

Overview clinical data

Study	Patients (n)	Localization	Lesion size (mm)	Procedure time (min)	Complications (n)	R0 Resection ¹
[1] Meier et al (2017) <i>Surgical Endoscopy</i> → Hybrid-FTRD (EMR)	10	rectosigmoid (1), sigmoid (1), ascending colon (4), cecum (4)	35.5 (30-50)	90.1 (65-140) ²	None	100 % (10/10)
[2] Lupu et al (2018) <i>Endoscopy</i> → Hybrid-FTRD (ESD) 	1	cecum (invading appendix)	40	N.a.	None	100 %
[3] Andrisani, Di Matteo (2019) <i>Dig Liver Dis.</i> → Hybrid-FTRD (ESD)	5	sigmoid (1), transverse colon (1), ascending colon (3)	31 (25-35)	127.4 (90-165)	None	100 %
[4] Andrisani et al (2020) <i>VideoGIE</i> → Hybrid-FTRD (EMR) 	1	cecum (invading appendix)	N.a. (specimen 52x30)	150	None	100 %
[5] Bauermeister et al (2021) <i>Endosc. Int. Open</i> → Hybrid-FTRD (EMR) 	17	rectum (6), sigmoid (5), colon transversum (2), cecum (3), appendiceal orifice (1)	29 (20-50)	69 (35-160) ²	- Post polypectomy syndrome (2) - minor bleeding (1) - prerenal failure during bowel preparation ³ (1)	76.4 % (13/17)
[6] Mahadev et al (2021) <i>Am J Gastroenterol</i> → Hybrid-FTRD (EMR)	31 ⁴ (of 69)	sigmoid (2), descending colon (2), splenic flexure (1), transverse colon (8), hepatic flexure (4), ascending colon (8), cecum (5), appendiceal orifice (1)	39 (15-70)	91 (58-198)	Perforation due to improper deployment of FTRD (1) -managed endoscopically	83.9 % (26/31)
[7] Chua et al (2021) <i>Endosc Int Open</i> → Hybrid-FTRD (EMR) 	6	transverse colon (1), ascending colon (3), cecum (2)	12.5 ⁵ (5-20)	84.5 (58-140)	None	83.3 % (5/6) ⁶
[8] Meier et al (2022) <i>Data from Ludwigsburg – interim results</i> → Hybrid-FTRD (EMR)	54	rectum (7), sigmoid (5), descending colon (1), splenic flexure (3), transverse colon (2), hepatic flexure (6), ascending colon (11), cecum (19)	36.6 (25-60)	83.7 (30-140)	- Bleeding (n=3) - Surgical management (oncological resection) (n=7)	No recurrence/ Residual 87.2 % (41/54) ⁷

¹ of FTRD specimen

² long times of intervention were due to additional polypectomy in other parts of the colorectum

³ not associated with FTRD intervention

⁴ comparison of standalone FTRD and Hybrid-FTRD (EMR+FTRD) in 69 procedures, of which 31 were in Hybrid-FTRD technique; only the latter one are considered here

⁵ only invasive part, not overall size of lesion

⁶ In the remaining case, one of the lateral edges of the invasive part could not be reliably assessed due to cauterization artifacts

⁷ without the patients with oncological resection



Full texts of the publications are freely accessible on the internet

[1]	<p>Hybrid endoscopic mucosal resection and full-thickness resection: a new approach for resection of large non-lifting colorectal adenomas. Meier, B., Caca, K., Schmidt, A. <i>Surg Endosc.</i> DOI: 10.1007/s00464-017-5461-9.</p>
<p>Abstract</p> <p>Background: Clip-assisted endoscopic full-thickness resection (EFTR) with an over-the-scope device has been recently described to be feasible and effective for the resection of non-lifting adenomas in the lower gastrointestinal tract. However, tumor size is the major limitation of that technique. We describe a hybrid technique using endoscopic mucosal resection (EMR) in ten patients with large non-lifting colorectal adenomas to reduce tumor size and facilitate clip-assisted EFTR.</p> <p>Methods: Data of ten consecutive patients (median age 72.5 years, SD 8.86) who underwent combined EMR and EFTR in the colon were analyzed retrospectively. The main outcome measures were technical success, histological confirmation of full-thickness resection, and adverse events.</p> <p>Results: All lesions (median size 35.5 mm, SD 5.99) could be resected successfully. No immediate or delayed adverse events were observed. Histology confirmed full-thickness resection in all cases. Three-month follow-up showed no residual or recurrent adenomas.</p> <p>Conclusions: Hybrid EMR–EFTR in the colon seems to be an effective approach for large non-lifting lesions with positive lateral lifting signs. Prospective studies are needed to further evaluate efficacy, safety, rate of recurrence, and long-term outcome of this technique.</p>	
[2]	<p>Hybrid endoscopic submucosal dissection using a full-thickness resection device allows enbloc resection of a large adenoma deeply invading the appendix. Lupu A, Jacques J, Rivory J, Saurin JC, Rostain F, Ponchon T, et al. <i>Endoscopy</i> 2018;50(October (10)):E296–8, DOI: 10.1055/a-0651-0393.</p>
<p>Abstract</p> <p>Endoscopic full-thickness resection using a full-thickness resection device (FTRD) (Ovesco; Tübingen, Germany) was introduced in 2014 and is mainly used for small colonic laterally spreading tumors (LSTs) with important fibrotic component, non-lifting after submucosal injection, or superficial recurrent lesions located at or near a surgical anastomosis. It has an 81% R0 resection rate for lesions ≤ 2 cm, with a 10% rate of adverse events [1][2]. The main limitations are large tumor size and proximal colonic lesions, as the FTRD cap is 23 mm in length, which sometimes makes cecal intubation difficult. The most important risks are bleeding, trapping of pericolonic organs when sucking the lesions into the cap, and luminal stenosis due to the clip [3].</p> <p>We present the case of a large LST invading the appendectomy site. Standard resection using the FTRD was not possible because the lesion ([Fig. 1]; [Video 1]) was too large (40 mm) to fit into the cap, so we first performed a circumferential incision and endoscopic submucosal dissection using the clip and rubber-band strategy ([Fig. 2]) [4][5]. We then used the FTRD system to trap the dissected corolla into the cap ([Fig. 3]). The clip was placed safely around the lesion and sectioning was performed using a standard polypectomy snare (failure of cutting with 13-mm FTRD integrated snare).</p>	

[3]	<p>Hybrid resection with ESD and FTRD: could this be a rescue treatment in the presence of severe submucosal fibrosis? Andrisani G, Di Matteo FM. <i>Dig Liver Dis.</i> 2019;51(4):607–609. Epub 2019 Jan 14. DOI: 10.1016/j.dld.2019.01.003.</p>
<p>Abstract</p> <p>Endoscopic submucosal dissection (ESD) is currently the endoscopic procedure of choice for the treatment of gastrointestinal neoplasms as it allows en bloc resection and accurate histological evaluation of the lesions and results in a low rate of local recurrence [1] . ESD, a time-consuming technique, requires specific training and a high level of skill in order to be safely performed. The presence of fibrosis makes the procedure more difficult and it is associated with low complete resection rates during colorectal ESD [1 , 2] . Factors that may predict the degree of submucosal fibrosis include tumour size, histology, depth of invasion, and pit pattern [2] . The FTRD® (full thickness resection device; Ovesco Endoscopy, Tübingen, Germany) is an over-the-scope device that allows EFTR with a clip-and-cut technique. In Europe, it was granted the CE Mark and the approval for lower gastrointestinal (GI) tract resection in September 2014 [3] . We describe the first hybrid technique case series using endoscopic submucosal dissection (ESD) and endoscopic full-thickness resection (EFTR) with FTRD (Fig. 1) in patients with severe fibrosis in order to achieve en bloc resection.</p>	
[4]	<p> Hybrid resection with endoscopic submucosal dissection and full-thickness resection device of a large cecal laterally spreading tumor involving the appendix. Andrisani G, Di Matteo FM. <i>VideoGIE.</i> 2020 Aug; 5(8): 372–374. DOI: 10.1016/j.vgie.2020.03.019.</p>
<p>Abstract</p> <p>Endoscopic submucosal dissection (ESD) allows for en bloc resection of large superficial neoplasms of the GI tract. However, ESD of lesions involving the appendix has a high risk of adverse events, even for experts.^{1, 2, 3} Endoscopic full-thickness resection (EFTR) using a full-thickness resection device (FTRD; Ovesco Endoscopy, Tübingen, Germany) is a new approach for these lesions, but the main limitation is tumor size.^{4, 5, 6} A recent case series described the hybrid ESD-EFTR technique as a rescue approach for “difficult” ESD (Fig. 1).⁷ We present the case of a large cecal laterally spreading tumor invading the appendix and resected with the hybrid technique Video 1, available online at www.VideoGIE.org; (Fig. 2).</p>	
[5]	<p> Hybrid resection of large colorectal adenomas combining EMR and FTRD. Bauermeister M, Mende M, Hornoff S, Faiss S. <i>Scandinavian Journal of Gastroenterology,</i> 2021. DOI: 10.1080/00365521.2021.1933583.</p>
<p>Abstract</p> <p>Background: The introduction of the full-thickness resection device (FTRD) allowed resection of difficult adenomas in the duodenum and colorectum with non-lifting. The main limitation of this endoscopic technique is the lesion size. We describe a hybrid approach combining endoscopic mucosal resection (EMR) and FTRD in a cohort of 17 patients to reduce tumor size and enable full-thickness resection.</p> <p>Methods: Retrospective analysis from data of 17 patients who underwent hybrid EMR-FTRD for large adenomas in the colorectum at our institution. Technical success, histological confirmation of margin-free resection and adverse events were studied.</p> <p>Results: 16 of 17 (94.1%) lesions could be resected macroscopically complete with confirmed full-thickness resection. Histological work-up of the full-thickness specimens showed free lateral margins in 13 patients (76.4%), unclear margins</p>	

in two patients (11.8%) and positive margins in two patients (11.8%). There were no immediate perforation or major bleeding, however one patient showed a stenosis after resection in the follow-up endoscopy. Follow-up endoscopy was available in 12 patients. In two of 12 patients a recurrent adenoma was detected.

Conclusions: Hybrid EMR-EFTR in the colorectum seems to be a safe and effective technique for large non-lifting lesions with positive lifting signs in the margins. Further prospective evaluation of efficacy, safety and long-term outcome of this hybrid technique is necessary.

[6] Outcomes of hybrid technique using endoscopic mucosal resection and endoscopic full-thickness resection for polyps not amenable to standard techniques (with video).

Mahadev S, Vareedayah AA, Yuen S, Yuen W, Koller KA, Haber GB.

Gastrointestinal Endoscopy (2021), DOI: [10.1016/j.gie.2021.02.009](https://doi.org/10.1016/j.gie.2021.02.009).

Abstract

Background and aims: The full-thickness resection device (FTRD) offers a safe and effective approach for resection of complex colorectal lesions but is limited to lesions <2 cm in size. A hybrid approach-combining EMR with the FTRD-significantly expands the pool of lesions amenable to this technique; however, its safety and efficacy has not been well established.

Methods: We report a single-center retrospective study of consecutive patients who underwent full-thickness resection (FTR) of colorectal lesions, either with a standalone FTRD or a hybrid (EMR + FTRD) approach. Outcomes of technical success, clinical success (macroscopically complete resection), R0 resection, and adverse events (AEs) were evaluated.

Results: Sixty-nine FTR procedures (38 standalone FTR and 31 hybrid EMR + FTR) were performed on 65 patients. The most common indications were nonlifting polyp (43%) or suspected high-grade dysplasia or carcinoma (38%). Hybrid EMR + FTR permitted resection of significantly larger lesions (mean, 39 mm; range, 15-70 mm) compared with standalone FTR (mean, 17 mm; range, 7-25 mm; $P < .01$). Clinical success (91%), technical success (83%), and R0 resection (81%) rates did not differ between standalone and hybrid groups. Most patients (96%) were discharged home on the day of the procedure. Three AEs occurred, including 2 patients who developed acute appendicitis.

Conclusions: A hybrid approach combining EMR and FTRD maintains safety and efficacy while permitting resection of significantly larger lesions than FTRD alone.

[7] Hybrid endoscopic mucosal resection and full-thickness resection for large colonic polyps harboring a small focus of invasive cancer: a case series.

Chua J.S., Dang H., Zwager L.W., Dekkers N., Hardwick J.C.H., Langers A.M.J., van der Kraan J., Perk L.E., Bastiaansen B.A.J., Boonstra J.J., on behalf of the Dutch eFTR Working Group.

Endosc Int Open 2021; 09: E1686–E1691. DOI: [10.1055/a-1529-1447](https://doi.org/10.1055/a-1529-1447).

Abstract

Endoscopic treatment of large laterally spreading tumors (LSTs) with a focus of submucosally invasive colorectal cancer (T1 CRC) can be challenging. We evaluated outcomes of a hybrid resection technique using piecemeal endoscopic mucosal resection (pEMR) and endoscopic full-thickness resection (eFTR) in patients with large colonic LSTs containing suspected T1 CRC. Six hybrid pEMR-eFTR procedures for T1 CRCs were registered in a nationwide eFTR registry between July 2015 and December 2019. In all cases, the invasive part of the lesion was successfully isolated with eFTR; with eFTR, histologically complete resection of the invasive part was achieved in 5 / 6 patients (83.3 %). No adverse events occurred during or after the procedure. The median follow-up time was 10 months (range 6-27), with all patients having undergone

≥ 1 surveillance colonoscopy. One patient had a small adenomatous recurrence, which was removed endoscopically. In conclusion, hybrid pEMR-eFTR is a promising noninvasive treatment modality that seems feasible for a selected group of patients with large LSTs containing a small focus of T1 CRC.

[8] Meier et al (2022) – Data from Ludwigsburg; interim results presented at DGE-BV 2022. *To date only available in German.*

Patientencharakteristika (n = 54)		Intervention (n = 54)	
Geschlecht, n (%)		Eingriffsdauer in min, Durchschnitt/Median (Range)	83.7/85 (30-140)
männlich	34 (63.0)	Technischer Erfolg, n (%)	54 (100.0)
weiblich	20 (37.0)	Makroskopisch vollständige Resektion, n (%)	53 (98.1)
Alter in Jahren, Durchschnitt/Median (Range)	73.3/77 (31-87)	Histologie, n (%)	
Lokalisation, n (%)		Rx*	52 (96.3)
Coecum	19 (35.2)	R1	2 (3.7)
C. ascendens	11 (20.4)	Übergang in Frühkarzinom	10 (18.5)
rechte Flexur	6 (11.1)	low-risk**	3 (5.5)
C. transversum	2 (3.7)	high-risk	7 (13.0)
linke Flexur	3 (5.5)	Komplikationen, n (%)	
C. descendens	1 (1.8)	Blutungen***	3 (5.6)
Sigma	5 (9.3)	Perforationen	0 (0.0)
Rektum	7 (13.0)	Chirurgisches Management****, n (%)	7 (13.0)
Klassifikation, n (%)			
Paris Is	29 (53.7)		
LST / Paris IIa	25 (46.3)		
Größe in mm, Durchschnitt/Median (Range)	36.6/30 (25-60)		
Rezidiv, n (%)			
ja (Z.n. 1-4 x EMR)	21 (38.9)		
nein (Z.n. Biopsie)	33 (61.1)		

* methodenbedingt (piece-meal Resektion)
 ** primär endoskopisch kurativ
 *** peri-interventionell, endoskopisches Management
 **** ausschließlich onkologische Nachresektionen (Frühkarzinome mit high-risk)

Endoskopisches Follow-Up (n = 47*)	
Follow-Up in Monaten, Durchschnitt/Median (Range)	8.4/6 (3-36)
Kein Rezidiv/residueller Befund**, n (%)	41 (87.2)
Rezidiv, n (%)	6 (12.8)
endoskopisches Management***	6 (12.8)

* kein endoskopisches Follow-Up bei Pat. nach chirurgischer Resektion erfolgt/vorhanden (n = 7)
 ** makroskopisch und histologisch (Biopsie der Resektionsstelle)
 *** jeweils Re-FTRD mit kosekutiver RO-Resektion und im weiteren Follow-Up kein erneutes Rezidiv