

## Efficacy and safety of full-thickness resection device based on over-the-scope clip system for resecting of gastric lesions in selected patients. Case series from a referral center for gastrointestinal diseases treatment and literature overview

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**SUMMARY: Efficacy and safety of full-thickness resection device based on over-the-scope clip system for resecting of gastric lesions in selected patients. Case series from a referral center for gastrointestinal diseases treatment and literature overview.**

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*Since gastroduodenal FTRD system is commercially available, several data have been reported in Literature concerning duodenal full-thickness resections, whereas few cases of gastric full-thickness resections has been described.*

*In this case series We report three patients treated with this innovative tool for resecting lesions of the gastric wall. The indications ranged notably: a neuroendocrine tumor in a difficult to treat environment in the first case, a recurrent adenocarcinoma in a poorly surgical candidate patient in the second case and a pre-pyloric lesion for the third patient. In the third patient, a complete pyloric stenosis due to the clip deployment occurred. Clinical success rate was 100%.*

*Even if current Literature is still poor of articles dealing with gastric full-thickness resection device based on over-the-scope-clip system. Our case series show how this novel tool might be take into consideration for whenever both surgery and standard endoscopic resection techniques are poorly feasible.*

KEY WORDS: Gastric lesions - Full-Thickness resection device - Over-The-Scope-Clip - Complete pyloric stenosis - Case series.

### Introduction

Since in 2018 the upper gastro-intestinal (UPG) full-thickness resection device (FTRD; Ovesco, Tuebingen, Germany) based on the over-the-scope-clip (OTSC) system has been introduced in Europe, several patients with gastroduodenal lesions, otherwise referred to surgery, have been treated effectively with this approach (1-3).

Main indications to UPG endoscopic full-thickness resection (EFTR) with the FTRD consists of small submucosal lesions (i.e. gastrointestinal stro-

mal tumor, submucosal lipomas, neuroendocrine tumors, submucosal epithelial tumors), adenomas with low-grade dysplasia or high-grade dysplasia, early mucosal-based cancers and pT1-invasive cancers in poor surgical candidate patients (1).

Before UPG FTRD system (gastroduodenal FTRD, gFTRD) introduction, the main treatment options for such lesions were represented by endoscopic mucosal resection (EMR), endoscopic submucosal dissection (ESD), hybrid techniques such as over-the-scope clip-assisted endoscopic full-thickness resection either with a OTSC (Ovesco Endoscopy AG, Tübingen, Germany) or with a Padlock clip (Aponos Medical Corp, Kingston, NH, USA); sometimes, if a deeper wall infiltration was documented, minimally invasive gastric resection or endoscopic-assisted minimally invasive gastric resec-

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tion were necessary in order to remove the neoplastic tissue (4-11).

Even if the current gastroduodenal FTRD-OVESCO system doesn't allow a full-thickness gastric wall resection, mainly due to the high thickness of the gastric muscular layers, in such instances this device could be a valid alternative to surgery.

The main advantage of FTRD device is the possibility of "one-shot" resection of a lesion together with secure defect closure.

In the light of colonic FTRD system (introduced in 2011 by Schurr MO. et al), the gastroduodenal device combines a modified OTSC mounted on the distal tip of a gastroscope (diameter 10.5-12 mm) (1, 3, 12).

The procedure starts with a preliminary endoscopic evaluation of the lesion, in order to assess the feasibility of the procedure and to mark the lateral margins with an appropriate high-frequency probe running inside the working channel.

Once withdrawn the instrument, the FTRD can be mounted on the scope.

The system is composed of a plastic cap (19.5×23 mm) loaded with a FTRD clip; an opened preloaded 14 mm polyfilament polypectomy snare is located inside the cap, whereas its handle runs on the outer surface of the scope under a plastic sheath. An appropriate grasping forcep inserted into the working

channel (minimum diameter 3.7 mm) allows to catch the tissue and pull it into the cap, together with a soft suction (Figure 1).

The device includes also a special balloon (diameter 20 mm, length 60 mm), which facilitates overcoming the upper esophageal sphincter and the pylorus, therefore allowing an easier FTRD advancing.

Once the target lesion is reached, the premarked gastric wall is pulled into the cap through the forcep together with a mild aspiration of the instrument, thereby allowing a duplication of the wall.

As soon as a good duplication is obtained, showed by the disappearance of the marking points, the clip is released and, subsequently, the electrocautery snare is activated using a monopolar current, excising the full-thickness tissue captured by the clip. The scope is withdrawn and a second-look evaluation is immediately done, in order to assess the completeness of the resection and to exclude bleeding or perforation.

In the current case series, in order to help orientating the pathologist to the deep and lateral margins, the specimen was pinned to a flat surface such as cork board. The procedure time was measured by a nurse or a second physician from the introduction of FTRD system to the withdrawn of the instrument after the second-look inspection.

Postoperatively, if no complication occurred, pa-

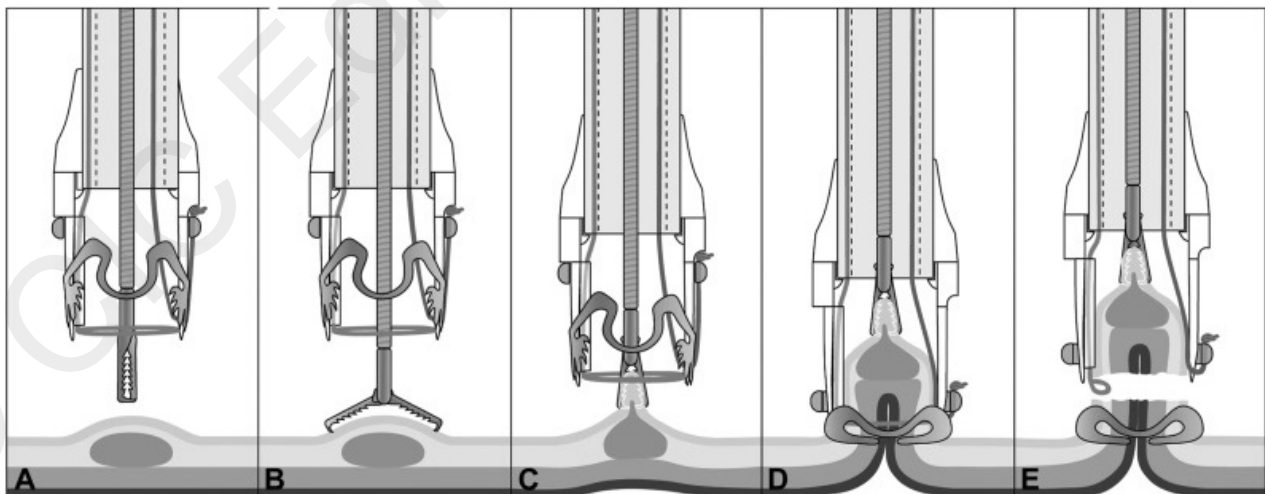


Figure 1 - FTRD-OVESCO procedural steps (FTRD; Ovesco, Tuebingen, Germany). A) The target lesion is identified and the grasping forcep is advanced through the working channel. B) The lesion is caught through the appropriate forcep. C) The specimen is pulled into the cap of the device, together with a mild suction. D) Once the duplication of the wall is obtained (showed by the disappearance of the marking points) the clip is deployed. E) Once lifted the lesion, a pseudopolyp appears: the specimen is cut above the clip through the appropriate preloaded snare.

tients received food orally on the first postoperative day.

The first endoscopic control was performed within three months after the procedure, whereas the following surveillance endoscopies were scheduled according to guidelines. If any suspicious mucosal irregularity was observed, biopsies were taken.

In this current article, we report our experience on FTRD system; additionally an overview of the current literature on the gFTRD-OVESCO system was performed, by using the Medline and PubMed databases up to July 2019.

## Case reports

We report three cases of patients with gastric lesions suitable for endoscopic resection, treated in our center ("Careggi" Teaching Hospital, Florence, Italy) from November 2018 and July 2019.

All the procedures were carried out by the same over twenty year experience endoscopist (RN). All the patients underwent a deep sedation with propofol and ketamine, according to the hospital guidelines.

Complete blood exams and an electrocardiogram were obtained at least one week before the endoscopic dissection, and a specific antibiotic-therapy was performed only in selected patients (i.e. previous cardiac valve implant, severe immunodepression, high risk of post-procedural infection).

FTRD was carried out in an inpatient setting using high-definition Olympus Exera CF-HQ190I/L colonoscope (Olympus optical, Japan, Tokyo) with CO<sub>2</sub> insufflation. At the beginning of the procedure the patients were left side positioned, and position changing where done during the procedure if needed, according to the gravity, to allow an easier resection.

Procedural time was measured from endoscope introduction until the second-look endoscopic control was achieved.

Once reached the marked neoplasm, the OVESCO grasping forcep was used to catch the lesion and pull it into the cap with a slight suction.

The clip was then deployed and grasped tissue was immediately resected with the preloaded snare. The resection specimen inside the cap was immedi-

ately extracted with the instrument and a second-look inspection was achieved.

The sample was put into formalin and sent for histopathological evaluation to the pathologists of the hospital. If no adverse event occurred, the patients received regular diet the next day and were discharged a few days after the procedure.

Patients underwent the first follow-up endoscopy within three months after EFTR, whereas the following endoscopic controls were scheduled according to guidelines. The resection site was inspected for macroscopic evidence of residual or recurrent lesion.

If still in place after three months, the apposite bipolar cutting device (remOVE System, OVESCO Endoscopy) was used for FTRD clip removal.

### Case 1

The first case concerns a 71-year-old man referring to our attention for a non-lifting submucosal lesion of the gastric fundus. The lesion, found out incidentally, was located along the greater curvature in the gastric fundus; its size was approximately 30 X 20 mm.

His past medical history was significant only for arterial hypertension and prostatic hyperplasia. His past surgical history was significant for abdominal perineal amputation (Miles's operation) for a low rectal cancer. Social history was insignificant. His current medications included anti-hypertensive drug and Tamsulosin. He denied any allergy.

No malignant findings were macroscopically seen on Narrow-Band Imaging (NBI); an endoscopic ultrasound (EUS) was performed, in order to visualize the gastric wall, revealing only a submucosal layer involvement, thus a stromal gastrointestinal tumor was suspected.

Considering the small size of the lesion, the previous surgical history of the man and the limited submucosal involvement, the multidisciplinary team meeting excluded primarily the surgical operation, proposing an endoscopic full-thickness resection with a gFTRD.

The resection was macroscopically complete, including the gastric wall till the muscular layers, whereas the serosa was preserved.

The patient was discharged in a couple of days without any post-procedural complication.

Histopathological examination revealed a well differentiated GIST with Ki 67 < 5% and a low mitotic index; lateral and deep margins were free from neoplastic tissue and the muscularis layer were confirmed.

The surveillance endoscope performed three months after the procedure showed the clip still in place, therefore the apposite bipolar cutting device (remOVE System) was used for FTRD clip removal.

Subsequent endoscope didn't reveal any tumor recurrence.

### Case 2

The second case is a 81-years-old woman with multiple comorbidities (hypertension, previous surgery for cecal adenocarcinoma, hysterectomy, cholecystectomy, thyroidectomy, diverticulosis) presenting to our attention as a previous endoscopic removal of a flat polyp along the gastric small curvature resulted in intestinal adenocarcinoma (T1) at the histological examination.

We performed a preliminary endoscopic ultrasound (EUS) examination, in order both to study the gastric wall involvement and to exclude a nodal invasion.

The EUS documented a 5 X 7 mm size lesion along the small curvature with a submucosal invasion, without neither a muscular layer nor a nodal involvement.

Considering the several comorbidities of the patient and her age, a surgical approach was excluded, and the case was discussed at the multidisciplinary team meeting of the hospital. Therefore, the patient was scheduled for an EFTR with the FTRD system.

The procedure was carried out without any intraprocedural complication, and the patient was discharged on the third post-procedural day. The final histology confirmed the diagnosis of intestinal adenocarcinoma (Lauren classification); no deep invasion beyond 0.1 mm in the submucosal layer was documented and the lateral margins were negative.

### Case 3

The third case involves a 86-years-old man with a medical history suggestive for chronic atrial fibrillation and multiple episodes of transient ischemic attacks, whereas his surgical history included total thyroidectomy for cancer with subsequent radioiodine (I-131) therapy.

His medications included anticoagulant drug (Apixaban) and Levothyroxine.

He underwent an upper gastrointestinal endoscopy for severe anemia (hemoglobin 7.5 g/dL) revealing a type Forrest III-A pre-pyloric ulcer (maximum diameter 1 cm in size); the remaining parts of the stomach showed a chronic atrophy (Figure 2). During the hospital the patient underwent transfusions of pooled red blood cells and endovenous anti-acid therapy. The histological examination upon the biopsies performed on the ulcer tissue, revealed an exudative flogosis with areas of high-grade dysplasia, without excluding with certainty an intestinal adenocarcinoma. After this first episode, the patient experienced other similar admissions to the hospital because of the bleeding ulcer; considering the age and the comorbidities of the patient, a surgical intervention was excluded, whereas the multidisciplinary team meeting suggested an endoscopic full-thickness resection of the tissue. Written informed consent was obtained from the patient and an antibiotic pre-medication was done.

The procedure was carried out in an inpatient setting under deep sedation.

A preliminary esophago-gastroscopy was performed in order to show exactly the localization of the lesion and to mark its lateral margins with the FTRD marking-probe.

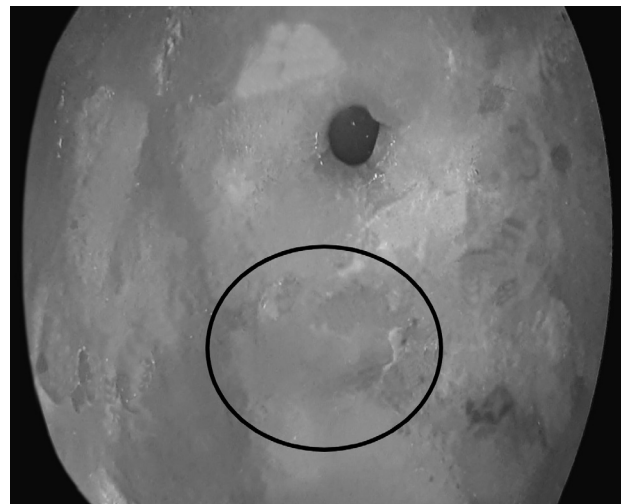
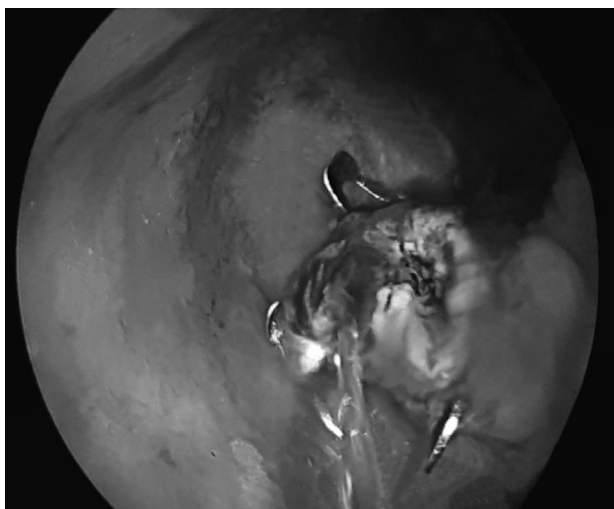
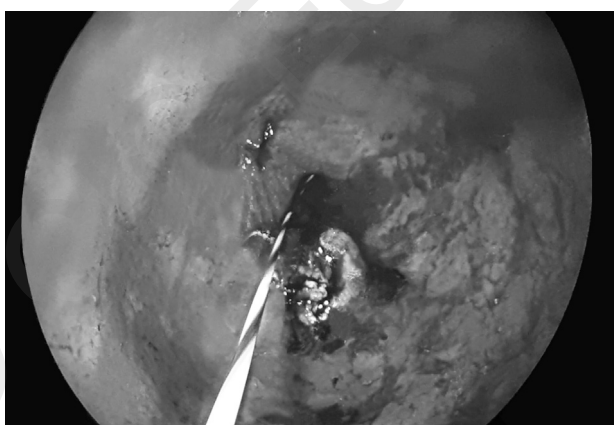


Figure 2 - Third patient's endoscopic appearance of the pre-pyloric lesion, highlighted inside the black circle. The histological examination upon the biopsies revealed an exudative flogosis with areas of high-grade dysplasia.

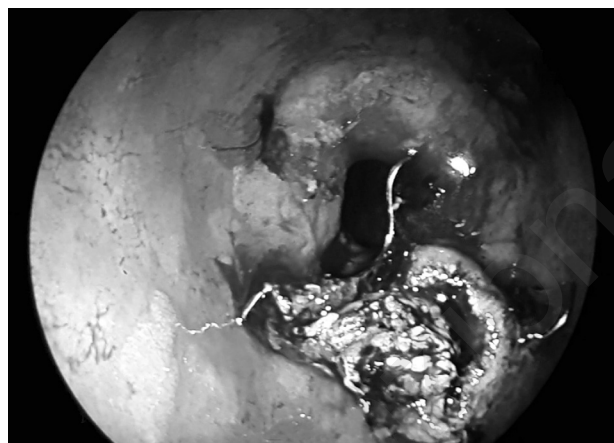


**Figure 3 - Third patient's endoscopic appearance of the gastric wall after the clip deployment. The pyloric outlet is no more visible beyond the clip.**

Once the FTRD clip was deployed and the lesion cut, the scope was reinserted. A low-grade bleeding of the gastric wall included inside the clip was observed, therefore the hemostasis was carried out with the coagrasper. Surprisingly the pylorus outlet was no more visible and it appeared as if the clip had closed completely the pylorus itself (Figure 3). After several unsuccessful wire-guided attempts to overcome the clip, the duodenum was reached passing the wire along the roof of the clip, where pylorus outlet was more likely (Figures 4, 5).



**Figure 4 - Third patient's endoscopic image of the pylorus as appeared after the progressive dilation up to 20 mm with CRE balloon (Boston Scientific, Natick, MA), till obtaining a good passage into the duodenal lumen. The guide-wire had been previously passed along the roof of the clip, where the duodenal lumen was more likely.**



**Figure 5 - Third patient's final endoscopic appearance of the pylorus after the dilation: the duodenal lumen is clearly visible beyond the pyloric opening.**

As a partial closure of the pylorus had been caused by the clip release, several progressive CRE balloon (Boston Scientific, Natick, MA) dilations up to 20 mm were performed, till the disappearance of the waist of the balloon at the fluoroscopy.

The patient received a liquid diet on the first post-procedural day, whereas a soft diet was tolerated on the second post-operative day.

Neither episodes of vomit nor gastrointestinal bleeding occurred, so that the patient was discharged on third post-procedural day. Apixaban therapy was reintroduced after ten days of anticoagulant therapy with enoxaparine.

The histology of the removed tissue confirmed an high-grade dysplasia, excluding areas of adenocarcinoma; lateral and deep margins resulted negative.

## **Discussion**

Since gFTRD has been introduced for clinical use in 2018, endoscopic field of gastric and duodenal lesions excision has further spread out (1-4).

This innovative technique has become an effective alternative to ESD and EMR for the resection of upper gastrointestinal lesions, since its combines multiple advantages compared to these two endoscopic approaches (3, 6, 15, 17, 18). First, FTRD offers a full-thickness excision of the neoplasm, at least in the duodenum, whereas in the stomach the depth of the resection is closely related to the gastric

wall thickness, which is variable among people. Second, it is particularly useful in case of recurrent or non-lifting lesions, in which the scar of the previous excision might make very challenging procedures such as EDS or EMR. Third, FTRD ensures an en-bloc resection, avoiding fragmentation of the specimen, thus leading to a more radical resection with a considerable reduction of the recurrent rate; nowadays it's well established that incomplete resections contribute to an higher risk of developing interval cancer, leading to additional more aggressive interventional approaches. Fourth, its learning curve is considerably shorter compared to EDS and EMR ones, so that it constitutes a relatively easy to perform technique also for short time-experience endoscopists.

Fifth, this new device offers a resection of the lesion in "one-shot", combining the removal of the polyp together with the closure of the wall defect, thus sealing it and avoiding the risk of intra-abdominal leakage. Sixth, it's less time consuming, especially if it's compared to EDS.

On the other hand, there are several possible FTRD related-complications to remember, which sometimes might lead endoscopists to exclude this approach (1-3).

To our knowledge, gFTRD related-adverse events are similar to those reported with the colonic FTRD system, such as bleeding, missed clip deployment, luminal stenosis (if applied in the duodenal lumen or across the pylorus), clipping the adjacent abdominal structures (vessels, intestinal structures, lymph nodes), closing the grasping forcep inside the clip itself, missed integrated snare closing, clip insufficiency due to the size of the lesion, clipping the neighboring tissue inside, missed full-thickness resection due to the high structure thickness (2, 3, 12, 13).

The most important aspect to underline related to FTRD use concerns the distance from the duodenal papilla; a minimum distance of at least 20 mm is recommend, in order to avoid its closure. Here in, this aspect might represents a limitation to FTRD utilization in the duodenum (1, 2, 4).

Cost is another aspect to take into consideration when using this device; in fact, even if the system permits a one-shot clip-and-cutting, it's more expensive if compared to those devices used for EDS (such as Dual-Knife, TT-Knife, etc.) or, moreover, for EMR (polypectomy snares).

As well described by Bauder M. et al. in a recent published retrospective pilot study, the advancement of this system to the target lesion can very challenging, especially if the target lesion is located at the superior or the inferior duodenal flexure (1).

Whereas several papers concerning colonic endoscopic full-thickness resection with the FTRD-OVESCO are available, current Literature is still poor of articles dealing with gastroduodenal resections with this system, especially in the stomach (1-4, 12-16). To date, the articles concerning with the FTRD-OVESCO use (both the colonic and the novel gastroduodenal one) for resecting of gastric lesions are reported in (Table 1).

Actually, the only publication concerning a large number of patients treated with the gastric FTRD is Meier B.'s one (3).

In this well organized study, the Authors reported the first prospective pilot study (RESET trial) on EFTR in the stomach using the gastroduodenal FTRD. A total of 29 patients with gastric subepithelial tumors (SET) were included in this prospective observational multicenter pilot trial up, considering as primary endpoint the technical success (complete en-bloc resection) and as secondary endpoints R0-re-

TABLE 1 - PREVIOUSLY REPORTED CASES OF FTRD-OVESCO SYSTEM USE FOR RESECTING OF GASTRIC LESIONS.

Article	Type of Article	Dispositive	Histology	Number of Cases	Complications
Meier et al. (2019) (3)	Prospective pilot study (RESET trial)	Gastroduodenal FTRD-OVESCO	Subepithelial Endocrine Tumor (SET)	29	Bleeding (31%)
Robert JR et al. (2018) (15)	Video Case Report	Colonic FTRD-OVESCO	Gastric Adenocarcinoma	1	None
Kratt T et al. (2016) (16)	Video Case Report	Colonic FTRD-OVESCO	Melanoma Metastasis	3	One case of Esophageal Laceration

section, full-thickness resection, adverse events and recurrency at 3-months follow-up. Primary endpoint was reached in 89.7%, histologically complete (R0) and a full-thickness-resection specimen were achieved in 76% and 65.5%, respectively. Periprocedural minor bleeding was observed in about 31% of cases. Follow-up was available in 79.3% and no signs of residual or recurrent tumors were observed after 3 months. This well organized paper showed for the first time that EFTR of gastric SET with gastroduodenal FTRD is feasible, safe and effective especially for diagnostic indication, yielding a clear diagnosis in 100% with a 76% rate of R0-resection. They concluded that “this technique should be considered as a powerful diagnostic tool for gastric SET which might obviate the need for multiple surveillance endoscopies, especially in younger patients”.

Of course, this prospective pilot study has the inherent limitation that all the patients treated had subepithelial tumors, and none of them presented a mucosal lesion.

In 2018 Roberts JR published a video case report describing a gastric adenocarcinoma full-thickness resection with this system; thus far, he carried out the procedure with a colonic kit, so that this device was used in an off-label modality (15). Another similar description of colonic FTRD use for UPG lesions concerns Kratt T. et al.'s paper, in which three patients with gastric melanoma metastases were treated with this device (16).

In 2018 Kappelle WFW et al. published an interesting original article on Surgical Endoscopy describing 13 cases of endoscopic full-thickness resection using a new over-the-scope clip with a flat base (Padlock Pro-select, Aponos Medical Corp., Kingston, NH, USA) for subepithelial lesions of UPG tract (5). This system provides an en bloc resection but, differently from FTRD-OVESCO, it doesn't allow a one-shot clip-and-cutting.

In our case series, we report three resection of different gastric lesions (both for size and for localization) with the FTRD system. To our knowledge, this is the first case series concerning gastric EFTR with the new gFTRD device described in Literature since now.

Patients included had different indications to FTRD. The first case was a subepithelial tumor of the gastric fundus; the surgical operation would

have led the patient to undergo a total gastrectomy, whereas other endoscopic approaches (such as ESD or EMR) were excluded due to the high risk of perforation. Considering the challenging site of the lesion, this innovative system has permitted a R0 en bloc removal of the NET in such a difficult to treat environment. The procedure didn't present any complication and the endoscopic surveillance didn't reveal any local recurrence. Confirming Meier B. et al.'s paper, in front of the challenging surgical environment, FTRD system allows performing a complete resection minimizing the procedural morbidity (3).

The second case is an interesting example of how this tool can be used to treat patients with several comorbidities, thus eligible for surgery. This is one of the few cases in which FTRD was utilized for the resection of local recurrent adenocarcinoma after an endoscopic polypectomy. In this particular patient this system was considered since the first endoscopic approach failed, as a final option before surgery.

The third case is particularly interesting for multiple reasons.

First, it offers the possibility to show how this device could be suitable for patients poorly candidate for surgery or for other conventional endoscopic resection techniques. Second, to our knowledge, this is the first case reported in Literature in which such a complication (the closure of the pylorus outlet) occurred. Third, it's described how to solve such a rare adverse-event; fortunately, the closure was uncomplete, so that the advancement of a guide-wire thorough the small lumen was possible, in order to carry out a progressive dilation with a CRE balloon.

Considering the high thickness of the pre-pylorus gastric wall, a full-thickness incorporation of the wall into the applicator was impossible; nevertheless, the histological examination showed an R0 en bloc resection.

This particular complication, more frequent in the duodenum or the colonic lumen, is very uncommon in the stomach, where the only two portions in which virtually could occur are the cardias and the pylorus. Of course more data are needed, and no cardias closure has been reported in Literature since now.

It's curious to think about what would have been done if a complete pylorus obstruction had oc-

curred: clip removal with the remOVE System or a surgical approach?

In our case series the R0-resection rate was 100% and at the current follow-up controls, no recurrence has been described. Unfortunately, the technical success rate is partially decreased due to the third case, in which a pyloric obstruction occurred.

As already underlined by Meier B. et al., gastric FTRD can be considered a safe and effective strategy to carry out endoscopic removal of gastric lesions in selective patients. Indications can differ significantly, ranging from non-lifting (or flat) polyps to recurrent lesions (also adenocarcinomas) (3).

Of course, FTRD must be used carefully in case of scarring lesions (due to previous endoscopic approaches), if the lesion is located in challenging sites (such as the pylorus or the cardias) and in relation of the thickness of the gastric wall (if a full thickness resection is required) (1-4).

Unfortunately, as this system has been recently introduced, current Literature is still poor and further data are needed in order to prove the real effectiveness and safety of this approach compared to the standard endoscopic approaches or to the surgical intervention.

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### *Conflict of interest*

None declared.

### *Guarantor of submission*

The corresponding author is the guarantor of submission.

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### *Ethical approval*

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## Authors' contributions

All Authors contributed substantially to the manuscript as follow (*Contributor Roles in CRediT*):

- 1) Conceptualization: Damiano Bisogni, Roberto Manetti, Riccardo Naspetti;
- 2) Data curation: Damiano Bisogni, Fabio Staderini, Francesco Coratti, Michele Rossi;
- 3) Formal analysis: no formal analysis is expected in our paper;
- 4) Funding acquisition: no funding acquisition is expected for our paper;
- 5) Investigation: Damiano Bisogni, Fabio Staderini, Francesco Coratti, Michele Rossi;
- 6) Methodology: Damiano Bisogni, Roberto Manetti, Luca Talamucci;
- 7) Project administration: Damiano Bisogni, Roberto Manetti, Luca Talamucci;
- 8) Resources: Damiano Bisogni, Luca Talamucci, Fabio Staderini, Francesco Coratti, Michele Rossi;
- 9) Software: non expected;
- 10) Supervision: Damiano Bisogni, Riccardo Naspetti;
- 11) Validation: Damiano Bisogni, Riccardo Naspetti;
- 12) Visualization: Damiano Bisogni, Roberto Manetti, Luca Talamucci, Riccardo Naspetti;
- 13) Writing-original draft: Damiano Bisogni, Riccardo Naspetti;
- 14) Writing-review&editing: Damiano Bisogni, Roberto Manetti, Luca Talamucci, Riccardo Naspetti.



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