

Study Official Title:

Intrathoracic Esophagogastric Anastomosis
After Robot Assisted Minimally Invasive
Esophagectomy Using STRATFIX

NCT number: NCT02609425

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Describe Study Significance:	<p>Esophagectomy is regarded as one of the most complex surgical procedures. It involves multiple highly technical steps, the most crucial of which is the creation of an anastomosis between the remnant esophagus and the gastric conduit. The challenges posed by the success of this esophago-gastric anastomosis is made evident by the existence of multiple techniques employed by experienced surgeons for the creation of this anastomosis. Minimally invasive esophagectomy adds yet another degree of complexity to this procedure and to the creation of an esophago-gastric anastomosis. We have performed over 50 robot assisted minimally invasive esophagectomies with an intra thoracic esophago-gastric anastomosis. Our technique utilizes a series of interrupted absorbable suture to create the anastomosis. We propose to demonstrate the safety and efficacy of utilizing an absorbable running suture for completion of a hand sewn intra thoracic esophago-gastric anastomosis during minimally invasive esophagectomy. There are many advantages to hand sewn anastomosis compared with stapled, e.g. EEA, anastomosis. Two potential advantages are a lower leak rate and a lower stricture rate. Traditionally, hand sewn anastomosis is performed with interrupted suture of absorbable material. While effective, this technique requires multiple sutures, thus increasing operative time and material cost. Utilizing a running suture technique has the potential to reduce operative time and overall operative cost. Furthermore, it may lead to a reduction in postoperative morbidity by reducing anastomotic leak rate and stricture formation. The overall design of STRATFIX is ideally suited for such an application. The purpose of the proposed study is to demonstrate that a hand sewn anastomosis using STRATFIX is safe and effective after minimally invasive esophagectomy. If proven, one may reasonably conclude that STRATFIX may be safely used in other less complex anastomoses and closures throughout the gastrointestinal tract. Furthermore, the work may promote the utilization of STRATFIX for other applications, e.g. closure of the vaginal cuff after hysterectomy.</p>
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Describe hypothesis (research question):	<p>Use of STRATFIX in performing a hand sewn intrathoracic anastomosis after minimally invasive esophagectomy is non inferior (and may be superior) to historical cases in which the anastomosis was completed using other types of suture material.</p>
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Primary Endpoint:	<p>Anastomotic leak rate after esophagectomy.</p>
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Secondary Endpoints:	<p>Anastomotic stricture rate after esophagectomy.</p>
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Inclusion criteria:	<ol style="list-style-type: none"> 1. All patients with esophageal cancer who are deemed candidates for minimally invasive robot assisted Ivor Lewis esophagogastrrectomy. 2. Patients who provide written informed consent for the study.
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Exclusion criteria:	<ol style="list-style-type: none"> 1. Any patient with esophageal cancer who is not deemed a surgical candidate or who is not deemed a candidate for the Ivor Lewis technique of esophagectomy (with Intrathoracic anastomosis). 2. Any patient less than 18 years of age.
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Study Procedures:	<p>Our standard minimally invasive esophagectomy technique will be employed.</p> <ol style="list-style-type: none"> 1. Creation of gastric conduit laparoscopically. 2. Robotic assisted esophageal mobilization through the right chest. 3. Robotic assisted intrathoracic anastomosis at or above the level of the azygous vein. 4. Barium swallow performed on post operative day 5-7 to assess anastomotic integrity. 5. Periodic clinical follow up on an outpatient basis to assess need for any interventions for anastomotic stricture.
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Steps to protect
rights of study
subjects:

Patients will be identified by number only.
All patient data will be stored in a password protected computer to which only Dr. Hammoud has access.
The computer containing patient data is located in Dr. Hammoud's office under lock.

References:

1. Cerfolio RJ, Bryant AS, Hawn MT. Technical aspects and early results of robotic esophagectomy with chest anastomosis. *Journal of Thoracic and Cardiovascular Surgery* 145: 90-6;2013.
2. Inderpal S, Sarkaria*, Nabil P, Rizk, David J, Finley, Manjit S, Bains, Prasad S, Adusumilli, James Huang and Valerie W. Rusch. Combined thoracoscopic and laparoscopic robotic-assisted minimally invasive esophagectomy using a four-arm platform: experience, technique and cautions during early procedure development. *Eur J Cardiothorac Surg* 2013, 1-9.
3. Sebastian G. de la Fuente • Jill Weber • Sarah E. Hoffe • Ravi Shridhar • Richard Karl • Kenneth L. Meredith. Initial experience from a large referral center with robotic-assisted Ivor Lewis esophagogastrectomy for oncologic purposes. *Surg Endosc* (2013) 27:3339–3347.
4. Lyall A. Gorenstein, MDa, Marc Bessler, MDb, Joshua R. Sonett, MD. Intrathoracic Linear Stapled Esophagogastric Anastomosis: An Alternative to the End to End Anastomosis. *Ann Thorac Surg* 91: 314-316;2011.
5. Hiroshi Okabe, Eiji Tanaka, Shigeru Tsunoda, Kazutaka Obama, Yoshiharu Sakai. Intrathoracic Esophagogastric Anastomosis Using a Linear Stapler Following Minimally Invasive Esophagectomy in the Prone Position. *J Gastrointest Surg* (2013) 17:397–402.