

# Endoscopic Full-Thickness Resection of Colorectal Lesions with the New FTRD System: Single-Center Experience

Susana Mão de-Ferro<sup>a</sup> Joana Castela<sup>a</sup> Daniela Pereira<sup>b</sup> Paula Chaves<sup>b</sup>  
 António Dias Pereira<sup>a</sup>

<sup>a</sup>Gastroenterology Department, Instituto Português de Oncologia de Lisboa Dr. Francisco Gentil, EPE, Lisbon, Portugal; <sup>b</sup>Pathology Department, Instituto Português de Oncologia de Lisboa Dr. Francisco Gentil, EPE, Lisbon, Portugal

## Keywords

Full-thickness resection · Colorectal adenomas · Nonlifting lesions

## Abstract

**Background and Aims:** Endoscopic full-thickness resection (EFTR) is an emerging technique for the treatment of various conditions for which classic endoscopic resection techniques have failed or were considered to be at high risk for perforation. The full-thickness resection device (FTRD) is an over-the-scope system which allows a single-step EFTR. The aim of our study is to describe our experience in EFTR of colorectal lesions using the FTRD. **Methods:** Nine patients (10 colorectal lesions) were proposed for EFTR. Safety, R0 resection and endoscopic treatment success were evaluated. **Results:** Reasons for referral included nonlifting adenomas ( $n = 4$ ), nonlifting adenoma recurrence ( $n = 5$ ), and submucosal lesion ( $n = 1$ ). EFTR was technically successful in all patients. The mean duration of the procedure was 55 min. R0 resection was obtained in all patients. No major complications were detected. All lesions were successfully treated by the endoscopic technique and no patient was referred for

surgery. In patients with available follow-up ( $n = 6$ ), no recurrence was detected. **Conclusions:** EFTR is a feasible, reasonable time-consuming, safe, and promising endoscopic resection technique. **Key Messages:** FTRD is an additional tool for difficult-to-treat colorectal lesions.

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**Ressecção endoscópica transmural de lesões colorectais com o sistema FTRD: experiência de um centro**

## Palavras Chave

Ressecção endoscópica transmural · Adenomas colorectais · Adenomas cólicos com sinal de não elevação

## Resumo

**Introdução e objetivos:** A ressecção endoscópica transmural (RET) é uma técnica promissora para o tratamento de várias lesões não passíveis de ressecção endoscópica

pelas técnicas convencionais ou naquelas em que estes procedimentos apresentam elevado risco de complicações. O “full-thickness resection device” (FTRD) é um sistema pré-montado, que se acopla ao colonoscópio e que permite efetuar RET com um procedimento único. Pretende-se descrever a experiência do nosso centro na realização de RET com o FTRD. **Métodos:** Nove doentes (10 lesões cólicas) foram propostos para RET. Foram avaliadas a segurança, ressecção R0 e taxa de sucesso do procedimento endoscópico. **Resultados:** As indicações para o procedimento incluíram adenomas ( $n = 4$ ), recidivas de adenomas ( $n = 5$ ) sem elevação após injeção submucosa e lesão submucosa ( $n = 1$ ). A RET foi tecnicamente bem-sucedida em todos os doentes. A duração média dos procedimentos foi de 55 minutos. Ressecções R0 em todos os doentes. Não se registaram complicações major. Todas as lesões foram eficazmente tratadas com a ressecção endoscópica e nenhum doente foi proposto para cirurgia. Nos doentes já submetidos a exames de vigilância ( $n = 6$ ) não foram detetadas recorrências. **Conclusões:** A RET é uma técnica exequível e segura para a terapêutica de lesões coloretais. **Mensagens Chave:** A RET parece ser uma promissora ferramenta adicional para manejo de lesões colo-rectais difíceis de tratar.

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## Introduction

Conventional endoscopic resection techniques, including polypectomy, endoscopic mucosal resection (EMR), and endoscopic submucosal dissection (ESD), are well-known techniques for the treatment of superficial gastrointestinal lesions. They adhere to the basic principles of identification and delimitation of the lesion, submucosal injection to lift the lesion in most techniques, and endoscopic resection of the mucosal and part of the submucosal layer [1].

However, endoscopic resection of colorectal nonlifting lesions, early cancer, and subepithelial lesions may be very demanding or even impossible in some cases [2]. Endoscopic full-thickness resection (EFTR) is an emerging method for minimally invasive resection, which obviates the need for surgical therapy in selected patients. Indications for EFTR include 0–Is or 0–II and selected 0–III [3] colonic lesions with nonlifting sign [4], recurrence of adenomatous lesions resected with conventional endoscopic techniques such as EMR, ESD, or snare polypectomy considered not manageable with a conventional endo-

scopic resection technique, lesions located in difficult anatomic sites, such as diverticulum [5] or appendix where the perforation risk during EMR/ESD resection is significant, and subepithelial colonic lesions.

EFTRs are usually performed with a “clip first and cut later technique” in order to close the gut wall before resection, thus preventing perforation. In the first cases described, the lesions were targeted and aspirated into the transparent distal cap, and standard over-the-scope clips (OTSC) were deployed. The pseudopolyps located above the clip were then resected using an oval electrocautery snare [6–8]. The full-thickness resection device (FTRD; Ovesco Endoscopy, Tuebingen, Germany) is an over-the-scope system which allows a single-step EFTR after the placement of a modified OTSC [9].

In this report, we present our experience in EFTR of colorectal lesions using the FTRD system.

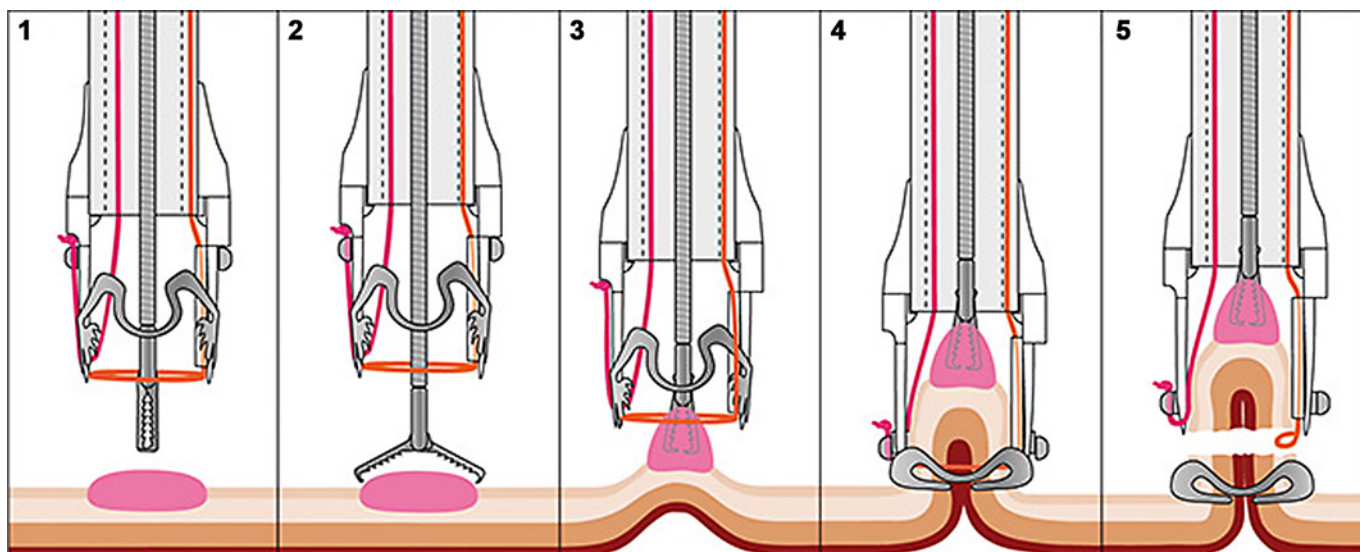
## Patients and Methods

Data from a prospectively collected database of all patients proposed for EFTR were analyzed. From March 2017 to February 2018, a total of 9 patients (1 of them scheduled for 2 EFTR procedures) underwent colonoscopy for EFTR of colonic or rectal lesions.

The performing endoscopist had undergone a 1-day training in EFTR using the FTRD which included hands-on training on ex vivo pig models prior to the first procedure. All patients provided informed consent to undergo colonoscopy and endoscopic resection with the FTRD technique. Prophylactic antibiotic therapy (cefazoline 1 g + metronidazole 500 mg) was instituted immediately before the procedure.

All procedures were performed under deep sedation with propofol under supervision of the anesthesiologist. Intravenous butylscopolamine was given at discretion of the operator to reduce bowel peristalsis. Lesions' removal with the FTRD (Ovesco Endoscopy) was performed following a standardized method [9] (Fig. 1). Initially, the lateral margins of the lesions were marked with coagulation using a FTRD marking probe (Ovesco Endoscopy). Next, the FTRD system was mounted on the colonoscope (Olympus CF-H190L).

The FTRD is a preassembled over-the-scope device. A transparent cap with a modified 14 OTSC is mounted over a standard colonoscope. The cap has an inner diameter of 13 mm and is 23 mm long. A 13-mm monofilament polypectomy snare is preloaded in the tip of the cap. The snare runs at the outer surface of the endoscope under a plastic sheath. For resection, grasping forceps (Ovesco Endoscopy) are advanced through the working channel of the endoscope to grasp the lesion. The lesion is slowly pulled into the cap to incorporate a double full-thickness layer of the colonic wall. Having the lateral margins of the lesion pulled into the cap, the OTSC is deployed. The pseudopolyp created by the OTSC is then resected with the preloaded snare while the OTSC secures patency of the colonic wall.



**Fig. 1.** The FTRD system is presented ([www.ovesco.com](http://www.ovesco.com)). **1** Marking of the lesion before mounting the FTRD system. **2** Grasping of the target tissue with the FTRD grasper. **3** Retrieval of the target tissue within cap and fixation. **4** Double check whether the target

tissue is completely within the FTRD cap. Release of the clip with handwheel. **5** Closure of the snare and electrical cut of the target tissue. Retrieval of the resected sample. Check of the resection site.

Technical success was defined as reaching the lesion, deploying the clip, and performing an en bloc and macroscopically complete resection.

Clinical success of the endoscopic treatment was defined as R0 resection and histopathology evaluation compatible with adequate endoscopic treatment (lesions with no invasive potential or malignant polyps with no risk factors for lymph node metastasis) [10]. All patients were monitored for at least 1 night after the procedure. Follow-up colonoscopy was scheduled 4–6 months after the initial procedure. All histologic specimens were evaluated by 2 pathologists with gastrointestinal differentiation.

## Results

Ten full-thickness resections were performed in 9 patients (6 males, 3 females, mean age 69 years, ranging from 51 to 92 years) (Fig. 2). In patient number 7, both EFTRs were performed the same day. Patients' and lesions' characteristics are described in Table 1.

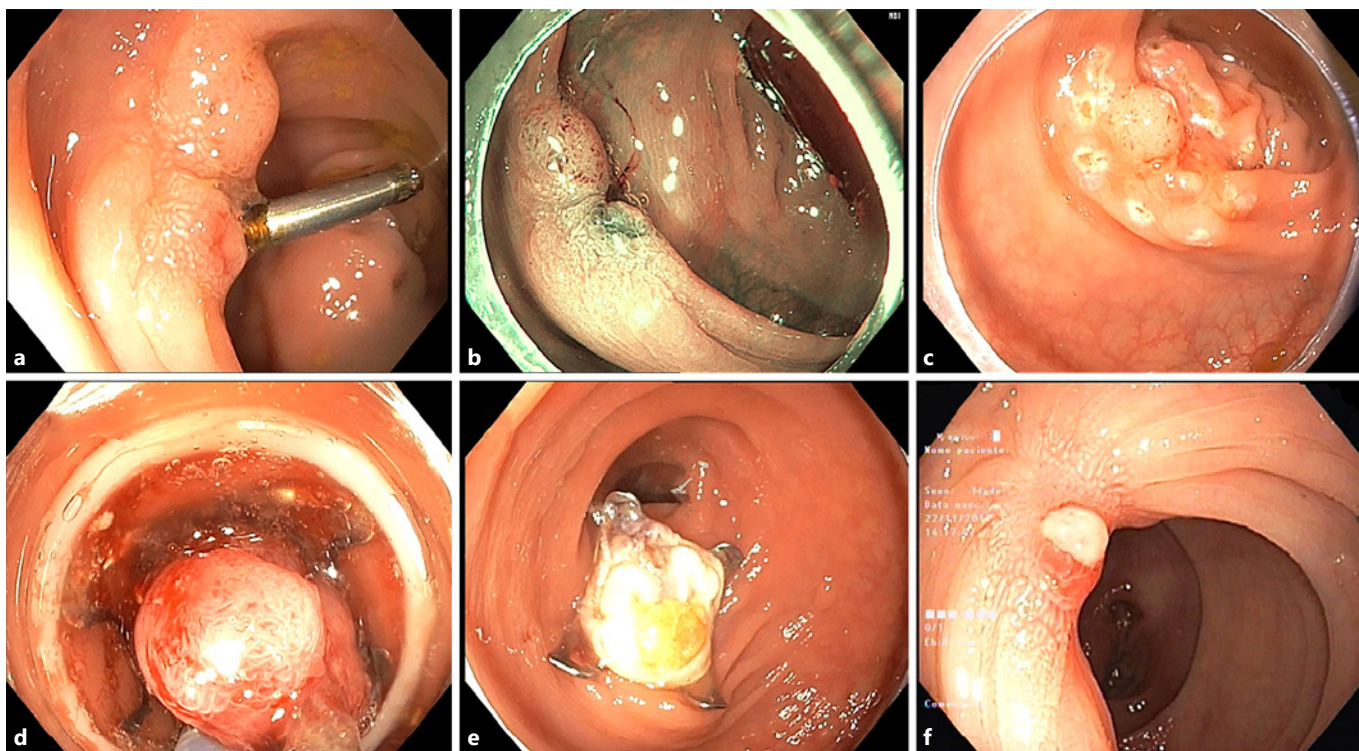
Lesions were located in the appendix remnant ( $n = 1$ ), ascending colon ( $n = 1$ ), hepatic flexure ( $n = 1$ ), transverse colon ( $n = 3$ ), splenic flexure ( $n = 1$ ), sigmoid colon ( $n = 1$ ), and rectum ( $n = 2$ ). The target lesion was reached with the FTRD and the resection was technically successful in all patients. In 2 patients (patients 1 and 8), there was a tear of the mucosa after OTSC deployment, resulting in

the release of the lesion from the grasping forceps. In these cases, the lesions were removed with a conventional 20-mm snare (Olympus SD-230U-20) above the OTSC.

The duration of the procedure ranged from 25 to 80 min (mean duration of 55 min). There were no major complications associated with sedation or the endoscopic procedure, including perforation or post polypectomy syndrome. Three patients referred very mild abdominal pain for less than 24 h. One patient presented with self-limiting minor rectal bleeding at the day of the procedure, with no hemodynamic or analytic repercussion and no need for endoscopic hemostasis. The mean hospital stay was 1.4 days (ranging from 1 to 2 days).

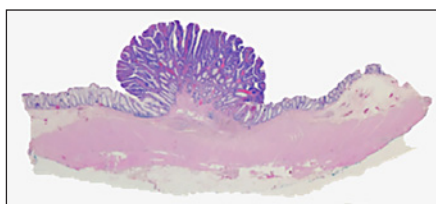
Histologic complete (R0) resection was obtained in all patients (Fig. 3). Mean size of the resection specimens was 22.6 mm. Histologic full-thickness resection was obtained in 7 of 10 cases. Full-thickness resection was not possible in patients number 2 and 5 (both presenting rectal lesions) and in patient number 1 that was one of the cases in whom release of the lesion from the graspers occurred during OTSC deployment. The histological examination of the specimens revealed 1 well-differentiated appendicular neuroendocrine tumor (NET G1), 3 adenomas with low-grade dysplasia (tubular:  $n = 2$ ; tubulovillous:  $n = 1$ ), 5 tubular adenomas with high-grade dysplasia, and 1 sessile serrated adenoma. Patient number 3,





**Fig. 2.** EFTR of a nonlifting adenoma recurrence (patient number 4). **a** White light image: Paris 0–IIa + 0IIc 15-mm lesion with a through-the-scope clip that was placed after mucosectomy due to bleeding. **b** Narrow-band image (Nice 2) after clip removal. **c** Lim-

its were marked with the marking probe. **d** Lesion grasping into the cap. **e** Resection site with the OTSC in situ. **f** After 3 months of follow-up.



**Fig. 3.** Histology specimen of a FTRD procedure. Full-thickness resection of a tubulovillous adenoma with low-grade dysplasia, R0 resection.

with the diagnosis of NET, was staged with CT scan, Gallium-DOTANOC-PET scan, and chromogranin A with no evidence of active diseases and, after multidisciplinary team discussion, surveillance was proposed. Therefore, all lesions were considered to be successfully treated by this technique and no patient was referred for surgery. Follow-up colonoscopy was available in 6 patients and no residual lesion was detected. In 5 of 6 patients, the clips had spontaneously detached from the colonic wall.

### Discussion

We present our data on the use of the FTRD system, an all-in-one “first and cut later technique” for EFTR of colorectal lesions. The FTRD system has been marketed in 2014 [9], and the evidence available with this technique is continuously increasing. A multicenter prospective study with 181 patients [11] and a few case series, the largest including 60 patients, have been published so far [12–16]. Data show that this technique may offer a simple and reasonable time-consuming procedure for the treatment of various conditions for which classic endoscopic resection techniques, such as EMR and ESD, have failed or were considered to be at high risk for perforation [2]. One difficulty of the technic is advancing the FTRD to the target lesion as the cap with the loaded clip has an outer diameter of 21 mm and impairs endoscopic vision and flexibility of the endoscope tip.

All procedures were performed successfully, and the duration of the EFTRs in this case series was on average 55 min. This included reaching and marking the lesions,

**Table 1.** Patients' characteristics and outcomes following FTRD

Patient No.	Sex	Age, years	Reason for FTRD proposal	Location	Size of lesion, mm	Procedure duration, min	Size of specimen, mm	Histology	R0 resection	FTR	Complication	Surgery	Follow-up
1	M	73	Nonlifting adenoma relapse after EMR	Hepatic flexure	15	75	17×12	Tubulovillous adenoma LGD	Yes	No	No	No	6 months, no recurrence
2	F	79	Nonlifting adenoma relapse after EMR	Rectum	12	47	14×12	Tubular adenoma LGD	Yes	No	No	No	6 months, no recurrence
3	F	51	Submucosal lesion	Appendix remnant	12	80	28×18	NET	Yes	Yes	No	No	12 months, no recurrence
4	M	68	Nonlifting adenoma relapse after EMR	Sigmoid colon	15	50	28×22	Tubular adenoma LGD	Yes	Yes	No	No	4 months, no recurrence
5	F	67	Nonlifting adenoma relapse after EMR	Rectum	15	25	28×20	Tubular adenoma HGD	Yes	No	No	No	6 months, no recurrence
6	M	52	Nonlifting adenoma	Ascending colon	15	70	24×22	Tubular adenoma HGD	Yes	Yes	No	No	6 months, no recurrence
7a	M	74	Nonlifting residual adenoma	Transverse colon	15	40 <sup>a</sup>	20×20	Tubular adenoma HGD	Yes	Yes	No	No	Scheduled
7b			Nonlifting adenoma	Transverse colon	20	40 <sup>a</sup>	23×21	Tubular adenoma HGD	Yes	Yes	No	No	Scheduled
8	M	92	Nonlifting adenoma	Ascending colon	20	70	20×	SSA	Yes	Yes	No	No	Scheduled
9	M	65	Nonlifting adenoma, submucosal invasion?	Splenic flexure	15	50	24×19	Tubular adenoma HGD	Yes	Yes	No	No	Scheduled

EMR, endoscopic mucosal resection; NET, neuroendocrine tumor; R0, complete resection; FTR, full-thickness resection; LGD: low-grade dysplasia; HGD, high-grade dysplasia; SSA, sessile serrate adenoma. <sup>a</sup> Total of 80 min for the 2 procedures.

mounting the FTRD system on the colonoscope, reaching the lesion with the FTRD, performing the resection, and then reaching the lesion again to re-evaluate the site. In patient number 5 with a rectal adenoma, the procedure took only 25 min. This is in line with what has previously been published. As this is a very small series, we cannot infer if experience may reduce the time to complete the procedure. All lesions were completely resected and in patients for whom follow-up was available, no recurrence was detected. The R0 resection rate with FTRD in published series ranged from 75 to 80% [11, 13].

The median size of the resected lesions was 22.6 mm which is also similar to what has been previously reported [11, 13]. The size of the lesions is one of the major problems of the EFTR with the FTRD system, as they are limited by the size of the cap (length 23 mm, inner diameter 13 mm, allowing for a volume of up to 3 cm<sup>3</sup>), lesions' characteristics, and is strongly dependent on the rigidity

of the colonic wall. While resection specimens of up to 54 mm have been reported in experiments with healthy porcine colon [17], all clinical series on EFTR with the FTRD support the removal of lesions with an estimated size of up to 30 mm. However, as has been previously reported, resection success decreased significantly for lesions >20 mm. In fact, R0 resection decreased for 58% for lesions >2 cm as compared to 81.2% for lesions <2 cm. Therefore, patients' selection is crucial for technical success [11, 13]. Some hybrid techniques have been proposed to overcome the size problem of the lesions. Hybrid EMR-EFTR consists in the reduction of the size of the lesion with EMR followed by same-day EFTR and seems to be an effective approach for large nonlifting lesions with positive lateral lifting signs [18].

Fischer et al. [19] presented a case report of hybrid polypectomy EFTR. In this case, the volume of the polyp was too large for FTRD resection alone. After partial snare

polypectomy, full thickness resection of the polyp remnant was performed. The authors suggest that if incomplete snare polypectomy can be expected, additional resection of the polyp base remnant with the FTRD in the same session may be reasonable.

In our case series, no case of invasive cancer was detected and no patient was referred to surgery. Surgery has been proposed to 10–11% of patients submitted to FTRD, most cases due to carcinoma with noncurative endoscopic resection, unsuccessful technique, or recurrence not amenable to endoscopic therapy. Only 2% of the patients were referred for surgery due to procedure-related adverse events [11]. We had no major complications and, surprisingly, only a minority of patients presented very mild abdominal pain.

In the first prospective multicenter study on EFTR, procedure-related adverse events were described in up to 10% of cases. This complication rate is higher than what has been previously described in published case series, but still considered to be acceptable.

Procedure-related events included bleeding, perforation, most of them endoscopically managed, and postpolypectomy syndrome. A case of enterocolonic fistula (probably caused by entrapment of the small bowel in the OTSC) has also been described [11]. Acute appendicitis is also a known complication for EFTR of appendicular lesions and may arise in up to 10% of cases; most of them are dealt with conservatively.

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## Conclusion

We believe that after specific training, EFTR is a feasible, safe, and promising all-in-one endoscopic resection technique and is an additional tool for difficult-to-treat colorectal lesions.

Our data and the data reported in the literature show that EFTR allows complete resection of lesions <20 mm with an acceptable risk of adverse events. The FTRD system has some limitations as it only allows the removal of lesions of <30 mm and some lesions are difficult to reach with the 21-mm cap. Hybrid EMR-EFTR or polypectomy EFTR and technical modifications of the device may ameliorate these limitations.

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## Statement of Ethics

The authors have no ethical conflicts to disclose.

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## Disclosure Statement

The authors have no conflicts of interest to disclose.

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