Q&A Webinar

A Decade of FTRD® – Global Insights and Future Directions

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General Questions

What safety measures should be taken if a nearby organ enters the clip while being deployed? *(asked in chat, answered by Ovesco)*

This issue can be easily avoided by refraining from using excessive suction while mobilizing tissue into the cap. Utilizing the grasping forceps allows for controlled tissue mobilization, thereby eliminating the risk of inadvertently capturing a nearby organ at the clip application site. Suction should be employed in a very controlled manner and only as supplementary support once the tissue has already been secured inside the cap.

One of the major pain points for me is slippage of the grasper when trying to pull the lesion into the cap. A tissue helix works much better. What advice/tips could you provide for using the FTRD® Grasper? What is Ovesco doing to improve this part of the procedure?
(asked in chat, answered by speakers post hoc)

Challenges and tips for using the FTRD® Grasper:

Grasping technique:

- Grasping the base of the lesion rather than the top, as the base is sturdier.
- Grasping proximal to the lesion in a softer part if the lesion is heavily scarred or infiltrated.
- Combining gentle suction with a slow, steady pull, especially for fixed tissue. For subepithelial lesions, grasping at the base or neck and pulling sideways into the cap is suggested.
- Switching to alternative tools like anchoring devices (i.e. OTSC® Anchor 220tt) or the Apollo tissue helix is advised if necessary.

Avoiding slippage:

- Factors such as the lesion's site and the amount of tissue captured are key to avoiding slippage. Tips include: capturing an adequate amount of tissue, avoiding overdistension of the lumen, minimizing tension on surrounding mucosa, using alternative accessories like the tissue helix, and gentle suctioning as a last resort.
- Grasping some normal colonic mucosa or bowel wall along with the lesion to prevent tearing. Closing the grasper slowly while applying suction and pressure to the mucosa is also recommended.

Ovesco continuously evaluates feedback to identify product enhancements while balancing cost-benefit considerations. The shared tips and tricks from experienced users are expected to further improve usability.

How do you determine to what size you can still use FTRD®? Do you have any algorithm? MDT often rejects cases with lesions over twenty millimeters. How can you argue in favor of FTRD®? *(discussed live during webinar)*

Mobility and location of tissue:

B. Bastiaansen: Emphasizes that the two-centimeter cutoff is not strict. The decision depends on the tissue's mobility and the lesion's location. For highly mobile lesions, especially in the right side of the colon, it is possible to resect pieces up to 35 millimeters or even 4 centimeters. If in doubt, using the prOVE Cap can help determine if the lesion fits, often yielding surprising results.

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Pragmatic approach:

G. Haber: Suggests a similar approach by using a regular cap on the scope to assess the lesion. If the lesion can be sucked into the regular cap, it indicates that the FTRD® might be feasible. This technique provides a basic yet effective way to evaluate the lesion's size and suitability for FTRD®.

Trial and error with hybrid techniques:

K. Caca: Recommends that if the lesion seems too large, to start with Endoscopic Mucosal Resection (EMR) and transition to a Hybrid-EMR-EFTR approach as advice. For lesions in the intra-abdominal part of the colon that are not attached to the retroperitoneum, resection specimens up to 4 centimeters can be achieved if the lesion is untreated.

Conclusion:

The decision to use FTRD® for lesions over 20 millimeters is not based on a strict size cutoff but rather on the lesion's mobility and location. Utilizing tools like the prOVE Cap can help assess the lesion's suitability. In cases where the lesion appears too large, a combination technique of EMR and FTRD® can be employed to achieve successful resection.

With surgery we would obviously get 100% R0 resection and the idea of the FTRD® is to avoid any surgery, but I am surprised to see that the R0 resection with FTRD® in all the studies is at best 77%. Did I understand it correctly? *(asked in chat, answered by speakers post hoc)*

Challenging cases:

Z. Nabi: Highlights that FTRD® is typically used in challenging cases where conventional endoscopic resection methods may be inadequate, such as non-lifting adenomas, scarred recurrences, and lesions in difficult locations (e.g., peri-appendicular, juxta diverticular). In these scenarios, FTRD® offers a minimally invasive alternative to surgery and has been curative in over 75% of cases.

Appropriate use and repeat procedures:

K. Caca: Emphasizes that most lesions treated with FTRD® are benign. FTRD® is not necessary for straightforward cases where EMR is sufficient. Additionally, FTRD® can be repeated in cases of incomplete resection (Rx/R1).

Skill level and lesion selection:

G. Haber: Points out that lower R0 resection rates may be due to the varying skill levels of endoscopists and the inclusion of more advanced cancers that should have been referred to surgery. In a single-center experience, R0 resection was achieved in 34 out of 35 cancer cases, with the one exception being an advanced lesion inappropriately chosen for FTRD® by a less experienced endoscopist.

Published and unpublished data:

B. Bastiaansen: Notes that published studies, including many small retrospective studies, show overall R0 resection rates around 80-82%. Unpublished prospective data from a large number of T1 CRC eFTR resections indicate R0 rates of 88-91%, even with deeper invasive lesions. Further details are available in the webinar presentations.

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Conclusion:

While the R0 resection rate with FTRD® may appear lower than surgical rates, it is important to consider the context in which FTRD® is used. FTRD® is often employed in challenging cases where other endoscopic methods may fail, providing a minimally invasive alternative to surgery. The variability in R0 resection rates can be attributed to the complexity of cases, the skill level of endoscopists, and the selection of lesions. Despite these challenges, FTRD® has demonstrated high curative potential, particularly in experienced hands and appropriate cases.

Questions: Lower GI Tract

Another pain point is occasional difficulty delivering the device to the right colon. Use of an overtube would make this easier. Are there plans to introduce some type of overtube to make delivery to the right colon easier? *(asked in chat, answered by speakers post hoc)*

Challenges and tips for delivering FTRD® to the right colon:

Device compatibility:

P. Ge: Emphasizes that the FTRD® does not fit through an overtube. Reaching the right colon can be challenging, and the key advice is to be careful and patient.

Standard maneuvers and guidewire use:

Z. Nabi: Notes that the outer diameter of the colonic FTRD® (about 21 mm) does not fit through conventional overtubes. Standard colonoscopy maneuvers (position changes, water immersion, abdominal pressure) are usually sufficient. In challenging cases, a guidewire can be helpful. Experience improves the success rate of reaching the right colon with FTRD®.

Alternative techniques:

K. Caca: Points out that using an overtube would be too tedious and no suitable overtube is available. Pain points include passage through the rectosigmoid junction and the right flexure. Techniques such as using X-ray, a guidewire, or balloon dilation can assist.

Loop management and positioning:

B. Bastiaansen: Stresses the importance of patience, patient position changes, and external compression for successful passage to the right hemicolon. Proper loop management is crucial, as a bad alpha loop in the sigmoid can hinder further passage. In rare cases (2-3%), the longer FTRD® cap may make passage to the right colon impossible.

Ovesco: Acknowledges that while the FTRD® can typically reach the lesion in nearly all cases, challenges may still arise. Product enhancements have been implemented to improve device insertion. Currently, no commercially available overtube accommodates the FTRD®, and developing a new size overtube would need to justify its cost-benefit ratio.

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Conclusion:

Delivering the FTRD® to the right colon presents challenges due to its size and the lack of compatible overtubes. Standard colonoscopy maneuvers, guidewire use, and proper loop management are essential techniques to facilitate passage. While overtubes are not currently feasible, ongoing product enhancements aim to improve device usability. Patience and experience play significant roles in overcoming these challenges, and the shared tips and tricks from experienced users can further aid in successful procedures.

What was Dr. Haber's advice on the administration of antibiotics in case of lesions involving the appendix? *(discussed live during webinar)*

G. Haber: We give everybody prophylactic antibiotics at the time of the procedure. But for the appendix in particular, we maintain antibiotics for one week. I don't have any objective evidence to say it prevents the appendicitis or not, but we do it routinely, just empirically.

B. Bastiaansen: I totally agree with that. For appendiceal lesions, it is just exactly as you say. We don't have any proof it prevents the secondary appendicitis, but at least it gives a better feeling. Although I must add, that for all other indications in the colon we stopped giving any antibiotics already quite early, so for at least the last seven years we gave no antibiotics for any procedure in the colon outside the appendix, and so far without any consequences.

Conclusion:

Both Dr. Haber and Dr. Bastiaansen support the use of prophylactic antibiotics for lesions involving the appendix, maintaining them for one week despite the lack of objective evidence. This practice is done empirically to potentially prevent appendicitis and provide reassurance. For other colonic procedures, the routine use of antibiotics in the Netherlands has been discontinued without negative outcomes.

If you remove a lesion near the appendiceal orifice with the FTRD®, can you cause a closure of the appendiceal orifice? Is there a risk of appendicitis in these situations? *(asked in chat, answered by Ovesco)*

The appendiceal orifice will not be completely closed but rather partially occluded by the FTRD® clip. The design of the FTRD® clip allows for continued microperfusion and partial drainage of liquids. However, due to the partial occlusion, there is a risk of developing appendicitis. According to published data on the use of FTRD® at the appendix, the risk of secondary appendicitis is approximately 15-20%. Of these cases, around 50% can be managed conservatively with antibiotics, while the remaining cases may require surgical intervention. It is crucial to inform the patient about the potential risk of secondary appendicitis. Most FTRD® users, as per published literature, administer antibiotics for several days (typically 3-5 days) to mitigate this risk.

How do you approach the patients with FTRD® on the appendiceal orifice, for example CT abdomen, given that the patient is still asymptomatic? How long should we follow them up? *(discussed live during webinar)*

K. Caca: Emphasizes the importance of discussing the risks with the patient. The risk of developing appendicitis post-FTRD® is around 10-15%, with about half of these cases treatable with antibiotics and the other half potentially requiring surgery. Patients are given the choice between immediate surgery or taking the risk of needing surgery later. Most patients prefer to address the issue immediately.

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G. Haber: Was initially concerned about the possibility of leaving a remnant of the appendix that could lead to a mucocele. To address this concern, a delayed CT scan is recommended about a year and a half after the procedure. In their experience, no patients developed a mucocele, which was reassuring.

Follow-up and recanalization:

B. Bastiaansen: Shares similar experiences, noting that the clip typically falls off around four months post-procedure, leading to recanalization of the appendix. Follow-up ultrasounds show that the appendix appears shortened but otherwise normal. The appendiceal remnant remains vital and re-canalizes, which is a positive outcome.

Conclusion:

When dealing with FTRD® on the appendiceal orifice, it is crucial to discuss the risks of appendicitis with patients, who generally prefer immediate resolution. Concerns about appendiceal remnants leading to complications like mucocele can be mitigated by conducting a delayed CT scan, which has shown reassuring results. Follow-up typically reveals that the appendix re-canalizes and appears normal, providing further reassurance about the procedure's safety and efficacy.

I am interested about following up patients after FTRD® for T1 colorectal cancer who are not send to surgery *(discussed live during webinar)*

Scar resection and initial histology:

B. Bastiaansen: Highlights the importance of the initial histology in determining follow-up. If the initial histology shows no risk factors and the EFTR results in a clean scar, the lesion is considered low-risk. However, if the initial histology is unassessable due to poor quality (e.g., burned material from piecemeal resection), these patients are at higher risk. For such cases, more intense surveillance is recommended, including yearly CT scans and half-yearly CEA levels.

Recurrence rates and follow-up duration:

G. Haber: Discusses the recurrence rates, noting that most recurrences occur within the first three years. The average follow-up time in B. Bastiaansen's study was nearly three years, with some patients followed for up to seven years. The recurrence rate observed was around five percent, which is not expected to increase significantly with longer follow-up.

Lymphovascular invasion:

B. Bastiaansen: Differentiates between large vessel (venous) and small vessel (lymphatic) invasion, noting that small vessel invasion is more indicative of lymph node metastasis. Cooperation with pathologists is crucial to accurately identify the type of invasion, as it significantly impacts the risk assessment and follow-up strategy.

Oncologic surveillance:

P. Ge: Emphasizes the need for endoscopists to adopt oncologic surveillance practices when dealing with malignant cases. This includes understanding surgical oncology principles and following established guidelines for follow-up, such as the NCCN guidelines in the United States. Variability in pathology and radiology underscores the importance of thorough and consistent follow-up.

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Intensive surveillance and ongoing studies:

B. Bastiaansen: Mentions ongoing studies, such as the European SCAR trial and the Dutch LOCAL trial, which aim to provide more data on the efficacy of scar excision followed by intense surveillance. These studies will help determine if scar excision should become a standard procedure.

Conclusion:

Follow-up after FTRD® for T1 colorectal cancer requires careful consideration of the initial histology and the presence of risk factors. Intense surveillance, including regular CT scans and CEA level monitoring, is recommended for cases with unassessable initial histology. Most recurrences occur within the first three years, and the type of lymphovascular invasion significantly impacts the risk of metastasis. Endoscopists must adopt oncologic surveillance practices and follow established guidelines to ensure comprehensive patient care. Ongoing studies will provide further insights into the optimal follow-up strategies for these patients.

Do you provide PET-CT, and if yes, when? *(asked in chat, answered by speakers post hoc)*

P. Ge: Emphasizes the importance of following NCCN guidelines for oncologic surveillance in GI malignancies, including colorectal cancer. Local excision techniques like EFTR for malignant indications are not standard care, and adherence to established oncological surveillance guidelines is crucial.

Timing and purpose:

G. Haber: Recommends performing PET-CT three months post-resection. This timing allows for the detection of nodal metastases after sufficient growth for metabolic activity to be visible and reduces the likelihood of the resection site lighting up during the healing phase. MRI is also favored for detecting and following up on pelvic nodes.

B. Bastiaansen & K. Caca: Indicate that PET-CTs are not performed routinely in their practice.

Conclusion:

The use of PET-CT varies among practitioners. While some follow established guidelines and perform PET-CT at specific intervals post-resection (e.g., three months), others do not routinely use PET-CT, especially for T1 lesions. Adherence to oncological surveillance guidelines and the timing of PET-CT are important considerations to ensure accurate detection of metastases and effective patient follow-up.

Should scar excision always be done after hybrid or en bloc for high-risk patients and in which time after the first procedure? *(asked in chat, answered by speakers post hoc)*

Multidisciplinary consultation:

P. Ge: Stresses that scar excision should only be performed after consultation with a multidisciplinary team, including surgical oncology, as local excision is not standard care for managing T1 cancers.

Indications and timing:

Z. Nabi: Indicates that scar excision is an alternative to surgery for high-risk lesions and can be planned after 4 weeks, allowing time for scar formation. The decision to perform scar excision in all high-risk cases is still debated and should be individualized based on various factors, including the number of high-risk features, patient age, comorbidities, and patient expectations.

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Detection and recurrence concerns:

G. Haber: Notes that there is no absolute timeline for scar excision. It is typically performed if there is concern for recurrence, with a minimum waiting period of 3 months to allow for sufficient neoplastic growth for detection. In cases of incomplete resection, scar excision can be repeated as early as 6 weeks.

Avoiding local recurrences:

B. Bastiaansen: Explains that scar excision is usually performed after incomplete (R1/Rx) resection of low-risk T1 colorectal cancers to avoid local intramural recurrences. This secondary excision can confirm the radicality of the previous resection or provide a second chance for radical resection of any residual cancer. The oncological safety of this strategy is still being evaluated in ongoing trials (LOCAL study and SCAR trial). Registry data shows that residual cancer is detected in 12% of eFTR specimens, with a 3% risk in normal-appearing scars. Scar excision can be performed within 6 weeks after an incomplete endoscopic resection. For high-risk T1 cancers, additional scar excision is generally not recommended due to the higher risk of lymph node metastasis, which would require oncological resection for surgery-fit patients.

Conclusion:

Scar excision after hybrid or en bloc resection for high-risk patients should be considered on a case-by-case basis, ideally after multidisciplinary consultation. The timing of scar excision varies, with some recommending a minimum of 4 weeks to allow for scar formation, while others suggest waiting at least 3 months to detect neoplastic growth. The practice aims to avoid local recurrences and confirm the radicality of the initial resection, but its oncological safety is still under investigation in ongoing trials. For high-risk T1 cancers, scar excision is generally not recommended due to the need for oncological resection.

Questions: Upper GI Tract

Is there an anatomical or technical explanation for the significant delta in the R0 resection rates for NETS in the bulb vs rest of the duodenum? *(discussed live during webinar)*

Anatomical challenges:

K. Caca: The anatomical location behind the pylorus makes it difficult to bend the device properly, leading to lower R0 resection rates.

Fixed vs. flexible mucosa:

Z. Nabi: Mentions that the first part of the duodenum is more fixed, making it harder to bring lesions inside the cap, especially flatter lesions. In contrast, the second part of the duodenum has more flexible mucosa, making it easier to mobilize and resect lesions. Careful lesion selection and experience are crucial for achieving higher R0 resection rates.

Technical considerations:

G. Haber: Emphasizes the importance of advancing the entire cap and ring beyond the lesion towards the junction of D1 and D2 to avoid issues with the pyloric sphincter. Care must be taken to avoid sucking in soft mucosa from the pyloric ring, which can cause obstruction. Ensuring the device and ring are fully inside the duodenum is critical.

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Use of anchoring devices:

K. Caca: Suggests using an anchoring device to pull subepithelial lesions into the cap, although this approach requires meticulous coagulation to manage bleeding risks.

Bleeding and safety:

K. Caca: Highlights the risk of bleeding (20-25%) from vessels at the resection site and the need for careful coagulation.

G. Haber: Stresses the importance of staying away from the major and minor papilla to avoid complications, recommending the use of a duodenoscope for clear identification.

Conclusion:

The significant delta in R0 resection rates for NETs in the bulb versus the rest of the duodenum is primarily due to anatomical and technical challenges. The fixed nature of the first part of the duodenum and the difficulty in maneuvering devices behind the pylorus contribute to lower resection rates. Technical strategies, such as ensuring the entire device is inside the duodenum and careful lesion selection, can improve outcomes. The use of anchoring devices can aid in lesion mobilization but requires careful management of bleeding risks. Safety considerations, including avoiding the major and minor papilla, are essential to prevent complications.

What may be the probable reasons for low R0 resection rates in D1 lesions? *(asked in chat, answered live by Ovesco)*

In most cases, it is due to challenges in accessibility, particularly for lesions located in close proximity to the pylorus. The FTRD® cap may not fully traverse the pylorus, the latter potentially compromising the clip application mechanism. To mitigate these issues, thorough pre-dilation of the pylorus is strongly recommended, along with the administration of agents such as Buscopan to relax the muscle.

Additionally, in the duodenal bulb, the degree of scope angulation with the mounted FTRD® is reduced, which may hinder effective tissue mobilization.

Is pylorus dilatation an independent factor for R0 resection in duodenal bulb? *(asked in chat, answered by speakers post hoc)*

Proximity to pylorus:

P. Ge: Suggests that proximity to the pylorus may impact R0 resection rates in the duodenal bulb due to technical limitations. Lesions very close to or on the back side of the pylorus are likely to have lower R0 resection rates.

Pyloric dilation:

Z. Nabi: Recommends pyloric dilation for all cases where the lesion is in the duodenum. However, failure to negotiate the pylorus does not appear to be an independent factor for R0 resection. There is no data to support or refute this claim.

Technical challenges:

K. Caca: States that pyloric dilation helps with the passage of the FTRD® device through the pylorus, but the rigid cap of the device (2.3 cm) makes resection of lesions right behind the pylorus more challenging.

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Study findings:

B. Bastiaansen: Indicates that pyloric dilation is not related to R0 resection as far as current knowledge goes. A large study on duodenal NETs shows that lesions located within the proximal third of the duodenal bulb (close to the pylorus) are associated with lower chances of complete (R0) resection compared to more distal locations due to limited mobility of this part of the bulb.

Conclusion:

Pylorus dilation is not considered an independent factor for achieving R0 resection in the duodenal bulb. The proximity of the lesion to the pylorus and the associated technical challenges play a more significant role in impacting R0 resection rates. While pyloric dilation can aid in the passage of devices, it does not independently determine the success of R0 resection. However, it is recommended to thoroughly pre-dilate the pylorus prior to FTRD® resection in the duodenum. The anatomical location and mobility of the lesion within the duodenal bulb are crucial factors influencing resection outcomes.

Is it contraindicated to do FTRD® on the pyloric sphincter due to risk of stenosis? *(asked in chat, answered live by Ovesco)*

Lesions located at or near the pylorus do not constitute a contraindication. However, it is imperative to maintain a minimum distance of 2 cm from the major papilla, as stipulated by the instructions for use. Such lesions may involve more technical challenges though as outlined in the previous questions. Lesions situated closer to the major papilla are considered contraindicated.

Any risk of CBD suctioning into the FTRD® cap in D1? *(asked in chat, answered live by Ovesco)*

From an anatomical perspective, it is theoretically possible. It is advisable to minimize the use of excessive suction when employing the FTRD®. Instead, the primary reliance should be on the grasping device. Once the tissue has been mobilized into the cap, only careful and controlled additional suction is recommended. Notably, there have been no documented instances of the common bile duct (CBD) being inadvertently captured during FTRD® procedures in this anatomical region.

We use OTSC® for closure of bleeding ulcer, but what is the source of delayed bleed after clip closure in FTRD®? *(asked in chat, answered by speakers post hoc)*

Vessel penetration through gaps:

P. Ge: Delayed bleeding after FTRD® can occur due to vessels penetrating through gaps in the FTRD® clip, even though the clip is very tight.

Tissue perfusion and clip strength:

Z. Nabi: The FTRD® clip is strong enough to securely close the defect while allowing tissue perfusion, preventing necrosis.

Clip design and vasculature:

K. Caca: The FTRD® clip is designed to allow perfusion to avoid necrosis and secondary perforation. The duodenum, especially beyond the first part, has significant vasculature and is prone to bleeding at the wall duplication.

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Compression force and proactive cauterization:

G. Haber: There is a balance between preventing bleeding and allowing enough perfusion to avoid necrosis. Immediate oozing is proactively cauterized after clip release to mitigate this risk.

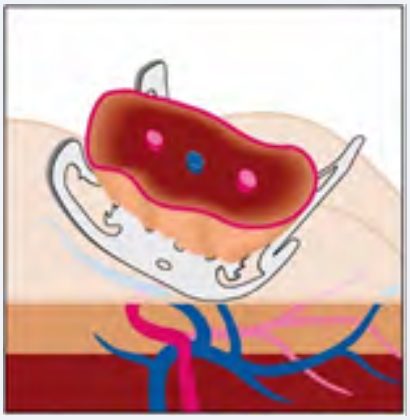
Rare delayed bleeding in colonic eFTR:

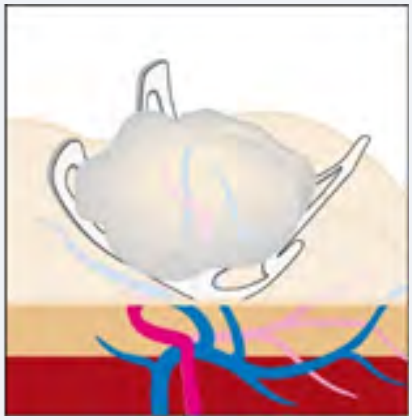
B. Bastiaansen: Delayed bleeding requiring blood transfusion or re-intervention in colonic eFTRs is rare (1.3%).

Differences between OTSC® and FTRD® Clips:

Ovesco: The OTSC® used for ulcer treatment benefits from edema and scarring, enhancing tissue compression. In contrast, FTRD® clips used for EFTR must provide adequate compression force to approximate tissue while maintaining microperfusion to ensure tissue viability. EFTR involves complete transection of the duodenal wall, unlike EMR, which only ablates superficial layers.

EFTR (left) vs. ulcer (right):





Conclusion:

Delayed bleeding after FTRD® clip closure can occur due to vessels penetrating through gaps in the clip. There is a balance between preventing bleeding and allowing tissue perfusion, and the significant vasculature in the duodenum. The FTRD® clip is designed to avoid necrosis by allowing perfusion, but this can also lead to bleeding. Immediate proactive cauterization and careful monitoring are essential to manage this risk. The differences in tissue characteristics and procedural requirements between OTSC® and FTRD® clips also play a role in the occurrence of delayed bleeding.

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