Clinical Summary



EndoRotor EPRTM

(Endoscopic Powered Resection)



EndoRotor EPR[™] Safety and Efficacy

Safety	%	
Delayed bleeding	2% ⁸⁻¹¹	
Perforation	0% ⁸⁻¹¹	
Other (appendicitis, entercolonic fistula, thermal injury)	0% ⁸⁻¹¹	
TOTAL	2% ⁸⁻¹¹	
Efficacy	%	
Efficacy Complete resection	% 97% ⁸⁻¹¹	
Efficacy Complete resection Lesion size limitations	% 97% ⁸⁻¹¹ No limit ⁸⁻¹¹	
Efficacy Complete resection Lesion size limitations Hinderance of future endoscopic intervention	% 97% ⁸⁻¹¹ No limit ⁸⁻¹¹ None ⁸⁻¹¹	



Challenges associated with Endoscopic Mucosal Resection

Incomplete Resection:

Incomplete resection rate increases with polyp size and lesion type:

- 5-9 mm 6.8%¹
- 10-20 mm 17.3%¹
- Sessile serrated adenomas 20-30%^{1,2}

Fibrosis/Scarring from Previous Manipulation: Previous endoscopic manipulation (partial snare resection/ incomplete resection) is an independent predictor of:

- Inability to perform complete resection without ablation³
- Lesion recurrence³

Fibrosis prevents the separation of lumen wall layers and lifting of lesions² Non-lifting lesions are difficult to grasp and resect with a snare, sometimes making standard EMR impossible to perform³

Fibrotic/Scarred Recurrent Lesions

Difficulty defining when endoscopic treatment of recurrence has been achieved because there is a high incidence of multiple recurrences after endoscopic resection for recurrent adenomas³

- Patients with recurrence require endoscopic resections²⁻⁷
- 7% of inconspicuous polypectomy scars contain residual adenoma⁵

Anatomical Location Peri-appendiceal lesions

- Poor visualization of lateral margins⁶
- Vertical approach of endoscopic devices and absence of muscle layer (higher risk of perforation)⁶

AnoRectal junction

- Poor endoscopic access and visualization⁷
- Recurrence: up to 22%7



Therapeutic Challenges Associated with Removal of Scarred/Fibrotic Lesions

Endoscopic Full Thickness Resection

Resection size limitations¹²

16% of patients experience technical failure¹³

Major adverse events¹²

Appendicitis, delayed perforation, entercolonic fistula¹²

Difficulty navigating through anatomy¹²

Technical learning curve lowers curative rate (80%)¹⁴

Argon Plasma Coagulation

Higher rate of recurrence¹⁶

 Patients who are treated with APC to ablate residual tissue post-EMR experience a 20% recurrence rate^{16,17}

Should not be used on macroscopically visible tissue¹²

• APC use at the time of polypectomy has been shown to be an independent predictor of residual adenoma at follow-up colonoscopy up to 40%^{12,17}

Salvage Endoscopic Submucosal Dissection

Difficulty creating adequate submucosal lift¹²

 Salvage ESD due to recurrent lesions carries a 10.7% AE rate vs a 3.8% AE rate for primary ESD¹⁵

Lower curative rate (83%)¹²

Procedural inefficiency¹⁵

• Salvage ESD due to recurrent lesions has a significantly longer mean dissectio and procedure time compared to primary (naïve) ESD (78 minutes vs 55 minutes)¹⁵

Avulsion

Hot Avulsion:

- Risk of deep mural injury and thermal destruction of tissue¹²
- Recurrence rate when using hot avulsion as an adjunct therapy is higher than EMR without hot avulsion (17.52% vs. 16.02%)18

Cold Avulsion:

- Risk for deep muscle injury¹²
- Recurrence rate of 15%¹²
- ¹ Pohl, Heiko, et al. Incomplete Polyp Resection During Colonoscopy—Results of the Complete Adenoma Resection (CARE) Study. Gastroenterology, vol. 144, no. 1, 2013, doi:10.1053/j.gastro.2012.09.043.
- ² Kim, Myung Hee, et al. The Incidence and Risk Factors of Sessile Serrated Adenomas in Left Side Colon Cancer Patients after Curative Surgery. Medicine, vol. 99, no. 29, 2020, doi:10.1097/ md.000000000020799
- Kim H, Friedland S, et al. Effect of prior biopsy sampling, tattoo placement, and snare sampling on endoscopic resection of large nonpedunculated colorectal lesions. GIE. 2015. Volume 81, No. 1.

⁴ Emmanuel A, Haji Á, et al. Risk factors for early and late adenoma recurrence after advanced colorectal endoscopic resection at an expert Western center. GIE. 2019. Volume 90, No.1 ⁵ Knabe M, Shumacher B, et al. Standardized Long-Term Follow-Up After Endoscopic Resection of Large Nonpedunculated Colorectal Lesions: A Prospective Two-Center Study. Am J Gastro. 2014. Volume 109, No. 2.

- ⁶ Song E M, Byeon J, et al. Endoscopic Resection of Cecal Polyps Involving the Appendiceal Orifice: A KASID Multicenter Study. Dig Dis Sci. 2017. 62:3138-3148.
- ⁷ Holt B A, Bourke M J, et al. Advanced mucosal neoplasia of the anorectal junction: endoscopic resection technique and outcomes (with videos). GIE. 2014. Volume 79, No. 1. ⁸ Kandiah K, et al. A novel non-thermal resection tool in endoscopic management of scarred polyps. EIO. 2019; 07: E974-E978.
- ⁹ Emmanuel A, Haji A et al. The incidence of microscopic residual lesion left after apparent complete wide-field EMR of large colorectal superficial neoplastic lesions: evidence for the pathophysiological mechanism of recurrence superficial neoplastic lesions: DDW Poster Session 2018.
 ¹⁰ Ayub K, Kaul V et al. SAFETY & EFFICACY OF THE NOVEL ENDOROTOR® MUCOSAL RESECTION SYSTEM: FIRST MULTICENTER USA EXPERIENCE. American College of Gastroenterology 2020.

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 ¹³Ichkhanian, Y., et al. A Large Multicenter Cohort on the Use of Full-Thickness Resection Device for Difficult Colonic Lesions. *Surgical Endoscopy*, 2020, doi:10.1007/s00464-020-07504-9.
 ¹⁴Non Helden, Annabell et al. Endoscopic full-thickness resection using an over-the-scope device for treatment of recurrent / residual colorectal neoplasia: a single-center case series.
 BMC gastroenterology vol. 19, 1121. 10 Jul. 2019, doi:10.1186/s12876-019-1043-8

15 Jung, Da Hyun et al. Secondary endoscopic submucosal dissection for locally recurrent or incompletely resected gastric neoplasms. World journal of gastroenterology vol. 24,33 (2018): 3776-3785. doi:10.3748/wjg.v24.i33.3776

¹⁶Moss A, et al. Long-term adenoma recurrence following wide-field endoscopic mucosal resection (WF-EMR) for advanced colonic mucosal neoplasia is infrequent: results and risk factors in 1000 cases from the Australian Colonic EMR (ACE) study. Gut 2015;64:57–65...

¹⁷Moss, Alan, et al. Endoscopic Mucosal Resection Outcomes and Prediction of Submucosal Cancer From Advanced Colonic Mucosal Neoplasia. Gastroenterology, vol. 140, no. 7, 2011, pp. 1909–1918., doi:10.1053/j.gastro.2011.02.062.

18Kumar, Vinod et al. Safety and efficacy of hot avulsion as an adjunct to EMR (with videos). Gastrointestinal endoscopy vol. 89,5 (2019): 999-1004. doi:10.1016/j.gie.2018.11.032

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