Please cite this article as: Laxminarayan Bhandari, Novel stapling device for open and thoracoscopic esophageal anastomosis in congenital esophageal atresia. *Hypothesis* 2011, **9**(1): e?.

Novel stapling device for open and thoracoscopic esophageal anastomosis in congenital esophageal atresia

Laxminarayan Bhandari

Esophageal atresia, with or without trachea-esophageal fistula, are relatively common congenital anomalies. The surgical correction requires placement of anastomotic sutures, which are considered technically demanding, relatively imprecise and are associated with a steep learning curve. The need for a mechanical device for anastomosis has been stressed, as conventional stapling devices have their own limitations in this regard. We propose a unique anastomotic device that can be used in open and thoracoscopic repairs. This device is based on the principle that ideal healing requires adequate approximation and minimal tension. We try to achieve this by placing staples circumferentially, with the body of the staple being parallel to the long axis of the esophagus.This novel technique has many advantages. The tedious part of anastomosis can be done easily, quickly and safely. Adequate approximation would minimize scarring and stricture, and there will be no purse-string effect, and hence no impedance to the growth of neonatal esophagus. Such a device would be very helpful, and it needs to be manufactured, tested and modified to tackle unforeseen hurdles.

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Received: yyyy/mm/dd; Accepted: yyyy/mm/dd; Posted online: yyyy/mm/dd

Introduction

ESOPHAGEAL ATRESIA (EA), with or without trachea-esophageal fistula (TEF), are relatively common congenital anomalies with an estimated incidence of 1 per 3000–4000 live births. It occurs sporadically and sometimes is associated with VACTREL anomalies (Vertebral anomalies, Anal atresia, Cardiovascular anomalies, Tracheoesophageal fistula, Esophageal atresia, Renal anomalies, Limb defects). The exact etiology and embryology are not clearly known (1). It presents in the early post natal period with excessive drooling, respiratory distress and cyanosis due to aspiration. The clinical diagnosis is confirmed by the inability to pass a nasogastic tube into the stomach. Radiographic evaluation would reveal coiling of the tube in the esophageal pouch. The presence or absence of gas in the stomach would help to determine the type. There are 5 types described: Atresia without a fistula (Type A, 13% incidence), Atresia with proximal fistula (Type B, 1%), Atresia with a distal fistula (Type C, 78%), Atresia with both proximal and distal fistula (Type D, 2%) and H type (Type E, 2%) (Fig. 1) (1, 2).

The traditional surgical treatment for TEF/EA is by the extra pleural thoracotomy approach on the side opposite of the aortic arch. After collapsing and retracting the lung, the azygous vein is divided to reveal the underlying fistula, if present. The fistula is suture ligated, and the proximal esophagus is mobilized adequately. The distal esophagus is not mobilized generously as it does not have a robust blood supply like that of the proximal segment. The suturing is done with 4–0 or 5–0 Polydioxanone, Polyglactin or silk in one or two layers (1,2). One-layer anastamosis is associated with increased incidence of leaking, while the two-layer technique is associated with more stricture formation (2).

Esophageal gaps are very common and are tackled with one of numerous esophageal lengthening procedures such as Kimura, Livaditis, Scharli, and Foker (3,4). Other procedures include gastric tube, colonic conduit (left chest or substernal), gastric pull-up and jejunal vascularized graft segments. A recent study shows favourable results for the Foker technique used for serial dynamic lengthening of the esophagus (4). This technique involves the placement of traction sutures in the esophageal ends and increasing the tension on these sutures daily until the ends are close enough to be sewn together. In the first thoracotomy, anchoring sutures are placed securely at the two ends of the atretic esophagus and are brought out diagonally to the chest wall. Over a period of days to weeks, the two ends are brought closer together by a series of daily lengthening procedures, achieved by traction on the exposed sutures. The closure of the gap is monitored radiologically with radio-opaque markers at the atretic ends. A second thoracotomy is then performed to produce a tension-free anastomosis (4).

Recent advancements in minimally invasive surgery have made it possible to correct TEF/EA thoracoscopically. Thoracoscopic repair has a definite advantage over an open procedure, not only in avoiding musculoskeletal deformity, but also better visualization and minimal collateral damage (5). The major technical hurdle is in the anastomosis: placement of sutures and knot tying which are considered technically demanding, relatively imprecise and associated with a steep learning curve (1, 5, 6). The need for a mechanical device for this procedure has been suggested (1). The conventional end-to-end anastomotic stapling mechanism has its own limitation in this scenario. It requires the placement of sutures circumferentially along the wall of the cut end (purse-string sutures), which is technically difficult (7). Furthermore, the staples would be placed perpendicular to the long axis of the esophagus, limiting its future growth potential.

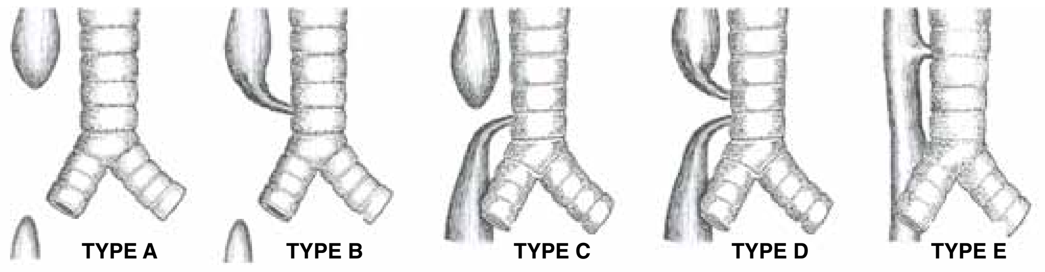

Figure 1 | Different types of esophageal atresia with or without tracheo-esophageal fistula.

With the advent of an early diagnostic facility, improved surgical technique, neonatal anesthesia, advanced neonatal intensive care and neonatal ventilators, survival of even very low birth weight babies is expected. It is generally accepted that associated anomalies, especially severe cardiac defects, and not the esophageal atresia, are the cause of death in such low weight cases (8, 9).

Hypothesis

We propose a novel and unique stapler for anastamosis of the esophagus in esophageal atresia, which can be used both in the open and thoracoscopic procedures.

Principle

The esophagus in a newborn has to grow to attain adult size. Since scar tissue would impede growth and lead to stricture, scarring has to be minimized. This device works on the principle that ideal healing with the least scarring depends on adequate approximation and freedom from tension over anastamosis. The mucosa would eventually regenerate with minimal or no scaring. Smooth muscle, however, heals with scar formation and any gap, inversion, or eversion would lead to excess scar formation (10, 11). Thus adequate approximation would minimize scarring. Since TEF/EA are usually associated with esophageal gaps (4), both ends of the esophagus have to be mobilized and thus there would always be a tension at the anasta-

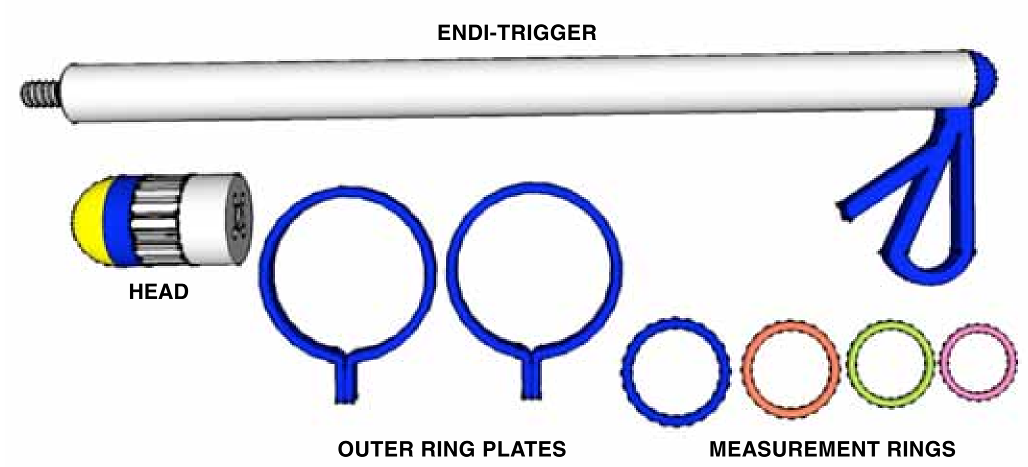

Figure 2 | Schematic showing the components of the stapler device—the head, endo-trigger, outer ring plates and measurement rings.

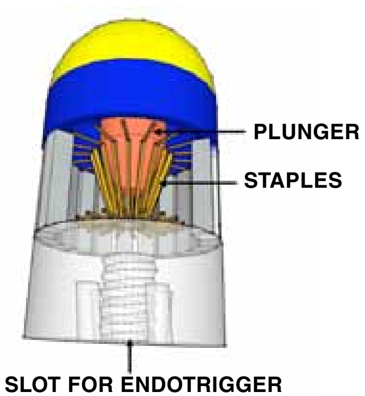

Figure 3 | Diagram depicting the head with titanium staples arranged around the plunger. When the plunger is pulled forward the staples are displaced outward.

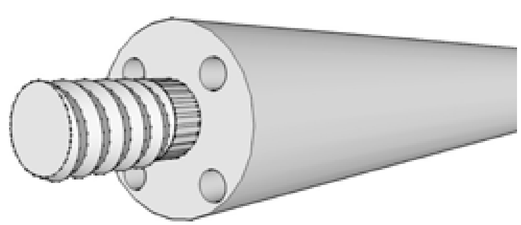

Figure 4 | Distal end of the endo-trigger has two types of ports, a central port to connect to the head, and another to pull the plunger.

motic site. This needs to be bypassed from the anastamotic site, which is done by using staples that act as to splint the esophagus.

Thus the goal is to achieve adequate approximation and splint it in that position while allowing natural healing to occur with minimal scarring.

Stapler details

The device consists of the following parts

1. The Head
2. Endo-trigger (Reusable)
3. Outer Ring Plates
4. Measurement Rings

The head (Fig. 3): This disposable part is 4-5 cm in length and would come in various size diameters. It contains the staples which are arranged around a plunger. When the plunger is pulled by the trigger, it would push the staples out. At the proximal end it has two types of slots; a central slot for mounting the endo-trigger and others for pulling the plunger.

Endo-trigger (Fig. 4): This reusable device has a diameter of 8-10 mm diameter and is 20-25 cm in length. The proximal end has a handle and a trigger, which is used to fire the staples. The distal end has two types of ports corresponding to the slots of the head.

Outer ring plates (Fig. 2): These are metallic strips which are curved into a circle. They have a complete circular ring and two vertical limbs. They can be stretched open by separating the two limbs. These are available in various diameters corresponding to the size of the head. Each head piece would be accompanied by its corresponding sized ring plate.

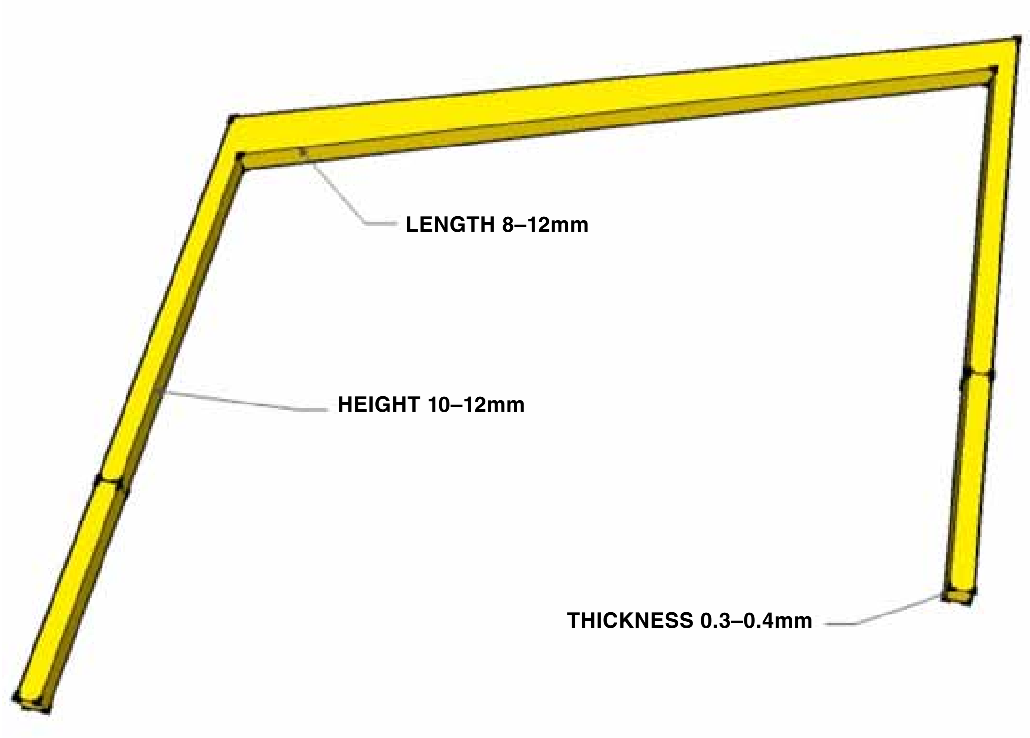

Figure 5 | Dimensions of Titanium Staples

Measurement rings (Fig. 2): These are plastic rings of various sizes used to measure the endoluminal diameter of the esophagus and to select the appropriate head and ring plates.

Staples (Fig. 5): The staples are made of titanium and are arranged in the head parallel to the long axis of the head. They are about 0.3-0.4 mm thick, 8-12 mm long (body) and 10-12 mm in height (limbs).

Stapling technique

During the surgery, after excising fistula, both the proximal and distal esophagus are mobilized adequately. Their ends are opened to achieve adequate sized lumen, and are then approximated and aligned to make sure there is no tension.

Step 1:

Measurement of endoluminal diameter and selection of head and outer ring plates

With the help of measurement rings, the endoluminal diameter of the esophagus is determined and the corresponding set of head and outer ring plates are selected. The diameter of the corresponding head would be 5-6 mm more than that of the lumen. This is done so that the esophagus is stretched over the head and does not move during the procedure. The corresponding outer ring plates would have a diameter of 9-10mm more than the head to accommodate the thickness of esophagus. The measurement ring, the corresponding head and outer ring plates would be colour coded to help in selection.

Step 2:

Placement of head and endo-trigger

First, the head is placed in the gap, and then the endoluminal trigger is inserted via the oral cavity (Fig. 6). The head is mounted on the trigger by rotating the head over the endo-trigger. When mounted properly the triggering port and its slot will be aligned. Both ends of the esophagus are stretched over the head and approximated. Adequate approximation is achieved in all direction by ensuring both surfaces are facing each other and are in contact without inversion and eversion. This is the most important step as a gap can lead to leaking, and over approximation will lead to excessive fibrosis and stricture.

Step 3:
Firing and locking staples

The endo-trigger is fired, which in turn fires the staples into the esophageal wall (Fig. 6) Ring plates are then applied, engulfing the esophagus on both sides of the anastomosis. These ring plates are moved manually towards the anastamosis to bend the protruding part of the staples, thus good locking of the staples is achieved. Outer ring plates are removed by stretch-opening them, and the endo-trigger, along with the head, is removed from the oral cavity. Finally an esophagoscopic examination is done to look at the stapling line.

Modifications for thoracoscopic procedure

In order to apply this device in the thoracoscopic approach, there would be certain modifications. The endoluminal diameter would be determined endoscopically, and the head and the endo-trigger would be a single unit which would be inserted from the oral cavity. The esophagus would then be moved over the head by graspers. After firing the staples, there would be a thoracoscopic outer ring plate to lock the staples.

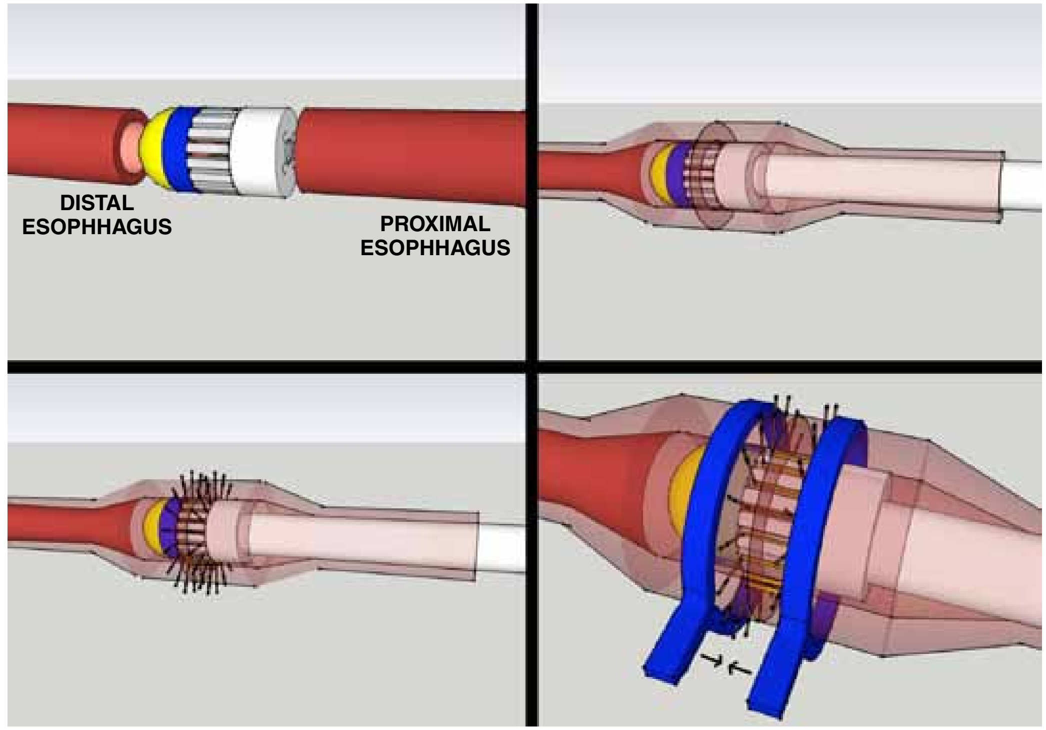

Figure 6 | Series of diagrams showing the stapling technique. ***UPPER LEFT:*** Head is placed in the gap between the proximal and distal ends of the esophagus. ***UPPER RIGHT:*** Endo-trigger is inserted through the oral cavity and it is fixed to the head. Both ends of esophagus are positioned over the head ensuring adequate approximation. ***LOWER LEFT:*** When the plunger is pulled by the endo-trigger, the staples are fired outward through the esophageal wall. ***LOWER RIGHT:*** The ring plates are applied on both sides and moved towards the anastomosis to bend and lock the staples.

Discussion

Prognosis of TEF is dependent on other co-existing conditions, such as cardiac and renal abnormalities, while the prognosis of isolated TEF/EA is good and depends upon the surgery (12). A significant amount of complications depend upon the suturing technique. Over approximation, like eversion or inversion, is associated with more scarring and may eventually lead to stricture which would compromise esophageal motility and swallowing function. Conversely, any gap in anastamosis would lead to a leak of saliva and pharyngeal secretions, causing infection in the mediastinal cavity, which would have serious consequences. Developing this stapler would

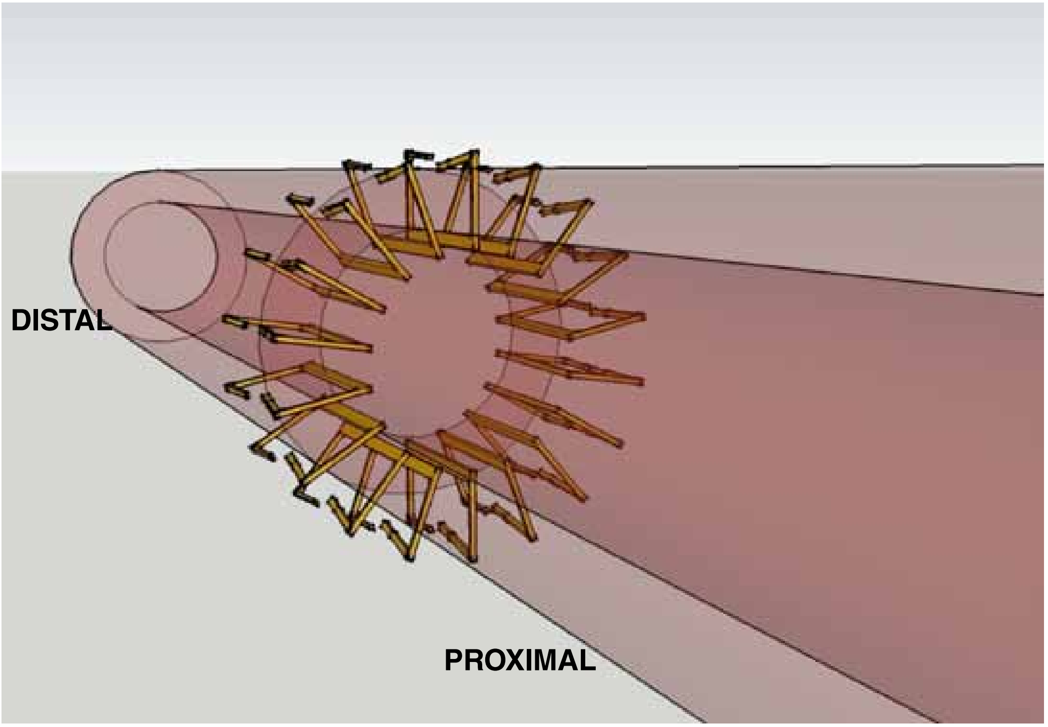

Figure 7 | Final appearance of anastomosis.

help to minimize these complications and achieve good healing.

Advantages of Novel Technique

1. *Procedural convenience:* The tedious part of esophageal anastamosis can be done easily, quickly and safely.

2. *Thoracoscopic repair:* The thoracoscopic approach has a definite advantage over an open procedure. The major technical hurdle in thoracoscopic repair is the suturing technique (1,5). Intracorporeal or extracorporeal knot tying and placing sutures all around the esophagus are technically difficult and time consuming. Since this novel stapling device avoids the cumbersome procedure, it would make thoracoscopic repair easier to perform. Further, significant esophageal gaps would be more amenable to staged thoracoscopic repair.

3. *Less scar tissue:* Adequate approximation, one of the principles of this instrument would minimize the scarring and thus stricture formation, reduced tension at the anastomotic site and have minimal crushing effects.

4. *More staples:* Since this device has more staples than conventional sutures, there would be smaller gaps and the possibility of leaks should be minimal.

5. *No purse-string effect:* Conventional end-to-end anastomotic staplers fire staples with their limbs parallel to the long axes of tubular-shaped tissue, such as the bowel. The bodies of these staples are perpendicular to the long axes of these tissues. This produces a purse-string effect by causing circumfrential tension that would not allow the esophagus to increase its diameter. Our stapler places staples, with their bodies parallel to the long axis of the esophagus. Thus they do not form any purse-string effect, allowing the newborn esophagus to grow in diameter (Fig 8).

6. *No crushing effect and ischemia:* The conventional suturing technique produces crushing at the suture sites and in inexperienced hands this can cause ischemia. This device does not produce crushing and thus no ischemia.

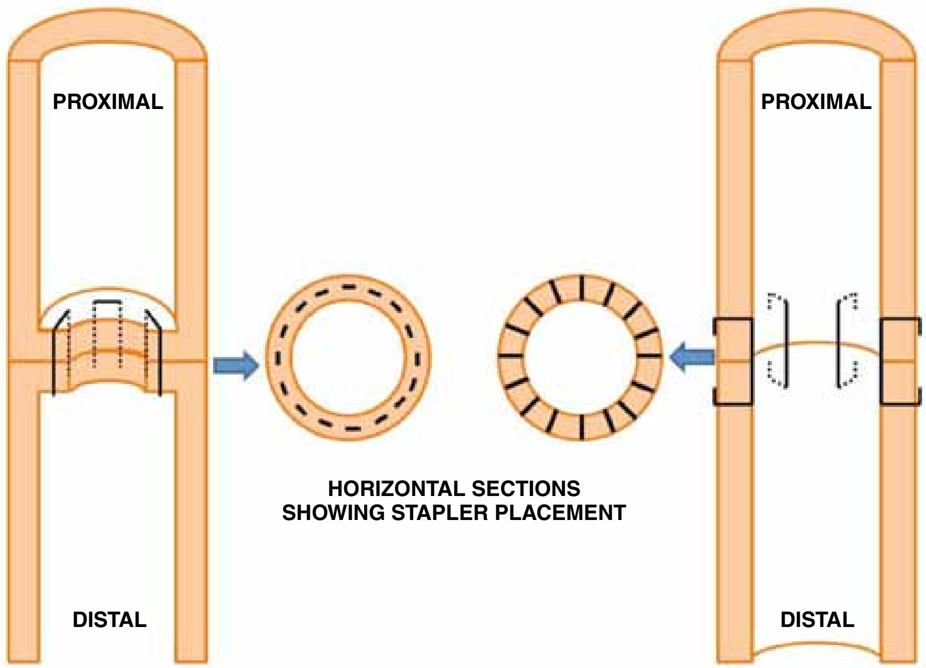

Figure 8 | Sagital and horizontal sections of the esophagus showing placement of staples in conventional EEA and the proposed device. Conventional EEA places staples with the body of the staple perpendicular to the long axis of the esophagus limiting future growth. The proposed stappler device would place the staples with their body parallel to the long axis of the esophagus. Thus it would not impede future growth.

7. *Possible endoscopic staple removal:* After the wound has healed adequately, staples can be removed endoscopically.

Limitations:

A device such as the one presented here would be very beneficial, however it requires manufacturing, which must be followed by testing and possible modification in order to tackle unforeseen hurdles. In cases where the two cut ends of the esophagus are asymmetrical, this device may not be helpful and may require fashioning of the ends of the esophagus.H

About the Author

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References

1 S A Engum, J A Grossfeld; Surgical Repair of Tracheo-esophageal fistula and Esophageal atresia In: Mastery of Surgery. J. E. Fischer, K. I. Bland, M. P. Callery et al editors. 5th ed (Vol 1); Lippincott Williams & Wilkins, New Delhi, 2008: 795–808.

2 B W Warner; Pediatric Surgery, In: Sabiston Textbook of Surgery, Editors C. M. Townsend, R. D. Beauchamp, B. M. Evers et al 17th ed (Vol 2), Elservier, New delhi, 2008: 2056.

3 A Livaditis; Esophageal atresia: A method of overbridging large segmental gaps. Z Kinderchir, 1973; 13: 298.

4 J E Foker, T C Kendall, K Catton et al; A flexible approach to achieve a true primary repair for all infants with esophageal atresia. Semin Pediatric Surg, 2005; 14:8–15.

5 G W Holcomb, S S Rothenberg, K M Bax et al. Thoracoscopic repair of esophageal atresia and tracheoesophageal fistula: a multi-institutional analysis. Ann Surg, 2005; 242(3):422–8.

6 S S Rothenberg; Thoracoscopic repair of tracheaesophageal fistula in newborn. J Pediatr Surg, 2002; 37: 869–72.

7 I M Buriev, M V Knazev; Stapling Techniques in Operations on the Gastrointestinal Tract, In: Mastery of Surgery 5th ed, Editors J E Fischer, K I Bland, Lippincott Williams and Wilkins, New Delhi [CD-ROM].

8 L Spitz, E Kiely, R J Brereton, D Drake; Management of Esophageal Atresia. World J. Surg, 1993, 17: 296–300.

9 S A Engum, J L Grosfeld, K W West et al. Analysis of morbidity and mortality in 227 cases of esophageal atresia and/or tracheoesophageal fistula over two decades. Arch Surg, 1995, 130(5):502–8.

10 R N Mitchell, R S Cotran; Tissue repair: Cell regeneration and fibrosis In: Robbins Basic Pathology 7th ed, editors V Kumar, R S Cotran, S L Robbins, Saunders, New Delhi, 2004, 61–64.

11 Rehman J, Ragab MM, Venkatesh R, Sundaram CP, Khan SA, Sukkarieh T et al; Smooth-muscle regeneration after electrosurgical endopyelotomy in a porcine model as confirmed by electron microscopy. J Endourol,2004, 18(10):982–8

12 Jong EM, Haan MA, Gischler SJ, Hop W, Cohen-Overbeek TE, Bax NM et al; Pre- and postnatal diagnosis and outcome of fetuses and neonates with esophageal atresia and tracheoesophageal fistula. Prenat Diagn, 2010,30(3):274–9.