Lessons learned from the compassionate use of Connect-EA in ten patients with long-gap esophageal atresia

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Background/Objective

Connect-EA™:

- A novel minimally-invasive device system for repair of esophageal atresia (EA)
- Performs magnetic compression anastomosis (MCA) to establish esophageal continuity
- Avoids an invasive operative intervention
- Engineered to minimize anastomotic complications (e.g. leak, stricture)

- We describe the ten first-in-human cases using the Connect-EA™ and key lessons learned

Device Description

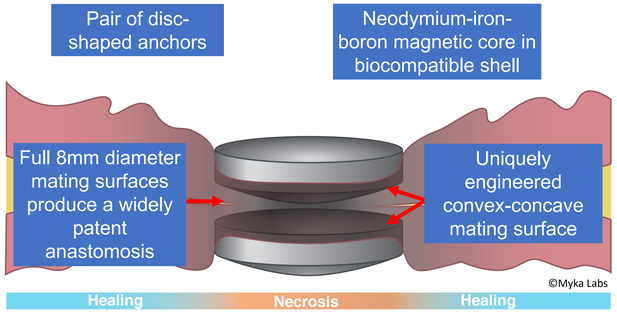


Figure 1. Schematic of tissue compression between magnetic anchors. Unique mating surface geometry creates higher central pressure inducing necrosis, while lower peripheral pressure minimizes perianastomotic inflammation and allows for epithelialization. This work has been used with the permission of Myka Labs.

Inclusion Criteria

Long-gap EA

Pouches approximated on endoscopic gap study

Institutional Review Board (IRB) and FDA compassionate use approval

High risk for perioperative morbidity/mortality due to significant physiologic and anatomic comorbidities

Device Placement and Anastomosis Formation

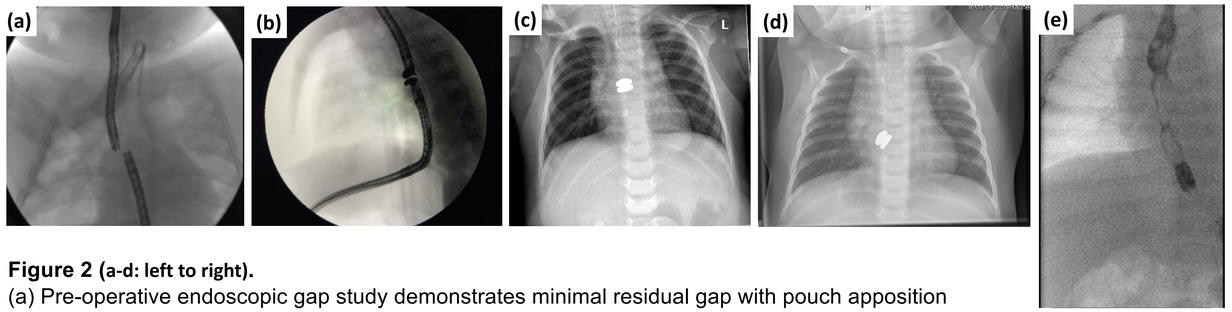


Figure 2 (a-d: left to right).
(a) Pre-operative endoscopic gap study demonstrates minimal residual gap with pouch apposition
(b) Anchors delivered endoscopically – upper pouch anchor trans-orally and lower pouch anchor via existing gastrostomy
(c) Post-operative daily chest radiographs confirm well-positioned mated anchors and monitor for device migration
(d) Upon anastomosis maturation, device spontaneously releases from tissue and can be excreted or retrieved endoscopically
(e) Post-operative esophagram demonstrates esophageal patency

Preliminary Results

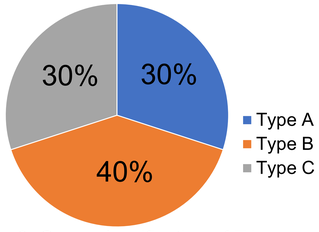


Figure 3. Gross classification of EA among study participants (n=10).

Table 1. Patient demographics and characteristics

	n=10
Median Age at Anchor Placement, months (range)	2 (1-13)
Presence of Severe Concomitant Medical Comorbidities, n (%)*	2 (20)
Prior Surgical Interventions, n (%)	
Esophageal Pouch Suture Approximation	9 (90)
Tracheoesophageal Fistula Ligation	7 (70)
Other**	2 (20)

Trisomy 21, Pulmonary, Cardiac, GI, Vascular, Endocrine
***Esophageal, Cardiac*

- Successful esophageal continuity = 90%
- Device-related adverse events = 0%

- Median OR time for placement = 29.5 minutes
- Median time to anastomotic patency = 12 days (5-21)
- Anchors retrieved endoscopically in 5 patients

- Median esophageal dilations = 4 (1-11)*
- Anastomotic leak = 0%
- Recalcitrant anastomotic stricture = 0%*
- 8/9 patients tolerating oral intake

*Median follow-up time 14 months (range 1-42)

- No thoracotomy or single-lung ventilation required
- Minimal operative and anesthesia time (<30min)
- Feasible in patients with prior intra-thoracic operations
- Avoidance of esophageal diversion and/or replacement in a high-risk surgical population

Key Lessons

1. Connect-EA™ is a safe minimally-invasive alternative for primary EA repair in diverse EA patients, including high-risk and long-gap EA

2. In long-gap EA, pouch approximation should not be performed with metallic clips or permanent suture – which will preclude future Connect-EA™ use

3. Occasional anastomotic narrowing after Connect-EA™ use is highly responsive to a minimal dilation regimen

4. Timing of first anastomotic dilation should be determined by patient-specific factors (e.g. tissue quality and perfusion, anastomotic tension, nutrition)

Conclusions

- Magnetic compression anastomosis with Connect-EA™ is a safe and feasible minimally-invasive alternative for primary EA repair in long-gap EA patients at increased risk for perioperative complications due to high-risk medical and anatomic comorbidities

- Future study should evaluate the use of Connect-EA™ for primary EA repair in all patients with EA, regardless of subtype

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