The Orvil end-to-side anastomosis for Ivor-Lewis minimally invasive esophagectomy: technique, considerations, and challenges

Andrew D. Grubic^, Blair A. Jobe^

Allegheny Health Network Esophageal Institute, Pittsburgh, PA, USA

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Correspondence to: Blair A. Jobe, MD. Allegheny Health Network Esophageal Institute, 4815 Liberty Avenue, Suite 439, Pittsburgh, PA 15224, USA. Email: blair.jobe@ahn.org.

Abstract: Novel modification of the end-to-end anastomosis (EEA) circular stapler anvil for transoral passage significantly bypassed the technical challenges of intracorporal anvil placement for minimally invasive upper gastrointestinal anastomoses. Since commercialization of this concept as the Orvil (Covidien, Minneapolis, MN, USA), circular double-stapled techniques have been utilized for reconstruction following Ivor-Lewis minimally invasive esophagectomy (MIE). Despite its relative simplicity and popularity, the anastomosis has received critique for the issue of overlapping staple lines, which may increase rates of leak and stricture. Although these concerns have validity, their impact can be greatly reduced with strong consideration of procedural nuances. Meticulous care is needed to reduce microvascular trauma, maintain proper alignment, and eliminate tension. Overall construction of a successful anastomosis is a dynamic process which is dependent on a combination of numerous patient and technical factors. Based on the most recent literature, rates of both clinically significant leak and stricture are approximately 4% for the Orvil double-stapled esophagogastric anastomosis. Here we present our own technique and highlight the technical challenges which must be considered for successful creation of the Orvil EEA double-stapled anastomosis during Ivor-Lewis MIE. With proper understanding of technical aspects, experience, and practice refinement, the anastomosis adds an effective and convenient reconstructive option to the esophageal surgeon's repertoire.

Keywords: Orvil; end-to-end anastomosis (EEA); double-stapled; minimally invasive esophagectomy (MIE); Ivor-Lewis

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Introduction

Circular surgical staplers were first pioneered in the post-World War II Soviet Union, and in 1958, Drs. Ravitch and Brown brought this technology to the United States (1). The original pistol-shaped device utilized an "anvil" which was secured within the opposing lumen and approximated the tissue prior to staple deployment. In 1977 the United States Surgical Corporation introduced the first American circular staplers, which would eventually be known as end-to-end anastomosis or "EEA" staplers. In the decades that

^ ORCID: Andrew D. Grubic, 0000-0002-1135-925X; Blair A. Jobe, 0000-0001-6550-5315.

Figure 1 Twenty-five mm Orvil (Covidien, Minneapolis, MN, USA).

Figure 2 Laparoscopic port configuration for abdominal portion of MIE. (*) 12 mm and (^) 5 mm. Note two additional right lower quadrant ports for jejunostomy tube placement. MIE, minimally invasive esophagectomy.

followed, EEA stapling techniques gained popularity for colorectal as well as foregut anastomoses (2). While these staplers were quite efficient for open approaches, placing and securing the anvil was substantially more cumbersome during minimally invasive surgery.

Novel, transoral placement of the EEA anvil has been practiced as early as the 1990's, however due to the difficult passage through the oropharynx the stapler diameter was often limited to 21 mm (3) and hypopharyngeal perforation was also reported (4). To circumvent these issues, Gagner described a method in which the anvil spring could be removed, the anvil shaft invaginated in to an orogastric tube, and the cutting disc held flexed against the anvil shaft with suture (5). This configuration allowed for substantially easier passage of a 25 mm anvil. In 2002, a similar method was reported by Sutton *et al.* in a small series for transthoracic esophageal reconstruction (6). The novel modification was eventually commercialized as the Orvil (Covidien, Minneapolis, MN, USA) (*Figure 1*).

Due to its technical simplicity and successful outcomes in bariatric procedures, the Orvil EEA became an attractive option for the emerging minimally invasive esophagectomy (MIE) in the mid-2000's. Nguyen *et al.* first described the Orvil EEA end-to-side esophagogastric anastomosis for Ivor-Lewis MIE in 2008 (7). Since this time it has become the preferred method of transthoracic esophageal anastomosis at many centers, owing to its simplicity, reproducibility, and outcomes. Although minor variations exist, the anastomosis follows a standard sequence. Here we present our own technique, address technical challenges, and review literature outcomes of the Orvil EEA esophageal anastomosis for Ivor-Lewis MIE.

Technique

The following technique is based on our own practice and surgeon preferences. Primary abdominal ports are placed in the upper abdomen in a shallow inverted "U' configuration and a Nathanson liver retractor is placed in the epigastrum for hiatal exposure (*Figure 2*). The stomach is completely mobilized, including duodenal Kocherization, with preservation of the gastroepiploic pedicle. A generous pedicle of omentum, contiguous with the developing gastric conduit, is also mobilized. A 5 cm diameter gastric conduit is created by sequential linear staple firings along the lesser curvature beginning 5 cm proximal to the pylorus, and continued up to the cardia. After the cardia is transected, the proximal conduit is sutured to the distal resection margin of the esophagogastrectomy specimen. This facilitates eventual deliverance of the conduit and omental pedicle through the hiatus during the thoracic portion of the procedure.

Once the abdominal portion of the procedure is complete the patient is converted to the left lateral decubitus position. Thorascopic access is achieved at the mid-axillary 10th intercostal space (camera). Additional ports are placed: 12 mm posterior-axillary eighth intercostal space (working right hand), 5 mm posterior axillary fourth intercostal space (working left hand), 5 mm anterior-axillary eighth intercostal space (assistant), and 12 mm anterior-

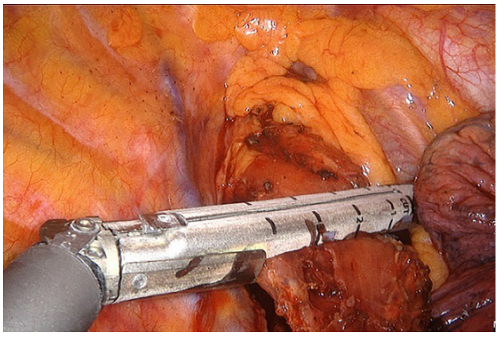

Figure 3 Division of the proximal esophagus above the level of the azygous vein, with linear endoscopic stapler.

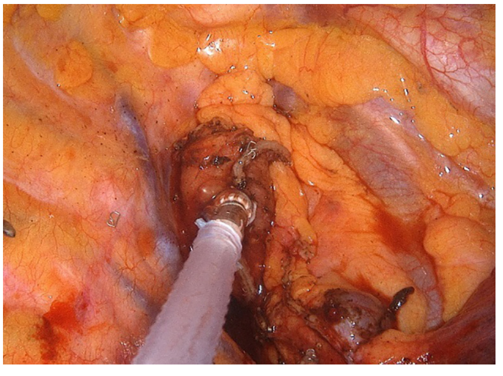

Figure 4 Passage of the Orvil through the exact center of the esophageal stapler line. Note that the anchoring suture between the anvil and orogastric tube has been cut.

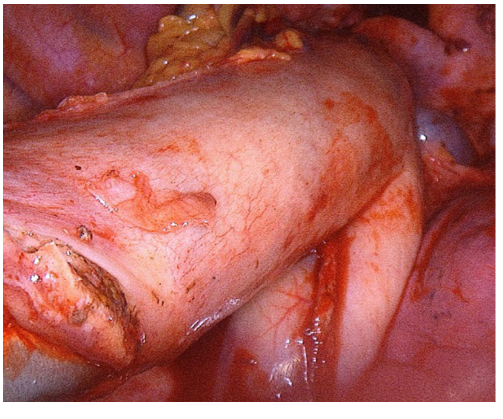

Figure 5 Insertion of the 25 mm EEA stapler head into the gastrotomy. The gastric conduit is pulled over the stapler and folding the conduit such that the lesser curvature staple lines are in approximation. EEA, end-to-end anastomosis.

axillary 5th intercostal space (retractor). The esophagus is mobilized above the level of the divided azygous vein, and transected with a linear stapler (*Figure 3*). Care is taken to ensure that the proximal esophageal stump is completely mobile and free all of posterior attachments. The specimen and attached conduit with omental pedicle is pulled into the thoracic cavity, and the suture is cut. After sufficient widening of the inferior, posterior axillary working port site, a wound protector is placed, and the esophagogastrectomy specimen is externalized. A small esophagotomy is created in the exact center of the esophageal staple line using harmonic scalpel. The anesthesiologist transorally advances the orogastric tube portion of the Orvil, until the tip is visualized through the esophagotomy (*Figure 4*). The tip is then grasped and carefully pulled through the wound protector site. Once the Orvil shaft has fully emerged from the esophagotomy, the anchoring suture to the orogastric tube is cut. At this point the tube is discarded from the field and the Orvil cutting plate should be flush against the esophageal stump within the lumen.

The gastric conduit is then positioned as to avoid any twisting with the lesser curvature staple line oriented toward the patient's right. The EEA stapler head is passed through the wound protector and into the thorax. A gastrotomy is made at the distal aspect of the conduit with harmonic scalpel, and the stapler is inserted into the gastric lumen. Edges of the gastrotomy are the pulled over the stapler so as the tip abuts the greater curvature side of the conduit, and the conduit folded such that the lesser curvature staple lines are in contact with each other (*Figure 5*). The stapler spike is carefully deployed through the gastric wall (*Figure 6A*), with caution to avoid any short gastric vessel remnants. The Orvil shaft and stapler spike are connected (*Figure 6B*), the unit is approximated while avoiding incorporation of extraneous tissues, and the staples are deployed (*Figure 6C*). After the stapler is externalized, the anvil is disconnected and examined for two, intact anastomotic "doughnuts" ensuring proper firing (*Figure 7*). A linear stapler is then used to close the gastrotomy with resection of the proximal conduit tip and attention to prevent narrowing of the anastomosis (*Figure 8*).

Upper endoscopy is then performed to confirm patency and appropriate mucosal approximation, and a decompressive nasogastric tube is paced into the conduit antrum. Within the right thorax, the anastomosis is

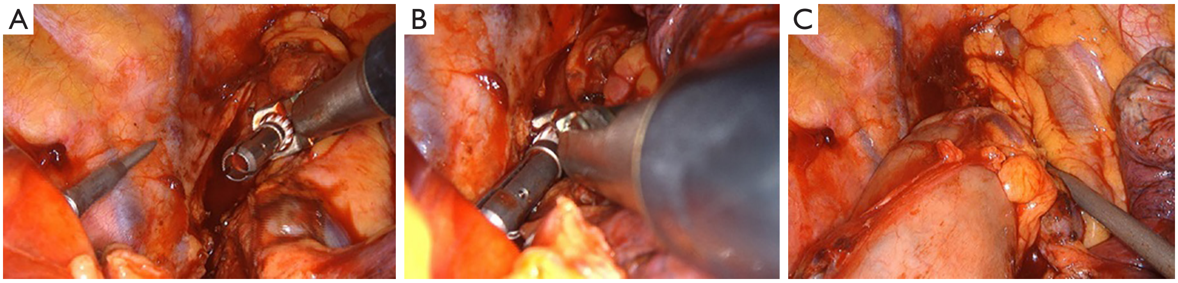

Figure 6 Assembly and approximation of the Orvil and EEA stapler. (A) Deployment of the EEA stapler spike through the greater curvature and manipulation of the anvil. Note the anvil grasper controlling the white, ribbed portion proximal to the anvil flanges. (B) Complete engagement of the EEA stapler spike and anvil, with coverage of the stapler spike ring by the anvil flanges. (C) Approximated EEA stapler and anvil. EEA, end-to-end anastomosis.

Figure 7 Removed EEA stapler and anvil following firing, with two intact anastomotic rings. EEA, end-to-end anastomosis.

submerged in saline to evaluate for leak. The omental pedicle is then circumferentially placed around the anastomosis and secured with 1 or 2 sutures. At the hiatus, a single suture is placed between the conduit and right crus to obliterate potential space for herniation and to reduce tension on the conduit. A 10F Jackson-Pratt drain is positioned posterior to the anastomosis which is connected to gravity drainage (bile bag). The third to eleventh intercostal spaces are injected with 0.5% bupivacaine for regional anesthesia. An apically placed, 28-F chest tube is used for thoracic decompression.

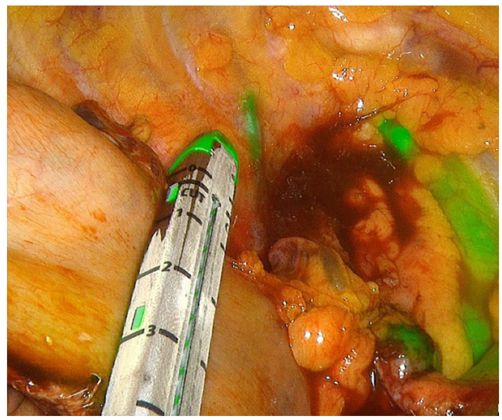

Figure 8 Closure of the gastrotomy and resection of the proximal conduit tip with a linear stapler.

Providing clinical patient stability and low 24-hour gastric output (<300 mL), the patient undergoes iopamidol contrast esophagram. If there is no evidence of radiographic leak or obstruction, the nasogastric tube is removed and diet is advanced to clear liquids. On post-operative day-4, we withdraw and re-secure the drain approximately 3 cm in order to "crack" any loculated air/fluid pockets and to adjust the points of contact to reduce erosion. Volume and consistency of liquids are gradually advanced, and patients are typically discharged on a full-liquid diet 5–7 days after surgery with the drain in place.

Pearls and pitfalls

Selection of the proper stapling components is crucial to the formation of the anastomosis. Under typical circumstances we prefer the EEA "extra-long" XL stapler which provides 35 cm of shaft length for anastomosis at or above the level of the azygous vein. In almost every instance we utilize a 25 mm diameter stapler. Although insertion of 21 mm components may be technically easier, 21 mm EEA esophageal anastomoses have been shown to result in considerably higher rates of stricture (8,9), and to our knowledge a 28 mm Orvil is not commercially available. In regard to staple height, we favor 4.8 mm in the majority of cases. While 3.5 mm staples may be practical in more petite patients with benign processes, inflammation secondary to chronic gastroesophageal reflux, hiatal hernia, neoadjuvant radiation, and peritumoral immune mediators usually result in regional fibrosis and thickening.

Although the Orvil greatly simplified transoral passage of the EEA anvil into the esophagus, placement is still not without challenges. It is critical to advise the anesthesiologist to orient the Orvil with the rounded side of the disc facing posteriorly against the palate as it is advanced. Resistance of the flexed disc at the level of the hypopharynx is not uncommon. Gentle anterior displacement of the mandible (jaw thrust) will facilitate passage in most instances. Occasionally, temporary deflation of the endotracheal tube may also be required. If these initial measures fail, manual adjustment should be performed to ensure the disc is oriented perpendicular to the upper esophageal sphincter. Additional gentle finger pressure on the superior edge of the disc may provide the last needed force to overcome the sphincter pressure.

Difficulty inserting the EEA stapler head into the thorax may be encountered notably in shorter patients or those with more robust musculature. With the patient in the left lateral decubitus position, flexion of the operating table such that the apex of the flexion is centered at the patient's iliac crest provides additional widening of the intercostal spaces. Prior to insertion, a water-soluble lubricant applied to the sides of the stapler head reduces any friction with the wound protector. Inserting the stapler head "sideways" with gentle pressure will allow the rounded edges to spread the intercostal space for passage almost all instances. Rib resection is almost never necessary if the aforementioned steps are taken.

The task of connecting the Orvil shaft to the stapler spike may also prove daunting during some cases. Exposure of the upper thorax is paramount prior to engagement. A 10 mm laparoscopic fan retractor is useful for wide anterior retraction of the lung. Sufficient hemostasis should be achieved and fluid pooling in the superior sulcus completely suctioned. A 10 mm laparoscopic anvil grasper provides superior control of the Orvil shaft compared to linear graspers and the shaft should always be held proximally on the white plastic portion to avoid bending the distal flanges. Any damage to the flanges may prevent complete alignment with the stapler spike, and endoscopic retrieval of a damaged Orvil only adds additional frustration. An auditory/tactile "click" as well as visual coverage of the colored ring on the stapler spike by the flanges confirms engagement. Proper visualization while the anvil and stapler are approximated is needed to avoid incorporation of extraneous tissues. When the engaged anvil and stapler are fully approximated a green bar will appear on the top of the stapler. We hold this position for 30 seconds to allow complete tissue compression prior to firing. Finally, surgeon ergonomics including steadying of the stapler is extremely important during firing to avoid shearing forces and microvascular injury.

A major advantage of the described Orvil EEA technique is that the most proximal portion of the conduit is not included in the anastomosis and is resected with closure of the gastrotomy. This region, which is furthest from the right gastroepiploic pedicle, is at highest risk for ischemia. The potential downfall to this feature is that it also decreases the overall length of the conduit, which may be problematic in cases with very proximal tumors or unfavorable body habitus. For this same reason, complete gastric mobilization including duodenal Kocharization is critical to ensure the anastomosis reaches the anticipated point of esophageal transection and is tension-free. We have found that intraoperative fluorescent imaging, 90 seconds after intravenous bolus of 3 mg indocyanine green (ICG) is helpful during placement of the stapler into the gastrotomy to subjectively evaluate perfusion of the intended location of the anastomosis. It is important to mention that our utilization of ICG is anecdotal, and that there is no consensus on formal ICG protocol nor its impact on leak risk-reduction (10).

The chief criticism of the Orvil EEA esophageal anastomosis is the issue of "crossing staple lines". This concept is based on longstanding surgical tenants, that overlapping staple lines produce thin, acutely-angled tissue remnants which are at risk for ischemia (11). This issue is unique to the Orvil technique such that the linear staple line is excised and the anvil secured with a pursestring suture or enodloops for intracorporal placement of the EEA anvil. During proper creation of the anastomosis, the Orvil should be placed through the exact center of the linear esophageal staple line, effectively becoming a geometric diameter to the

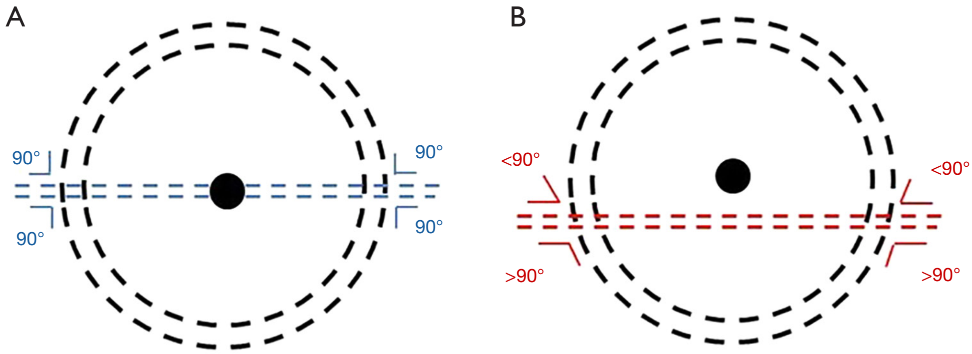

Figure 9 Cross sectional representations of the circular and linear staple line intersections. (A) A properly positioned anvil and stapler through the exact center of the transected esophageal staple line (blue). All four tissue remnants at the intersection of the staple lines form 90-degree angles. (B) A poorly positioned anvil and stapler with the transected esophageal staple line (red) serving as a geometric secant. Note that malalignment produces two acutely angled tissue remnants.

EEA head when approximated (*Figure 9A*). Without precise placement, the linear staple line may serve as a geometric secant or chord, producing two, sub 90-degree "dog ears" which are theoretically higher risk for ischemia (*Figure 9B*). We suspect that these thin regions are more susceptible to microvascular injury with decreased perfusion capacity. A similar phenomenon has been observed by colorectal surgeons in leaks with obliquely angled low anterior anastomoses (12), but more direct studies are needed to validate this theory.

Once anastomosis creation is complete, we employ several methods for confirming integrity. The most critical of which is the presence of two, intact anastomotic rings or "doughnuts" on the extracted Orvil. Failure to form complete rings is most commonly due to the presence of extraneous tissue within the anastomosis and/or inadequate staple height for the tissues. If two complete rings are not found, the anastomosis should be reconstructed (13). Endoscopic, underwater leak test is useful for identification of very small defects which could potentially be addressed with simple oversew and omentopexy. We have found that ICG fluorescent imaging is also useful after the anastomosis is finalized. Delayed perfusion in a previously well-perfused conduit tip may suggest excessive tension, and additional tension relieving maneuvers should be considered.

In our experience contrast esophagram is most useful for identifying delayed emptying and need for additional nasogastric decompression. Although the pylorus is classically implicated, we have identified a few patients with obstruction at the hiatus requiring laparoscopic hiatal widening. This has also increased our vigilance regarding the size of the omental pedicle which was implicated in these cases. We have yet to identify radiographic leaks which were not clinically apparent.

Outcomes

Early experiences with the Orvil EEA technique for MIE produced promising results, comparable to other MIE anastomoses. In a retrospective series of 37 patients who underwent oncologic, Ivor-Lewis MIE with 25 mm Orvil 4.8 mm EEA esophagogastric anastomosis from 2007–2009, Campos *et al.* reported only a single leak (2.7%) as well as a 13.5% rate of symptomatic stricture (14). In 2011 Jaroszewski *et al.* found a higher leak rate of 9.8% however rates of stricture were comparable at 13.7% in their analysis of 51 patients using an Orvil EEA technique (15). Of note 3 patients died within 90-day of surgery but the etiology of their mortality was non-surgical in nature.

Schröder *et al.* used the EsoBenchmark database to investigate outcomes among 966 patients who underwent transthoracic MIE, and found a leak rate of 23.3% for double-stapled circular anastomoses (16). Compared to linear stapled and purse-string circular stapled anastomoses, double-stapled circular anastomoses did have a statistically significant higher risk of leak. It should be mentioned however that double-stapled circular anastomoses were not performed at all study institutions and potentially underrepresented, comprising 16.8% of the sample. Additionally, the authors were hesitant to draw any major conclusions citing unknown variables of tumor location, surgeon preferences, and surgeon experience.

Most recently, Foley *et al.* published the largest series to date of Orvil upper gastrointestinal anastomoses and compared their institutional data to pooled literature totals (17). Of their 227 patients with thoracic esophagogastric anastomoses, the authors found rates of clinically significant leak and stricture of 3.52% and 1.98% respectively. This was lower than the reported literature averages of clinically significant leak 4.65% and stricture 8.72%. With institutional and literature data combined, clinically significant leak and stricture rates were 4.01% and 4.26% respectively.

Learning curve

As with any surgical technique, experience and volume can significantly affect outcomes. Mungo *et al.* described the development of their Ivor-Lewis MIE technique over 4 years (18). In this study the authors originally used a 25 mm Orvil 3.5 mm EEA for anastomosis. Due to a 30.8% leak rate, they abandoned the technique for a linear side-to-side anastomosis. Eventually the authors returned to the 25 mm Orvil, however increased the staple height to 4.8 mm, resulting in a leak rate of only 4%. While staple height may have certainly played a factor in the early leaks, the surgeons felt their experience significantly improved outcomes. In 2018, Stenstra *et al.* presented the evolution of their Ivor-Lewis MIE technique (19). Similar to Mungo *et al.* the authors systematically refined their technique over the course of several years based on patient outcomes. Adjustments ranged from changing size of the stapler as well the as the size and degree of the omental covering. Although the authors eventually abandoned the 25 mm Orvil for a standard EEA anvil secured with endoloops, the study emphasized the importance of surgical proficiency and outcome driven modification.

MIE technical progression was better quantified by van Workum *et al.* by tracking operative outcomes for Ivor-Lewis MIE among four different European centers over time (20). The two centers which performed circular end-to-side anastomosis initially reported leak rates of 33.3% and 21.6% during the initial study quintile. In the final quintile these same centers found that leak rates decreased to 2.8% and 2.7% respectively, which were similar to another center performing linear stapled side-to-side anastomosis. From the pooled data the authors found a learning curve of 119 cases at non-high volume centers before anastomotic leak rates plateaued. It is likely that practice modification was easier at high-volume centers.

Conclusions

The Orvil EEA anastomosis offers simplicity and reproducibility while providing comparable outcomes to other reconstructive techniques for Ivor-Lewis MIE. Although the ease of use is quite attractive, surgeons must have respect of its technical nuances. Reduction of tension with adequate gastric and duodenal mobilization is needed to prevent shearing force and ischemia. Meticulous geometric placement through the exact center of the transected esophageal staple line is paramount to eliminate thin "dogears" at the staple line junctions. Ultimately experience and practice refinement will optimize outcomes.

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are

appropriately investigated and resolved.

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