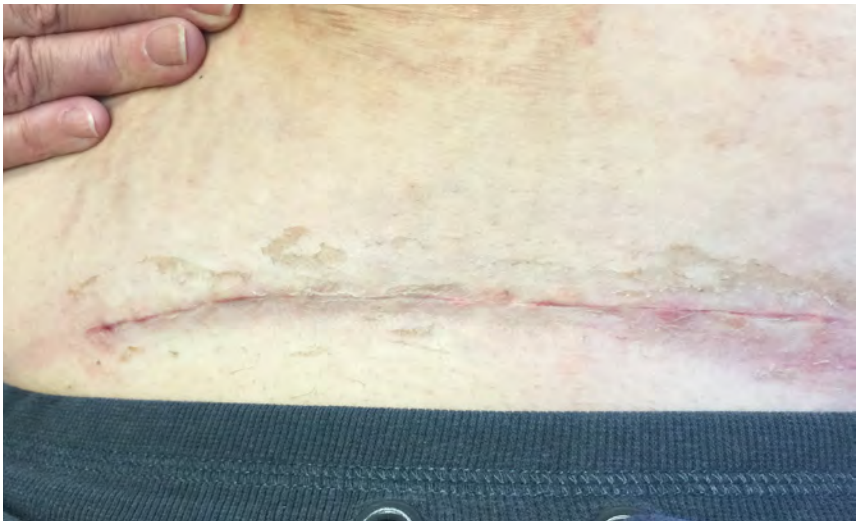


Figure 11
10 days post-op — incision is fully healed

FOLLOW UP

At the patient's 10 day follow-up, the incision was fully healed without signs of infection (Figure 11). This was impressive considering the large pannus fully covering the incision site. Consequently, the Dermabond® peeled away more than expected due to the incision site dampness. The patient also indicated that she had less pain and a faster recovery compared to her prior deliveries, and resumed normal activities, such as cleaning her home on post-op day 7.

CONCLUSION

Patient comorbidities and prior clinical history can increase risks during C-section delivery, as well as risk of post-op complications. OBGYNs may be required to alter their approach to address the most critical concerns. In this case, the original plan was slightly altered to address the areas that were considered highest risk. AmnioFix is a versatile graft that can help modulate inflammation, enhance healing, reduce scar tissue formation, and act as a barrier membrane. In this case example, the graft was used to address various patient needs during a C-section delivery.

REFERENCES

1. Morales KJ, Gordon MC, Bates GW Jr. Postcesarean delivery adhesions associated with delayed delivery of infant. Am J Obstet Gynecol. 2007 May;196(5):461.e1-6.
2. Lyell DJ. Adhesions and perioperative complications of repeat cesarean delivery. Am J Obstet Gynecol. 2011 Dec;205(6 Suppl):S11-8.
3. Wilson JA, Clark JJ. Obesity: impediment to postsurgical wound healing. Adv Skin Wound Care. 2004 Oct;17(8):426-35.

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