



Background and Aims

Endoscopic resection, especially of neoplastic lesions of the mucosa, should be performed horizontally in sano in order to avoid residual recurrences and vertically as deep as possible (in the colorectum > 1000 µm) below the muscularis mucosae, without perforating the organ wall, in order to facilitate pT1 staging. This is problematic in so far as the submucosa in which the RF-surgery cutting takes place is < 1000 µm thin below flat (Paris typ II) lesions, e.g. in the colorectum (Fig. 1), and can swell by a maximum factor of 5, i.e. < 5 mm, as a result of submucosal injection.

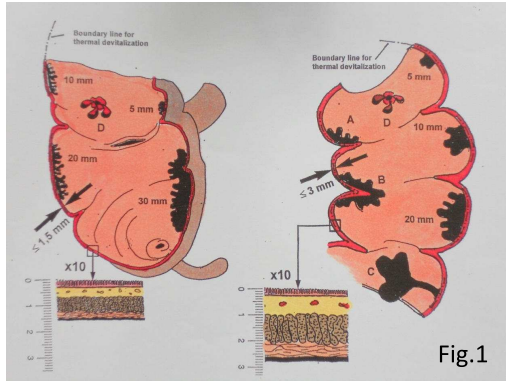


Fig. 1

In order to confirm the horizontal in sano resection histopathologically, lesions should be resected en bloc. This is only possible with EPE and EMR for lesions < 2 cm, with ESD also with >> 2 cm. However, ESD is known to be technically difficult.

In order to avoid perforations, in EPE, EMR and ESD the RF-cutting is distanced as far as possible from the muscularis propria (cutting direction B in Fig. 2). This can be possible in hyperplastic Paris type I lesions on sufficiently thick submucosa without or after submucosal injection. But in neoplastic lesions, especially with cancer penetration through the muscularis mucosae, it can be a serious problem. In flat lesions on < 1 mm submucosa or < 5 mm after submucosal injection RF-cutting is practised close the muscularis mucosae.

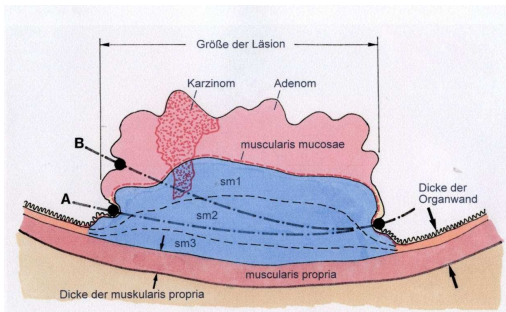


Fig. 2

Since 2014, novel RF-surgical resection instruments have been available with which lesions of the mucosa up to approx. 4 cm, can be resected en bloc and especially neoplastic or T1 suspect lesions can be removed near the muscularis propria (cutting direction A in Fig. 2) and theoretically without the risk of perforation.

Following successful in vitro tests on pig stomachs, we used these instruments, which have been approved for clinical use since 2014, in 27 selected and informed patients.

Material and Method

The novel "Flat Adenoma Resection Instruments (FARIn)" (Fig. 3) [MICRO-TECH Europe, Düsseldorf, Germany] each consists of a special symmetrical or asymmetrical RF-surgical resection effector (2) at the distal end and an ergonomically optimized manipulation handle (3, 4) at the proximal end of a flexible catheter (1) for manipulating the effector and precise controlling the resection speed.

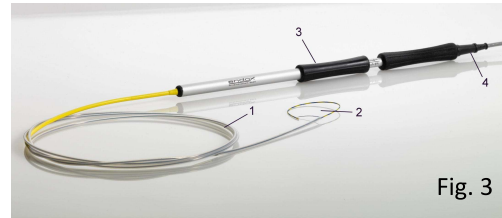


Fig. 3

The symmetrical resection effector (Fig. 4) of the FARIn used by us is electrically insulated in its proximal section (2, 3) and equipped distally with a sliding runner (5) made of electrically non-conductive ceramic. The actual RF-surgical cutting wire (4) is standardized 1.5 cm short for all RF-effectors. This RF-effector only cuts horizontally in its closing direction and may therefore be pressed against the organ wall during the RF-surgical cutting and, if the lesion has previously been circumferential incised as close as possible to the muscularis propria, also against it.

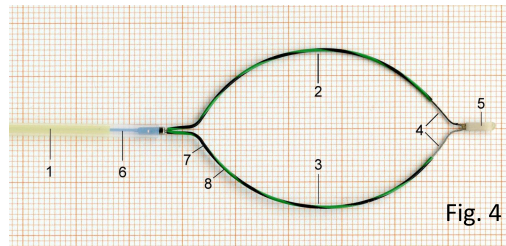


Fig. 4

In the first 22 applications of the FARIn with symmetrical effector, we refrained from circumferential incision the lesion to be on the safe side and after pressing the RF-effector against the organ wall during the RF-cutting did not cause any perforation, in 5 further applications the lesions were circumferential incised laterally in sano after primary injection with a novel incision instrument FARIn U (Fig. 5).

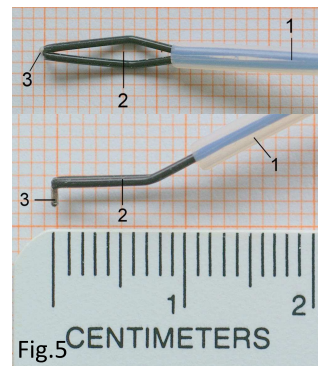


Fig. 5 CENTIMETERS

This instrument has a 1 mm or 1.5 mm short cutting needle (3) on an electrically insulated sliding runner (2) that can and may be pressed against the mucosa during RF-incision and cutting, automatically aligning the cutting needle against the mucosa before and during incision and cutting. The maximum cutting depth per cut corresponds to the needle length. After the primary circumferential incision, a secondary injection under the lesion was performed, whereby the lesion protruded more or less equidistantly from the submucosa under the lesion depending on the normal layer thickness of the submucosa. Bleeding during circumferential incision could be stopped by coagulation with this instrument.

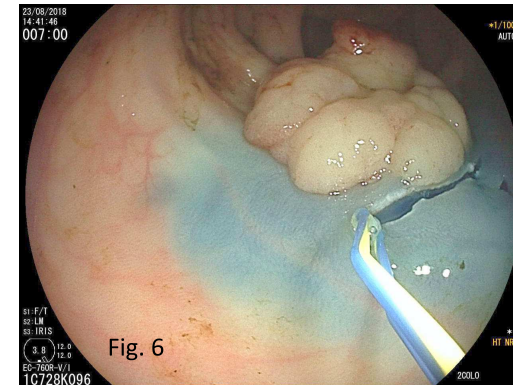


Fig. 6

We have also tested the FARIn U before clinical use on pig's stomach.

In the 5 later applications the symmetrical RF-effector was applied deep at the ground of the circumferential incision. The RF-cutting quality depends on an intended cut-synchronous vessel occlusion (cut-speed slow) or on avoiding a wide cutting gap and deep coagulation (cut-speed fast).

Post resection hemostasis was endoscopically controllable despite large areas of resection close to the muscularis propria.

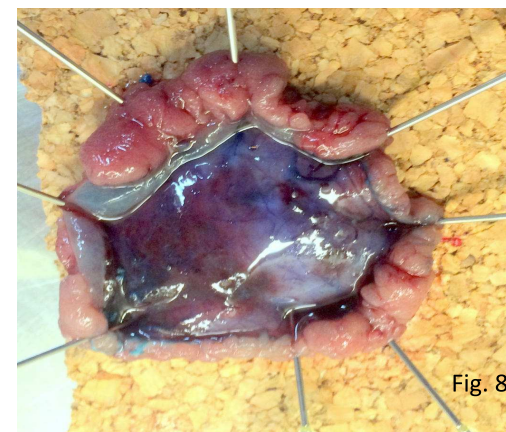


Fig. 8

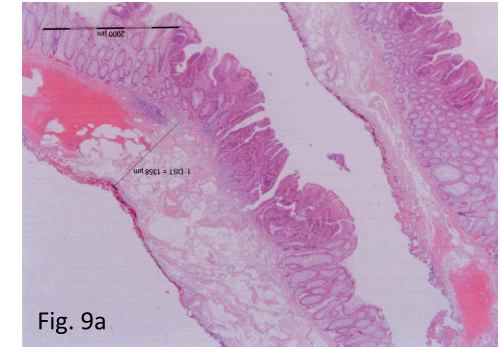


Fig. 9a

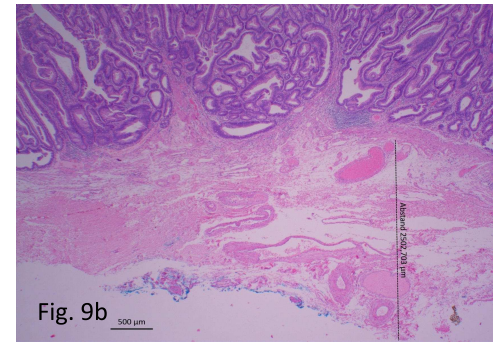


Fig. 9b

Results and Conclusion

The results of the first 22 + 5 clinical applications of the FARIn with the resection effector shown in Fig. 4 and also with FARIn U shown in Fig. 5 are:

- Mucosal lesions up to 4 cm can be resected en bloc without cut-delay
- Mucosal lesions up to 4 cm can be resected en bloc without perforation
- Pressing the RF-effector against the organ wall during the RF-cutting did not cause any perforation
- Mucosal lesions can be resected without mechanical or thermal artifacts (Fig. 8)
- RF-surgical cutting quality is well controllable with the novel manipulation handle
- The standardized and constant 1.5 cm length of the cutting wire is a prerequisite of reproducible cutting quality (Fig. 8)
- Submucosa > 1000 µm without mechanical and / or thermal artifacts on the resected specimen can be available for histopathological pT1 staging (Fig. 9)
- Effective RF-cutting time per specimen up to 4 cm takes < 30 seconds