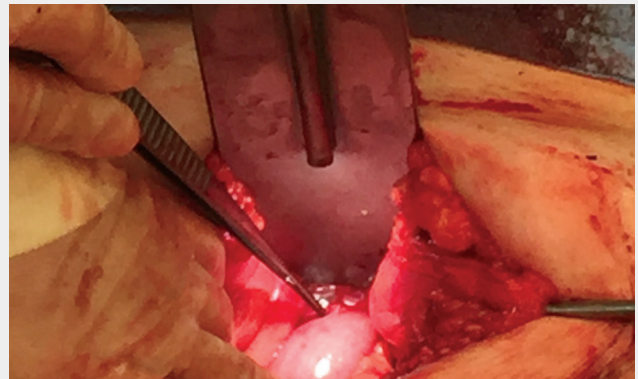


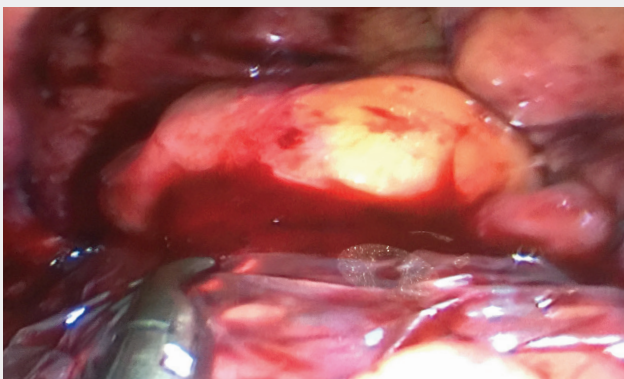
# ADVANCED PLACENTAL-BASED ALLOGRAFTS GENERAL AND COLORECTAL SURGERY CASEBOOK



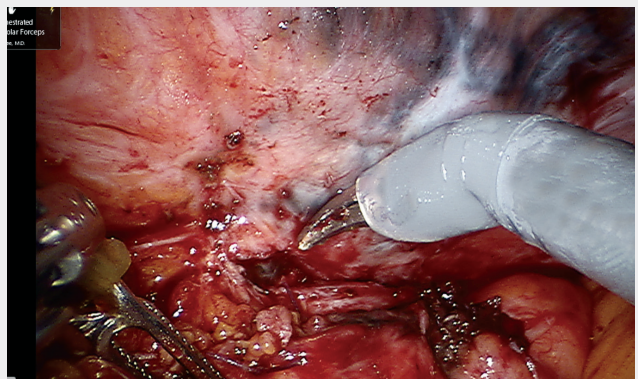
ACUTE ABDOMINAL WALL DEHISCENCE  
WITH EPIFIX®



RETROSPECTIVE MULTI-CENTER STUDY  
POSTER PRESENTATION: COLORECTAL  
ANASTOMOSES WITH AMNIOFIX®



COLOSTOMY REVERSAL WITH AMNIOFIX



COLOVESICAL FISTULA REPAIR WITH AMNIOFIX

# Acute Abdominal Wall Dehiscence With EPIFIX

John Ko, MD, PhD, FACS | Plastic Surgery | Elmhurst, NY

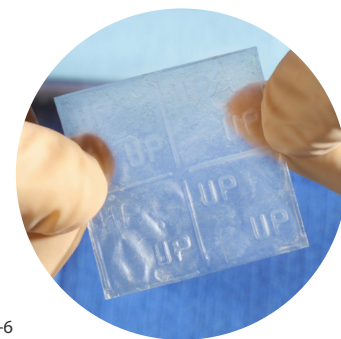
## Challenge

A 62-year-old obese male patient, BMI of 29, type II diabetes, with a history of hypertension, myocardial infarction with stent placements, multiple abdominal surgeries, and over forty years of cigarette smoking, underwent large ventral hernia repair. At one week postop, the patient developed ischemia at the incision line, which led to an incisional dehiscence.

Studies have shown a direct correlation between the number of comorbidities and clinical outcomes. A significant rise in complications, length of stay, and mortality rates is associated with the rise in number of patient comorbidities.<sup>1-3</sup>

## Surgical Intervention

The patient was managed with serial debridement and wet-to-dry dressings for two months, then placed on negative pressure wound therapy (NPWT) for four weeks at home. After one month of NPWT, the wound had only decreased by 30%. NPWT was discontinued, and EPIFIX was applied every other week, instead of weekly, due to the travel distance for the patient. EPIFIX is a dehydrated human amnion/chorion membrane allograft. The product provides a protective barrier that supports the healing cascade and protects the wound bed to aid in the development of granulation tissue in acute and chronic closures. It provides a biocompatible human extracellular matrix and contains 300+ regulatory proteins.<sup>4-6</sup>



EPIFIX

## Follow-Up

Upon examination at his two month EPIFIX follow-up visit, the wound was fully closed and re-epithelialized. The patient returned for a routine one-year visit and has remained fully closed and asymptomatic.



Following debridement



Four weeks of NPWT, only 30% size reduction, first EPIFIX 4 cm x 4 cm applied



Week 2: Two 2 cm x 3 cm EPIFIX applied



Week 4: One 2 cm x 3 cm EPIFIX applied



Week 8: Wound closed and stable

# Colostomy Reversal With AMNIOFIX

Francis S. Lee MD, FACS, Quan Le, Christina W. Lee | General Surgery | Irvine, CA

## Challenge

A 68-year-old male patient underwent an emergency Hartmann's procedure with a rectosigmoidectomy and end colostomy with a rectal pouch, due to a perforation of the sigmoid colon from acute diverticulitis.

Though wound healing in elderly people is not necessarily impaired, age related changes are evident. Comorbidities, which are associated with impaired healing, are more prevalent in older patient populations and can delay healing by 20-60%.<sup>12</sup>

Anastomotic leakage is the most common and much feared intraoperative complication in colostomy reversal.<sup>13,14</sup> One study showed the anastomotic leakage rate at as high as 3.8%.<sup>15</sup> In addition to anastomotic leakage, other common postoperative complications include wound infection, incisional hernia, ileus, and enteric fistula formation.<sup>13,14</sup>

## Surgical Intervention

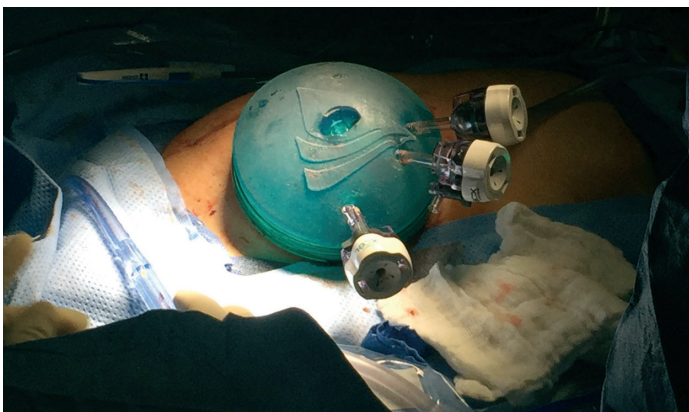
Five months later, when the patient's overall condition improved, a colostomy reversal using a single-port laparoscopic technique with AMNIOFIX was performed. A 2 cm x 6 cm AMNIOFIX graft was placed laparoscopically on the colorectal anastomotic, stapled site and stitched into place with absorbable sutures. AMNIOFIX is a dehydrated human amnion/chorion membrane allograft. The product provides a protective barrier that supports the healing cascade. It provides a biocompatible human extracellular matrix and contains 300+ regulatory proteins.<sup>4-6</sup>



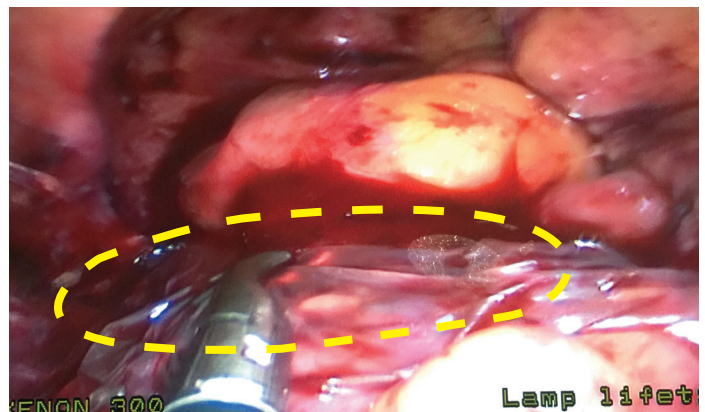
AMNIOFIX

## Follow-Up

The patient was seen two weeks after the surgery with no postoperative complications. The patient was having normal bowel movements daily.



Single-port laparoscopic approach



2 cm x 6 cm AMNIOFIX sheet placed on anastomosis

# Dehydrated Human Amnion/Chorion Membrane in Colorectal Anastomoses: A Retrospective Multi-Center Study<sup>4</sup>

F. Raymond Ortega, MD, FACS; Dennis Choat, MD, FACS, FASCRS; Emery Minnard, MD; Jeffrey Cohen, MD  
*The American College of Surgeons Clinical Congress, Oct 22-26, 2017, San Diego, CA*

## Background

- Anastomotic leaks following colorectal surgery have been reported to occur at a rate of approximately 6% and represent a significant postoperative complication with devastating consequences.<sup>7</sup>
- Anastomotic leaks are associated with severe post operative morbidity, prolonged hospital stay and poor outcomes, including mortality. At least one third of the mortality after colorectal surgery is attributed to anastomotic leaks.<sup>8</sup>
- Although risk factors and consequences of anastomotic leaks are well documented, little information regarding use of adjunct techniques to ameliorate this problem is available.

## Dehydrated Human Amnion/Chorion Membrane Allografts

- PURION® processed Dehydrated Human Amnion/Chorion Membrane (DHACM) (AMNIOFIX, MIMEDX Group, Inc., Marietta, GA) provides a protective barrier to support the healing cascade. The product contains human extracellular matrix components and 300+ regulatory proteins.<sup>1-3</sup>
- The DHACM allografts are available in a variety of sizes and configurations for use in acute and chronic wounds and surgical, tendon, and nerve applications.
- Previous peer-reviewed publications have described the surgical application of DHACM in patients having lumbar fusion with posterior instrumentation,<sup>7</sup> nerve sparing radical prostatectomy procedures,<sup>8</sup> and in women undergoing laparoscopic surgery for endometriosis.<sup>9</sup>

## Purpose

- To evaluate the incidence of anastomotic leaks in patients undergoing colorectal resections with and without the use of DHACM at three surgical centers.

## Methods

- A retrospective systematic review was conducted on the utilization of DHACM to wrap colonic anastomoses at the time of primary surgical repair by three surgeons at three different centers.
- With IRB approval, data from clinical records of patients that underwent colonic resection between 08/05/2015 and 09/30/2016 were reviewed.
- Use of DHACM to wrap the anastomoses (Y/N) and occurrence of leakage (Y/N) was identified in the clinical record at baseline and at each follow-up visit.
- In those receiving DHACM, either a 4 cm x 6 cm or 2 cm x 12 cm allograft was cut as needed and applied circumferentially to the anastomosis.
- The anastomotic leak rate was compared between patients whose anastomoses were wrapped with DHACM and those that were not.

## Results

- 390 anastomoses were wrapped with DHACM and 2,000 were not wrapped with DHACM.
- Without DHACM, 80 of the 2,000 (4.0%) of patients developed an anastomotic leak, while 4 of the 390 (1.03%) anastomoses wrapped with DHACM leaked (p=0.0022).

*The poster that was originally presented during the ACS 2017 conference and has minor edits incorporated. Note: The procedures in this study included colorectal, colo-colonic, and ileocolonic anastomoses.*

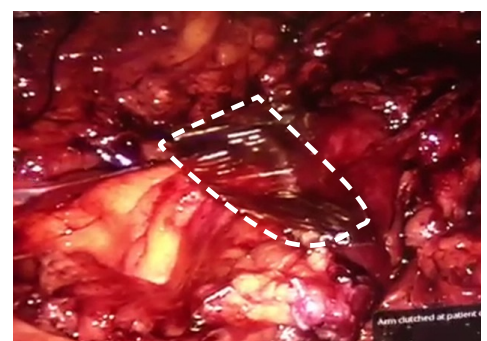
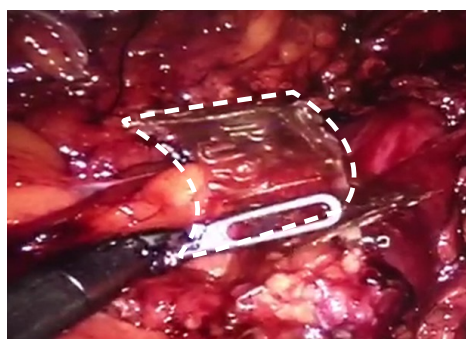
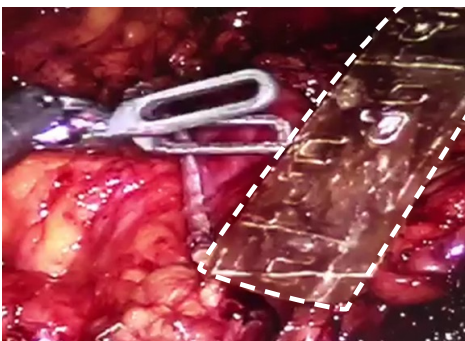
## Conclusion

- Anastomotic leaks are associated with increased post operative morbidity, prolonged hospital stay and poor outcomes.
- Materials that can act as a barrier to support the healing cascade are highly desirable to surgeons performing colorectal surgery.
- Inherent properties of amniotic membranes present significant therapeutic potential in this patient population.
- In this retrospective review, DHACM appeared to reduce the number of anastomotic leaks significantly in colon resection surgery ( $p=0.0022$ ) and may, therefore, reduce the prolonged hospital length of stay and/or the need for readmission.

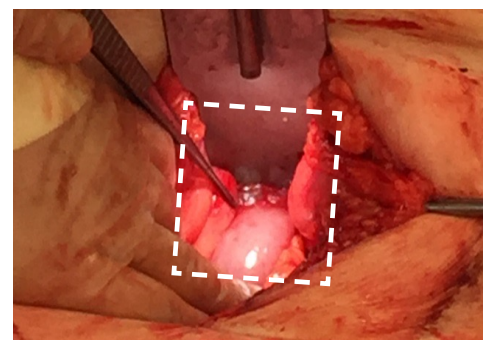
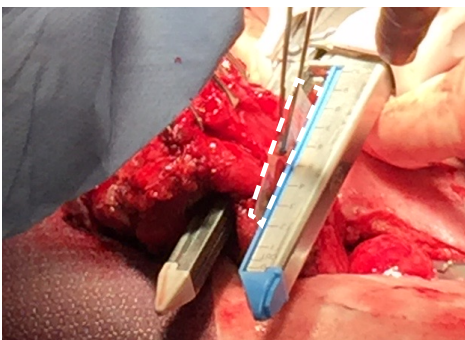
| Clinical Characteristics Overall (N=390) |                        | Anastomotic Leak Rate With and Without DHACM   |  |
|--|------------------------|--|--|
| Gender:                                  |                        | <p>4.00%</p> <p>74.25%</p> <p><math>p=0.0022</math></p> <p>1.03%</p> <p>No DHACM      DHACM</p> <p>Leak / N    80 / 2,000      4 / 390</p> |  |
| Female                                   | 254 (65.1%)            |  |  |
| Male                                     | 136 (34.9%)            |  |  |
| Age (years)                              | 60 ± 13<br>61 (15, 95) |  |  |
| BMI (kg/m <sup>2</sup> )                 | 32 ± 8<br>30 (16, 62)  |  |  |
| Diagnosis:                               |                        |  |  |
| Inflammatory Disease                     | 207 (53.1%)            |  |  |
| Cancer                                   | 183 (46.9%)            |  |  |

Data presented as mean +/- sd, median (min, max), or number (percent) as indicated.

## Examples of DHACM Applied in Colorectal Surgery



Laparoscopic placement of DHACM allograft wrapped around a bowel anastomosis



Low anterior resection with DHACM placed at anastomosis

Placement of DHACM allograft

DHACM wrapped around anastomosis

# Colovesical Fistula Repair With AMNIOFIX

Francis S. Lee, MD, FACS, Shahn Thaliffdeen, Alexander T. Phan, Christina W. Lee | General Surgery | Irvine, CA

## Challenge

A 71-year-old male patient presented with diverticulitis of the distal colon. Significant medical history included diabetes mellitus, nephrolithiasis with bilateral nephrostomy tubes, and kidney failure with ongoing hemodialysis. After responding to conservative therapy, the patient began passing gas through his urethra. A CT scan identified a small fistula between the patient's colon and bladder.

In this case, the treatment of the patient's colovesical fistula was further complicated by advanced age, several comorbidities, and significant medical history. An elderly patient with these comorbidities is at higher risk of postop complications from extensive surgery; therefore, it was decided to avoid a sigmoidectomy.

## Surgical Intervention

With the use of a robotic surgery approach and AMNIOFIX, the patient was able to undergo a less invasive and lower risk procedure. This approach allowed for a simple fistula resection and primary repairs on both sides of the fistula tract. 2 cm x 3 cm AMNIOFIX sheets were placed on both bladder and colon primary repair sites.

AMNIOFIX is a dehydrated human amnion/chorion membrane allograft. AMNIOFIX sheets provide a protective barrier that supports the healing cascade. AMNIOFIX provides a human biocompatible extracellular matrix (ECM) and contains 300+ regulatory proteins.<sup>4-6</sup>



AMNIOFIX

A loop ileostomy diversion was placed for eight weeks to further minimize risk of fistula recurrence. After eight weeks, the patient returned for an ileostomy reversal. A 4 cm x 6 cm AMNIOFIX sheet was placed on the loop ileostomy repair site and stitched into place with an absorbable suture. Prior to stoma site closure, a laparoscope was inserted at the ostomy site to observe the previous fistula repair site. There were no adhesions observed where the AMNIOFIX was placed, and the bladder was smooth and shiny in appearance. The stoma site was then closed, and the patient was discharged two days later without complications.

## Follow-Up

The patient's follow-up was two weeks after the ileostomy takedown. He had normal bowel movements and no complications.

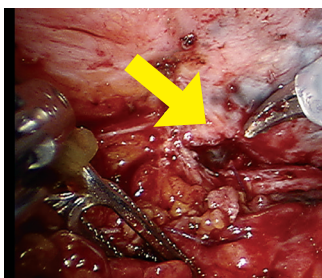
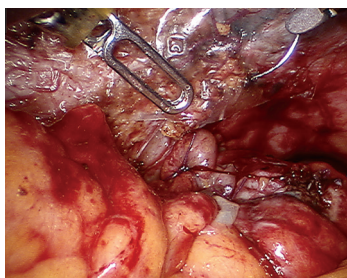
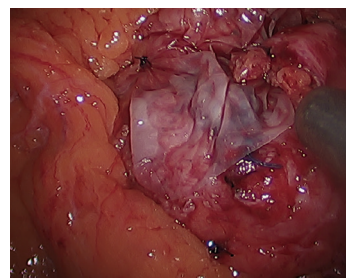


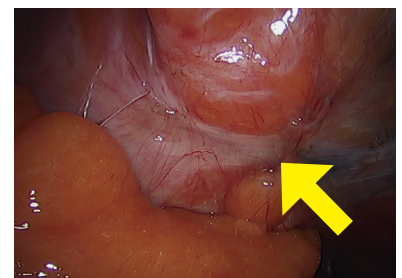
Image of fistula



2 cm x 3 cm AMNIOFIX sheet placed on bladder repair



4 cm x 6 cm AMNIOFIX sheet placed on ileostomy reversal at 8 weeks



2nd look at 8 weeks – repaired fistula with no adhesions observed

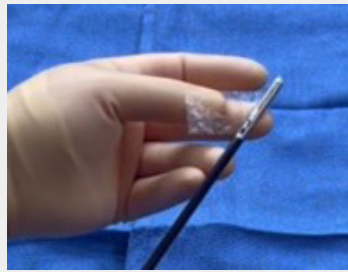
# Tips for Minimally Invasive Procedures

- Cut allograft to desired size, if needed, prior to introduction into the port.
- A minimum 8 mm port is recommended.
- Assure an optimal field of view by suction/ aspiration/evacuation of the relevant surgical field. This will optimize exposure and prevent accidental poor positioning or accidental removal of the allograft.
- Surgical equipment and surgical site should be dry and clean of debris (pass gauze in and out of cannula).
- Ensure allograft is not hydrated / wet prior to introduction.
- Use an atraumatic grasper to introduce the allograft sheet through the assistant port.

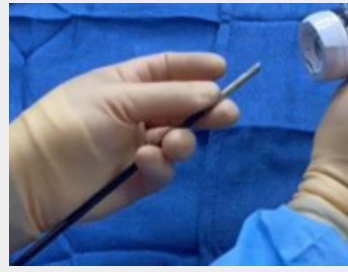
## Smaller Sheet Method



1. For a smaller sheet (e.g., 2 cm x 6 cm), grasp corner of allograft.



2. Wrap allograft around atraumatic grasper.



3. Hold the end of allograft in place while slowly and gently inserting it through cannula.

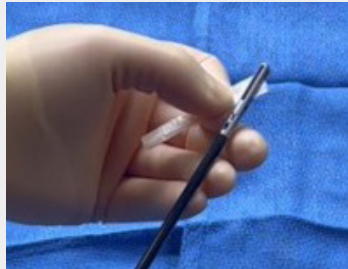


4. Release allograft from grasper and apply it to treatment area.

## Larger Sheet Method



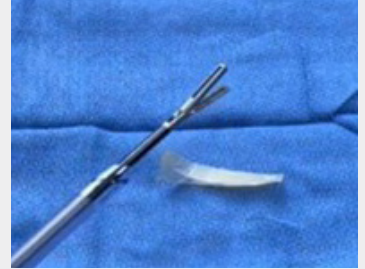
1. For a larger sheet (e.g., 4 cm x 6 cm), roll or fold allograft on a dry flat surface.



2. Grasp corner of allograft and wrap the remaining end of sheet around the grasper.



3. Hold the end of allograft in place while slowly and gently inserting it through cannula.



4. Release allograft from grasper.



5. Unfold or unroll the allograft and apply it to treatment area.

## To find out more about MIMEDX® products:

 Please Call: 866.477.4219  Email: [customerservice@mimedx.com](mailto:customerservice@mimedx.com)

**REFERENCES:** **1.** Thombs BD, Singh VA, Halonen J, Diallo A, Milner SM. The effects of preexisting medical comorbidities on mortality and length of hospital stay in acute burn injury: evidence from a national sample of 31,338 adult patients. *Ann Surg.* 2007;245(4):629-634. **2.** Myles PS, Iacono GA, Hunt JO, et al. Risk of respiratory complications and wound infection in patients undergoing ambulatory surgery: smokers versus nonsmokers. *Anesthesiology.* 2002;97(4):842-847. **3.** Dunne JR, Malone DL, Tracy JK, Napolitano LM. Abdominal wall hernias: risk factors for infection and resource utilization. *J Surg Res.* 2003;111(1):78-84. **4.** Koob TJ, Lim JJ, Masee M, Zabeck N, Denozière G. Properties of dehydrated human amnion/chorion composite grafts: Implications for wound repair and soft tissue regeneration. *J Biomed Mater Res B Appl Biomater.* 2014;102(6):1353-1362. **5.** Lei J, Priddy LB, Lim JJ, Masee M, Koob TJ. Identification of Extracellular Matrix Components and Biological Factors in Micronized Dehydrated Human Amnion/Chorion Membrane. *Adv Wound Care (New Rochelle).* 2017;6(2):43-53. **6.** MIMEDX Internal Report. MM-RD-00086, Proteome Characterization of PURION Processed Dehydrated Human Amnion Chorion Membrane (DHACM) and PURION PLUS Processed Dehydrated Human Umbilical Cord (DHUC) Allografts. **7.** Hammond J, Lim S, Wan Y, Gao X, Patkar A. The burden of gastrointestinal anastomotic leaks: an evaluation of clinical and economic outcomes. *J Gastrointest Surg.* 2014;18(6):1176-1185. **8.** Kirchoff P, Clavien PA, Hahnloser D. Complications in colorectal surgery: risk factors and preventive strategies. *Patient Saf Surg.* 2010;4(1):5. **9.** Subach BR, Copay AG. The use of a dehydrated amnion/chorion membrane allograft in patients who subsequently undergo reexploration after posterior lumbar instrumentation. *Adv Orthop.* 2015;2015:501202. **10.** Patel VR, Samavedi S, Bates AS, Kumar A, Coelho R, Rocco B, Palmer K. Dehydrated human amniotic membrane allograft nerve wrap around the prostatic neurovascular bundle accelerates early return to continence and potency following robot-assisted radical prostatectomy (RALP): propensity score-matched analysis. *Eur Urol.* 2015;67(6):977-980. **11.** Dulemba J, Mirzakhani P, Istwan NB. Evaluation of dehydrated human amnion/chorion membrane as an adhesion barrier in women undergoing robotic laparoscopy. *Gynecol Obstet. (Sunnyvale)* 2016;6(10):405. **12.** Sgonc R, Gruber J. Age-related aspects of cutaneous wound healing: a mini-review. *Gerontology.* 2013;59(2):159-164. **13.** Khan S, Alvi R, Awan Z, Haroon N. Morbidity of colostomy reversal. *J Pak Med Assoc.* 2016;66(9):1081-1083. **14.** Pittman DM, Smith LE. Complications of colostomy closure. *Dis Colon Rectum.* 1985;28(11):836-843. **15.** Kaiser AM, Israelit S, Klaristenfeld D, et al. Morbidity of ostomy takedown. *J Gastrointest Surg.* 2008;12(3):437-441.