

## Percutaneous treatment of a duodenocutaneous high-flow fistula using a new biological plug

Eduardo Crespo Vallejo, Mario Martinez-Galdamez, Lourdes Del Olmo Martínez, Eduardo Crespo Brunet, Ernesto Santos Martin

### ABSTRACT

Enterocutaneous fistula is a challenging entity and a gold-standard treatment is not settled so far. Here, we describe the successful closure of a duodenocutaneous fistula with the use of the Biodesign enterocutaneous fistula plug (Cook Medical), which is derived from a biological plug that has been used in recent years in order to close anorectal fistula tracts.

**E**nterocutaneous fistula is defined as an abnormal communication between the small or large bowel and the skin. It is a well-known surgical complication associated with long hospital stay and high morbidity and mortality. Mortality rate varies between 5% and 20%, and it is frequently associated with sepsis and nutritional abnormalities. Spontaneous closure rate varies among studies, ranging from 7% to 70% (1). Patients unresponsive to conservative therapy require surgical repair, therefore, a treatment that could shorten fistula closure time avoiding a second operation would be highly beneficial.

Recently, multiple attempts have been made to treat these patients using nonsurgical methods. Image-guided percutaneous drainage is one of the most used interventional radiological procedures, widely proven as a feasible, safe, and effective treatment of intra-abdominal abscess and fluid collections. However, the presence of a concomitant intestinal fistula remains a significant challenge and drainage has proven to be associated with a low success rate.

Here, we present a case in which a biological plug was inserted percutaneously to close a duodenocutaneous fistula. This device is well known for its application in anorectal fistulas (2).

### Technique

Institutional review board approval and patient consent were obtained for the reporting of the following case.

A 66-year-old man underwent emergent surgery due to second duodenal portion perforation secondary to endoscopic cauterization of a diverticulum angiodysplasia. During the follow-up, a big abscess was drained and a high-flow enterocutaneous fistula (500 mL/24 hours) was confirmed (Fig. 1). Parenteral nutrition was the initial intentional curative treatment, but after two months of nonresponse vascular and interventional radiology unit was consulted.

Investigation of the fistula was done by fistulogram through the multipurpose 8 F drainage catheter (Cook Medical). A wide fistula with a long tract was identified, running between the abdominal wall and the duodenum. Surgeons preferred to avoid a second high-risk surgery and interventional radiology was consulted. A multidisciplinary committee considered the insertion of the new Biodesign plug (Fig. 2) to be a good treatment option due to the features of the fistula, including straight path, single orifice, large diameter (3 mm) and length (6 cm) and its high output (500 mL/24 hours). Our decision was based on several factors; namely, high success rates of the plug reported for other pathologies, its biological nature, and known failures with other agents like glue on similar cases.

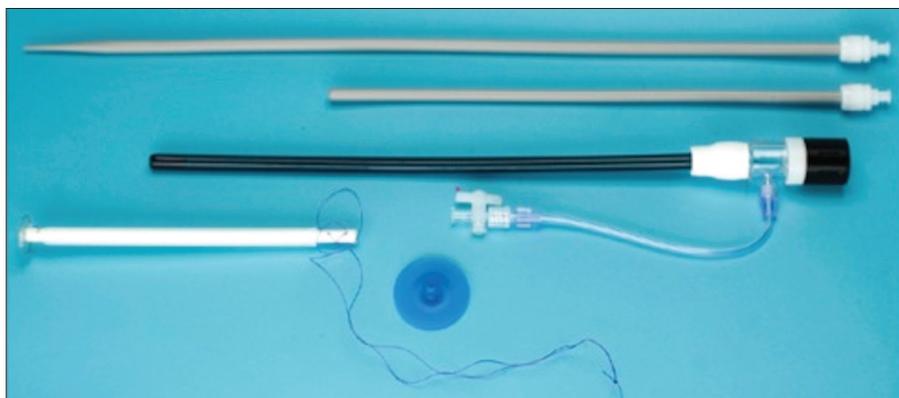
From the Vascular and Interventional Radiology Unit (E.C.V.✉ [dreduardocrespo@gmail.com](mailto:dreduardocrespo@gmail.com), M.M.-G.) and the Endoscopic Unit (L.D.O.M.), Hospital Clinico Universitario de Valladolid, Valladolid, Spain; the General Surgery Unit (E.C.B.), Hospital San Telmo of Palencia, Palencia, Spain; the Vascular and Interventional Radiology Unit (E.S.M.), UPMC, Pittsburgh, Pennsylvania, USA.

Received 07 October 2014; accepted 28 October 2014.

Published online 1 April 2015.  
DOI 10.5152/dir.2014.14421



**Figure 1.** Gastroduodenal oral study one month after the duodenal perforation demonstrates fast filling of the fistulous tract from the duodenum, due to a wide enterocutaneous fistula.



**Figure 2.** Biodesign plug kit (Cook Medical) containing the plug, a Molnar disc, a 16 F sheath, a pusher, and a dilator.

Moderate sedation was initiated with intravenous midazolam and fentanyl. The procedure was performed in Philips Multidiagnost Eleva C-arm based remote controlled radiography/fluoroscopy system (Philips Healthcare).

A fistulogram was performed through the existing drainage catheter and, us-

ing a guidewire (Radiofocus guide wire, Terumo), a reversed curve 5 F catheter (Cook Medical) was delivered to the site of the leak. The catheter was advanced over the guidewire through the defect of the duodenal wall and placed with its tip in the distal portion of the duodenum. According to the estimat-

ed fistula diameter, we decided to use a 4-mm-thick plug.

The guidewire was exchanged for a stiffer wire (Lunderquist, Cook Medical) and the catheter was exchanged for a 9 F sheath. A second wire was advanced through the sheath in order to achieve more stability. Following this, fistula surface was gently brushed (Fusion Cytology Brush, Cook Medical) to facilitate colonization of the plug by fresh tissue (Fig. 3). For this purpose, we pulled back the sheath keeping the Lunderquist wire and brushed all along the fistula till bleeding was noted. At this point, we serially dilated the tract and a 16 F sheath was inserted. After confirming the intraluminal position with contrast injection, the plug was introduced with its pusher. The flange opened 2 cm further than the orifice (Fig. 4) and with a subtle maneuver we pulled back until resistance was noted, just in the same position the intraluminal contrast pointed the duodenal wall. Finally, the extra plug was removed and the superficial segment was fixed to the superficial tissue with a Molnar disc.

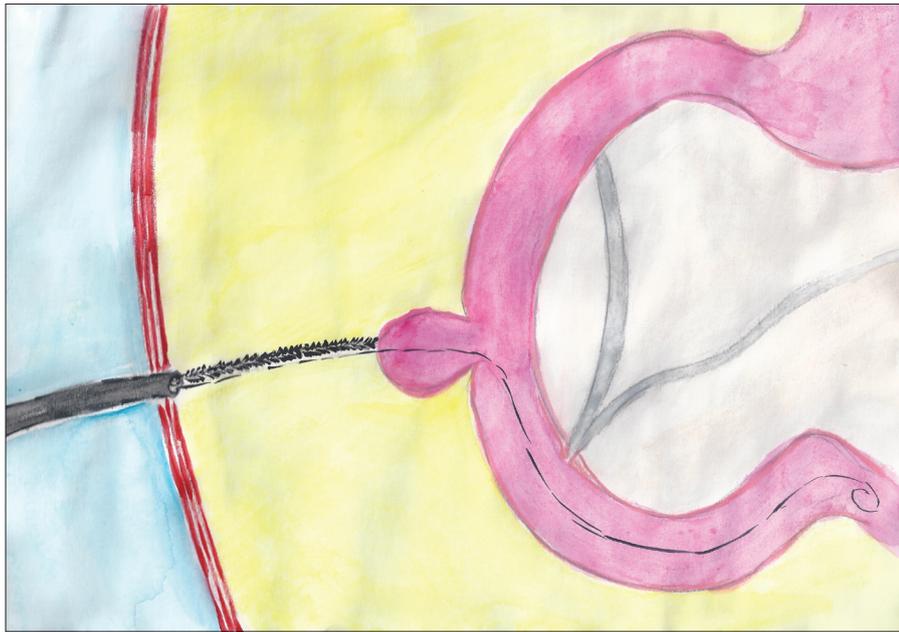
Drainage from the skin ceased immediately and the patient was discharged three days later with oral nutrition. Endoscopy was carried out the next day confirming the intraluminal position without obstruction of the papilla (Fig. 5).

Postimplantation gastroduodenal study was carried out 15 days after the procedure confirming the correct position of its anchoring, as well as the absence of contrast extravasation.

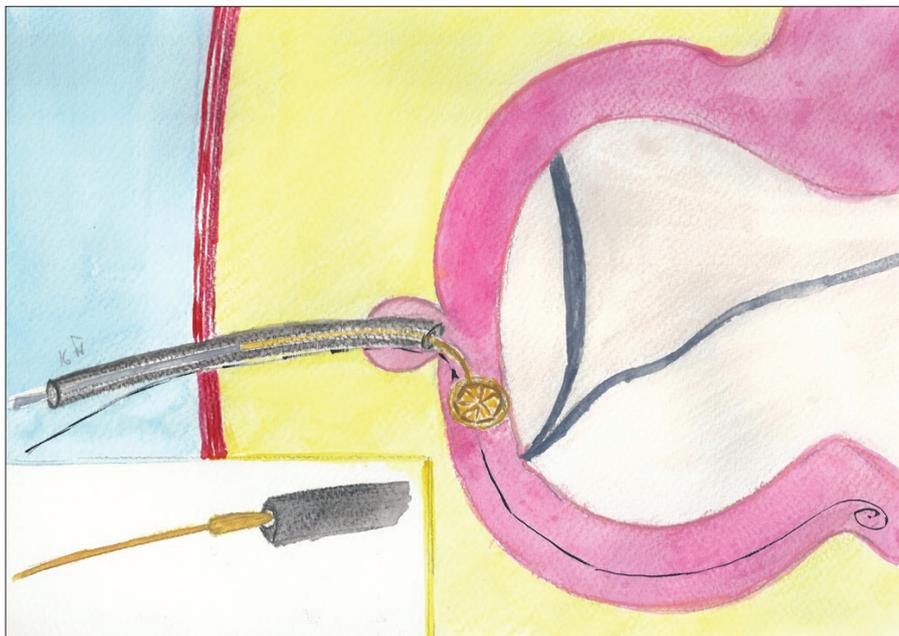
Endoscopy performed one month later showed minor signs of mucosa reaction probably secondary to the intraluminal flange. At this point, due to the asymptomatic status of the patient, external Molnar disc was released. Two months after the insertion, a third endoscopy study was performed and we decided to remove the flange endoscopically, which was lightly fixed in the diverticulum. Finally, 15 days later a new esophagogastroduodenal study showed no extravasation or any other potential complication (Fig. 6). Patient remains asymptomatic after 15 months of follow-up.

## Discussion

The problems associated with an intestinal wound breakdown were men-



**Figure 3.** Use a brusher for debridement of the tract keeping while the second wire *in situ*.



**Figure 4.** Technical aspects for adequate plug insertion. The flange has to be twisted so that it fits in the sheath lumen. The final position of the flange should contact the lateral wall of the duodenum.

tioned as early as 13 BC, by Celsus, who stated that “the large intestine can be sutured, not with any certain assurance, but because this doubtful hope is preferable to certain despair; for occasionally it heals up.” In the mid-19th century John Hunter, Scottish surgeon and one of the most distinguished scientists and surgeons of his day claimed that “in such cases nothing is to be done but dressing the wound superfi-

cially, and when the contents of the wounded viscous become less, we may hope for a cure.”

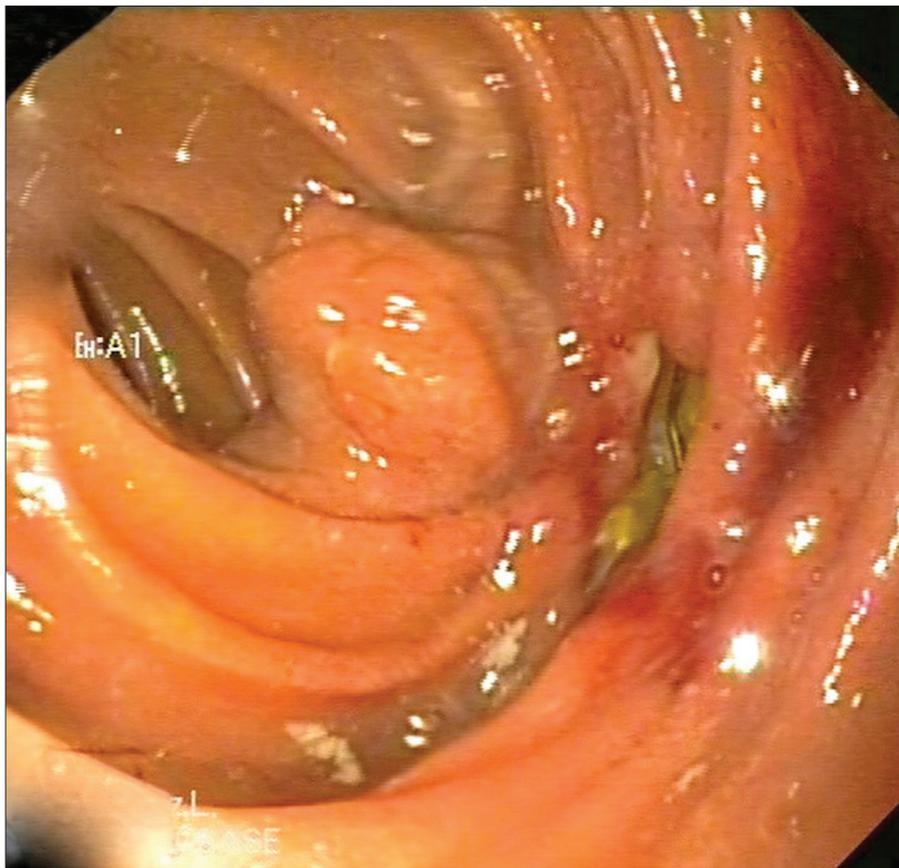
Enterocutaneous fistulas are classified according to different parameters: morphology, daily output, anatomic location, and cause. The type of enterocutaneous fistula, as based on the output of the enteric contents, also determines the patient’s health status and how the patient may respond to

the therapy. This pathology can be originated by postoperative, traumatic, or spontaneous causes. More than 75% of all cases are iatrogenic, postoperative complications due to anastomoses dehiscence or unintentional bowel lesion.

A multidisciplinary approach is critical for treatment. Advances in intensive care, nutritional support, antimicrobial therapy, wound care, imaging, and operative techniques have led to a dramatic decrease in the mortality rate, from as high as 50% in 1980s to as low as 20% (3). The principles of treatment have been clearly delineated and generally accepted. They include patient resuscitation, early recognition and treatment of sepsis, wound and skin care, nutritional support, and localization and study of the fistula. The aim is to return malnourished patients to health, allowing spontaneous closure or optimization for definitive treatment.

The decision of whether the fistula will resolve spontaneously or will require surgical or minimally invasive repair must be made according to several criteria including anatomical location, tract length, size of the defect, condition of the surrounding bowel, and nutritional status or sepsis of the patient. Conservative treatment is the most common procedure, but it is associated with a low success rate. Biliary-drainage multiple-sidehole catheters, T tubes, and sump drains appear to be safe and easy to apply to control intestinal output, limit infection, and allow spontaneous resolution of the enterocutaneous fistula. However, the presence of a concomitant intestinal fistula remains a significant challenge and drainage is associated with low treatment success.

Different techniques and materials that have been used percutaneously or endoscopically for treatment include vacuum assisted closure (VAC), cyanoacrylate glues, Gelfoam, and Amplatzer devices. VAC is based on a vacuum pump generating negative pressure. Aspiration applies negative pressure to the wound and the fistula orifice tends to close. Wainstein et al. (4) reported good results in high-flow fistulas, where 40% of patients had severe abdominal wall defects and 52% had



**Figure 5.** Endoscopic confirmation of the adequate position of the flange, the plug's anchor.



**Figure 6.** Esophagogastroduodenal transit shows absence of the flange three months after its insertion without extravasation of the contrast through the duodenum wall.

more than one defect. Another broadly used agent is n-butyl-2-cyanoacrylate glue (NBCA, Histoacryl, B. Braun). Most studies show good results mainly in low-flow output. Sapunar et al. (5) published seven cases of postoperative low-output enterocutaneous fistulas of the large bowel. Glue-Lipiodol ratio employed was 1:5 and 100% technical and clinical success was achieved. Our personal experience agrees completely that glue correction is suitable for low-flow output enterocutaneous fistulas. Conversely, high-flow output can drag the glue easily and reopen the fistula. An interesting case report from Bou-lougouri et al. (6) describes a high-flow duodenocutaneous fistula closure with the Amplatzer plug.

Biodesign is an extracellular matrix derived from porcine small intestine submucosa. All bacterial, viral, and cellular components are removed maintaining the natural, complex matrix. It is processed in a way that preserves its natural structure, supporting tissue remodeling and avoiding chronic inflammation and encapsulation. There is proven efficacy across a wide variety of procedures including ventral hernia repair, anal fistula repair (7), wound treatment, and pelvic floor restoration. Recently, Lyon et al. (8) reported six cases of enterocutaneous fistula closure with Biodesign, where clinical success was 85% and mean closure time of the fistula was two weeks.

We know that less than 25% of the fistulas heal spontaneously. Of the resolved ones, the vast majority do it within the first month. We also distinguish favorable and unfavorable factors. Based upon these principles, we firmly believe that therapeutic algorithm of enterocutaneous fistulas should evolve. We should wait a month before an interventional treatment in patients with favorable factors, but in the rest of the patients a procedure should be performed as soon as the patient is stable. In cases of low-flow output and a single orifice, VAC, glue, or plug insertion can be tried. Multiple orifices in the bowel would probably benefit from surgery, but in the meantime techniques like VAC could help. Conversely, when high-flow output is confirmed and a single orifice is shown, a biological plug is likely to

succeed. Again, multiple orifices in the intestine with high-flow output preclude a corrective surgery.

In conclusion, this new biological plug appears to be a promising alternative to the current treatment options for enterocutaneous fistulas and requires further evaluation.

#### Conflict of interest disclosure

The authors declared no conflicts of interest.

#### References

1. Hollington P, Mawdsley J, Lim W, Gabe SM, Forbes A, Windsor AJ. An 11-year experience of enterocutaneous fistula. *Br J Surg* 2004; 91:1646–1651. [\[CrossRef\]](#)
2. Draus JM Jr, Huss SA, Harty NJ, Cheadle WG, Larson GM. Enterocutaneous fistula: are treatments improving? *Surgery* 2006; 140:570–578. [\[CrossRef\]](#)
3. Amrani S, Zimmern A, O'Hara K, Corman ML. The Surgisis® AFP™ anal fistula plug: a new and reasonable alternative for the treatment of anal fistula. *Gastroenterol Clin Biol* 2008; 32:946–948. [\[CrossRef\]](#)
4. Wainstein DE, Fernandez E, Gonzalez D, Chara O, Berkowski D. Treatment of high-output enterocutaneous fistulas with a vacuum-compaction device. A ten-year experience. *World J Surg* 2008; 32:430–435. [\[CrossRef\]](#)
5. Sapunar LC, Sekovski B, Matic D, Tripkovic A, Grandic L, Družijanic N. Percutaneous embolization of persistent low-output enterocutaneous fistulas. *Eur Radiol* 2012; 22:1991–1997. [\[CrossRef\]](#)
6. Boulougouri K, Theodoropoulos E, Karydas G, Tachtaras E, Hatzinikolaou A, Georgountzos V. Combined endoscopic and percutaneous treatment of a duodenocutaneous fistula using an Amplatzer septal occluder. *Cardiovasc Intervent Radiol* 2009; 32:356–360. [\[CrossRef\]](#)
7. O'Connor L, Champagne BJ, Ferguson MA, et al. Efficacy of anal fistula plug in closure of Crohn's anorectal fistulas. *Dis Colon Rectum* 2006; 49:1569–1573. [\[CrossRef\]](#)
8. Lyon JW, Hodde JP, Hucks D, Changkuon DI. First experience with the use of a collagen fistula plug to treat enterocutaneous fistulas. *J Vasc Interv Radiol* 2013; 24:1559–1565. [\[CrossRef\]](#)