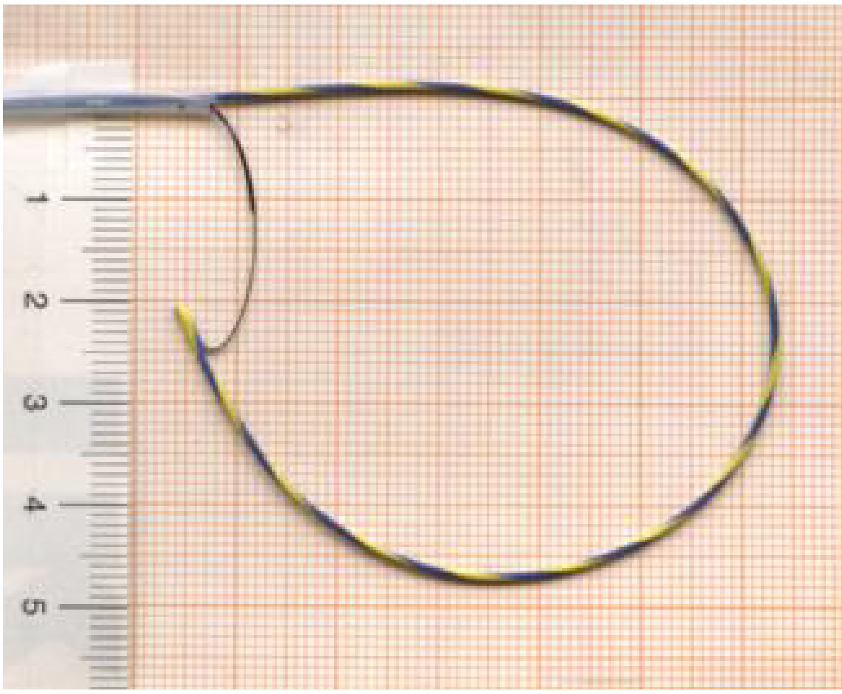
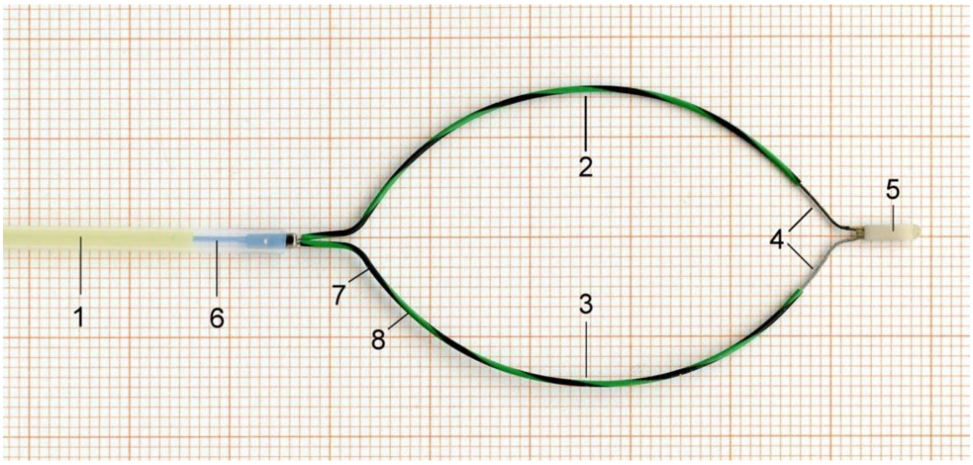
Endoscopic Submucosal Resection (ESR)

with Flat Adenoma Resection Instruments (FARIn)





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Flat **A**denoma **R**esection **In**strument (FARIn)

An important requirement of the endoscopic removal, in particular, of large (>2cm) polyps or flat lesions of the gastrointestinal tract´s mucosa is the compliance with the oncological requirements, i.e. the resection of the pathologic tissues in sano, and the pathological requirements, i.e. the resection of the pathological tissues preferably en bloc and beneath the sm1 zone of the submucosa as close as possible to the muscularis propria.

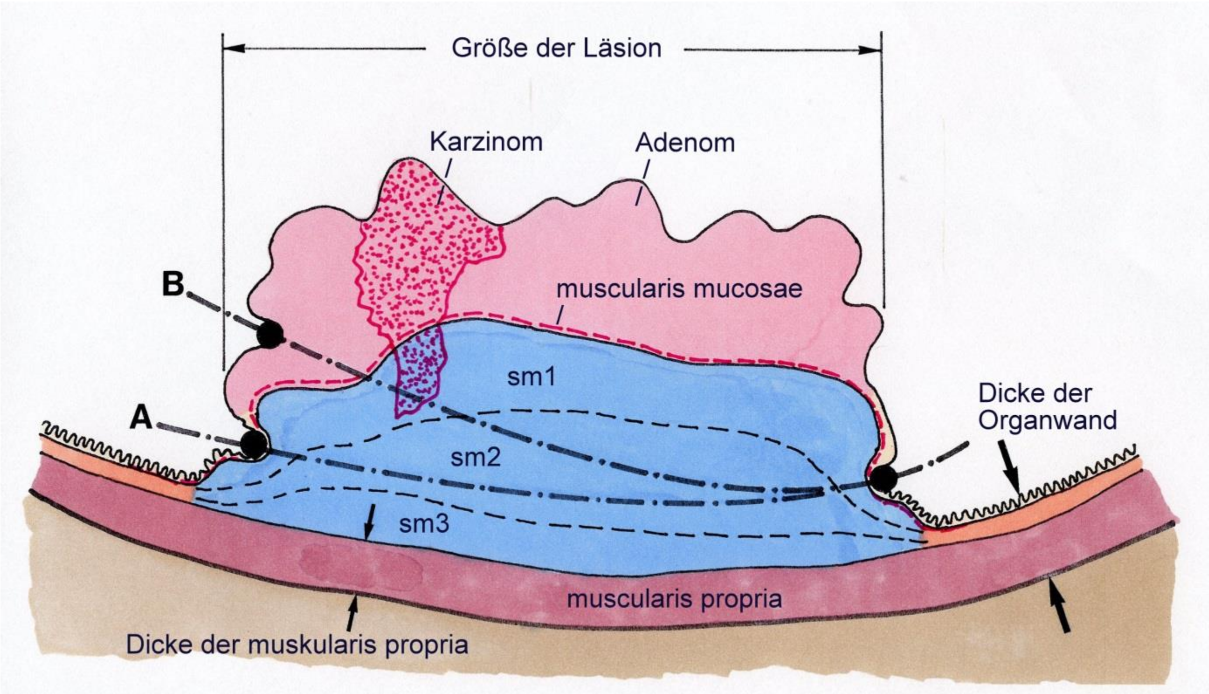

Fig. 1: Schematic depiction of the correct (A) and the non-correct (B) cut direction during snare resection of sessile polyps or flat adenomas without or after injection of a suitable liquid (blue).

In the case of sessile polyps as well as flat adenomas this is difficult to achieve or cannot be achieved at all with endoscopic polypectomy (**EPE**) or endoscopic mucosal resection (**EMR**), if EPE or EMR must be carried out with conventional polypectomy snares, because conventional polypectomy snares may also cut towards the organ wall and thus may cut through it and cause perforation. Hence, conventional polypectomy snares must become moved away from the organ wall during EPE or EMR (Fig.1: cut direction B).

Another problem of EPE or EMR with conventional polypectomy snares is the maximal diameter of polyps or flat adenomas which can be removed in sano and en bloc, which is 2 cm. The reason of this problem is the amount of HF-current needed to start the cutting effect during EPE or EMR. Polypectomy snares require an amount of HF-current of minimum 0.5 A_{eff} per cm effective cutting wire (= cutting wire in electrically conductive contact with tissue) to start the cutting effect immediately or with an acceptable short delay (< 3 sec.) after activation of the cutting mode of the

HF-generator. In flexible endoscopy normally available HF-surgical generators can generate a maximum amount of HF-current of 1.5 to 2.0 Aeff. In the case of sessile polyps or flat adenomas with a diameter of 2 cm (without or including a safety distance of minimum ca. 3 mm from the border of the pathologic tissue) cores-ponding to a circumference of 6 cm or more, an amount of HF-current of ca. 3 A_{eff} is required for an immediate start of the cutting effect.

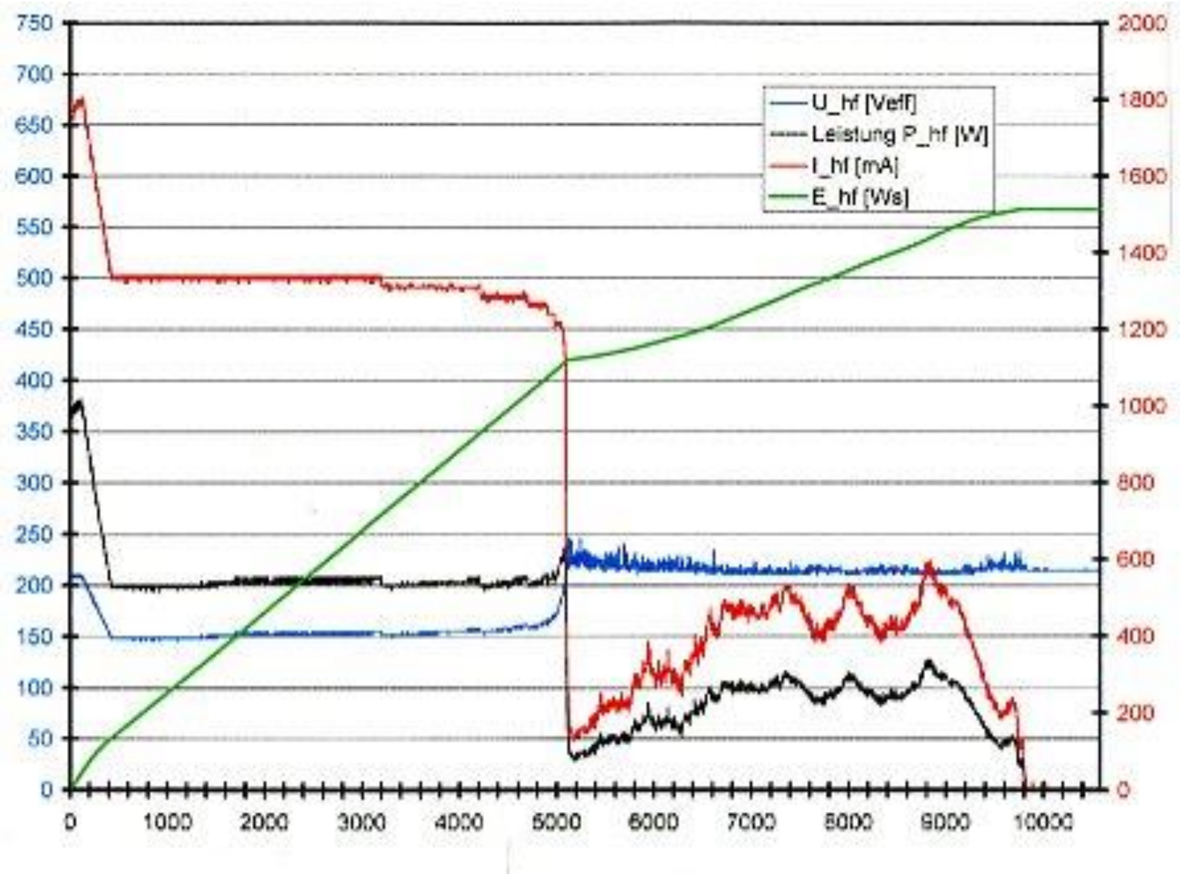

Fig. 2: General depiction of the amount of HF-current (red), HF-voltage (blue), electric power (black) and electric energy (green) during polypectomy with a conventional polypectomy snare.

In cases, in which the required amount of HF-current for an acceptable short, start delay (< 3 sec.) of the cutting effect is much higher than the amount of HF-current the HF-generator in use can generate, the consequently prolonged start delay (5 sec. in Figur 2) can cause thermal damage of the organ wall close the cutting wire (Figur 3) and hence delayed perforation of the organ wall can be the result.

In Figure 2 the thermal effects including the problem of prolonged cutting delay is shown schematically. The HF-surgical cutting effect is caused by very hot (> 500°C) electric sparks between the cutting wire of the snare and the tissue close the cutting wire. A precondition of the electric sparks which cause the HF-surgical cutting effect is an electrically insulating water-steam layer between the cutting wire and the tissue to be cut. Therefore the tissue close the cutting wire (black point in Fig. 2) must be heated up to the boiling temperature of water, which is ca. 100°C. Before this

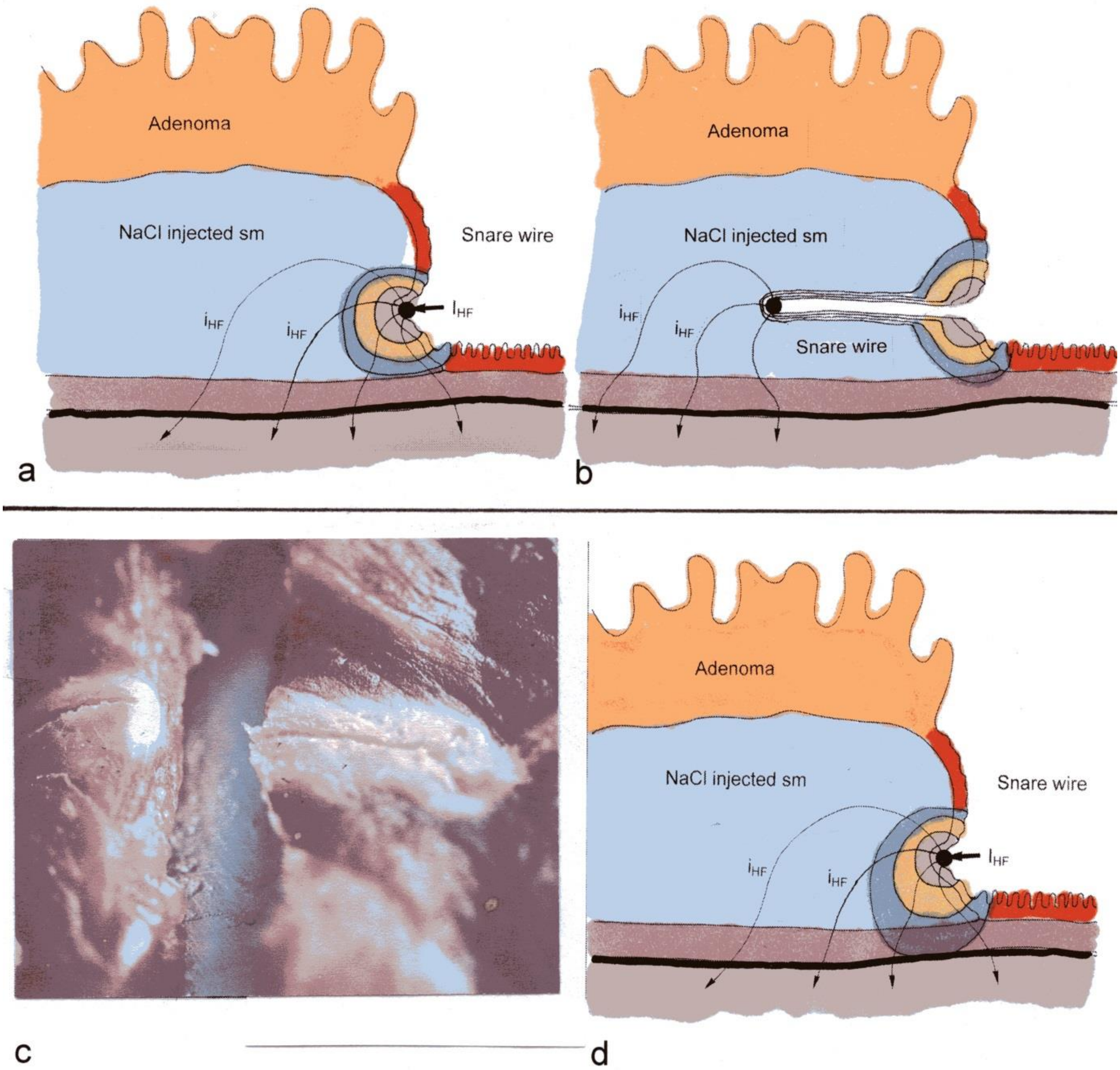

Fig. 3: Schematic depiction of thermal effects including damage of the organ wall (especially the muscularis propria, shown in Fig. 3d) as a result of prolonged start delay of the cutting effect and the relative high amount of HF-current during the start delay (Fig. 2).

temperature is reached in the tissue close the cutting electrode, the surrounding tissue becomes heated also and hence devitalized (dark blue zone), coagulated (yellow zone), and desiccated (violet zone) [Fig. 1a, 1b and 1d]. If the amount of HF-current is above ca. 0.5 A_{eff} per cm effective cutting wire (wire in conductive contact with tissue), the risk of thermal damage of the muscularis propria is minimal because the cutting delay is short and the cutting effect starts before the muskularis propria is damaged by thermal devitalization [Fig. 1b]. If the amount of HF-current is below ca. 0.5 Aeff per cm effective cutting wire, the cutting delay is prolonged and the risk of thermal damage of the muscularis propria is high before the cut-effect [Fig. 1 d].

This problem must be taken in consideration especially in the colon, where the organ wall is thin respectively very thin (Fig. 4).

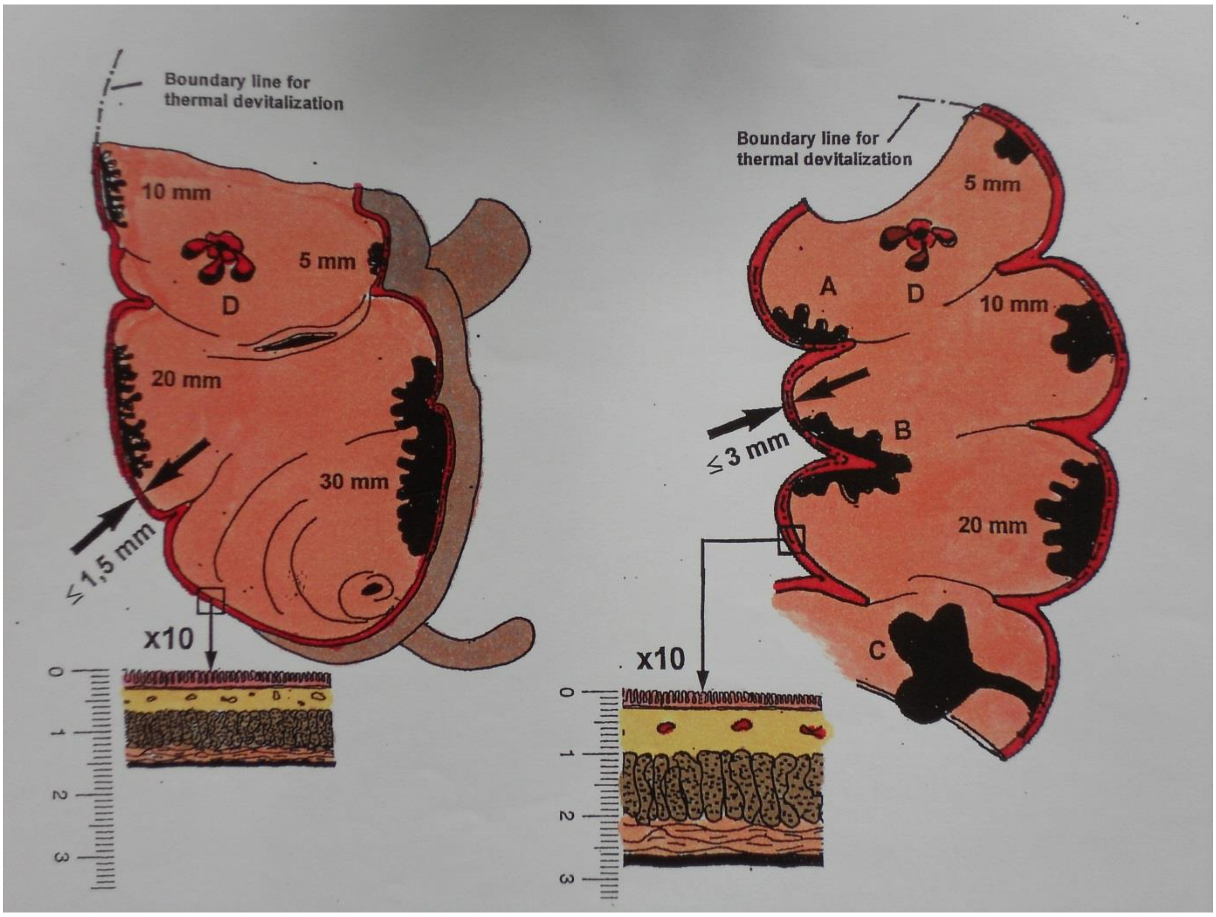

Fig. 4: Proportional depiction of the thickness of different parts of the human colon in comparison to different polyps. .

To avoid prolonged cutting delay, some HF-surgical generators are provided with a special start modus for the cutting effect, which generates a short but high HF-current pulse (>> 2 Aeff) after each activation of a cut-mode. If the amount of the HF-current pulse is too aggressive, the tissue can be cut to fast with the result that quick transected blood vessels cannot become HF-surgically closed synchronously during the quick transection.

To avoid the above discussed limitations and problems of EPE and EMR, the "**E**ndoscopically **S**ubmucosal **D**issection (**ESD**)" has be developed in Japan. However, ESD requires a lot of skills, experience and time, otherwise it can cause a high rate of complications, which increase with the size of the lesion to be removed in sano and en bloc.

To overcome the problems and limits of EPE and EMR as well as ESD, the so called "**F**lat **A**denoma **R**esection **In**strument (**FARIn**)" and the associated method of "**E**ndoscopic **S**ubmucosa **R**esection (**ESR**)" were developed. In appropriately and suitable cases, ESR with a FARIn not only meets the abovementioned requirements of oncology (removal in sano) and the requirements of pathology (removal en bloc and as close as possible to the muscularis propria), but also the requirements of endoscopy (easy to use and safe) and the requirements of economy (low cost, i.e. short resection time compared with ESD).

General description of the FARIn

The Flat Adenoma Resection Instruments (FARIn) consist of a catheter (1), an effector (2) on its distal end, and an actuator (handle) (3) on its proximal end.

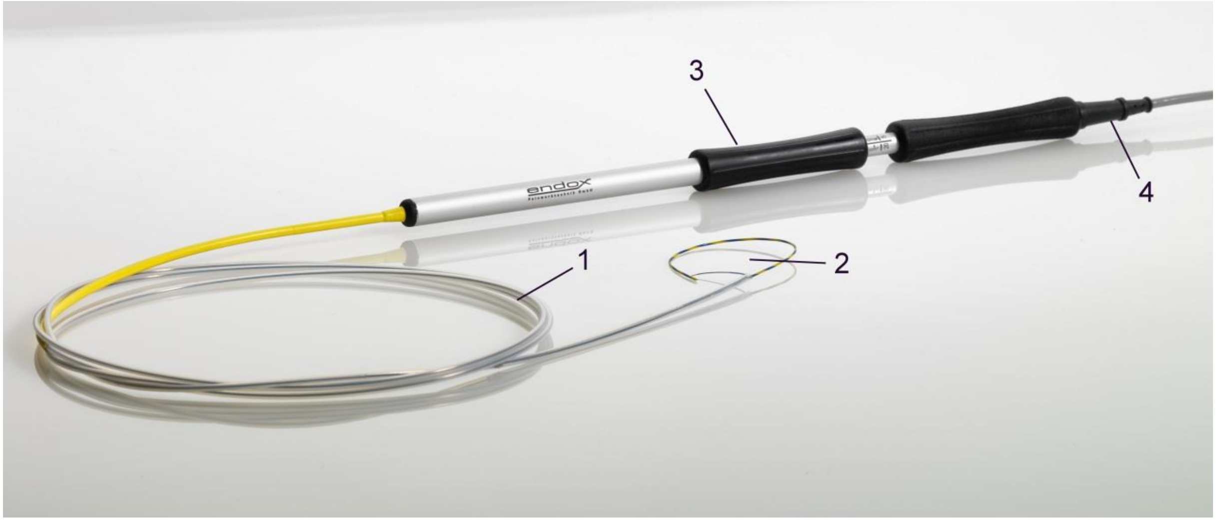

Fig. 5: Flat Adenoma Resection Instrument. 1 = catheter, 2 = effector, 3 = actuator, 4 = connector of the HF-Current Cable.

The catheter of the FARIn is made of PTFE, is 2 m in length and has an external diameter of 2.3 mm. The catheter is transparent for visual control of axial movements of the yellow / blue market arc of the effector (2) and hence control of opening or closing of the effector.

The FARIn is available with three different Effectors:

1. The effector is an asymmetric resection snare (Fig. 6)
2. The effector is a symmetric resection snare (Fig. 7)
3. The effector is an short needle electrode for circumferential incision of the mucosa (Fig. 8)

The asymmetric resection snare consists of an electrically insulated and hence HF-surgically inactive spring-elastic NITINOL wire (2), a 1.5 cm short flexible cutting-wire (3), an electrically insulated stop-wire (4), and an electrically insulated spur (5). The effector can be pushed out of the distal end of the catheter and pulled into it like an asymmetric polypectomy snare.

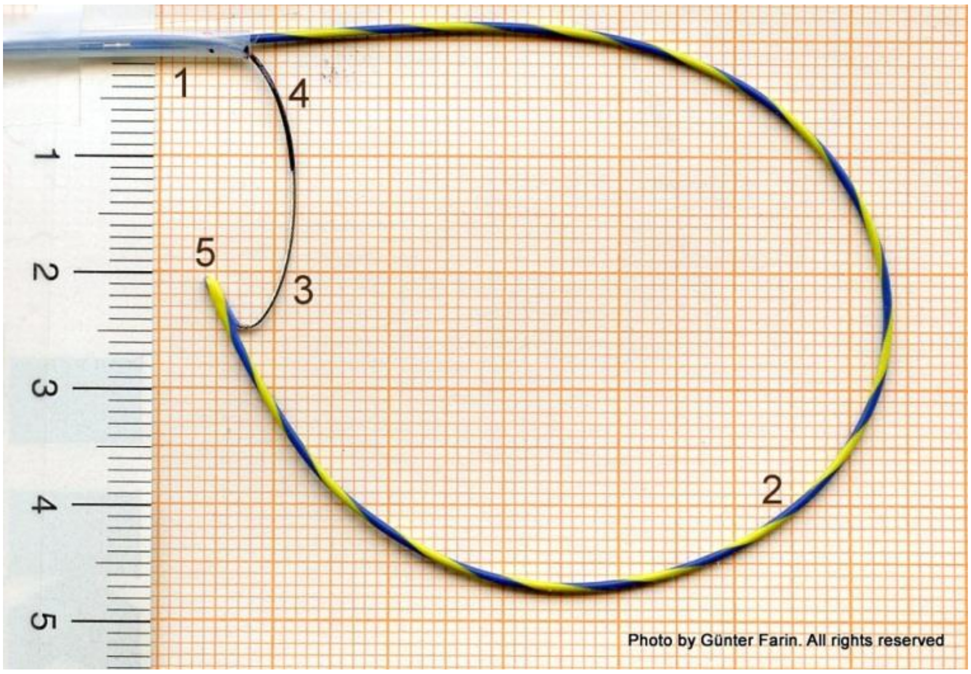

Fig. 6: The asymmetric effector consists of an electrically insulated spring-elastic NITINOL wire (2), an only 1.5 cm short flexible cutting-wire (3), an electrically insulated stop-wire (4), and an electrically insulated spur (5).

The arc (2) of the effector is made of dimensionally- and shape-stable spring-elastic NITINOL™ wire, which is coated with electrical insulation (yellow-blue). The arc is significantly more rigid and les flexible than the cutting wire (3) and tightens the flexible cutting wire like the bow used for archery tightens its bow string. The proximal end of the arc is extended within the catheter (1) as a manipulation wire up to the actuator (see Fig. 4). This manipulation wire is also rigid to such an extent that the torques to rotate the effector around the longitudinal axis of the distal end of the catheter respectively to tilt the effector over a sessile polyp or flat adenoma are transmissible from the actuator to the effector. This allows the user to forcibly tilt or push the effector against the target organ wall both during the application around a polyp or flat adenoma as well as during the HF-surgical cutting phase. The latter, how ever, is only possible if it can be assumed with sufficient certainty that no muscularis propria extends into the effector and thus into the intended section plane.

The cutting wire (3) of the effector measures constantly 1.5 cm. This has an important advantage over conventional polypectomy snares since large sessile polyps or large flat adenomas can be removed with a much lower amount of HF-current respectively electric power with a FARIn compared to a similar sized conventional polypectomy snare .

The electrically insulated distal end of the stop wire (4), which protrudes 1 cm out of the distal end of the catheter (1) when the effector is pushed out of the catheter, reduces the mechanical force for opening the effector.

The spur (5) at the distal end of the arc (2) is electrical insulated. The electrical insulated and hence HF-surgical inactive arc (2) together with the insulated and hence HF-surgically inactive spur prevent unintended cuts towards the organ wall if the instrument is used appropriately.

The actuator (handle) at the proximal end (A) of the catheter consist of a distal part (B) and a proximal part (D).

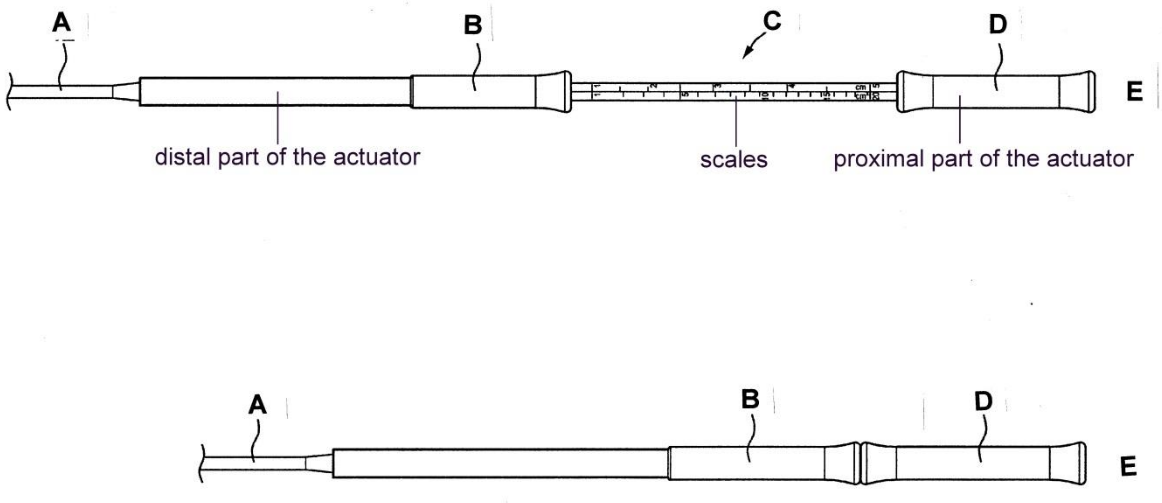

Fig. 7: Schematic depiction of the actuator (handle) at the proximal end (A) of the catheter.

The proximal end of the actuator can be used both to open and close the effector as well as to tilt it sideways around a poly or flat adenoma during the application or to guide the cutting wire during HF-surgical resection.

The actuator is designed ergonomically in a way that allows it to be operated with both hands, which has the advantage that the effector may be manipulated much more precisely than a conventional polypectomy snare. Precise application, manipulation, and guiding of the effector, especially of the cutting wire, is an important prerequisite for the submucosal resection of sessile polyps or flat adenomas close to the muscularis propria.

To open the effector, the proximal handle part is pushed into the distal handle part (B) and to close the effector, the proximal handle part is pulled out of the distal handle part.

The proximal handle part can also be used to tilt the effector to the side over a polyp or flat adenoma and / or to push the effector against the organ wall respectively against the muscularis propria during the application of the effector and / or during the resection,

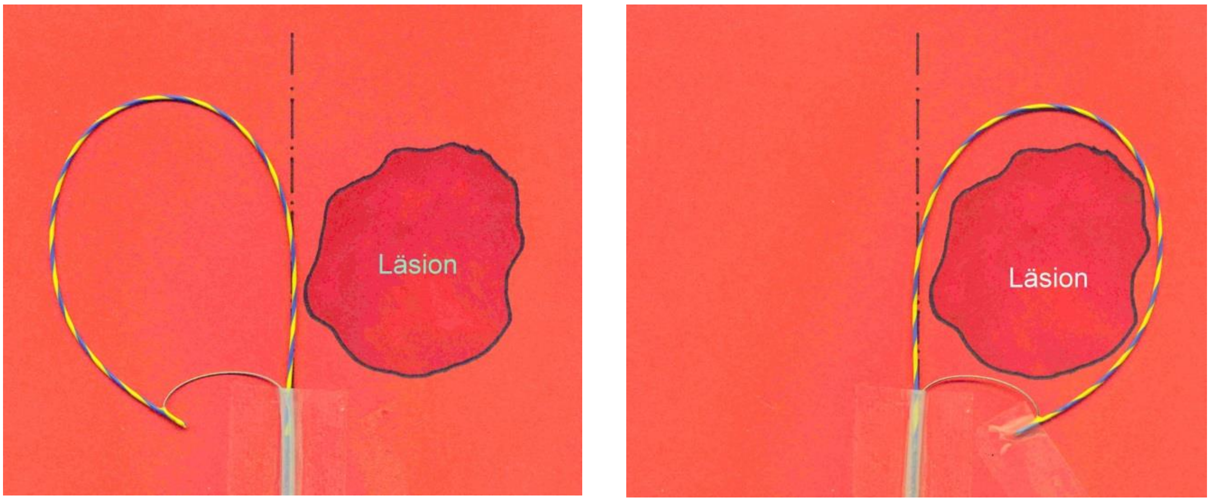

Fig. 8: The effector can be tilt over a lesion by rotating the proximal part (D) of the actuator.

Scales on the actuator. There are two scales on the actuator. One scale indicates the average value for the circle diameter, (i.e. how far the effector is opened (cm)), and one scale indicates the area covered by the effector (cm²).

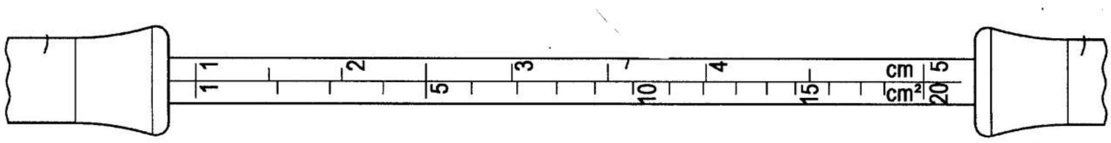

Fig. 9: Schematic depiction of the two scales on the actuator.

Since the mucosa and, in particular, the submucosa of the gastrointestinal tract are very elastic and hence also flexible and compressible, the area (cm²) and the derived average value for the diameter (cm) of the tissue covered by the effector coincide with the opening width of the snare if and only if the snare does not deform, compress or strangulate the tissue covered by tension or compression. If this is taken into account, it is now easier to make use of the FARIn to endoscopically determine the size of a polyp or flat adenoma respectively lesion before their resection as well as the size of the area of the resection field after the resection than it would be without endoscopically applicable aids. Since the mucosa or the resected lesion shrinks to some extent during the HF-surgical resection and is stretched to some extent when it is pinned, e.g. to a cork board, the determination of the diameter or area of the lesion from the resected tissue is not reliable. Hence, an endoscopic comparison of the size of the resection wound´s surface with the opening width of the snare is to be recommended.

The symmetric resection snare consists of electrical insulated spring elastic wire parts (2, 3) on its proximal end, as well as an electrical insulated spur respectively skid (5) on its distal end, and a relatively short (1,5 cm) electrical non-insulated RF cutting wire (4) between the electrical insulated parts (2, 3) of the snare and the electrical insulated skid (5). Because the electrical insulated parts (2, 3 and 5) do not cut, this resection snare cannot cut in vertical direction respectively into the muscularis propria, and hence it can be pressed against the organ wall respectively against the muscularis propria during the RF-surgical cutting process as depicted in Fig. 1 cut-direction A.

The proximal part of this resection snare is significantly more rigid respectively les flexible than the distal part and the cutting wire.

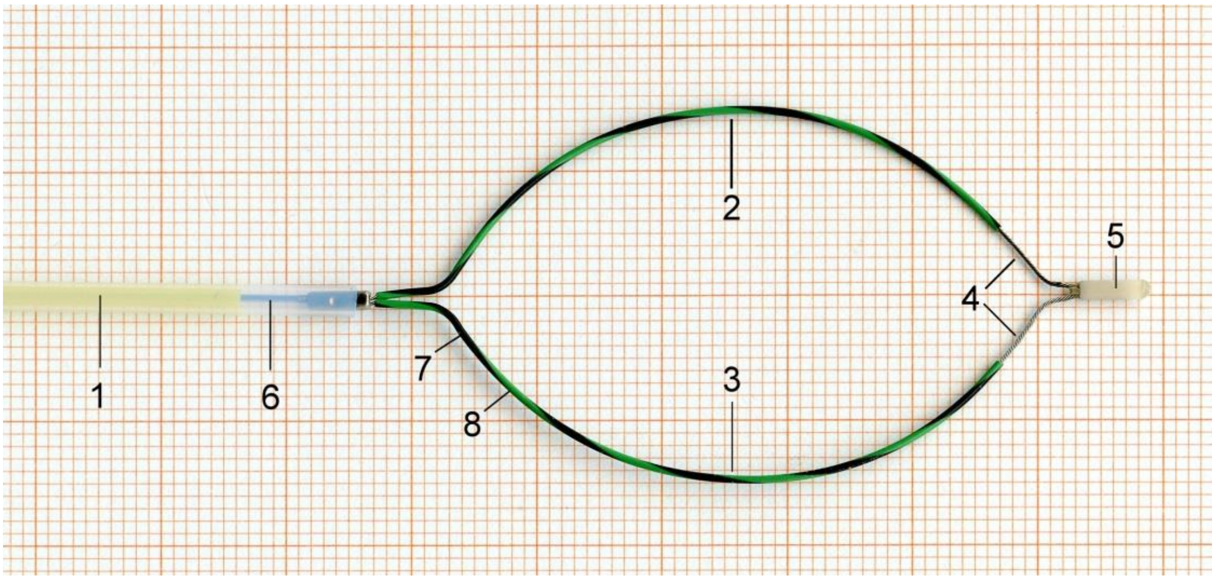

Fig. 10: Symmetric RF-resection snare. 1 = catherter, 2, 3 = electrically insulated parts, 4 = RF-cutting wire, 5 electrically insulated spur, 6 = semitransparent distal end of the catheter, 7, 8 = markings which can be seen endoscopically through the distal end 6 of the catheter for controlling the movement of the snare especially during the RF-cutting.

The actuator (handle) at the proximal end of the catheter of the FARIn with a symmetric resection snare is identical with that of the FARIn with a asymmetric resection snare, but without the scales.

The automatically adjusting incision needle

The automatically adjusting incision needle consists of an electrically insulated skid (2) with a HF-surgical incision respectively cutting needle-electrode (3) and is freely rotatable at the distal end of a 2.3 mm catheter (1). Because the skid is bended outside the distal end of the catheter, the needle electrode (3) becomes adjusted automatically vertical against the surface of a tissue when the skid is moderate pressed against the surface of the tissue. Hence, this incision instrument can be used without an assistant at the proximal end of the catheter for manual adjustment of the needle-electrode like a hooke knife.

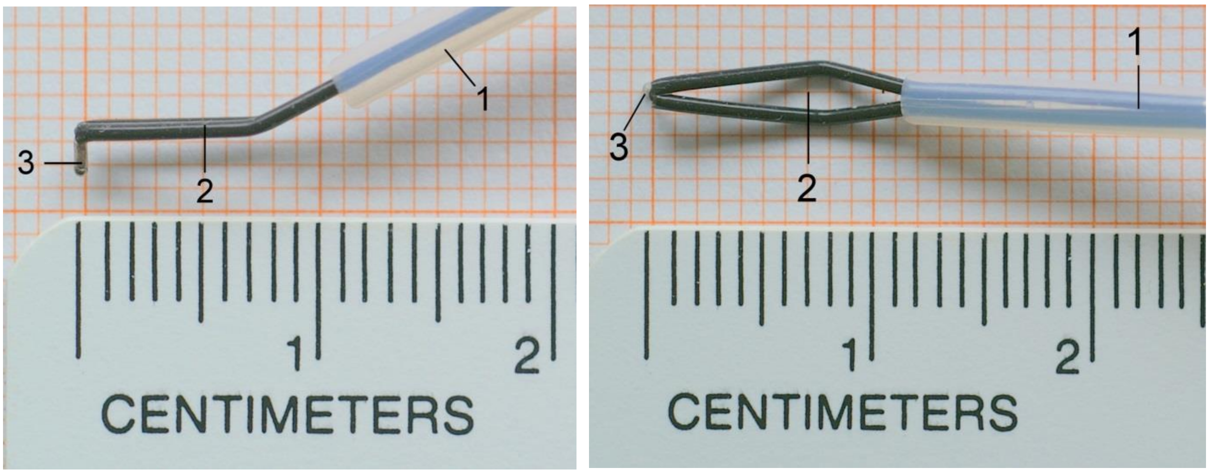

Fig. 11: Effector of the FARIn for circumferential incision of a lesion of the mucosa. 1 = distal end of the catheter, 2 = electrically insulated skid, 3 = needle electrode for RF surgical incision.

The length of the needle electrode (3) is 1 mm or 1.5 mm, and hence the depth of the cut is limited to 1 mm or 1.5 mm per cut. This effector can be used for circumferential incision of the mucosa / submucosa .

First in vivo results

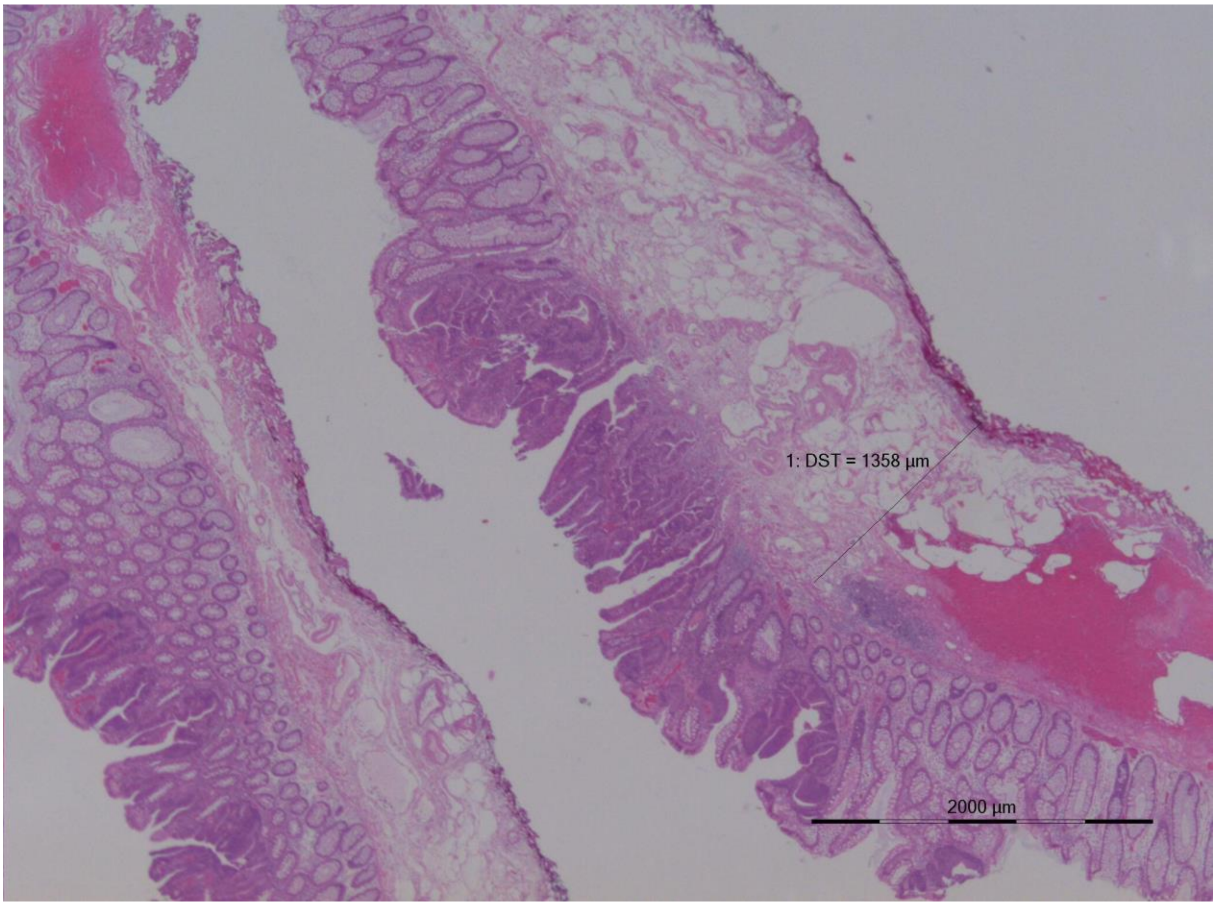

Fig. 12: Pathohistology of a flat adenoma resected with a FARIn by Dr. S. Gölder and Prof. H. Messmann. Pathology of the Zentral Klinikum Augsburg.

The cutting edge is very sharp over the whole resected piece. The sm1 zone of the submucosa is completely resected without any mechanical or thermal artifacts.

Advantages and disadvantages of EPE, EMR, ESD, and ESR (ESR with FARIn**)**

(- = no; + = yes)

Criterion / Aspect	**EPE**	**EMR**	**ESD**	**ESR**
* resection close the muscularis propria	-	-	+/-	+
* en-bloc resection up to 4 cm	-	-	+	+
* cutting beneath the sm 1 zone	+	+	+/-	+
*pure resection time < 1 minute	+	+	-	+
* minimal thermal artefacts in the resected tissue	+/-	+/-	-	+
* low amount of HF-current	-	-	+	+
* minimum or no cutting delay	-	+/-	+	+
* controllable cutting speed	-	-	+/-	+
* controllable cutting direction	-	-	+/-	+
* indication of the opening /closing diameter of the effector	-	-	---	+
* indication of the opening /closing area of the effector	-	-	---	+