Real-World Clinical Outcomes Utilizing Human Amnion/ Chorion Membrane (HACM) Allografts for Intracorporeal Surgical Wounds

Bidhan Das, MD, FACS[1]; Dennis Choat, MD, FACS, FASCRS[2]; Nezar Jrebi, MD, FACS, FASCRS[3]; Matthew Bardin, PharmD, BCPS[4]

[1]Southwest Surgical Associates, Houston, TX; [2]Piedmont Physicians Colon and Rectal Surgery of Fayetteville, GA; [3]North Texas Surgical Specialists, Ft. Worth, TX; [4]STC Clinical, LLC, Tampa, FL

INTRODUCTION

Human amnion/chorion membrane (HACM) allografts have been utilized for over a century to treat external wounds, such as skin ulcers, burns, and certain ophthalmic conditions. Recently, their application has extended to neuropathic wounds, dental uses, and orthopedics. However, there is limited published data on HACM's use in treating intracorporeal wounds associated with gastrointestinal surgery. This abstract discusses an interim analysis of real-world outcomes for patients receiving HACM allografts as a protective barrier after colonic resection operations.

HACM is an immune-privileged natural biological barrier rich in cytokines and growth factors, which promote the proliferation and migration of mesenchymal stem cells and provide a matrix for cell ingrowth. In vitro studies demonstrate HACM retains biologically active growth factors like platelet-derived growth factor, transforming growth factor, basic fibroblast growth factor, epidermal growth factor, and others such as interleukins and metallopeptidase inhibitors.[1-2] These factors support wound healing and tissue regeneration rather than supporting more inflammatory aspects of healing.

In animal models, HACM has shown benefits in healing anastomotic wounds, both in simple surgeries and those complicated by trauma, chemotherapy, and radiation. The results suggest HACM-treated anastomoses have higher bursting pressures, reduced inflammation, enhanced neo-angiogenesis, increased fibroblast activity, better epithelialization, and improved collagenization compared to untreated controls.[3-5] Encouraged by these positive results, some surgeons have started using HACM as a risk mitigator and augmentation after creating colorectal anastomoses.

METHODS

To assess the effectiveness of HACM in this context, the authors initiated a chart review of consecutive adult patients receiving HACM as a protective barrier for colorectal anastomoses between January 2016 and June 2023. Data collection is to continue through June 2024. Published data on colorectal leak rates from the National Surgical Quality Improvement Program (NSQIP)[6] and Premier Healthcare Database (PHD)[7] were used as control benchmarks. To match these controls, the following procedures without a protective ostomy were evaluated: right colectomy, left/sigmoid colectomy, and low anterior resection (LAR). The incidence of anastomotic leak was broadly defined as: re-operation, re-anastomosis, stent, colostomy, drainage, and/or abscess within 2 to 30 days post-surgery. The study was granted IRB exemption prior to data collection.

RESULTS

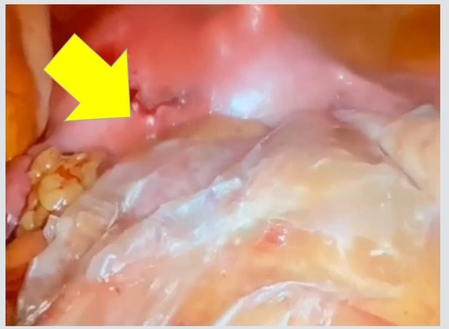
Table 1. Interim Dataset (n=398 HACM)	
Patient Demographics	
Protocol Defined Anastomotic Leak Rates	
HACM Cohort vs NSQIP[6]	**1.8% vs. 6%; p= 0.0010** (7/398 vs. 40/664)
HACM Cohort vs PHD[7]	**1.8% vs. 6.2%; p= 0.0004** (7/398 vs. 6,174/99,879)
30-Day All Cause Hospital Readmission	
HACM Cohort vs PHD[7]	**5.3% vs. 11.1%; p= 0.0003** (21/398 vs. 11,079/99,879)
Patient Demographics	
Mean Age (Range)	61 years (18-94)
Sex: Male/ Female	199 (50%) / 199 (50%)
Mean BMI (Range)	29.2 kg/m2 (13.5-52.7)
ASA Classification I / II / III / IV (n, %)	8 (2%) / 195 (49%) / 182 (45.7%) / 13 (3.3%)
Diverticulitis / Cancer/ Adenoma (n, %)	169 (42.5%) / 139 (34.9%) / 62 (15.6%)
Left or Sigmoid / Right / LAR (n, %)	55 (13.8%) / 148 (37.2%) / 195 (49%)
Laparoscopic / Robotic / Open (n, %)	302 (75.9%) / 61 (15.3%) / 35 (8.8%)

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HACM sheet



HACM wrapped on an anastomosis

DISCUSSION

Anastomotic leaks are one of the most serious complications of colorectal surgery due to their potential for increased morbidity and significant mortality with rates as high as 32% to 35%.[6,7] In the United States, the overall incidence of anastomotic leaks in colorectal surgery has been estimated to be around 5 to 6.2%.[6-8] Not surprisingly, these leaks are associated with an increased length of stay (LOS), rehospitalizations, and clinical sequelae, which also leads to higher costs.[6-8] For example, in a review of Medicare claims data, leaks were associated with significantly higher index costs ($48,982 vs $18,312), readmission costs ($17,055 vs $8,300), and LOS (19 vs 7 days), p<0.001 for all.[8] Furthermore, data from the PHD reiterates this point noting the LOS is 7.3 days longer and costs over $24,000 greater in patients with leaks than without, p<0.001 for both.[7] Considering the significant clinical and economic burden associated with anastomotic leaks, their prevention remains a priority.

CONCLUSION

Interim results from this study indicate HACM wrapped around a colonic anastomosis is associated with a significant reduction in anastomotic leaks and rehospitalizations. Notably, among the seven protocol-defined leaks, two cases were not true anastomotic leaks, but related to other causes (hernia repair and abscess at a catheter site). This is the largest known dataset describing the use of HACM for intracorporeal surgical wounds. Data collection is ongoing, with plans to publish the full results once complete. HACM allografts may prove to be an effective strategy for mitigating surgical risks in colorectal and other types of intracorporeal operations.