

Dehydrated Human Amnion/Chorion Membrane in Colorectal Anastomoses: A Retrospective Multi-Center Study

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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.¹
- 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.²
- Although risks 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 (dHACM)

- PURION® Processed dHACM is a minimally manipulated, dehydrated, non-viable cellular amniotic membrane allograft. The dHACM allografts contain human extracellular matrix components, essential growth factors, and specialized mediating cytokines that modulate inflammation, reduce scar tissue formation, and enhance healing.³⁻⁵
- 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,⁶ nerve sparing radical prostatectomy procedures,⁷ and as an adhesion barrier in women undergoing laparoscopic surgery for endometriosis.⁸

Purpose

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

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Methods

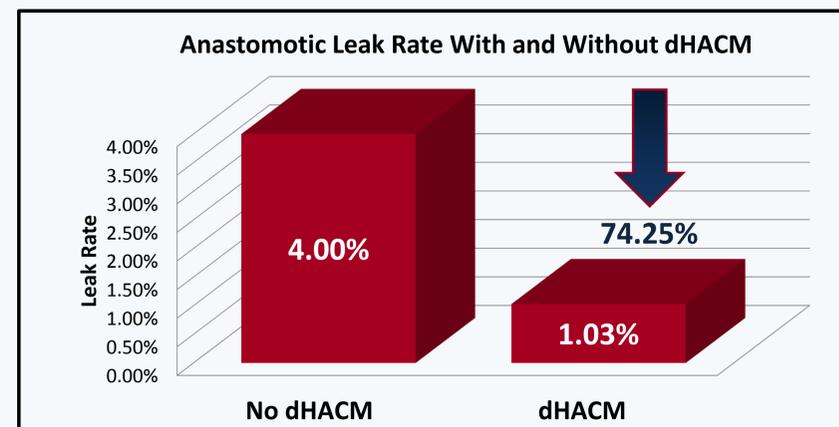
- A retrospective systematic review was conducted on the utilization of dHACM to wrap colonic anastomoses at the time of primary surgical repair by three surgeons at three different centers.
- With IRB approval, data from clinical records of patients that underwent colonic resection between 08/05/2015 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 a 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

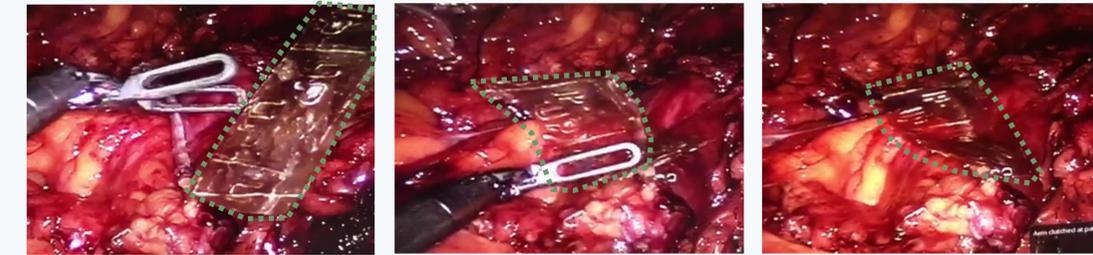
- 390 anastomoses were wrapped with dHACM and 2000 were not wrapped with dHACM.
- Without dHACM, 80 of 2,000 (4.0%) of patients developed an anastomotic leak, while 4 of 390 (1.03%) anastomoses wrapped with dHACM leaked.

Clinical Characteristics	
Overall (N=390)	
Gender:	
Female	254 (65.1%)
Male	136 (34.9%)
Age (years)	60 ± 13 61 (15, 95)
BMI (kg/m²)	32 ± 8 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



Lower anterior resection with anastomosis

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 immunologically 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.
- 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.

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