

Dehydrated Human Amnion/Chorion Membrane in Colorectal Anastomoses

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Abstract

Background: Anastomotic leaks following colorectal surgery represent a significant postoperative complication with devastating if not lethal consequences. This complication is associated with severe morbidity and mortality. Large patient series have demonstrated that this event can occur in as much as 3 to 15% of bowel anastomoses. Although there is much literature regarding the risks factors and consequence of this complications, few attempts have been made using adjunct techniques to ameliorate this problem. The aim of this study was to evaluate the use of dehydrated human amnion and chorion membrane (dHACM) to reduce the incidence of this complication.

Methods: A systematic review was made of a single surgeon's experiences utilizing dHACM to wrap his colonic anastomoses at the time of primary surgical repair. Eighty two of patients underwent colonic resections with anastomoses wrapped in dHACM. The leak rate was then compared to the surgeon's historic leak rate prior to the use of dHACM.

Results: Approximately 40 patients developed anastomotic leak in over 1000 surgeries prior to the adoption of dHACM wrapping of the anastomosis for an estimated leak rate of 4.0%. One of patient developed anastomotic leak in eighty-two of surgeries where dHACM wrapping of the anastomosis was used for a leak rate of 1.21%.

Conclusion: dHACM appears to significantly reduce the number of anastomotic leaks in colon resection surgery and can therefore reduce the prolonged length of stay and/or the need for readmission in these patients.

Background

- Anastomotic leaks have been reported to occur at a rate of 3-15% following colorectal surgery and represent a significant postoperative complication with often dire consequences.¹
- This complication is associated with severe morbidity and mortality. At least one third of the mortality after colorectal surgery is attributed to anastomotic leaks.¹
- Although risks factors and consequences of this condition 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) is a minimally manipulated, dehydrated, non-viable cellular amniotic membrane allograft. The dHACM products serve to regenerate damaged tissue and contain human extracellular matrix components, essential growth factors, and specialized mediating cytokines that modulate inflammation, reduce scar tissue formation, and enhance healing.²⁻⁴
- The dHACM allografts are available in a variety of sizes and configurations for use in surgical, soft tissue, tendon, and nerve applications.
- Previous peer-reviewed publications have described the use of dHACM in patients having lumbar fusion with posterior instrumentation,⁵ nerve sparing radical prostatectomy procedures,⁶ and as an adhesion barrier in women undergoing laparoscopic surgery for endometriosis.⁷

Purpose

- We sought to evaluate the incidence of anastomotic leaks in patients undergoing colorectal resections with and without the use of dHACM.

dHACM = AmnioFix®, MiMedx Group, Inc., Marietta, GA
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Methods

- With IRB approval, a retrospective study of data from clinical records of patients that underwent colonic resection performed by a single surgeon between 08/05/2015 and 09/30/2016 was conducted.
- 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, a 4 cm x 6 cm allograft was applied circumferentially to the anastomosis.
- A total of 82 patients that underwent colonic resection and had their anastomoses wrapped with dHACM were identified.
- The anastomotic leak rate was compared between patients whose anastomoses were wrapped with dHACM and those that were not.

Results

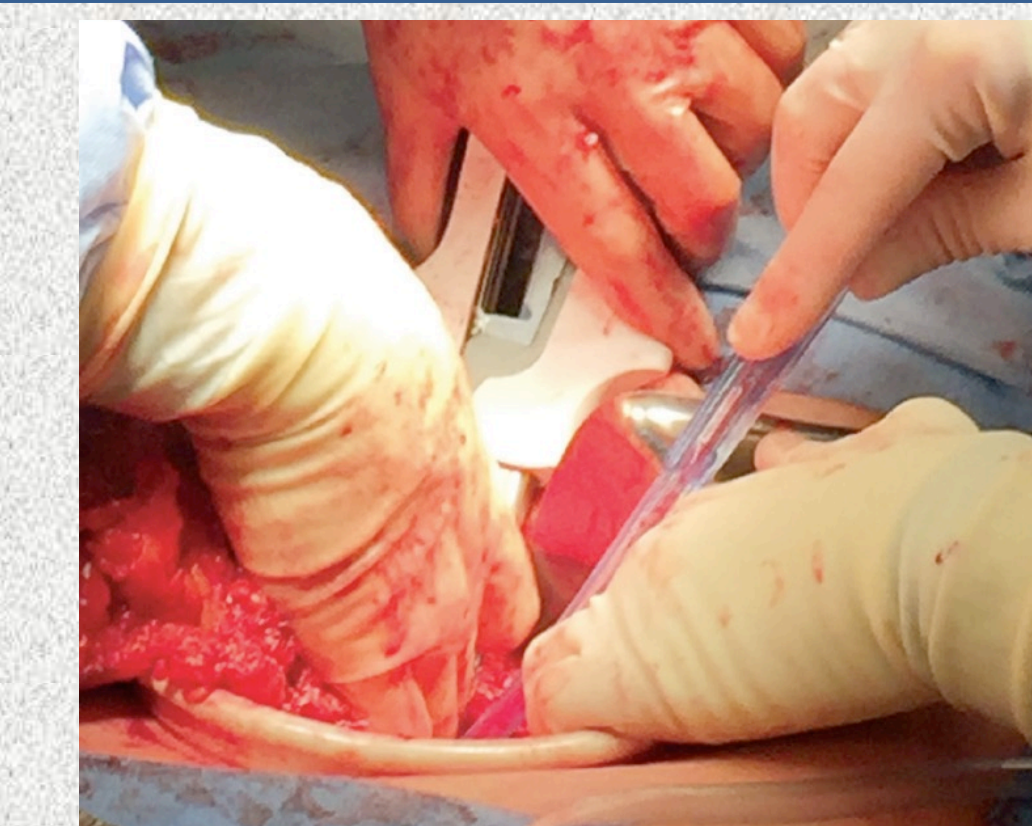
- In our practice, prior to the adoption of dHACM wrapping of the anastomosis, approximately 40 of 1,000 (4.0%) patients developed an anastomotic leak.
- 1 of 82 patients (1.21%) developed an anastomotic leak where the anastomosis was wrapped with dHACM.

Clinical Characteristics		dHACM (N=82)
Sex	Female	44 (53.7%)
	Male	38 (46.3%)
Age (years)	Mean	58
	SD	13
	Min	26
	Median	61
	Max	84
BMI (kg/m ²)	Mean	35.1
	SD	9.3
	Min	21.3
	Median	31
	Max	62
Diagnosis	Inflammatory Disease	34 (42%)
	Cancer	48 (58%)

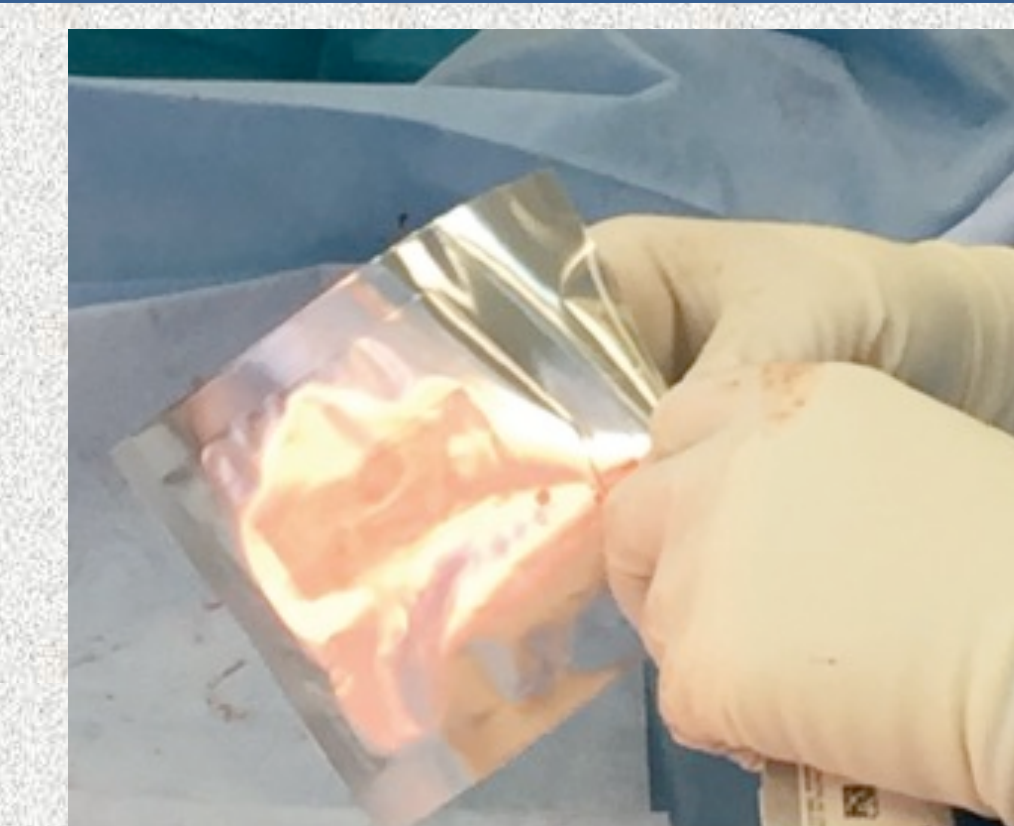
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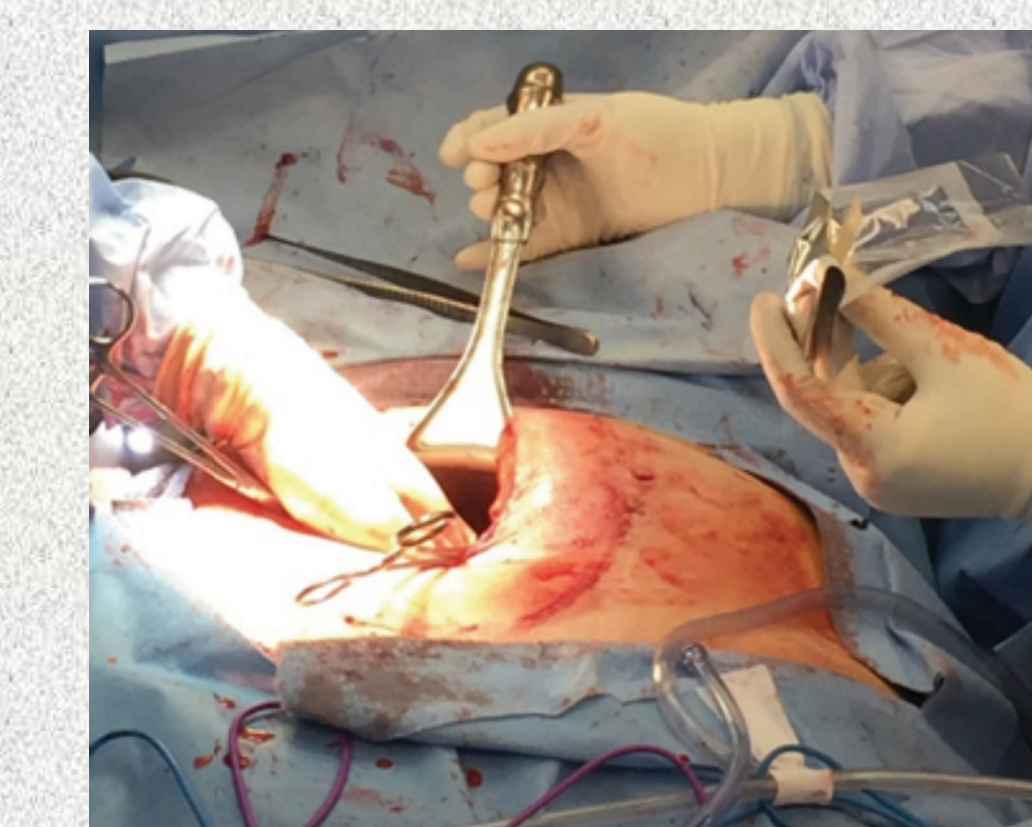
Example of dHACM Applied in a Colorectal Surgery Case



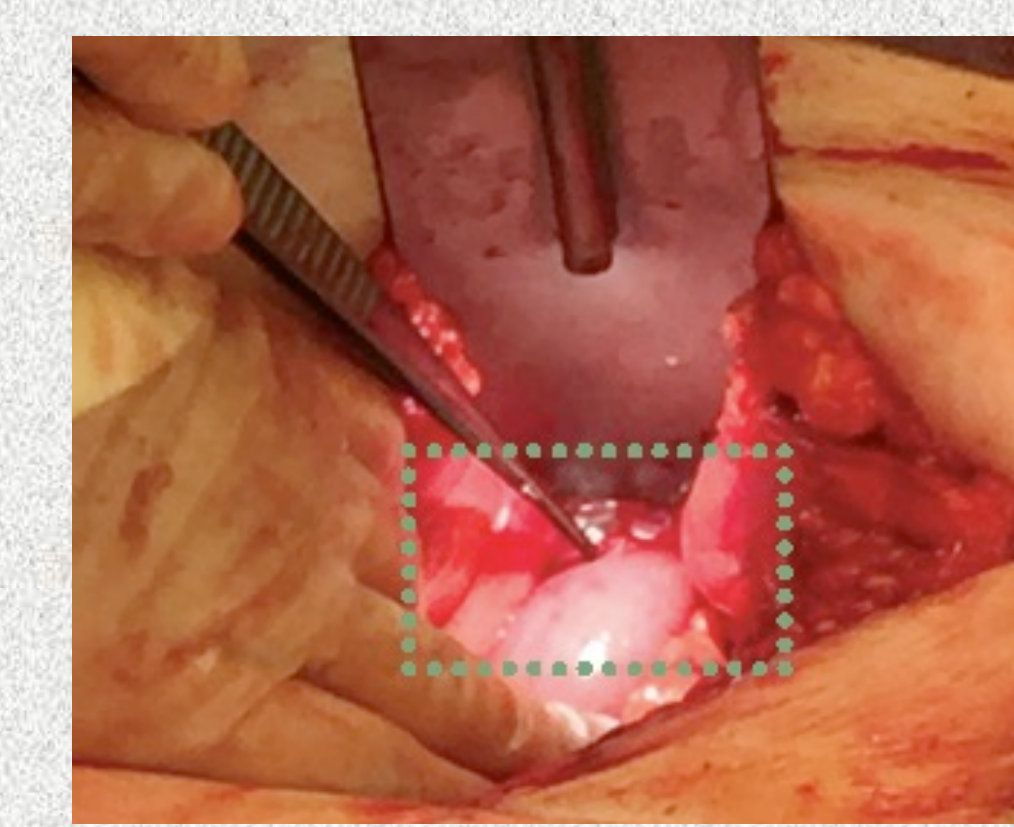
Lower anterior resection with anastomosis



dHACM allograft in a sterile pouch



Placement of dHACM allograft



dHACM wrapped around the anastomosis

Conclusions

- Materials that can act as a barrier, reduce scar tissue formation, modulate inflammation, and enhance healing are highly desirable to surgeons performing colorectal surgery.
- Amniotic membrane has inherent properties including being immune privileged, and having the ability to modulate inflammation and reduce scar tissue formation. Such properties present significant therapeutic potential for use of amniotic membrane during wound healing, tissue repair, and regenerative therapy.
- Anastomotic leaks are associated with increased post operative morbidity, prolonged hospital stay and poor outcomes.
- In this retrospective review, dHACM appears to significantly reduce the number of anastomotic leaks in colon resection surgery and may therefore reduce the prolonged hospital length of stay and/or the need for readmission.