

## AXIOS stents: not a solution to every problem – or the problems will keep surfacing

On the eve of the 16th International Symposium on Endoscopic Ultrasonography (EUS) in San Francisco in 2008, a working group of 20 international experts convened to chart a roadmap for interventional EUS, a discipline then in its infancy [1]. Among the group's key recommendations was the development of dedicated devices to facilitate EUS-guided drainage of pancreatic fluid collections (PFCs).

In response, Xlumena Inc. developed the cautery-enhanced AXIOS lumen-apposing metal stent (LAMS) and delivery system [2]. Following Xlumena's acquisition by Boston Scientific Corporation in 2015, the clinical footprint of the AXIOS stent expanded beyond PFC drainage to include gallbladder drainage for symptomatic acute cholecystitis. Subsequently, and largely off-label, the stent has been adopted for an increasingly broad range of complex interventions, including palliation of malignant distal biliary obstruction, creation of a gastroenterostomy in

gastric outlet obstruction, and EUS-directed transgastric endoscopic retrograde cholangiopancreatography (EDGE) in patients with Roux-en-Y gastric bypass [3].

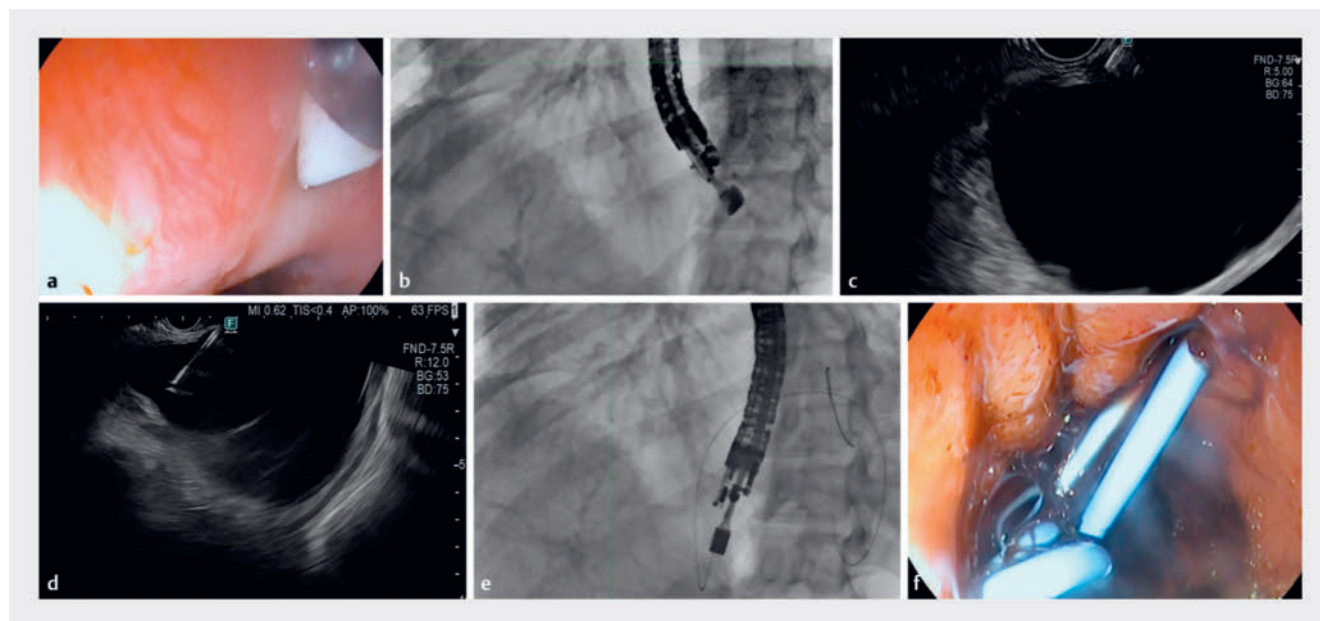
As with many transformative medical devices, this expansion has been accompanied by a series of "red flag" signals, each prompting incremental clinical or technical adaptations. The first such signal was reported by our group in 2016, during a randomized trial comparing the AXIOS with double-pigtail plastic stents for PFC drainage [4]. Prolonged LAMS indwelling, beyond 3–4 weeks, was associated with bleeding due to mechanical friction against adjacent vasculature, which led to recommendations for early LAMS removal or exchange to plastic stents.

Subsequent challenges emerged with biliary applications, where stent dysfunction prompted the adjunctive placement of double-pigtail plastic stents to optimize axis orientation [5]. Perforation has

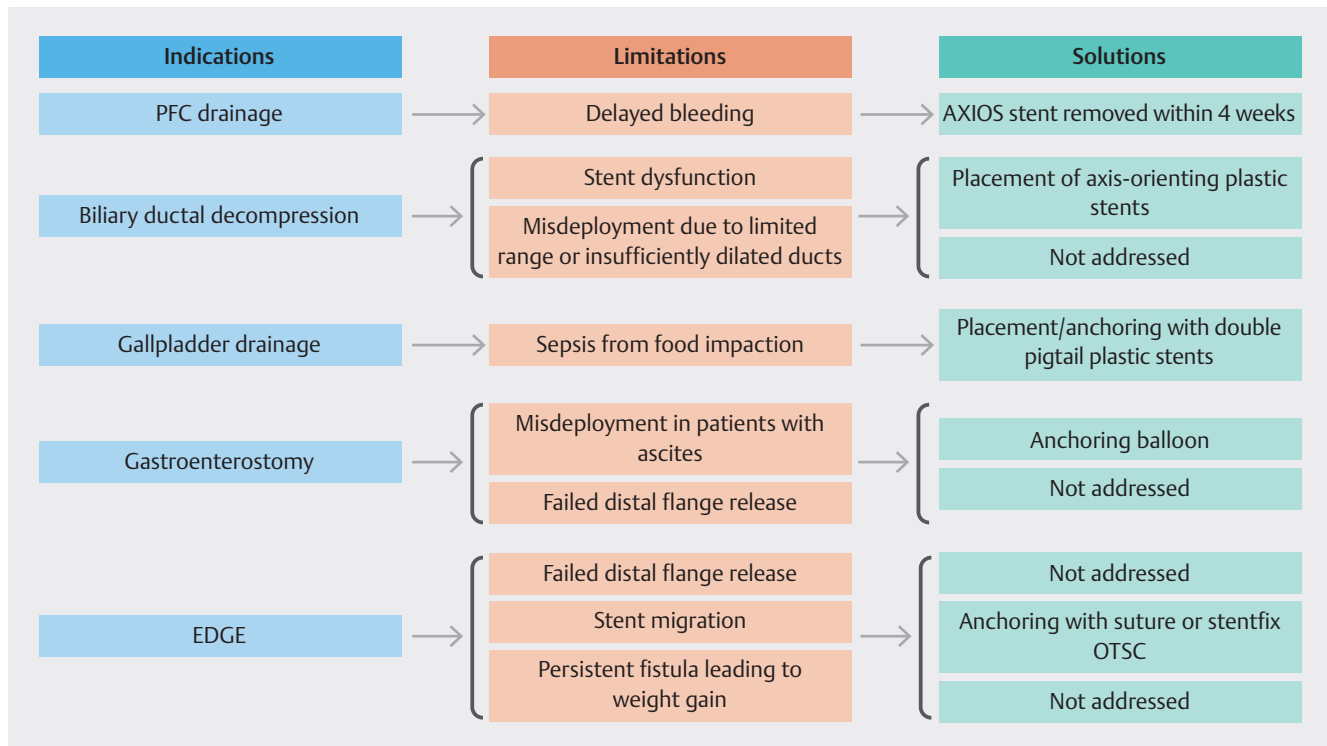
also been reported when the stent is deployed in nondilated bile ducts (<15 mm), reflecting limitations in deployment distance – an issue that remains unresolved.

More recently, the FDA approved the AXIOS stent for gallbladder drainage; however, we previously raised concerns regarding subsequent cholecystectomy, where the presence of a transmural fistula may compromise minimally invasive surgical approaches [6]. Food impaction of the gallbladder has also been described, managed – often suboptimally – by the placement of plastic stents or by exchanging the LAMS altogether.

The AXIOS stent has now entered the domain of EUS-guided gastroenterostomy for malignant gastric outlet obstruction [3], where reports of perforation, particularly in the setting of ascites, have driven the development of anchoring balloons to enhance safety. Similarly, spontaneous stent migration during EDGE procedures has necessitated anchoring



► **Fig. 1** Images during drainage of a subdiaphragmatic pancreatic fluid collection showing: **a–c** the inability to advance an AXIOS stent into the collection owing to angulation of the tip of the echoendoscope; **d–f** successful access to the collection using a 19G needle with subsequent placement of plastic stents.



► **Fig. 2** The expanding procedural indications for use of AXIOS stents with technical and clinical limitations and proposed solutions.

strategies using sutures or clips. The persistence of transmural fistulas after stent removal, with the attendant risk of weight gain, is a concern that remains unaddressed.

In this issue of the journal, Vanella and colleagues report 12 cases of intraprocedural failure of distal flange deployment [7]. To address this, they advocate rhythmic amplitude traction, rather than continuous retraction, at the deployment hub. The authors hypothesize that this oscillatory motion induces microretraction of the sheath at the catheter tip, facilitating distal flange release. This rescue maneuver is clinically important, particularly in critically ill patients undergoing high risk interventions, where procedural failure may have grave consequences.

Recently, the failure of distal flange deployment has resulted in three deaths during EUS-guided gastrojejunostomy and EDGE procedures. These adverse events have led the manufacturer to suspend the use of its 6-, 8-, and 20-mm Hot AXIOS stents [8]. While the precise mechanism leading to this issue remains uncertain, potential explanations include excessive adherence between the stent

and overlying sheath or incomplete transmission of hub movement to the distal catheter tip. In my own practice, technical failures have occurred when acute angulation of the echoendoscope prevented device deployment into the target lumen (► **Fig. 1**). Even during routine PFC drainage, distal flange release has occasionally failed, with successful deployment achieved only after a catheter “zigzag” manipulation, as described by Vanella et al. Some indications are however much riskier than undertaking PFC drainage.

What lessons emerge from this evolving experience?

The AXIOS stent was designed specifically for drainage of inflammatory fluid collections. Its core design – aside from dimensional variations – is now being applied to a growing spectrum of technically demanding and biologically distinct indications. Predictably, each new application has revealed new limitations, addressed not by redesign but by successive “sticking plaster” solutions (► **Fig. 2**). These off-label uses carry a liability for physicians and institutions and, more importantly, may expose patients to avoidable harm.

The broader lesson is clear: no single device can – or should – be expected to meet the diverse and expanding needs of therapeutic EUS. When we attempt to stretch a device beyond its original purpose, problems surface, some of which are consequential. Progress in interventional endoscopy will require the thoughtful redesign of existing platforms and development of purpose-built devices, rather than continued reliance on improvisation. Doing the latter can result in irreparable harm.

**Contributors’ Statement**

Shyam Varadarajulu: Writing - original draft, Writing - review & editing.

**Conflict of Interest**

S. Varadarajulu is a consultant for Boston Scientific, Olympus America, and Medtronic.

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