December 2019 | New randomized-controlled trial: OTSC® in first line has superior ability to reduce rebleeding in NVUGIB when compared to standard treatment

A randomized controlled trial presented at the American College of Gastroenterology (ACG) meeting shows the rebleeding rate after first-line OTSC treatment of NVUGIB to be 85 % lower than after standard treatment. At this year’s ACG Annual Scientific Meeting, taking place on October 25-30 in San Antonio, TX, USA, Dr. D. Jensen presented the study, which was performed at UCLA School of Medicine, Los Angeles, CA, USA. The study included patients scheduled for endoscopic treatment of severe non-variceal upper gastrointestinal bleeding (NVUGIB). The rate of rebleeding in the OTSC group was 4 % lower than in the control group (p=0.004). No differences were observed in the costs of treatment between the groups (€ 2,805 vs 3,081.76). The authors concluded that OTSC has a superior ability to reduce rebleeding in NVUGIB when compared to standard treatment.

December 2019 | Conference Report of DGVS and DGAfV 2019

The 74th annual conference of the German Society of Gastroenterology, and Digestive and Metabolic Diseases with Endoscopy Section (DGVS) took place together with the 13th autumn conference of the German Society of General Surgery and Visceral Surgery (DGAfV) on October 25-26, 2019 in Schladming, Germany. Ovesco products were presented in talks, posters, meetings, video forums, workshops and hands-on training sessions.

FTRD® System

Endoscopic full-thickness resection with the FTRD System is highly cost-effective when compared to surgical and endoscopic alternatives.

Additional costs per r0 resection in relation to EFTR are €27,000 for the surgical alternative and €4,800 for EMR/ESD

A. Kuellmer, University Hospital Freiburg, presented a cost-effectiveness study of the endoscopic full-thickness resection (EFR) for difficult-to-remove lesions with the FTRD System in comparison to available alternative therapies. The data for analysis was drawn from the patients of the WALL-RECt study, a hypothetically designed control group. The control group was generated by a systematic survey of the treating physicians of all participating centers of the study (University Hospital Freiburg, Hospital Ludwigshafen, Evangelische Krankenhaus Krefeld, University Hospital Ulm, University Hospital Wuerzburg, Hospital Augsburg, Hospital Dortmund, Hospital Krefeld, and Hospital Boeblingen-Sindelfingen) and comprised various alternative therapies (ESD, EMR, surgical resection). Costs and providers’ point of view were estimated. The defined effectiveness parameter was the primary endpoint of the WALL-RECt study, the r0 resection. For the control group, the r0 resection rates published in current literature were used. ICER (Incremental Cost-Effectiveness Ratio) and ACER (Average Cost-Effectiveness Ratio) were calculated for the cost savings. The authors concluded that endoscopic full-thickness resection with the FTRD System is highly cost-effective when compared to surgical and endoscopic alternative therapies.

Endoscopic full-thickness resection in the colorectum with the FTRD System – a cost-effectiveness analysis. (Die endoskopische Vollwandresektion im Kolorektum mit dem FTRD System – eine Kostenefektivitätsanalyse.)


Costs for EFTR are significantly lower by 5,049 € when compared to surgical segment resection

M. Rathmayer, Inspiring- health GmbH, Munich, presented first results of a study, which compares the costs for open-surgical and laparoscopic procedures with EFTR. In addition, an analysis of cost-covering by the G-DRG System was performed. Performance numbers were queried at the participating centers of the study (University Hospital Freiburg, Hospital Krefeld, and Hospital Boeblingen-Sindelfingen) and comprised various alternative therapies (ESD, EMR, surgical resection). The two groups were well matched concerning demographics, risk factors, lesion type and stigmata of hemorrhage. During the 30 day follow up, rebleeding occurred in one patient in the OTSC group (12/4, 4.2 %) and 7 patients in the standard treatment group (7/25, 28 %; p=0.024). The rebleeding rate was 85 % lower in the OTSC group than in the standard treatment group (p=0.015). The mean number needed to treat (NNT) was 4.2. Severe complications did not occur in the OTSC group (0/24, 0 %), but did occur in 4 patients in the standard treatment group (4/25, 16 %, p=0.041). Angiographic embolisation was not necessary in the OTSC group, but was necessary in 2 patients (8 %) of the standard treatment group (p=0.195). The median size of the resected bleeding lesion was 0.4 ± 0.2 in the OTSC group and 0.76 ± 1.64 in the standard treatment group, a Kruskal-Wallis test performed for statistical comparison. In summary, patients with severe NVUGIB, who received primary endoscopic treatment with the OTSC, experienced significantly lower rates of rebleeding, significantly less severe complications, and needed fewer red blood cell transfusions than patients treated with standard endoscopic or surgical hemorrhostasis. The authors concluded that the OTSC has a superior ability to obliterate arterial blood flow underneath the lesion and thereby reduce lesion rebleeding.

Randomized Controlled Trial (RCT) of Over-the-Scope Clip (OTSC) as Initial Endoscopic Treatment of Severe Non-Variceal Upper Gastrointestinal Bleeding (NVUGIB).


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Randomized Controlled Trial (RCT) of Over-the-Scope Clip (OTSC) as Initial Endoscopic Treatment of Severe Non-Variceal Upper Gastrointestinal Bleeding (NVUGIB).

Application-oriented lectures at the conference underline the establishment of the instrument in everyday clinical practice
Various other lectures, held e.g. by B. Schuhmacher, Elisabeth Hospital Essen, K. Caca, Hospital Ludwigswig, and S. Hollerbach, AKH Celle, explained application-oriented and practically the deployment of the FTRD in everyday clinical practice. By means of clinical examples, photos, videos and illustrations, the correct deployment and avoidable mistakes were illustrated and appropriate indications were explained as well as therapy alternatives.

In summary, 57% of patients (65.8 years, range 46-83) were included in the study from 2014 and 2018, was retrospectively evaluated. Patients (overall n=152) of 1 cm, 2 cm, 3 cm, and 4 cm in size were manually placed by the authors.

Tumor resection by tunneling and by full-thickness resection in the upper GI tract (Tumorresection durch Tunnel und per Vollwandresektion im oberen GI Trakt).

Caca K, Ludwigswig.


Endoscopic Full-Thickness Resection in the duodenum (Endoskopische Submukosadissektion im Duodenum). Caca K, Ludwigswig.

Medical Short-course: How to use the current endoscopic set of instruments. According to the authors, EFTR plays a particular role in the resection of adenoma with high-grade dysplasia and of small early-stage adenocarcinomas.

Medium risk of appendicitis after EFTR of adenoma near the appendicular orifice

S. Schmidt, University Hospital Ulm, reported on a study examining how high the risk for post-interventional appendicitis is after full-thickness resection at the appendicular orifice of colorectal lesions (endoscopic full-thickness resection, EFTR). In 34 patients, follow-up data was available, in 2 cases a residual/relapse adenoma was found, both could be curatively resected by means of EFTR.

The authors concluded that EFTR represents a safe and effective method, which usefully complements the present endoscopic set of instruments. According to the authors, EFTR plays a particular role in the resection of adenoma with high-grade dysplasia and of small early-stage adenocarcinomas.

Endoscopic full-thickness resection (eFTR) of colorectal lesions – a retrospective analysis of 50 consecutive cases. (Endoskopische Vollwandresektion „endoscopic full-thickness resection“, eFTR) für kolorektale Läsionen – eine retrospektive Analyse von 50 konsekutiven Fällen.


ESD+ is in ex-vivo model related to significantly shorter procedural time (24.5 s vs. 32.5 min) and causes significantly less muscular damage (1/32 vs. 6/32, p<0.04) than conventional ESD.

The authors concluded that medium risk of appendicitis must be presumed for EFTR of adenoma near the appendicular orifice. Thus, it is necessary to sufficiently inform the patients about the risk and the eventual necessity for surgical appendectomy. Possibly, the risk can be minimized by longer-time post-interventional antibiotics.

Further studies on this would be desirable.

Moderately increased risk of appendicitis after eFTR of adenoma near the appendicular orifice – a retrospective analysis. (Moderat erhöhtes Appendizitrisiko nach eFTR von Adenomen nahe des Appendixbogens – eine retrospektive Analyse.)

important it is for therapeutic success, to keep the time between discovery of the perforation and start of therapy as short as possible. After that, he presented common endoscopic closure techniques. These included through-the-scope clips, OTSC clips, stents (SEPS, SEMS) and sponge/drainage for endoscopic vacuum therapy. Endoscopic closure and piecemeal techniques were not part of the lecture. Depending on defect size, localization and local expertise, the different endoscopic closure techniques are employed for perforation management. Herein, inter-disciplinary peri-interventional patient care is of great importance. In cases of laparoscopic surgical studies not possible closure, or clinical worsening, surgical therapy is still the treatment of choice.

Perforations in endoscopy – do I still need my surgeon? (Perforationen bei der Endoskopie – brauche ich meinen Chirurgen noch?)

Schmidt A, Freiburg

For questions and further information:
Ovesco Endoscopy AG
Science Information Service
Friedrich-Miescher-Straße 9
D-72076 Tübingen
science@ovesco.com

November 2019 | EFTR is a useful tool for staging of early colorectal cancer and simultaneously can be sufficient treatment for low-risk lesions

In 156 patients with histologic evidence of adenocarcinoma, EFTR was technically successful in 92.3 % and R0 resection was achieved in 71.8 %. Exact risk stratification was possible in 99.3 %. Severe procedure-related adverse events were recorded in 3.9 % of patients. A. Kuellmer et al., University Medical Center Freiburg, Germany, conducted a multicenter, retrospective study aimed at defining EFTR efficacy, safety and clinical value of EFTR for early colorectal cancer. Current international guidelines recommend endoscopic resection for T1 colorectal cancer with low-risk histology features and oncologic resection for those at high risk of lymphatic metastasis. Exact risk stratification is therefore crucial to avoid under-treatment as well as over-treatment.

Records of 1234 patients undergoing EFTR for various indications at 96 centers were screened for eligibility. A total of 156 patients with histologic evidence of adenocarcinoma were identified. This cohort included 64 cases undergoing EFTR after incomplete resection of a malignant polyp (group 1) and 92 non-lifting lesions (group 2). Technical success was achieved in 144/156 patients (92.3 %). Mean procedural time was 42 minutes. R0 resection was achieved in 112/156 patients (71.8 %). A subgroup-analysis was performed assessing the R0 resection rate for subgroup 1 (previous incompletely resected malignant polyps, n=64) and subgroup 2 (non-lifting lesions, n=92). In group 1, a R0 resection rate of 87.5 % and in group 2 a R0 resection rate of 60.9 % had been reached (p<0.001). Severe procedure-related adverse events (all perforations) were recorded in 6 cases (3.9 % of patients). One perforation was diagnosed immediately during the intervention and closed successfully with an over-the-scope clip. Minor delayed perforations were observed after 1-8 days and required surgical intervention. Discrimination between high-risk versus low-risk tumor was successful in 155/156 cases (99.3 %). In group 1, 84.1 % were identified as low-risk lesions, whereas 16.3 % in group 2 had low-risk features. In total, 53 patients (34 %) underwent oncologic resection for endoscopic features. 96 patients (62 %) were followed endoscopically.

The authors concluded that in colorectal cancer, EFTR is technically feasible, effective and safe. It allows exact histological risk stratification and can avoid surgery for low-risk tumors. Preoperative stenting guidelines are required for further definition criteria for EFTR in malignant colorectal lesions and to evaluate long-term outcome.

Endoscopic full-thickness resection for early colorectal cancer.
Gastrointest Endosc 2019; 89(6):1180-89.

October 2019 | Resection techniques EFTR, EMR and ESD chosen as one of the top 3 endoscopic advances of 2018

The Gastrointestinal Endoscopy Editorial Board chooses resection techniques namely EMR/submucosal dissection and full-thickness resection as top 3 endoscopic advances of 2018. Votes from each individual of the 9-member board were tallied to identify a consensus list of 10 areas of endoscopic research they considered a top priority based on the criteria of significance, novelty, impact on national health and impact on global health. With 7 votes, gastrointestinal resection techniques including EFTR were listed as number 3 of this list.

To identify major new advances in gastrointestinal endoscopy in 2018, the American Society for Gastrointestinal Endoscopy’s (ASGE) Gastrointestinal Endoscopy (GE) column reviewed original research articles pertaining to GI endoscopy published during 2018 in Gastrointestinal Endoscopy and 10 other leading medical and gastroenterology journals. These journals were selected on the basis of impact factor and included medical journals (Annals of Internal Medicine, Journal of the American Medical Association, Lancet, New England Journal of Medicine), gastroenterology journals (American Journal of Gastroenterology, Clinical Gastroenterology and Hepatology, Gastroenterology, Gut, Hepatology), and specific endoscopic journals (endoscopy, GIE). Reviewing the titles, each member of the 9-member editorial board independently identified 10 areas of endoscopic research they considered a top priority based on the criteria of significance, novelty, impact on national health, and impact on global health. The list from each member was compiled, and the votes were then tallied to identify the consensus list of “Top 10 topics in GI endoscopy in 2018”. The list is arranged in order of priority based on the number of votes for each topic: adenoma detection (9 votes), bariatric endoscopy (8 votes), EMR/submucosal dissection/full-thickness resection (7 votes), artificial intelligence (7 votes), expandable metal stents for palliation of biliary obstruction (6 votes), pancreatic therapy with lumen-apposing metal stents (6 votes), endoscopic reprocessing (6 votes), Barrett’s esophagus (6 votes), interventional EUS (5 votes), and GI stenting (5 votes).

Acknowledging there may still be some bias and subjectivity, the board trusts that the list of the top 10 advances will guide educators by defining new endoscopic techniques that need to be propagated in clinical practice, and focus future research.

Gastrointestinal Endoscopy Editorial Board top 10 topics: advances in GI endoscopy in 2018.
Cohen J, Dealesl DJ, Huang JH, Baik KRWW, Leung FW, Maruni J, Okito PI, Swanstrom L, Chak A.

September 2019 | OTSC® Proctology: Pilot RCT shows efficacy and safety in achieving permanent closure of cryptoglandular anal fistulas

When compared to fistulectomy and primary sphincter reconstruction, the OTSC Proctology showed comparable results (93 % primary healing rate) but a significantly reduced number of hospitalization days and medications after treatment.

Marchesi D et al., Department of Surgical Sciences, Sapienza University, Rome, Italy, published a randomized controlled trial comparing the OTSC Proctology with standard fistulectomy and primary sphincter reconstruction for the treatment of anorectal low trans-sphincteric fistula. Between 02/2012 and 03/2013, patients operated by the anterior trans-sphincteric resection technique and allows for en

bloc resection of larger polyps, whereas 16.3 % in group 2 had low-risk features. In total, 53 patients (34 %) underwent oncologic resection for endoscopic features. 96 patients (62 %) were followed endoscopically.

The authors concluded that in colorectal cancer, EFTR is technically feasible, effective and safe. It allows exact histological risk stratification and can avoid surgery for low-risk tumors. Preoperative stenting guidelines are required for further definition criteria for EFTR in malignant colorectal lesions and to evaluate long-term outcome.

Endoscopic full-thickness resection for early colorectal cancer.
Gastrointest Endosc 2019; 89(6):1180-89.

October 2019 | EMR+: preclinical evaluation of the novel technique for endoscopic en-bloc resection proves it to be effective, safe, and easy and fast to perform

The novel EMR+ technique uses an additional working channel (AWC®) and a poloxamer agent for submucosal injection (LiUnP®). A preclinical study evaluated the technique in the EASIE-R1 Simulator (explanted pig stomach, 22 lesions) and subsequently in vivo in 13 in vivo explanted lesions. In vivo, resection was macroscopically complete in 92.3 %. Median procedure time was 5 min and median size of the resected specimens was 35 mm x 35 mm x 11 mm. Adverse events did not occur except from one minor periprocedural bleeding managed by coagulation. B. Meier et al., Ludwigsburg Hospital, Ludwigsburg, Germany, presented a preclinical study evaluating a modified EMR technique (EMR+) using an additional working channel (AWC, Ovesco Endoscopy) and a new agent for submucosal injection (LiUnP, Ovesco Endoscopy). The EMR+ technique is a modified grasp and snare technique and allows for en-bloc resection of larger polyps, which could be related with lower recurrence rates when compared to EMR (Ovesco Endoscopy) and with lower complication rates when compared to endoscopic submucosal dissection (ESD).

After the technique was established, 22 ex vivo resections were performed (EASIE-R1 Simulator, explanted pig stomach). Primary aim of this setting was to develop the concept of EMR+ (e.g. positioning of instruments, injection technique, resection technique). The procedure time was measured from the beginning of submucosal injection to the extraction of the resected specimen and lasted in median 7 min (range 5-11 min). Median size of the resected specimens was 30 mm x 26 mm x 11 mm. Afterwards, the technique was transferred and evaluated in 13 EMR+ resections in vivo in porcine models (stomachs of 3 domestic pigs). In vivo, median procedure time was 5 min (range 3-12) and median size of resected specimens was 30 mm x 26 mm x 11 mm. Major adverse events did not occur. During one resection (7.7 %), minor periprocedural bleeding occurred which could be managed by coagulation. The authors concluded that EMR+ showed to be effective and safe in porcine models and could be implemented in the porcine resection of lesions up to 40 mm. Further evaluation of the novel technique in clinical comparative trials is needed.

Meier B, Wannhoff A, Klinger C, Caca K.

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sphincteric anastomosis in a randomized controlled pilot trial.


Ovesco Research Update 32

September 2019 | The BougieCap provides visual control for effective and safe dilation of esophageal strictures and prevents complications from overdistention

In 50 patients with complex benign esophageal stenoses, endoscopic bougienage with the BougieCap was used (n = 96%). Symptoms of dysphagia decreased significantly after bougienage (59.0 points at Day 0 vs. 28.6 points at Day 14; p<0.001). No severe adverse events occurred.

B Walter et al., University Clinic Ulm, Germany, presented a multicenter study (Ulm, Southampton and Essen) evaluating dilating of benign esophageal strictures with the BougieCap. The BougieCap allows, in contrast to Savary bougies, direct visual control of the process without the need for x-ray.

50 patients (25 ± 2.5 m, median age 67.1 ± 16.8 years) with benign stenosis of the esophagus and clinically apparent symptoms of dysphagia were included. Genes of the stenosis was peptic (n=23), radiation (n=13), anastomotic (n=6), caustic ingestion (n=4), Post-ESD (n=2), EoE (n=1) and unknown (n=1). Dilation was successful in 96% of cases (48/50). In two cases with narrow and longer strictures (one peptic, one post-radiochemotherapy) located in the lower esophagus (length 40 mm, diameter 2 mm and 3 mm, respectively), bougienage failed due to high resistance, which caused buckling of the endoscope in the pharynx. Bougienage was aborted and balloon dilation was performed successfully. The mean number of sequential bougienages was 2.3 ± 0.7. A stabilizing guidewire was used in 10 cases, 8 of which were with a pediatric scope. Severe complications did not occur. In two cases, a BougieCap was lost in the stomach; no clinical discomfort of complications resulted. The BougieCaps evacuated spontaneously with the stool. Mean dysphagia-associated symptoms, using the DHI (Dysphagia Handycap Index), decreased from 59.0 (moderate dysphagia) to 28.6 points (mild dysphagia) over the short-term follow-up period of 14 days (p<0.001).

The authors concluded that endoscopic treatment of benign esophageal stenoses with the BougieCap allows direct visual control of the dilation process and of beginning mucosal injuries. This approach in contrast to the conventional blind method, overdistention and re-traumatization are reduced and the dilation process can be performed with better adaptation to the stenosis. Use of a guidewire is reasonable and necessary in special cases (i.e. very high-grade stenosis, usage of a pediatric gastroscope).

The BougieCap—a new method for endoscopic treatment of complex benign esophageal stenosis:

results from a multicenter study.


August 2019 | Gastrointestinal FTRD**: Full-thickness resection of gastric SETs enables definitive histological diagnosis, better than conventional biopsy

Gastric EFR in 29 patients with gastric SET led to en-bloc resection in 89.7%, 76% R0 resection and final histological diagnosis in all resected specimens. The only perioperative complication of minor bleeding was reported in 2 cases.

Dr B. Meier et al., Department of Gastroenterology, Ludwigsburg Hospital, Ludwigsburg, Germany, initiated the RESET trial in March 2017, a prospective observational multicenter pilot trial evaluating efficacy and safety of clip-assisted full-thickness resection (EFR) for gastric subepithelial tumors (SET). Gastric SET up to 15 mm were included in the trial. Primary endpoint was complete en-bloc resection. Secondary endpoints were R0 resection, full-thickness resection, adverse events and recurrence rate at 3-months follow-up.

29 patients underwent gastric EFR. Histology after conventional biopsy prior to EFR was only able to define histological tumor type in 31.2%. Complete en-bloc resection with the gFTRD System was achieved in 89.7%. Histology of the specimen defined the histological tumor type in 100%. 76% of all SET was resected histologically completely (R0), requiring no further diagnostic intervention; full-thickness-resection specimens were obtained in 65.5%. In the remaining cases resection reached deep into the wall. In 31% minor bleeding was observed and managed endoscopically in the same session. Follow-up was available in 79.3% and showed OTSC clip detachment in 78.3% and the OTSC clip in position in 21.7%. No signs of residual or recurrent tumors were observed after 3 months.

The authors concluded that EFR of gastric SET with the gFTRD is safe and effective. It provides a definitive diagnosis (including sufficient risk stratification in case of GIST or NET) in contrast to conventional biopsy. R0 resection is achieved in most cases and might obviate the need for further surveillance endoscopies.

Endoscopic full-thickness resection of gastric subepithelial tumors with the gFTRD-system: a prospective pilot study (RESET trial).


August 2019 | Conference Report of the Digestive Disease Week 2019

The 50th Digestive Disease Week (DDW) 2019 took place on May 18 – 21, 2019 in San Diego, CA, USA. Ovesco products were presented in talks, posters, state-of-the-art-lectures and debates.

National and international multicenter studies confirm that the FTRD allows for fast, safe, and effective resection of difficult colorectal and upper Gl lesions

FTRD System

U.S. multicenter FTRD study shows R0 resection rate of 79% in patients with difficult colorectal lesions.

Y. Ichkhanian et al., Baltimore, Maryland, USA, performed a retrospective study at 26 U.S. tertiary centers. 71 patients (76.3%) with difficult colorectal lesions were included in the trial. Primary endpoint was R0 resection rate of 87.5%, 60 min). 84.1% of Group 1 were identified as low-risk lesions, whereas 16.3% in Group 2 had low-risk features. In total 53 patients (34%) underwent oncologic resection due to high risk features whereas 98 patients (62%) were followed endoscopically.

The authors concluded that EFR in early colorectal cancer is technically feasible and safe. It allows exact histological stratification to avoid surgery for low-risk features.

Endoscopic full-thickness resection in colorectal cancer experience.


EFTR with the FTRD is a fast, safe and effective option for rectal neurendocrine tumors

B. Meier et al., Ludwigshurg hospital, Ludwigshurg, Germany, presented a study evaluating FTRD resection of rectal neuroendocrine tumors (NRE). Rectal NET are subepithelial tumors with potential for malignancy. Prevalence is rare but increasing over the last decades. Between 09/2015 and 05/2017, data of 40 cases of rectal NET were reported as recurrent NET. Median size of 8 mm (SD 4.43, range 3-25 mm). In 15% (6/40) rectal NET were reported as recurrent NET. Prevalence is rare but increasing over the last decades.

Küller A, Müller J, Caca K, Aeppli P, Dackk D, Schumacher B, Gultsch A, Schaller C, Waltadobe F, Hill R*, Edward A, Meier B, Bettiger D, Thimme R, Schmidt A Freiburg, 1Ludwigshurg, Luzem, 1Essen, 1Greifswald, 1Neumarkt, 1Leipzig, 1Mainz, 1Wuppertal

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snare). Endoscopic follow-up was available in 80% (32/40) and conducted after a median time of twelve weeks (range 1-48 weeks) after resection. In 72% (23/32) the OTSC had spontaneously detached and in 28% (9/32) the clip was still in situ. No evidence of a residual or recurrent lesion could be found.

The authors concluded that EFTR with the FTRD is a fast, safe and effective option for rectal NET < 20 mm. It should be considered as first-line therapy for rectal NET < 20 mm without risk factors.

Full thickness resection of neuroendocrine tumors in the rectum

86 % R0 resection rate achieved in large colorectal lesions resected with FTRD alone or hybrid technique A. Vareedeyah et al., NYU Langone Health, New York, New York, USA, performed a retrospective study on consecutive patients treated with the FTRD device at 9 North American centers. A total of 64 patients was included. The primary reason for FTRD was recurring adenoma (37 patients, 58%). Other indications included suspected high-grade dysplasia/cancer, lesions in the appendicular orifice and subepithelial lesions. The mean size of the resected lesion was 24 mm. The clip was not be advanced to the lesion in 4 patients. 56/60 lesions (93%) were successfully removed by FTRD alone (when <2 cm) or a combination of FTRD and EMR (when >2 cm). R0 (including clear vertical margin for hybrid procedures) was achieved in 48/56 patients (86%). Complications occurred in 3 patients. Perforation in one patient was treated endoscopically. Rectal bleeding in one patient did not require intervention. One patient required surgery for appendicitis 72 h after the procedure.

The authors concluded that EFTR is a safe and effective method for resection of large colorectal lesions.

Initial North American experience with endoscopic full-thickness resection of colorectal lesions: a multicenter retrospective cohort study
Vareedeyah A¹, Yuen PYS², Skinner M³, Koller K¹, Alkaade S¹, Dahl DL¹, Al-Haddad MA¹, Templeton AW¹, Hwang JH¹, Stavropoulos SN¹, Cohen J¹, Mendoza Ladd AH², Grajales-Figueroa G³, Mahadev SH³, Haber GB¹
¹New York, ²St. Louis, ³Danville, ⁴Indianapolis, ⁵Seattle, ⁶Redwood City, ⁷El Paso, ⁸México City, ⁹New York

First international experience of FTRD application in the upper GI tract shows high technical and clinical success rates K. Hajifathalian et al., Cornell, NYC, New York, United States, presented an international multicenter retrospective study including patients who had an endoscopic resection of an upper GI tract lesion using the FTRD System between 08/2017 and 11/2018. 54 patients from 11 centers with endoscopic resection of an upper GI tract lesion using FTRD were included. The most common lesions were mesenchymal neoplasms (n=22), followed by ectopic pancreas or scar tissue (n=12), adenomatous polyposis (n=7), hamartomatous polyposis (n=6), adenoma with high-grade dysplasia or adenocarcinoma (n=5), carcinoid tumors (n=2), and Peutz-Jeghers Syndrome (n=1). The lesion was located in the esophagus, 10 in the cardia/duodenum, 15 in the stomach body, 20 in the antrum, and 8 in the duodenum. The average size of lesions was 14 mm (SD 8 mm). Deployment of FTRD was technically successful in 92% of the patients (n=50) leading to complete and partial resection of the targeted lesion in 41 (78%) and 9 (16%) patients, respectively. Histological margin of resection was reported in 47 patients, and in these FTRD led to R0 resection in 74% (n=35), R1 resection in 21% (n=10), and Rx in 4% (n=2). Thus a R0 resection could be achieved in 35 patients (65%) out of 54 patients the procedure was attempted. Out of 4 patients with adenoma with high-grade dysplasia or adenocarcinoma, 3 had a R0 resection. FTRD was complicated by intra-procedural minor bleeding in 5 patients (11%) and major bleeding in 4 patients (9%), all of which were controlled endoscopically. 9 patients (17%) were taking antithrombotic medication at the time of the procedure. Previous biopsy or attempted resection by hot snare, VEER or ESD had been performed in 32 patients (59%). The authors concluded that these results suggest a high technical and clinical success rate with low risk of early recurrence and an acceptable complication rate for FTRD in the upper GI tract.

Full-thickness resection device (FTRD) for treatment of upper gastrointestinal tract lesions: the first international experience
Hajifathalian K¹, Dawod QM¹, Issa DI¹, Meining A¹, Schmidt A¹, Vossoughi K¹, Ichikhanian Y², Ngaumuneyong Y³, Kumberlin V³, Samaranayake JB¹, El Hage Chehade N¹, Tag SJD¹, Kasmin F¹, Templeton AW¹, Fukami N⁴, Goetz M⁴, Sampath K⁵, Glasser N⁶, Mahadev SH⁷, Mukerai S⁷, Call-Locke DL⁷, Hwang JH¹, Sharaa RH⁷, Khashab MA¹
¹New York, ²Baltimore, ³Utln, ⁴Freiburg, ⁵Irvine, ⁶Jackson, ⁷New City, ⁸Seattle, ⁹Scottsdale, ¹⁰Trebingen, ¹¹Stanford

Hybrid EMR-EFTR is associated with 76% negative vertical margins and low complications
P.Y.S. Vareedeyah et al., presented a comparative study, comparing consecutive patients treated with hybrid EMR-EFTR due to large colorectal lesions (n=17) with patients who underwent EFTR alone due to colorectal lesions (n=14). The mean lesion size in the EFTR group was 16.8 mm. The mean lesion size in the hybrid group was 33.6 mm. Mean procedure time was 67 minutes in the EFTR group and 100 minutes in the hybrid group. Histology confirmed R0 resection in 93% (13/14 patients) in the EFTR group and negative vertical margins in 76% (13/17 patients) of lesions in the hybrid group. Two of four in the hybrid group with positive vertical margins were due to technical difficulty (snare malfunction and lesion not entrapped by snare) and subsequently removed with EMR. Complications were relatively scarce. In one patient the snare was inadvertently closed with tissue resection prior to clip deployment resulting in a wall defect. One patient, who did not take the antibiotic medication as prescribed, developed appendicitis 72 h after the procedure. The authors concluded that Hybrid EMR-EFTR for colorectal lesions is a safe and effective method for resection of lesions that are otherwise too large for EFTR alone. There were no adverse events related to deployment of the clip into tissue with EMR defect. This approach is an alternative to ESPO.

A novel hybrid endoscopic mucosal resection (EMR) and endoscopic full-thickness resection (EFTR) for large colorectal neoplasms unsuitable by EMR alone
Yuen PYS¹, Vareedeyah AA¹, Skinner M³, Hoerter NA¹, Koller K¹, Mahadev SH³, Haber GB¹
¹New York City

OTSC® treatment of high-risk peptic ulcer bleeding is proven to be safe, effective, and cost-effective when compared to standard treatment
OTSC System
Treatment of recurrent peptic ulcer bleeding with the OTSC is associated with an average $2160 savings per patient when compared to standard treatment with clip application. J. Xu Y¹, Kallenchab T², Keyses E², Soetinko R², Ann Arbor, *San Francisco
¹Ann Arbor, *San Francisco

State-of-the-art lecture on the OTSC for severe upper GI bleeding
J. Hochberger, Vivantes hospital Friedrichshain, Academic Teaching Hospital of Humboldt University Charité, Berlin, Germany, held a state-of-the-art lecture on the OTSC treatment of severe upper GI bleeding. The OTSC is a Nitinol macro clip which provides controlled mechanical tissue compression. It has the working principle of a surgical stapler, therefore, tissue perfusion is preserved after clip application. The application of the clip is easy and similar to a band ligation device. The lesion is targeted, the OTSC cap is aligned to the lesion by pushing the anchor and advancing the endoscope. Thereby, the tip of the OTSC anchor can be mobilized into the cap, the anchor clips may remain external. In the next step, the clip is released. After clip application the OTSC Anchor is detached from the tissue. The OTSC bench data was collected on hemorrhosis (GIE 2012: 75; 152-9). OTSC showed a persistent pressure increase after application in comparison to the sealing pressure curve achieved with conventional clips. With OTSC, a significantly lower number of clips was needed for effective hemostasis and a significantly shorter time to effective hemostasis was proven with OTSC vs 2 TTS clips. In summary, the OTSC is easy to apply, application is fast, one single OTSC is sufficient in most cases. The OTSC provides a safe and reliable mechanical closure with maintained tissue perfusion. Early clip loss is rare with OTSC. Its special clinical strength are chronic peptic ulcers with fibrotic base. Limitations for the OTSC are rare, application is limited to access to the bleeding lesion because the housing is insufficient. This can be the case when there is a stenosis between endoscope and target area, then prior dilatation is necessary. Another reason for insufficient access is a lateral position of the bleeding source, in this case the housing is insufficient, use with a side viewing endoscope is not possible. Another limitation for OTSC application is diffuse tumor bleeding, in such a case, spray, injection and multiple conventional clips must be used.

The different types of over-the-scope clips have been developed. The OTSC 1 has teeth with small spigs, it provides compression plus anchoring. The OTSC 2 has round teeth, it provides mainly compression. The OTSC gc has prolonged teeth with spigs for gastric wall closure. There are three different hood sizes (8.5-11 mm, 10.5-12 mm, 11.5-14 mm) and 2 different cap depths (3 mm and 6 mm) on the market. The OTSC 1 (traumatic) is used for

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stomach and chronic duodenal ulcers at the level of the bulb. The OTSC a (atraumatic) is used for the small intestine and colon parts with thin wall.

Recent studies with the OTSC are

- A Meta-Analysis of 20 studies (n = 510 patients) regarding OTSC hemostasis showing a high technical and clinical success rate of 93.0 % and 97.5 % (Weiland T et al., MininTvn 2019)
- The multicenter FLETROck trial (n=118) of the OTSC as first line therapy revealing a total success rate of 92.5 %. The re-bleeding rate and re-bleeding associated mortality compared to the prophylactic application in comparison to the prognostic Rockall score was significantly reduced (Wedi E et al., Surg.End. 2018)
- The randomized controlled STING trial (n=66) proving that OTSC clipping is significantly superior to former guided hemostasis techniques. A new RCT has been planned by the study group to compare OTSC with standard visually guided hemostasis techniques. A new RCT has been planned by the study group to compare OTSC with standard visually guided hemostasis techniques.
- A large multicenter cohort study (n=286) on OTSC first-line treatment revealing superior technical and clinical success rates of 97.9 % and 96.4 % (Manta R et al., End Int open 2018).

In conclusion, the OTSC should be used as primary tool in all high-risk patients (Rockall 7 +), high-risk defined e.g. for patients under anticoagulation, for patients with hemoglobin < 10, for patients with cirrhosis and ulcer bleeding, for patients with a feeding tube draining ulcer that can easily be faced with an OTSC, and for patients with ulcers with ulcerated ulcer base. Besides, the OTSC should be used in all re-bleeders, if the lesion can be reached with OTSC and clip housing.

**Over-the-scope clip for severe upper GI-bleeding – Time for a change in practice?**

Hochberger J*, Wedi E*

*Berlin, 2Göttingen

The OTSC as first-line single therapy is as safe and effective as combined therapy for the management of high-risk bleeding peptic ulcers

C. Robles-Medranda et al., Guayaquil, Guayas, Ecuador, reported on an analysis of data on consecutive patients who presented with high-risk ulcer GI bleeding between 05/2014 and 09/2018. High-risk upper GI bleeding was considered as those ulcers located in a major arterial territory, if the lesion had an endoscopically visible large-caliber artery (>2 mm), if there was a fibrotic ulcer with high-risk endoscopic stigma (Forrest classification types I and II).

95 patients were included, 46 received an OTSC as primary therapy for HR bleeding ulcers and 49 matched cases received TTS hemostatic clips in combination with epinephrine injection (combined therapy). The mean age was 60 (19-91), 32.6 % female. Most lesions were gastric ulcers (71.6 %). The median number of OTSC used was 1 (1-3), whereas for combined therapy was 2 (1-8) TTS clips. Six cases of rebleeding (6.3 %) were observed: two in the OTSC group and four in the combined therapy group (p=0.444). Two cases of the OTSC group (4.3 %) had rebleeding after 48 hours of the procedure; meanwhile, one case of rebleeding was observed in the combined therapy group at the same period and was treated with APC (p=0.520). Three cases in the combined therapy group had rebleeding in less than 48 hours after the procedure (p=0.065). Patients with an OTSC and one APC. The median procedure time was 11 (10-15) mins for OTSC and 20 (15-40) for combined therapy (p<0.001).

The authors concluded that the OTSC as first-line single therapy is as safe and effective as combined therapy for the management of high-risk bleeding peptic ulcers; improving the procedure time.

**Over-the-scope clip as first-line therapy in the management of high-risk bleeding peptic ulcers: a case-match control study.**


*Guayaquil, Guayas, Ecuador

The OTSC is more effective in obliterating arterial blood flow in severe NVUGIB than standard visually guided endoscopic hemostasis

D.M. Jensen et al., David Geffen School of Medicine at UCLA, Santa Monica, California, USA, held a state-of-the-art lecture on the treatment of patients with severe non-variceal upper gastrointestinal bleeding (NVUGIB). Recurrent NVUGIB after standard visually guided endoscopic hemostasis is common in high-risk patients. A recent randomized controlled trial (ROCK) had shown that in high-risk patients (mean Rockall 8.1/20) 100% of patients had recurrent NVUGIB within 24 hours. For patients with recurrent NVUGIB, the OTSC was more effective in obliterating arterial blood flow as compared to other standard therapy techniques. The median procedure time was 11 (10-15) mins for OTSC and 20 (15-40) for combined therapy (p<0.001).

Two cases of the OTSC group (4.3 %) had rebleeding after 48 hours of the procedure; meanwhile, one case of rebleeding was observed in the combined therapy group at the same period and was treated with APC (p=0.520). Three cases in the combined therapy group had rebleeding in less than 48 hours after the procedure (p=0.065). Patients with an OTSC and one APC. The median procedure time was 11 (10-15) mins for OTSC and 20 (15-40) for combined therapy (p<0.001).

The authors concluded that the OTSC as first-line single therapy is as safe and effective as combined therapy for the management of high-risk bleeding peptic ulcers; improving the procedure time.
bleeding occurred and was managed by coagulation. The authors concluded that EMR+ allows for fast en bloc resection of lesions up to 30 mm. The technique needs to be further evaluated in vivo and in actual mucosal neoplasia. A novel technique for endoscopic en bloc resection for lesions up to 4 cm (EMR+)

Meier B¹, Caca K¹
Ludwigswig, Germany

For further information:
Ovesco endoscopy AG
Friedrich-Miescher-Straße 9
72076 Tuebingen
Germany

science@ovesco.com

August 2019 | Conference Report of the German Coloproctology-Congress 2019

The 45th Coloproctology-Congress of the German Society for Coloproctology (Deutsche Gesellschaft für Koloproktologie – DGP) together with the Association of Coloproctology Professionals (BCD) and the Surgical Working Group for Coloproctology of the German Society for General and Visceral Surgery (CACP of DGAV) took place on April 14 – 16, 2019 in Munich, Germany.

Cohon’s discussion and stoma were central topics of the congress. Almost 1250 participants and 45 exhibiting companies attended. As one highlight of the congress, a prize winners meeting was held on the last day of the congress, during which PD Dr. S. Blaumeyer and colleagues presented a multicentric long-term study with the OTSC Proctology.

The OTSC Proctology is safe, effective and continence preserving

Multicentric data on the OTSC Proctology confirms good healing rates (87%), low risk of complications and maintenance of continence in all cases

Blaumeyer S. et al. presented a multicenter-analysis evaluating the application of the OTSC Proctology regarding surgical practicability and long-term results. Data of all patients treated with the OTSC Proctology between 11/2012 and 04/2018 in 4 centers were retrospectively analyzed. Permanent fistula closure was defined as primary endpoint. Secondary endpoints were the surgical procedure, intra- and postinterventional complications, relapse rate and incontinence. Overall 62 patients (mf= 42:20, median age 50 years, range 25 – 84 years) were included in the study. The fistula was cryptoglandular in 87% of cases. 27 patients were presented with a low transphincteric fistula, 19 patients with a high transphincteric fistula, 5 patients with an intersphincteric fistula, 9 patients with a suprasphincteric fistula and 2 patients with an extraspincteric fistula. 34% of fistulas were relapse fistulas after other surgical therapy. Pre-interventional drainage was performed in all fistulas, median seton drainage time was 20 weeks. Healing after clip application was observed in 54/62 patients (87%). In 2 patients, a relapse fistula developed after presumed healing, in 2 patients a fistula persistence was observed after clip removal, in 2 patients the clip detached before fistula healing and in 1 patient the clip had to be removed prematurely due to pain. The average procedure time was 32 minutes; in all hospitals, the same standardized procedure was performed: (1) debindment, (2) rinsing of the fistula tract, (3) cutting out of the anoderm before fistula closure, (4) excision of the outer fistula orifice. Complications occurred in 6 patients: in 1 case pain after clip application, in 5 cases abscess/halit and in 1 case transmural clip migration. The follow-up time was 26 weeks on average. In 39 cases the clip was removed during follow-up, in 8 cases spontaneous clip loss was found during follow-up. Impairment of continence was not observed in any of the patients.

The authors conclude, that the OTSC Proctology is a technically simple, fast and safe option for the treatment of cryptoglandular anal fistulas. Good healing rates are achieved, the risk of complications is low, and the method does not carry the risk of incontinence. Clinical experience with the OTSC Proctology: a multicenter-analysis.

(Klinische Erfahrung mit dem OTSC Proctology: eine Multicenter-Analyse)

S. Blaumeyer¹, J. Luton², M. Maurus³, U. Nitsche⁴, W. Kauter⁵, Munich,¹ Schwieberdinger,² Immenstadt.

For further information:
Ovesco endoscopy AG
Friedrich-Miescher-Straße 9
72076 Tuebingen
Germany
science@ovesco.com

July 2019 | EMR+ achieves significantly higher R0 resection rate and requires significantly lower procedure time when compared to conventional EMR

In lesions of 3 cm, EMR+ reaches its best discriminatory power: R0 resection rate of 86.36% was achieved compared to R0 resection rate of 19.18 % with conventional EMR.

On April 4-6, 2019, ESGE Days (European Society of Gastrointestinal Endoscopy) took place in Prague, Czech Republic. At the conference, Knoop RF et al., University Medical Center Hamburg-Eppendorf presented a prospective trial systemically comparing EMR+ to the gold standard of classical EMR. Standardized lesions, measuring 1 cm, 2 cm, 3 cm or 4 cm were set in an ex-vivo animal model with pig stomachs placed into the EASIE-R simulator, a well-established endoscopic model.

Overall 152 procedures were performed. In lesions of 1 cm, both EMR and EMR+ were very reliable with a R0 resection rate of 100 %. In 2 cm lesions, EMR already dropped to 54.55 %. Classical EMR did not provide sufficient resection in 4 cm lesions for lesions with 3 cm or even 4 cm (18.16 % and 0 %). EMR+ still presented very satisfying results in 3 lesions (86.36 %) but also relevantly decreased at 4 cm (60.00 %). From 3 cm on, EMR + was significantly faster than conventional EMR. A perforation rate of 15 % was observed in the 4-cm group treated with EMR+. The authors summarized that EMR+ enables a grasp-and-snap technique and consequently facilitates en-bloc resection of larger lesions compared to conventional EMR.

In lesions > 2 cm, EMR+ outdoes its advantages, especially concerning the rate of R0 resections. At 3 cm, EMR+ reaches its best discriminatory power which comes to its inherent limits and the risk of perforations rises.

Then, ESD or surgery should be considered. The authors concluded that EMR+ could help to close a therapeutic gap in interventional endoscopy with manageable technical aspects and low risk of complications.

The use of an additional working channel (AWC) in endoscopic mucosal resection (EMR+) compared to conventional EMR


July 2019 | Meta-analysis comprising 475 patients demonstrates success of OTSC® as first and second line therapy for non-varical gastrointestinal bleeding

93 % primary hemostasis was achieved with primary OTSC therapy (288 patients), 91 % with rescue OTSC therapy (187 patients)

Ofosu A et al., The Brooklyn Hospital Center, Clinical Affiliate of the Mount Sinai Hospital, Brooklyn, NY, USA, performed a systematic review and meta-analysis to evaluate primary hemostasis rates and re-bleeding rates of the OTSC for primary therapy and rescue endoscopic interventions in patients with non-varical gastro-intestinal bleeding (NVGIB).

A total of 16 studies which involved 475 patients were included. 236 patients were treated with OTSC as primary therapy while 187 patients were treated with OTSC as rescue therapy. Primary hemostasis rate achieved with
primary endoscopic therapy with OTSC was 0.95 (p=0.99). Similarly, primary hemostasis rate achieved with rescue endoscopic therapy with OTSC was 0.91 (95\% CI: 0.84 – 0.94). Re-bleeding rates after primary endoscopic therapy with OTSC was 0.21 (95\% CI 0.10-0.38) and 0.25 (95\% CI 0.17 – 0.34) with rescue therapy. Then, a pre-treatment diagnostic bougienage in patients treated with OTSC as primary therapy versus rescue therapy RR = 0.52 (95\% CI: 0.31-0.89).

The authors concluded that this meta-analysis demonstrates success on the use of OTSC as primary and rescue therapy and represents an additional management of NVGIB. Further studies are however needed.

Over-the-scope-clips as primary and rescue therapy for non-variceal gastrointestinal bleeding: a systematic review and meta-analysis

June 2019 | FTRD®: Multicenter Italian experience confirms effectiveness and safety of the FTRD® for several high-risk indications in the colorectum

Technical success (lesion reached and resected) was achieved in 94.4\% of cases. R0 resection was achieved on lateral and deep margins in 90 \% and 92 \%, respectively. Major complications (requiring surgical treatment) occurred in 1.8 \%. Andrisani G et al., University Campus Bio-Medico, Rome, Italy, reported on 110 patients (61m/49f, mean age 68±11 years, range 20-80) from 12 Italian endoscopy centers who underwent ERFR using the FTRD System. Indications were adenoma or adenomatous polyp (39\%), incomplete resection at histology (26\%), non-lifting lesion (12\%), adenosia involving the appendix (2\%) or diverticulum (2\%), subepithelial lesions (10\%), suspected T1 carcinoma (16\%), and diagnostic resection (3\%).

Technical success (lesion reached and resected) was achieved in 94.4 \% of cases. R0 resection was achieved on lateral and deep margins in 90 \% and 92 \%, respectively. Mean size of specimens was 20 mm (range 6-42). In residual/regenerate adenomas, final analysis revealed: low-risk T1 (2\%), high-grade dysplasia (3\%) and adenoma with high-grade dysplasia (HGD) (3\%), scirrhus tissue (1\%). Histology reports of R1 resections were: adenoma with LGD (6\%), adenoma with HGD (1\%), low-risk T1 (6\%) and high-risk T1 (1\%), scar tissue (12\%). Non-lifting lesions were diagnosed as: adenoma with HGD (3\%), low-risk T1 (7\%) and high-risk T1 (6\%). Three perforations (2\%) occurred in 12 patients (11\%), 2 patients (1.8\%) required further surgical treatment: In one patient, stenosis of the sigmoid colon occurred after dip injection and had to be finally treated surgically after post-inflation treatment. One of 2 patients with resection involving the appendix developed acute appendicitis and underwent surgery. Three-months follow-up was available in all patients and revealed residue disease in 7 patients (6.4\%).

The authors concluded that ERFR using the FTRD System is a safe, effective and safe technique for the treatment of different high-risk colorectal lesions.

Colo-rectal endoscopic full-thickness resection (EFR) with the over-the-scope device (FTRD®): A multicenter Italian experience


June 2019 | Conference of DGE-BV 2019 with FTRD® Lunch Symposium

The 49th Conference of the German Society for Endoscopy and Imaging Procedures (DGE-BV) 2019 took place together with the learned societies of CAES, CATC, DEGEA, DEGUM, DGSTM, DGG, ÖGGH and BMSG on March 28 – 30, 2019 in Stuttgart, Germany. Ovesco products were presented in nine workshops on three different topics: “Hemostasis techniques”, “Management of complications: perforations and post-operative leakages” (OTSC®) and “ESD techniques” (RESECT®). Additionally, a workshop meeting of young endoscopists on OTSC® and RESECT® took place. Besides the FTRD® Lunch Symposium on the topic “EFTR with the FTRD® – where are we today?”, several talks and posters discussed products of Ovesco.

Advanced of ESD and EMR is subject of current endoscopic research – at Ovesco, too!

RESECT+

The novel high viscosity injection solution LiftUp® for ESD leads to a long-lasting lifting effect and could make the ESD procedure more effective.

Endoscopic submucosal dissection (ESD) is an established procedure for endoscopic treatment of early-stage neoplasms. A crucial step of the complex procedure is the injection of an ideally highly viscous injection solution.

E. Wedi et al., University Hospital Goettingen, Germany, presented the results of a prospective, randomized preclinical study comparing the new polymer injection LiftUp® to normal saline solution (NaCl 0.9 \%) and hydroxyethyl starch (HES 6 \%). A total of 60 standardized ESD procedures were performed in artificial lesions, each 3 x 3 cm in size, in an ex vivo porcine model (n=20 per injection solution). All 60 lesions were successfully resected using the standard ESD technique. R0 resection was achieved in 95 \% (n=19) with LiftUp, in 100 \% (n=20) with HAES and in 80 \% (n=16) with NaCl. LiftUp had no procedure related perforations, one perforation occurred in the HAES group, and two perforations in the NaCl group. Adequately sized was achieved in 16/20 cases (80 \%) using LiftUp, in 6/20 cases (30 \%) using HAES and in 6/20 cases (30 \%) using NaCl. General ESD procedure time was shorter in the LiftUp group than in the other two groups, the difference, however, did not reach statistical significance.

The authors concluded that LiftUp appears to be a safe alternative to established fluids for ESD. It had a significantly improved lifting effect and required significantly less injected volume compared to well established ESD techniques.

A novel high viscosity injection solution (LiftUp®) for Endoscopic Submucosal Dissection (ESD). A prospective comparison study with two established lifting solutions

(Eine neue hochvisköse injektionslösung (LiftUp®) für die Endoskopische Submukosa Dissektion (ESD). Eine prospektive Vergleichsstudie mit zwei etablierten injektionslösungen)


The Bougie Cap leads to high dilation rate in benign esophageal stenosis and to significant improvement of the clinical symptoms of dysphagia

BougieCap

Bougienage mit dem BougieCap bringt eine signifikant höhere Dilationsgeschwindigkeit (DHI) und eine bessere langfristige Stabilisierung des Eingriffs als konventionelle bougie (DDH) und operativen Fertigungen (RESECT+). Zudem ist die BougieCap leichter und lackiert, wodurch die Passage des Endoskops durch das Pharynx weitgehend unmerklich ist.


BougieCap - Management of complications: perforations and post-operative leakages (OTSC®)

BougieCap Therapy for colorectal cancer - clinical benefits versus other endoscopic therapies

R.F. Knoop et al., University Hospital Goettingen, Germany.

BougieCap® treatment of colorectal cancer is established for spasm and fistula treatment. We report our experience with 9 new patients with colorectal cancer undergoing resection with primary bougie treatment (BougieCap®). At Ovesco, too! All patients were treated with BougieCap® in the period from March 2018 to March 2019. The indications were bleeding in the postoperative period and fistula formation.

The results of this prospective multicenter study evaluating endoscopic treatment of benign esophageal stenoses (BougieCap study)

(Besprechung der Ergebnisse einer prospektiven multizentrischen Studie zur endoskopischen Behandlung gutartiger Ösophagusstenosen (BougieCap-Studie))

B. Walter, S. Schmidbaur, J. Rahman, B. Schumacher, D. Albers, A. Meininger, Ulm, Southampton/UK, Eesen

The FTRD® is used for risk stratification of colorectal carcinomas

FTRD System

Full-thickness resection of colorectal cancer with the FTRD® System allows exact histologic risk stratification and spares patients with "low-risk" features (62 % of the cohort) a surgical intervention. A. Kuellmer et al., University Hospital Freiburg, Germany, presented a retrospective multicenter study assessing efficacy, safety and clinical value of the FTRD System for colorectal cancer. Data of 1234 patient treated with the FTRD System for various indications at 96 endoscopic centers were screened for eligibility. 156 patients with histological evidence of an adenocarcinoma were identified. This cohort comprised 64 patients undergoing...
FTDR resection after incomplete resection of a malignant polyp (group 1) and 92 non-lying lesions (group 2). Endpoints of the study were: technical success, R0 resection rate, adverse events, successful discrimination of "low-risk" and "high-risk" tumors, as well as the need for surgical oncological resection.

Technical success was achieved in 144/156 patients (92.3%). Mean procedural time was 42 min. R0 resection was achieved in 122/156 cases (78.1%). Subgroup analysis showed a R0 resection rate of 97.5% in group 1 and of 90.9% in group 2 (p<0.001). Severe procedure-related adverse events were recorded in 3.9% of patients. Discrimination between high-risk versus low-risk tumor was successful in 155/156 patients (99.3%). In group 1, 84.1% were identified as low-risk lesions, whereas 16.3% in group 2 had low-risk features. In total 53 patients (34%) underwent oncologic resection due to high-risk features whereas 98 patients (62%) were followed endoscopically.

The authors concluded, that endoscopic full-thickness resection with the FTDR for colorectal cancer is feasible, effective and safe. It allows exact histological risk stratification and can avoid surgery for patients with "low-risk" lesions.

Endoscopic full-thickness resection of colorectal carcinomas with the FTRD-System - a retrospective multicentric study

(Endoskopische Vollwandresektion von Kolonkarzinomen mit dem FTRD-System - eine retrospektive multizentrische Studie)

A. Kuehmer¹, J. Mueller¹, K. Caca¹, P. Aspili⁴, D. Albers¹, B. Schumacher¹, A. Giltisch¹, H. Albrecht¹, I. Wallstäbel¹, C. Hofmann¹, A. Erhardt¹, B. Mayor¹, D. Bellingrind¹, R. Thimm¹, A. Schmidt¹, and the FTRD study group

"Freiburg, Ludwigshurg, Luzern/Switzerland, Essen, Gießen, Neumarkt i.d.OPf, Leipzig, Mainz, Wuppertal"

Increased risk of appendicitis following FTDR resection of adenomas arising from the appendiceal orifice

A. Wannhoff et al., Ludwigshurg Hospital, Germany, presented a study assessing the risk of post-interventional appendicitis after FTDR resection at the appendiceal orifice. Data of all patients at the Ludwigshurg Hospital or the University Hospital Ulm, who had undergone full-thickness resection with the FTRD System at the appendiceal orifice between 2014 and 2016, was retrospectively evaluated. Follow-up data was analysed regarding development of appendicitis. Patients with appendectomy before FTDR application were excluded from the study.

Overall 44 patients (median age 66 years, range 47-85 years, n=25 female) matched the inclusion criteria. EFTDR was successfully performed in all patients. During follow-up (median follow-up time 21 weeks, range 0-126 weeks) acute appendicitis occurred in 9 patients (23.7%). 5 patients developed appendicitis within 10 days after resection, the remaining patients more than a month after the intervention. Staphylococcus aureus was the most common causative agent, and 3 patients conservative treatment. All patients recovered completely.

The authors concluded that acute appendicitis can develop after full-thickness resection with the FTRD at the appendiceal orifice. Development of appendicitis can occur early after the intervention or after a period of longer latency. During informed consent discussion, patients should be informed about the appendicitis risk and a possible need for surgical treatment.

Evaluation of the risk of appendicitis following FTDR resection of adenomas arising from the appendiceal orifice

(Untersuchung des Appendizitis-Risikos nach FTDR-Resektion am Appendixabgang)

A. Wannhoff¹, J. Mueller¹, P. Kreuzer¹, G. Schmidbaur¹, B. Mayer¹, A. Meining¹, K. Caca¹

"Ludwigshurg, Ulm"

Application of the FTDR System can avoid surgical resections in many patients with colorectal resection adenoma

A. Schmidt, University Hospital Freiburg, Germany, held an expert review on the treatment of colorectal resection adenomas. Non-pedunculated adenomas are mostly resected by EMR. Meta-analyses show that the risk of a relapse adenoma following this resection method is about 15%. Piece-meal resection is a significant risk factor for recurrence of the adenoma. The risk of recurrence is about 20% after piece-meal resection, while it is 3.3% after en-bloc resection (p<0.0001). The ESD technique carries a risk of recurrence of about 4.8%. Especially problematic for the follow-up resection is the fact that the previous result remains in scar formation around the area, the relapse adenoma shows a non-lifting sign in most cases. In non-lifting lesions, EMR resection is usually not possible, ESD resection is time-consuming and technically extremely difficult when the lesion is located beyond the rectum. Besides, the risk of perforation is high when using the ESD technique. In conclusion, Caca stated that endoscopic full-thickness resection with the FTRD System is very suitable for therapy of colorectal resection adenomas. On the one hand it can be used within the entire colon and rectum, on the other hand, also non-lifting lesions can be resected with the FTRD System.

Several multi- and centeroncological clinical studies, among them the prospective multicenter study WALL RESECT incorporating 181 patients, showed technical success rates of about 90%, R0 resection rates of about 80% and rates of major complications of about 2%. FTDR application is related to short procedural times and is relatively simple. FTDR usage is limited in large lesions, the optimal lesion thickness for this method is ≤ 2 cm. In larger lesions often hybrid techniques are possible (i.e. EMR + FTRD). In conclusion, application of the FTDR represents for many patients with colorectal resection adenoma the avoidance of revision surgery.

Colorectal resection adenomas: always FTDR?

(Rezidiv-Adenome im Kolonrektum: Immer FTDR?)

A. Schmidt¹

"Freiburg"

Lunch Symposium on the FTDR System at the Conference of the DGE-BV 2019

During the 49th conference of the German Society for Endoscopy and Imaging Procedures (DGE-BV), which took place on March 28th - 30th, 2019 in Stuttgart, experts in endoscopy and imaging procedures, and representatives of the industry presented their latest findings. Indication for FTDR application were: non-lifting adenomas (n=454), native non-lifting adenomas (n=223), adenoma at diverticula (n=10), adenoma at appendiceal orifice (n=87), follow-up resection of malignant polyp (n=171), early carcinoma (n=64), submucosal tumor (n=74), diagnostic FTDR without lesion (n=20) and others (n=73). Location of lesion and intervention was in 52.1% rectal, in 14.2% sigmoidal, in 5.3% in the descending colon, in 12.8% in the transverse colon, in 18.3% in the ascendant colon, in 19.2% coecal, and in 5.2% in other locations (right flexure, appendix, mixed left sigmoidal lesions, transverse sigmoid, flexure, coecal pole). Average lesion size was 15 mm (range 2 – 56 mm, lesions with very large diameter were resected by hybrid-technique). Median procedure time was 35 min (range 2 – 203 min), technical success rate was 89.5%, the rate of full-thickness resection was 87.3% and of R0 resection 77.3%. Minor or moderate complications (no need for surgery) occurred in 14.5% of cases, major complications (need for surgery) in 1.8%. Follow-up data after median 4.8 months was available for 595 patients. The observation period was median 15 months. In 2.4% of cases to a suspected local recurrence of initially diagnosed R0 resected lesion in 38 patients (6.4%). Most of these patients underwent EFTDR recurrence more than (33.3%) or EMRRS (30.8%). (note: the listed data is preliminary, outstanding information on the large registry is still delivered by users. Therefore, some values might still change. Final data can be extracted from the following publication).

For summary, Schmidt presented a pooled-proportion analysis of the registry data in comparison with recent meta-analysis data of EMRRS of large adenomas (>2 cm). With regard to technical success rate and R0 resection rate, the EFR is in the range of the ESD, significantly higher than the success rates of the EMR. In regard to complication rates the following applies: the EFTDR is in all steps in comparison with the conventional techniques, the perforation rate of EFR is about as high as with EMR, which is significantly lower than with ESD. The need for surgery because of complications is with EFR technique approximately as high as with the conventional resection techniques, however, this is frequently owed to a wrong sequence of the intervention steps.

Schmidt concluded, that the German colonic FTDR registry confirms that the colonic FTRD is safe and efficacious; the registry has thus far registered 1176 cases. An example of the WALL RESECT study, a prospective multicenter study. Hence, the colonic FTDR has found broad-based applicability with comparable quality to large centers. The German colonic FTRD registry – final evaluation of 1176 cases

(Deutsches kolonc FTRD Register –)
The PMCF database was systematically searched for clinical data on OTSC therapy of GI hemorrhage (H), acute leaks/perforations (AL) and chronic leaks/fistulae (CL). Major outcomes were successful clip application and durable hemostasis/closure of defects. 457 publications were reviewed. 58 articles comprising 1965 patients were identified for data extraction. These consisted of retrospective analyses, prospective observational trials, one randomized-controlled trial (STING) and one quasi-controlled study (FLETRock). The pooled proportion analysis revealed high overall proportions of technical success: H – mean 93.0% [95% CI 92.0 – 94.5], AL-mean 89.7% [95% CI 81.9 – 92.9] and CL – mean 83.8% [95% CI 76.9 – 89.7]. Pooled durable clinical success proportions were: H – mean 87.5% [95% CI 80.5 – 93.2], AL – mean 81.4% [95% CI 77.0 – 85.3] and CL – mean 63.0% [95% CI 53.0 – 72.3]. By pooling all clinical data gained, the authors concluded that OTSC application in GI hemorrhage and closure of GI lesions is safe and effective in real clinical use.

Efficacy of the OTSC System in the treatment of GI bleeding and wall defects: A FTRD meta-analysis.


Minimally Invasive Therapy & Allied Technologies, DOI: 10.1080/13645706.2019.1550418

https://doi.org/10.1080/13645706.2019.1550418

April 2019 | FTRD® resection in the colorectum ensures local radical excision where other endoscopic techniques do not suffice and reduces the need for surgery

Prospective data from 51 FTRD-procedures shows technical success in 88% (45/51) and a R0-resection rate of 89% (40/45). EFTR-specimens, obtained for indeterminate previous T1 colorectal carcinoma resection, were free of residual carcinoma in 25 of 26 cases (96%).

Van der Spek B et al., Department of Gastroenterology and Hepatology, Northwest Hospital group, Alkmaar, The Netherlands, published a single-center case series evaluating resection of colorectal lesions with the FTRD device.

Between 07/2015 and 10/2017, 51 EFTR procedures were performed in 48 patients (63% men, median age 69). Indications for EFTR were non-lifting adenoma (n = 19), primary resection of malignant lesion (n = 2), resection of scar tissue after inadequate endoscopic resection of focal risk T1 colorectal carcinoma (n = 26), adenoma involving a diverticulum (n = 2) and neuroendocrine tumor (n = 2). Two lesions were treated by combining endoscopic mucosal resection and EFTR. Technical success was achieved in 45 of 51 procedures (88%). Five resections were macroscopically incomplete and in one case no specimen could be obtained due to inability to mobilize the lesion into the cap. Mean estimated lesion size was 12.2 mm (range 2 – 30). Mean maximum resection specimen diameter was 23 mm (range 11 – 45). Histopathology confirmed full-thickness resection in 43 of the remaining 45 specimens (96%) and radical resection (R0) in 40/45 procedures (89%). EFTR-specimens, obtained for indeterminate previous T1 colorectal carcinoma resection, were free of residual carcinoma in 25 of 26 cases (96%). In six patients (13%) a total proctectomy was performed, occurred within 30 days after EFTR. Four of these patients had minor bleeding not necessitating blood transfusion. One patient suffered major bleeding needing blood transfusion. One perforation occurred, which was corrected endoscopically. No emergency surgery was necessary. Six patients needed additional surgery because of either high risk for lymph node metastases (n = 4; three patients with T2-T3 CRC and one patient with lymphatic invasion in T1 CRC), technical failure of EFTR (n = 1) or endoscopically unresectable adenoma recurrence at surveillance (n = 1). The authors concluded that the AWC enables timely endoscopic tool can be inserted through the AWC and used for a distinct tissue traction and counter-traction during endoscopic resection, as the distance between working channels can be adjusted. Eight patients with large lesions or early stages of cancer in the upper or lower gastrointestinal tract were treated with endoscopic mucosal resection (EMR) with a modified grasping-and-snare technique (4 cases) and endoscopic submucosal dissection (ESD, 4 cases) using the AWC. Mean procedure time (scope-in to scope-out) was 65 minutes. R0-resection was achieved in all of the four cases treated by ESD and in two cases treated by EMR. The remaining two cases were treated by piecemeal EMR with positive lateral margins. Complications were acute arterial bleeding post-EMR in two cases treated by endoscopic clipping. No delayed bleeding, no perforation and no further severe adverse events occurred. The authors concluded that the AWC enables endoscopic resection of large lesions in the upper and lower gastrointestinal tract. Benefits are its suitability for EMR and ESD, no need for extended endoscopy and an adjustable distance of working channels. Improved endoscopic resection of large flat lesions and early cancers using an external additional working channel (AWC): a case series.

Walter B, Schmidbaur S, Krieger Y, Meining A.


March 2019 | FTRD® is feasible and safe in T1 early rectal cancer: a case series and video report

6 consecutive T1-ERC patients underwent FTRD application which resulted in complete endoscopic resection in all cases. No complications nor disease recurrence were observed during the 1-year follow-up period.

Schedlbauer P et al., RCCS Policlinico San Donato, San Donato Milanese, Milan, Italy performed a study aiming to assess the feasibility and long-term clinical impact of endoscopic treatment with the FTRD in patients with high-risk malignant rectal polyps = T1 early rectal cancer (T1-ERC). According to Ueno et al. and colleagues, high risk malignant polyps are defined as follows: low tumor differentiation grade (G3), Haggitt’s levels (pedunculated polyps) 3-4, Kikuchi’s levels (sessile polyps) sm3, width of submucosal invasion ≥ 4000 μm, depth of submucosal invasion ≥ 2000 μm, and distance from the excision margin < 1 mm, presence of vascular invasion. 6 consecutive patients (5 men, mean age 63 years, range 51-78 years), who had undergone a rectal ERM within the unusable and reduces the need for surgery in selected cases.

Endoscopic full-thickness resection in the colorectum: a single-center case series evaluating indication, efficacy and safety

Van der Spek B, Haasoot K, Meisch C, Heine D.

Endoscopy International Open 2018; 06:E1227-E1224

April 2019 | First case series with the AWC (Additional Working Channel) shows bimanual instrumentation to facilitate endoscopic resection of large GI lesions

The AWC was used in 8 patients with GI lesions 17-45 mm (average 35.9 mm) in size for EMR with modified grasping-and-snare technique (4 cases) or ESD (4 cases). R0-resection was achieved in 6 cases. Complications were acute arterial bleeding post-EMR in two cases treated by endoscopic clipping.

Walter B et al., Department of Gastroenterology, InExen, University Hospital Ulm, Ulm, Germany reported on the use of the AWC (Additional Working Channel) in eight patients with large, flat lesions or early stages of cancer in the upper or lower gastrointestinal tract.

Efficacy of the endoscopic en-bloc resection on large, flat GI lesions is challenging. No bimanual tasks are possible using standard endoscopes. Dual-channel endoscopes are not available everywhere and have a small distance between the channels. The AWC can be fixed to the tip of a standard gastrointestinal or pediatric endoscope. A second endoscopic tool can be inserted through the AWC and used for a distinct tissue traction and counter-traction during endoscopic resection, as the distance between working channels can be adjusted. Eight patients with large lesions or early stages of cancer in the upper or lower gastrointestinal tract were treated with endoscopic mucosal resection (EMR) with a modified grasping-and-snare technique (4 cases) and endoscopic submucosal dissection (ESD, 4 cases) using the AWC. Mean procedure time (scope-in to scope-out) was 65 minutes. R0-resection was achieved in all of the four cases treated by ESD and in two cases treated by EMR. The remaining two cases were treated by piecemeal EMR with positive lateral margins. Complications were acute arterial bleeding post-EMR in two cases treated by endoscopic clipping. No delayed bleeding, no perforation and no further severe adverse events occurred. The authors concluded that the AWC enables endoscopic resection of large lesions in the upper and lower gastrointestinal tract. Benefits are its suitability for EMR and ESD, no need for extended endoscopy and an adjustable distance of working channels.

Improved endoscopic resection of large flat lesions and early cancers using an external additional working channel (AWC): a case series.

Walter B, Schmidbaur S, Krieger Y, Meining A.


February 2019 | Large multicenter study with 286 patients confirms safety and efficacy of the OTSC® for hemostasis of high-risk lesions

96.4% hemostasis rate is reported from 286 emergency endoscopies for either upper or lower gastrointestinal bleeding in whom the OTSC was used as first-line treatment. Manta R et al., Digestive Endoscopy Unit, S. Agostino-Estense Hospital, Modena, Italy, published a study comprising data from all patients with upper or lower gastrointestinal bleeding from eleven Italian tertiary endoscopic referral centers who underwent OTSC placement as first-line treatment between 2014 and 07/2017. The decision to use an OTSC as first-line endoscopic treatment depended on the endoscopist's evaluation. Briefly, all high-risk patients and/or those with high-risk bleeding lesions were considered for the OTSC approach. Patients on antithrombotic therapy and those with relevant comorbidities (heart, kidney, and hepatic impairment) were considered as high-risk. Bleeding lesions were classified as high-risk when at least one of the following conditions was present: lesion with bleeding or vessel larger than 2 mm in diameter visible, lesion that was deeply penetrating, excavated or fibrotic in which the presence of a microperforation could not be completely ruled out or thermal energy could increase risk of perforation, and lesion not suitable for safe treatment by other endoscopic devices. Overall, 286 patients with either UGIB (n=214) or LGIB (n=72) were included. 112 patients (39.2%) were receiving antithrombotic therapy at the time of the intervention. Technical success and primary hemostasis rates were 97.6% and 96.4%, respectively. Early re-bleeding occurred in 4.4%, more frequently in those with antithrombotic therapy, and no late re-bleeding was observed. Following a successful primary hemostasis, only 5.2% of patients needed blood transfusions, the median hospital stay was 4 days (range 3–11), 18 patients with other technical failure (n=3) or re-bleeding (n=12) underwent radiological or surgical approaches. Overall, bleeding-related deaths occurred in 5 patients (1.7%), including 3 patients with technical procedural failure and 2 in the re-bleeding group. The authors conclude that the data from this large multicenter study show that OTSC placement is an effective first-line treatment for hemostasis in high-risk patients with lesions in the upper or lower gastrointestinal tract. First-line endoscopic treatment with over-the-scope clips in patients with either upper or lower gastrointestinal bleeding: a multicenter study. Manta R, Magnifico S, Zullo A, Bertani H, Canuso A, Grande G, Zito FP, Magniavillano B, Pasqua L, Parisot A, Germana B, Bassotti G, Monza F, Zilli M, Pisani A, Mutignani M, Coniglio R, Galloro G. Endoscopy International Open 2018;6:E1317-E1321.

February 2019 | OTSC® is safe and effective in pediatric patients for acute GI bleeding throughout the GI tract

Case series of 11 OTSC applications in 10 pediatric patients shows 100% technical success with immediate hemostasis and no complications. Tran P et al., Pediatric Gastroenterology and Nutrition Center’s Health – Children’s Medical Center Dallas, TX, USA, published the center’s experience utilizing OTSCs for nonvariceal gastrointestinal bleeding in pediatric patients. Overall 10 patients (median age 14.7 years, range 3.5–16.8 years) underwent endoscopic intervention, including 17.4–35.6 months of follow-up after showing no sign of disease recurrence at the 6-month oncological work-up. The authors concluded that this study provides initial evidence in favor of the FTRD System as therapeutic option for T1 early rectal cancer in patients either unfit for surgery or refusing the standard surgical approach. A full-length descriptive video as well as high resolution endoscopic images displaying the original rectal lesions, the FTRD procedures, and the follow-up have been published in Endoscopy International Open: https://doi.org/10.1055/s-0043-118657. Endoscopic full-thickness resection for T1 early rectal cancer: a case series and video report. Soriani P, Tontini GE, Neumann H, de Nucci G, De Toma D, Bruni B, Bavassano S, Pastorelli L, Vecchi M, Lappouss P. Endoscopy International Open 2017; 5:E1081–E1086. Risk factors for an adverse outcome in early invasive colorectal carcinoma. Ueno H, Misaki T, Hashiguchi Y et al. Gastroenterology 2004; 127: 385 – 394.

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March 2019 | Application of the FTRD® in duodenal lesions is feasible, efficacious and safe

EFTR of duodenal lesions in 20 patients showed technical success in 17/20 (85.0%), R0 resection rate of 12/17 (70.6%) and only minor peri-procedural bleeding in 3/20 cases (15.0%). No major bleedings or perforations occurred. Saurau M et al., Department of Gastroenterology and Oncology, Ludwigshafen Hospital, Ludwigshafen, Germany, performed a study investigating the safety and efficacy of FTRD application in the duodenum. Between 03/2014 and 06/2017, a total of 20 patients underwent EFTR of a duodenal lesion. Indication for EFTR was: adenomas (n=13), seven treatments naïve, six pretreated, subepithelial tumors (n=5) and T1 adenocarcinoma (n=1). The FTRD could be advanced to the lesion in 19/20 cases (95%). In one case advancing the FTRD through the pylorus was not possible despite balloon dilation. Overall technical success was 17/20 (85.0%). In two cases the FTRD clip was deployed correctly, but the integrated snare could not be closed because of device dysfunction. Both lesions were then resected with a standard snare above the FTRD clip after extraction of the device. In both cases there was no macroscopic evidence of residual adenoma. However, R0 resection could not be confirmed in both cases. R0 resection rate in the technically successful FTRD applications was 12/17 (70.6%). Minor bleedings occurred at the first post-interventional day in 3/20 patients (15.0%). No major bleedings or perforations occurred. During follow-up after 3 and 12 months, there were two recurrent adenomas that were successfully re-resected by FTRD. The authors concluded that the FTRD indicates good technical efficacy and safety for resection of duodenal non-ampullary adenomas and subepithelial tumors. It offers the possibility of re-resections at the same site. Especially in pretreated or difficult lesions, such as non-lifting adenomas, EFTR should be considered. Endoscopic full-thickness resection of duodenal ulcer disease of the stomach and duodenum, respectively, secondary to nonsteroidal anti-inflammatory drug use. 1 patient had peptic ulcer disease of unknown etiology and 1 had duodenal ulcers secondary to active Helicobacter pylori infection. Upper intestinal bleeding was found in 2 other patients, 1 with postpolypectomy bleeding in the stomach and 1 with biliary obstruction. Upper intestinal bleeding was seen in the remaining 4 patients. 1 patient had an ulcer located in the sigmoid colon presumed to be secondary to intestinal ischemia, 1 had postpolypectomy bleeding in the sigmoid colon, and 2 patients had ulcers presumed to be secondary to infection. Infection included 1 an ulceric colitis and 1 an infective anastomosis. 4 patients (40%) had OTSC placed as first-line intervention. Placement of the OTSC was technically successful in all patients resulting in immediate hemostasis. No complications occurred. The two patients with anastomotic ulcers have continued to have clinical bleeding resulting in chronic anemia. One of these patients continues to require monthly iron infusions and the other remains transfusion dependent. The remaining 8 patients have had no evidence of ongoing bleeding at follow-up (median follow-up time 12.9 months, range 21.2 – 39.4 months). The authors concluded that the OTSC System is a reliable and effective tool for active GI bleeding or high-risk lesions and should be considered for high risk or urgent/emergent bleeding from the upper gastrointestinal tract. Over the Scope Clips for Treatment of Acute Nonvariceal Gastrointestinal Bleeding in Children Are Safe and Effective. Tran P, Carroll J, Barth BA, Channabasappa N, Torende DM. JPGN 2018;67:458-463.

February 2019 | FTRD® is rated a highly effective, time-sparing and safe alternative to ESD for the treatment of non-lifting colorectal lesions and/or scars from R1 resection

Italian single-center study of 20 consecutive patients with non-lifting lesions, adenoma recurrence/relapse of previous endoscopic resections, and scars from incomplete endoscopic resection reports on 100% full-thickness resection and no major bleeding or perforation. Andrisani G et al., University Campus Bio-Medico, Rome, Italy, published a single center study evaluating consecutive patients with superficial colorectal neoplasms, who underwent endoscopic full-thickness resection (EFTR) with an OTSC device. EFTR was used on lesions, adenoma recurrence/relapse of previous endoscopic resections with a negative lifting sign, and scars from incomplete endoscopic resection with a positive deep margin (R1 resection). Between 2016 and 2018, 20 patients (12 m/8 f, mean age 67, range 51-79 years) met the inclusion criteria. Indications included scars of incomplete resections of polypectomy/mucosectomy (7/20), non-lifting lesions (9/20), and adenoma recurrence/relapse (4/20). The lesions were located in the rectum (n=10), descending colon/sigmoid (n=5), transverse colon (n=1), ascending colon (n=3) and caecum (n=1). Technical success, defined as full-thickness resection, was obtained in 100% and was subsequently histologically confirmed. Among the 7 unintentionally treated cases with FTRD, all were histologically negative for neoplasia. Among the 9 non-lifting lesions, seven were histologically diagnosed as T1/G1/sm1, one as T1/G1/sm2, and one as T1/G1/sm3; this patient underwent a surgical resection. Mean size of the resected lesions was 26 mm, ranging from 10 to 42 mm. No major immediate or delayed bleeding was observed. There was no perforation or need for emergency surgery. One (5%) patient developed abdominal pain, fever and leukocytosis after the intervention. Perforation or abscess was excluded by CT scan; the patient was treated conservatively with medical line therapy. The endoscopic follow-up after 3 months showed spontaneous OTSC dislocation in 100% of patients and the scar histology was negative for neoplasia. The authors concluded that EFTR is a feasible and effective technique and a valid alternative to EMR and ESD in the management of recurrent adenomas, non-lifting Ovesco Research Update | Research and clinical trials | Version 33 | 2019-12-20

January 2019 | OTSC®: A meta-analysis of 1517 cases over 9 years confirms its outstanding clinical effects for rescue therapy OTSC use in patients with refractory gastrointestinal diseases achieved an overall clinical success rate of 78%, 85% for bleeding, 53% for perforation, 52% for fistula, 66% for anastomotic dehiscence, and 95% for other conditions. Overall OTSC-associated complications were 1.7%, severe OTSC-associated complications 0.59%.

Kobara H et al., Departments of Gastroenterology and Neurology, Faculty of Medicine, and Gastroenterological Surgery, Faculty of Medicine, Kagawa University, Takamatsu, Japan, published a meta-analysis clarifying the current status and limitations of OTSC according to different indications of GI refractory disease, including refractory bleeding, perforation, fistula, and anastomotic dehiscence. They analyzed the literature search identified studies reporting on 10 or more cases, in which the OTSC System was applied. A total of 1517 cases described in 30 articles were retrieved. The clinical success rates and complications were calculated overall and for each indication.

The average clinical success rate was 78.3% (n = 1517) overall, 84.6% for hemorrhage (n = 559), 84.6% for perforation, 51.5% for fistula, 66% for anastomotic dehiscence, and 95.1% for other conditions, respectively. The authors stated these results, despite the lower performance of the OTSC System for fistula, as more than satisfactory when considering that there are no other effective endoscopic methods currently available and these refractory conditions hitherto required surgical interventions. With respect to safety, the overall OTSC-related complication rate was 1.7% (20/1517 cases), the incidence rate of severe complications that required surgery was 0.59% (81/1517 cases). The authors concluded that the OTSC system serves as a safe and effective device for GI refractory diseases, which hitherto required surgical interventions. Over-the-scope clip system: A review of 1517 cases over 9 years.


January 2019 | Multicentric analysis: OTSC® is highly effective as first- and second-line treatment for NVUGIB in high-risk patients with cardiovascular disease and complex, large ulcer

In a multicentric cohort of 100 consecutive patients with mean age 72 y; 51% severe cardiovascular comorbidity, and 73% on antplatelet orand anticoagulation therapy presenting with non-variceal upper GI bleeding from ulcers with median size of 3 cm, OTSC® therapy led to 94% emergency endoscopy for high-risk NVUGIB in two academic centers and were treated with OTSC as first-line (n = 81) or second-line therapy (n = 19). 100 consecutive patients (mean age 72 years, range 27-97) were included in the study. 51% had severe cardiovascular comorbidity (ischemic heart disease, congestive heart failure, hypertension, valvular heart disease, peripheral arterial, occlusive disease and atrial fibrillation) and 73% were on antplatelet or and anticoagulation therapy, other comorbidities in the patient cohort included kidney disease (n = 20), former or recent malignancy (n = 23), respiratory disease (n = 25), and previous surgeries (n = 26). The median size of the treated ulcers was 3 cm (range 1-5 cm), the patients in 85% of cases were classified as ASA 3 to 5 (ASA 3: 40%, ASA 4: 40%, and ASA 5: 5%). In 94% of patients (n=94) primary hemostasis with OTSC was achieved. The primary endpoint: successful initial hemostasis and no early (≤ 24 h) or delayed (≤ 30 days) re-bleeding was achieved in 86% of patients. Mean number of OTSCs placed on the initial endoscopic exam was 1 (range 1-3). Long-term hemostasis (6 months) was achieved in 86%.


December 2018 | Significant reduction of rebleeding rates in patients with high-risk NVUGIB by OTSC® OTSC use decreased the rebleeding rate in high-risk (RS ≥ 8) patients with statistical significance compared to the rates reported by the Rockall study (0% vs. 53%, p < 0.01). Also in intermediate-risk (RS = 4 – 7) patients rebleeding was reduced (0% vs. 24%, p = 0.08). Asokkumar et al., Singapore General Hospital, Singapore, studied rebleeding and mortality rates of patients treated with OTSC for high-risk adverse outcome (HR-AO) non-variceal upper gastrointestinal (NVUGIB) bleeding. The Rockall data and a historic cohort of the same institution’s prior study, a decrease in the rebleeding rate for high risk Rockall score patients as compared to the rates reported by the Rockall study, respectively, was observed. The authors concluded that the OTSC System was highly effective as first- and second-line treatment for NVUGIB in high-risk patients with cardiovascular disease and complex, large ulcers.

December 2018 | Conference Report United European Gastroenterology Week (UEGW) 2018: RESECT+ additional working channel (AWC®) and temperature-dependent agent for submucosal injection (LiftUp®) enable fast endoscopic en-bloc resection of specimens up to 30 mm • BougieCap: prospective multicenter study shows 96% successful resection with no complications • FTRD®: endoscopic full-thickness resection of rectal neurentochorine tumors is feasible, safe and effective and allows for definite diagnosis and treatment in the same session • Lifting technique: large systematic review (2462 patients) shows 77-96% clinical success by OTSC in various indications without the need for further intervention

The 26th United European Gastroenterology Week (UEGW) was held on October 20-24, 2018, in Vienna, Austria. Several workshops, talks and posters presented original research with Ovesco technology and procedures. Hands-on training sessions in the ESGE learning area with the OTSC System attracted lively interest.

RESECT+ Additional working channel (AWC) effectively supports endoscopic resection of large lesions in the upper and lower GI tract B. Walter et al., Department of Internal Medicine I, University Hospital Ulm, Germany, presented first experiences using the additional working channel (AWC). The device can be fixed at the tip of a standard gastroscope or pediatric colonoscope. The distance of the two working channels can be adjusted by the endoscopist. Via the AWC a second endoscopic tool can be inserted and used for bi- manual handling. ESD and EMR with a modified “two- hand- and snare’ technique was performed, EMR in 4 patients (1 with lesion in the upper GI tract, 3 with lesions in the lower GI tract), and ESD in 4 patients (2 with lesions in the upper GI tract, 2 with lesions in the lower GI tract). Mean procedure time was 68.5 min. Reported complications were acute arterial bleeding post EMR in two cases treated in the same session. No delayed bleeding or perforation were reported. Passage with the AWC-equipped endoscope was possible in all cases. The authors concluded that the AWC effectively supports endoscopic resection of large lesions in the upper and lower GI tract. Potential benefits are its suitability for EMR and ESD, no need for dual-channel endoscope and an adjustable distance or working channels.

EMR+: the new technique allows for fast endoscopic en-bloc resection of lesions up to 30 mm B. Meier and K. Caca, Department of Internal Medicine, Klinikum Ludwigshburg, Germany presented predilectional data on a new EMR technique (EMR+). This technique allows for en-bloc resection of specimens > 20 mm, which are usually resected in piecemeal EMR or by ESD, which however is time-consuming and associated with a higher risk for complications. EMR+ was developed and evaluated in an ex vivo porcine stomach. The stomach was adjusted in a special simulation model to be accessible to endoscopy. An additional working channel (AWC) was mounted on a standard gastroscope and used for a resection snare. The conventional working channel of the scope was used for an anchor device. For submucosal injection the newly developed LiftUp® agent (Lift-dependent viscosity (LiftUp)) was used. The agent has liquid consistency at room temperature, which allows submucosal injection. At body temperature, the agent gels and forms a stable cushion within seconds, which provides stable resection condition. Pre-injections or re-injections are not necessary. The effectiveness and safety of this agent has already been shown in vivo in domestic pigs. Imaginary lesions of 30 mm were marked by endoscopy. The device can be fixed at the tip of a standard gastroscope or pediatric colonoscope. The distance of the two working channels can be adjusted by the endoscopist. Via the AWC a second endoscopic tool can be inserted and used for bi-manual handling. ESD and EMR with a modified ‘two-hand- and snare’ technique was performed, EMR in 4 patients (1 with lesion in the upper GI tract, 3 with lesions in the lower GI tract), and ESD in 4 patients (2 with lesions in the upper GI tract, 2 with lesions in the lower GI tract). Mean procedure time was 68.5 min. Reported complications were acute arterial bleeding post EMR in two cases treated in the same session. No delayed bleeding or perforation were reported. Passage with the AWC-equipped endoscope was possible in all cases. The authors concluded that the AWC effectively supports endoscopic resection of large lesions in the upper and lower GI tract. Potential benefits are its suitability for EMR and ESD, no need for dual-channel endoscope and an adjustable distance or working channels.

Ovesco Research Update 29 December 2018 | Significant reduction of rebleeding rates in patients with high-risk NVUGIB by OTSC® OTSC use decreased the rebleeding rate in high-risk (RS ≥ 8) patients with statistical significance compared to the rates reported by the Rockall study (0% vs. 53%, p < 0.01). Also in intermediate-risk (RS = 4 – 7) patients rebleeding was reduced (0% vs. 24%, p = 0.08). Asokkumar et al., Singapore General Hospital, Singapore, studied rebleeding and mortality rates of patients treated with OTSC for high-risk adverse outcome (HR-AO) non-variceal upper gastrointestinal (NVUGIB) bleeding. The Rockall data and a historic cohort of the same institution’s prior study, a decrease in the rebleeding rate for high risk Rockall score patients as compared to the rates reported by the Rockall study, respectively, was observed. The authors concluded that the OTSC System was highly effective as first- and second-line treatment for NVUGIB in high-risk patients with cardiovascular disease and complex, large ulcers.

December 2018 | Conference Report United
authors concluded that the EMR+ technique allows for fast en-bloc resection and obtains resection specimens of 30 mm.

**BougieCap**

Endoscopic treatment of benign stenosis using the BougieCap enables direct visual control of the bougienage

B. Walter et al., Department of Internal Medicine I, University Hospital Ulm, Germany, presented a prospective interventional study on patients with a benign oesophageal stricture treated with direct visual control of the bougienage procedure with the BougieCap at three endoscopic units in Germany and UK. 51 patients (m/f: 25/25) underwent the procedure, mean age was 61 years (±16.8). Etiology of strictures was peptic (n=23), radiation (n=13), anastomosis (n=6), caustic ingestion (n=3), idiopathic (n=2), unknown (n=1). Successful dilatation with the BougieCap was possible in 96% (n=48). On average, 2.3 (±0.7) BougieCaps of subsequent sizes were used per patient. A stiff guide-wire was used in 10 cases to aid with bougienage, using a pediatric scope in 8 cases and a standard gastroscope in 2 cases. In two cases a narrow stricture and no usage of guide wire treatment failed as a result of high resistance at the site of stricture causing buckling of the endoscope in the pharynx. Symptoms of dysphagia (as assessed by Dysphagia Handicap Index score) decreased significantly after bougienage in short-time follow-up (14 days post-interventional). No severe complications were reported. Adverse events were loss of 2 BougieCaps in the stomach causing no symptoms. The authors concluded that endoscopic treatment of benign stenosis using the BougieCap enables direct visual control of the bougienage procedure and therefore of mucosal damage within the area of strictures. This might help to adapt endoscopic treatment even more precisely to the stricture. Symptoms of dysphagia are improved in short-term follow-up. Additional wire guidance is reasonable.

**FTRD System**

3-year multicenter UK experience: EFTR highly successful in the treatment of colonic lesions not previously amenable to endoscopy

I. Rahman et al., Department of Gastroenterology University Hospital Southampton, UK, presented data from the UK EFTR registry. Registry data from 04/2015 – 01/2018 comprised 52 cases of FTRD application in 8 centers, with a mean age of 72 years (±16.8). The target lesion could be reached with the FTRD mounted on top of the endoscope in 51/52 patients (98%). 1 case could not be reached due to sigmoid diverticulosis. Technical success was achieved in 96% (85/45%). Technical difficulty was experienced in 9 cases: In 6 cases snare closure was not possible, 3 cases the lesion slipped from the grasper on clip deployment. R0 resection was achieved in 74% (38/41), for 2 patients, histological data was incomplete. Residual/recurrent lesions at follow-up were found in 7% (2/30). Complications occurred in 3 patients: 1 acute appendicitis at day 6 after resection of appendix base adenoma, 1 arterial fibrillation and hypotension, and 1 rectal bleeding. There were no cases of perforation or fistula. The authors concluded that treating colonic lesions with the FTRD shows high success rates and low complication rates, making EFTR a viable alternative to surgery.

Pooled analysis from all studies that report on FTRD use (532 patients): 77.5% R0-resection rate, 5.4% complication rate

A. Wannhoff et al., Department of Internal Medicine, Klinikum Ludwigshurg, Germany, presented a systematic literature study analyzing all so far published data with the FTRD System (published studies and relevant congress abstracts). A total of 18 studies were included, 9 of them published as a full text and 9 as congress abstracts, which comprised a total of 532 patients from 7 countries. The target lesion was reached with the FTRD mounted on top of the endoscope in 522 (98.1%) patients and technical success was achieved in 486 (91.4%) patients. The full-thickness resection was histologically confirmed in 326 of 401 (81.3%) patients, in the remaining 131 no data on this endpoint was reported. The R0 resection rate was 77.5% and achieved in 383 of 494 patients for which data on resection margins was reported. Technical problems were mostly related to the impact of the study and study design. In most cases in this successful resection however was achieved by use of a conventional resection nare following clip application with the FTRD. Complications included minor bleeding and post-polypsctomy syndrome in 11 (2.6%) patients each. Severe bleeding occurred in 2 (0.4%) patients and perforations were reported in 13 (2.4%) patients. A surgical intervention due to a FTRD related complication was necessary in 9 (1.7%) patients. The authors concluded that the FTRD system provides highly efficacious treatment for rectal NETs. The complication rate is low and most complications can be managed conservatively or endoscopically.

**EFTR with the FTRD for rectal NET is feasible, safe and effective and allows for definite diagnosis and therapy at once**

B. Meier and K. Caca, Department of Internal Medicine, Klinikum Ludwigshurg, Germany, presented a study evaluating EFTR for rectal neuroendocrine tumors. All cases of rectal NETs in the German FTRD registry which comprises data of FTRD procedures of 31 German centers, were retrospectively analyzed. 40 patients (19 male, 21 female, median age 58 years, range 28-81) met the inclusion criteria. Lesions were located in the lower (n=13), middle (n=24) and upper rectum (n=9). Median size of the lesion was 6.4 mm (3-25). Biopsies were taken before EFTR in 19 patients and EFTR had been performed in 10 patients prior to EFTR, histology had shown well differentiated NET in all cases. However, in all cases resection status was unclear or incomplete. 6 NET (15%) were recurrent NET and had been treated previously (multiple forceps biopsies or snare resection). Mean procedure time of EFTR was 23 minutes (range 7-60 minutes). A full-thickness resection specimen could be obtained in all cases. R0-resection was achieved in all cases. However, in 7 cases (28%) a NET could no longer be proven. Adverse events occurred in 5 cases (12.5%), 4 patients suffered peri-interventional bleeding, which could be managed endoscopically in all cases, in 1 patient a technical problem occurred (rupture of the FTRD snare, resection margin was incomplete). In 2 cases in a conventional snare technique. Follow-up data was available for 32/40 patients. Mean follow-up time was 17 weeks (1-45 weeks). Residual or recurrent tumors were not found during follow-up.

The authors concluded that EFTR of rectal NET < 20 mm is feasible, safe and effective and allows diagnosis/risk stratification and treatment (R0 resection) at one go. The technique should be considered as first-line therapy.

**OTSC System**

Lively interest in Hands-On Trainings with the OTSC System

The European Society of Gastrointestinal Endoscopy (ESGE) offered an ESGE Learning Area to all delegates of the EUGG to provide a platform for live encounter and interaction among aspirating endoscopists and renowned experts in their field.

In the ESGE Learning Area, three 90-minute Hands-On OTSC trainings were held with the OTSC System. The authors concluded that the OTSC has a high rate of technical success and second-line treatment of peptic ulcer bleeding. Potential risk factors for treatment failure are location in the duodenal bulb, longer ICU stay, higher amount of transfusions and a higher reimbursement per case.

For questions and further information:

Ovesco Endoscopy AG
Scientific Information Service
Dorffackerstraße 26
D-72074 Tübingen
science@ovesco.com

**November 2018 | Korean multicenter study confirms efficacy and safety of OTSC® for GI fistulas, leaks and perforations**

All 19 patients were treated successfully with the OTSC System. In 74% of cases, complete healing of the leakage was achieved using OTSC clips. Lee HK et al., Department of Internal Medicine, Hanyang University College of Medicine, Seoul, Korea, performed a prospective multicentre multicenter study at seven centers in Korea aiming to examine the therapeutic success rate of OTSC for treatment of gastrointestinal perforations, fistulas and anastomotic leakages using the OTSC System in Korean patients.

A total of 19 patients were included, with gastrointestinal perforations in 8 cases, leaks in 7 cases and fistulas in 4 cases. The indications for OTSC placement in Group B were fistula closure (37.9%), perforation closure (33.9%), bleeding (14.1%), EFTR (7.9%) and leaks (6.2%). Pooled technical success in this group was 99.3% and clinical success 99.6%. 7/17 (41.2%) patients required surgical intervention despite OTSC placement. Complete luminal obstruction in 1/177 patients and small bowel fixation with pneumoperitoneum in 1/177 patients were the only OTSC related adverse events reported.

The authors concluded that the OTSC is a safe and effective, surgery-sparing endoscopic tool in today’s GI practice, with 77.3% of patient achieving clinical success without the need for further intervention. Technical success of > 95% has been reported across all indications.

**OTSC for high-risk peptic ulcer bleeding: one and done in 75%**

S. Gölder et al., Department of Internal Medicine III, Klinikum Augsburg, Germany, presented a study evaluating the use of OTSC for the treatment of high-risk peptic ulcer bleeding (HRUB). Between 4/2014 and 03/2018, 100 patients with peptic ulcer bleeding (Forrest la-ib), in the stomach of the duodenum were treated with OTSC. The OTSC was used as first-line procedure in 66 patients. Successful primary hemostasis could be achieved in 89.4%. The OTSC was used as second-line procedure in 34 patients. Technical success was achieved in 75.8% (n=50) in the primary-OTSC arm and in 73.5% (n=25) in the secondary-OTSC arm, respectively. OTSC failure occurred more often in large ulcers (> 3 cm, p=0.03), in the duodenal bulb (p=0.03) and in ulcers with hemorrhagic procoagulability (p=0.045). The patients with OTSC failure received more blood transfusions (p=0.002). No statistical difference was found for the Rockall score (median 7.5), the Glasgow Blatchford score (median 15.5), NSAID use or anticoagulation.

The authors concluded that OTSC has a high rate of technical success and one and second line treatment of peptic ulcer bleeding. Potential risk factors for treatment failure are location in the duodenal bulb, longer ICU stay, higher amount of transfusions and a higher reimbursement per case.
leakages from gastrojejunoanostomy sites (n=3), esophago-jejunoanostomy sites (n=3), esophago-gastroanostomy sites (n=4), esophago-colonanostomy sites (n=1), jejuno-jejunal sites (n=1), endoscopic full thickness resection site closures (n=2), Boerhaave’s syndrome (n=1), esophagobronchial fistulas (n=2), gastro-locular fistula (n=1), and colonic fistula (n=1). Size of the leakages ranged from 5 to 30 mm (median diameter 10 mm). The median procedure time was 16 min. All cases were technically successful. Complete healing of the leakage was achieved in 14 of 19 patients (74%) using OTSC alone. There were no complications associated with the OTSC procedures.

The authors concluded that the OTSC System is a safe and effective method for the management of gastrointestinal defects, especially in cases of anastomotic leakage after surgery.


• On-line ISSN 2234-244.

November 2018 | Visually controlled dilatation with the BougieCap is effective and prevents complications due to over-dilatation

Multicenter study shows high technical success rate and significant improvement of dysphagia symptoms.

B Walter et al. presented a multicenter study (Ulm, Southampton and Essen) evaluating dilatation of benign esophageal stenoses with the BougieCap. The BougieCap allows, in contrast to Savary bougies, direct visual control of the process without the need for x-ray. 50 patients (25 f, 25 m, median age 67.1 ± 16.8) with benign stenosis of the esophagus and clinically apparent symptoms of dysphagia were included. Cause of the stenosis was peptic (n=23), radiation (n=13), anastomotic (n=9), caustic ingestion (n=4), Post-ESD (n=2), EoE (n=1) and unknown (n=1). Dilatation was successful in 96 % of all cases (48/50). In eight cases a pediatric gastroscope with guidewire was used. In two cases a standard gastroscope with guidewire was used. In the two cases, passage of the stenosis was not possible, no attempt with guidewire had taken place. BougieCap (median 2.3 ± 0.7) of different sizes were used per session. Dysphagia symptoms were reduced from a median DS value of 3.0 ± 0.6 before dilatation to 1.6 ± 0.7 after dilatation (Mann-Whitney, p < 0.0001). No major complications occurred. In two cases, a BougieCap was lost in the stomach; no clinical discomfort or complications resulted. The authors stated that endoscopic treatment of benign esophageal stenoses with the BougieCap allows direct visual control of the dilatation process and of beginning mucosal lacerations. Thus, in contrast to the conventional blind method, over-dilatation and re-traumatization are reduced and the dilatation process can be performed with better adaptation to the stenosis. Usage of a guidewire is reasonable and necessary in special cases (i.e. very high-grade stenoses with suspicious (pediatric) gastroscope).


Walter B, Schmidbaur S, Rahman I, Schumacher B, Albers D, Meining A.

*UEG Week, Vienna, Austria, October 20-24, 2016.

November 2018 | Conference Report DGVS / DGAV

The 73rd annual conference of the German Society of Gastroenterology, and Digestive and Metabolic Diseases with Endoscopy Section (DGVS) took place together with the 12th autumn conference of the German Society of General Surgery and Visceral Surgery (DGAV) on September 12-15, 2016 in Munich, Germany.

Ovesco products were presented in talks, posters, research, innovation and video forums and hands-on training sessions. Dr med. Edith Wedi (University Hospital Goettingen) received the DGVS endoscopy research award and the award of the Olympus Europe foundation 2018 for his work.

FTRD® is described as effective and safe resection device for lesions otherwise difficult to treat endoscopically. Colonic FTRD® for colorectal adenomas and early T1 adenocarcinomas: A single centre experience.

Lithographic examination confirmed full-thickness resection in 326 of 401 (81.3 %) cases and R0 resection in 385 of 494 (78 %) cases; respectively information was not available for the remaining cases. Complications occurred in overall 8 %, thereof 13 post-polypectomy-syndroms (1.7 %), 16 minor haemorrhage (2 %), 2 major haemorrhage (0.3 %), 12 perforations (0.6 %, due to wrong order of operational steps), and 5 appendicitis (0.6 %); surgery because of complications was necessary in < 1 % of patients. The authors concluded that FTRD application in the colorectum is safe and the target lesion can be successfully resected in the majority of cases.

Efficacy of the Over-the-Scope Resection Device (FTRD) in the colorectum: Ergebnisse einer gepoolten Analyse bisher veröffentlichter Daten (Efficacy and safety of the Full-Thickness Resection Device (FTRD) in the colorectum: Results of a pooled analysis of to date published data).


University Hospital of Erlangen achieves 85 % R0 resection rate of adenomas and early adenocarcinomas with FTRD

I Rath and colleagues presented the experiences gathered at the University Hospital of Erlangen with the FTRD System. Between 06/2015 and 09/2017, the FTRD was applied in 14 patients (7 m, 6 f, median age 64.5 ± 6.1 y) with colorectal adenomas and early T1 adenocarcinomas. The lesions had a median size of 16 ± 4.7 mm and were located in the rectum (n=6), caecum (n=2), ascending colon (n=2), left flexure (n=1), and right flexure (n=3). The technical success rate was 100 %. The procedural time was 72 ± 15 min. R0 resection was achieved in 85 % of cases (11/13) in 1 case specimen was lost (R1). The primary technical success rate was 71 %. No complications occurred. In one patient, a relapse lesion was found at the resection site during follow-up, which could be resected once again with the FTRD. In conclusion, the authors rated the endoscopic full-thickness resection with the FTRD a procedure with few complications and high technical success and resection rate.

Endoskopische Vollwandresektion mittels FTRD für die Resektion von kolorektalen Adenomen und frühen T1 Adenokarzinomen: eine Single Center Erfahrung (Endoscopic full thickness resection using the FTRD for resection of colorectal adenomas and early T1 adenocarcinomas: A single centre experience).


Ovesco Research Update 33 | Research & clinical trials

14

FTRD® is suitable for therapy of early colorectal cancer.

S Herrmann et al. presented the experiences of the Clinical Center Ludwigsburg and the University Hospital Ulm regarding endoscopic full thickness resection at the appendiceal area using the FTRD between 2014 and 2018 indication for eFTR was previously known (8 adenocarcinomas, thereof 2 verified by histological examination confirmed full-thickness resection and a low rate of procedural complications. The FTRD is a safe and technically successful procedure, which can be successfully used in all cases for lesions otherwise difficult to treat endoscopically. Colonic FTRD® for colorectal adenomas and early T1 adenocarcinomas: A single centre experience.


Ovesco Research Update 33 | Research & clinical trials
appendicitis occurred within 10 days after FTRD application, in the 4 remaining cases more than a month after the procedure. In 6 cases, an appendectomy was performed, the remaining 3 patients were treated conservatively. The authors concluded that about a fifth of all patients undergoing FTRD application at the approach with full-thickness resection (FTRD) could develop a complication may occur early after FTRD application or with greater latency. Patients should be informed about the risk of appendicitis development before FTRD application at the appendicular origin. Untersuchung des Appendixz-Risiko nach endoskopischer Vollwandresektion von Adenomen im Bereich der Appendix mit dem FTRD System (Evaluation of the risk of appendix following endoscopic full-thickness resection of adenomas close to the Appendix with the FTRD System) - Krützler T, Walter B, Schmidt A, Meier B, Wannhoff A, Schmidbaur S, Meinling A, Caca K, Ludwigsburg/Ulm.

gastric FTRD
RESSET study: reliable dignity determination of gastric SETs using gFTRD
Meier B and colleagues presented a multicenter prospective pilot study evaluating the use of the gFTRD for endoscopic full-thickness resection of sub-epithelial tumors (SETs) of the stomach. Gastric SETs are rare, mostly benign and usually coincidentally found during gastroscopy. Superficial biopsy is often insufficient for reliable histological assessment. Endoscopic resection with standard methods (EMR/ESD) is often not possible and associated with an increased risk for complications. The study assessed feasibility, efficacy and safety of endoscopic full-thickness resection using the gFTRD for resection of gastric SETs in 29 patients. Lesions up to 15 mm in size were included. In 77 % of cases initial histology could not provide a reliable dignity determination of the SET. With full-thickness resection, the dignity of all SETs could be reliably determined. Average lesion size was 11 mm (range 5 – 15 mm). Median procedure time was 36.3 min (24 – 90 min). 76 % (22/29) of the specimen were resected in R0, 65.5 % (19/29) in full-thickness. In 31 % of cases per-interventional minor bleeding occurred, which could be directly treated endoscopically. In the follow-up examination after 3 months, clips were already discolored in 81 % of the cases, there was no evidence for relapse or residual lesions in any case. The authors concluded, that endoscopic full-thickness resection with the gFTRD is a safe and effective procedure, which enables in contrast to conventional biopsy a reliable dignity determination of gastric SETs. Sufficient risk stratification (in case of GIST/NET) is possible. Besides, sufficient therapy by R0 resection was achieved in 92 patients (92 %, n=80 primary therapy, n=32 secondary therapy). In 8 cases hemostasis could not be achieved with one single OTSC clip. In 17 cases recurrent bleeding occurred 1-12 days after initially successful hemostasis (n=10 primary therapy, n=7 secondary therapy). The group of patients with unsuccessful OTSC treatment showed significantly larger lesions (median size 3 cm, IQR 2 – 3, 13; p=0.03), more frequent bleeding in the duodenal bulb (22 vs. 2, p=0.03), more frequent negative H.p. status and a significantly higher number of transfused ECs (p=0.002). No significance was reached regarding the Rockall score (median 7.5, p=0.69) nor regarding the Glasgow-Blatchford score (median 15.5, p=0.15). Also, NSAID or antiagregant cotherapy was not significantly different between the groups (p=0.53 and p=0.44, respectively). The authors concluded, that OTSC Clip application for peptic ulcer bleeding shows high clinical success rates as primary and secondary therapy. Possible risk factors for therapy failure are ulcer size, localization of the bleeding source in the duodenal bulb, negative H.p. status and increased demand for transfusion.

Over the Scope Clip (OTSC) bei Magen- und Duodenalulcera mit hohem Blutungsrisiko – ein Optionsvergleich
Gölder S, Neumann T, Thiemann C, Caca K, Schmidt A, Freiburg Ludwigsburg, Deutschland.

Augsburg: closure of ulcer bleedings with high risk of recurrence: one and done in 75 %
S Gölder et al. presented a retrospective study comprising all patients with high-risk-bleeding ulcers (Forest Ia-IIb), treated with OTSC at the Augsburg Hospital. A total of 100 patients with peptic ulcer, primarily or secondarily treated with OTSC, were included (n=25 with gastric ulcer, n=75 with duodenal ulcer, primary OTSC treatment n=66, secondary OTSC treatment n=34). Primary hemostasis by OTSC withdrawal was achieved in 36 patients (92 %). In 92 patients (92 %, n=80 primary therapy, n=32 secondary therapy). In 8 cases hemostasia could not be achieved with one single OTSC clip. In 17 cases recurrent bleeding occurred 1-12 days after initially successful hemostasis (n=10 primary therapy, n=7 secondary therapy). The group of patients with unsuccessful OTSC treatment showed significantly larger lesions (median size 3 cm, IQR 2 – 3, 13; p=0.03), more frequent bleeding in the duodenal bulb (22 vs. 2, p=0.03), more frequent negative H.p. status and a significantly higher number of transfused ECs (p=0.002). No significance was reached regarding the Rockall score (median 7.5, p=0.69) nor regarding the Glasgow-Blatchford score (median 15.5, p=0.15). Also, NSAID or antiagregant cotherapy was not significantly different between the groups (p=0.53 and p=0.44, respectively). The authors concluded, that OTSC Clip application for peptic ulcer bleeding shows high clinical success rates as primary and secondary therapy. Possible risk factors for therapy failure are ulcer size, localization of the bleeding source in the duodenal bulb, negative H.p. status and increased demand for transfusion.

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Cross-sector routine data from social health insurance concerns safety and efficacy of colonoscopic tool OTSC (Over the Scope Clip [OTSC])
D Höft et al, University-Sommerfeld-Clinic, General Practitioners’ Health Insurance, Hamburg, presented a study based on cross-sector routine data gathered by social health insurance (>10 million insured parties), examining OTSC application in the colon. Indication, patient characteristics, outcome and complications were assessed in the actual care setting. 348 patients (median age 67 years, 60 % male) were subject to colonic OTSC (OPS-Code 54603s). Using further codes from different performance sectors, suspected indications were identified. (iatrogenic) perforation (n=58), polypectomy (n=210), bleeding (n=34) and others (n=46). A total of 16 patients (4.6 %) underwent an additional endoscopic intervention within 10 days of the initial procedure, 43 patients (12.4 %) within 100 days after the intervention. The authors concluded that, in the actual care setting, OTSC is mostly applied for polypectomies and iatrogenic perforations. The presented data supports first findings indicating that OTSC application in the colon is safe and helps to prevent surgery and endoscopic colonic interventions.

Sind OTSC-Clips am Kolon effektiv und sicher? Evidenz-Generierungen von endoskopischen Innovationen durch GKV-Routinedaten (Are OTSC-Clips in the colon effective and safe? Evidence generation of endoscopic innovations with health insurance routine data.)

OTSC as part of combination therapy of esophageal perforations and anastomotic insufficiencies following resections
C Jung et al. presented a retrospective evaluation of all patients, that had been treated since 2014 at the University Hospital Goettingen for iatrogenic esophageal perforation (IEP) or post-surgical anastomotic insufficiency (PAI) with the EndoVac system, with iatrogenic perforations and OTSCs. A total of 21 patients were recorded, 4 out of these with iatrogenic esophageal perforation and 17 with PAI. 12/17 PAI patients had received a preoperative radiochemotherapy (5 CROSS, 1ICF, 1 FLOT-RT2, 1ICF + Chemo, 1IXIC). OTSC intervention was done in 6/17 cases, 3/17 cases received an EndoVac as primary therapy. Complementary therapy was necessary in 6 patients (28.6 %) (2 stent + EndoVac, 1 EndoVac + Stent, 1 EndoVac + stent + fibrin, 1 stent + EndoVac + OTSC, 1 stent + OTSC). In overall 16/21 patients (76.2 %) complete restoration of the anastomosis
was achieved. In 5 cases, continuity could not be restored. 2 of the patients died; 3 patients received a cervical drainage. The authors concluded that the group of patients examined was heterogeneous and showed complex disease courses. The concept of combination therapy using EndoVac, esophageal stent, OTSC and endoscopic debulking seems to be promising. Further large scale studies are necessary to reliably describe the efficacy of this approach.

Multimodale endoskopische Behandlung von Ösophagusperforationen und postoperativen Anastomoseninsuffizienzen nach onkologischen Resektionen. Wiederholte endoskopische Therapie des sterilen Peritonitis. Was ist die Richtige Strategie? (Multimodal endoscopic treatment of esophageal perforation and post-surgical anastomosis insufficiency following oncolgical resection. Which is the right strategy?)

remove System – endoscopic removal of OTSC and FTRD clips is effective and safe
M Schmidbaur et al presented a multimodal prospective registry data regarding application of the remove System. Data on 119 patients from 63 centers were submitted. Main indications for clip removal were: necessity of local re-therapy (62/119), local clip-associated complications (27/119), and ineffective clip placement (16/119). Cutting of the clip through both bows was successful in 89.1 % of cases, endoscopic retrieval of both clip fragments was possible in 82.4 %. Uncovering the clip from granulation tissue before application of the remove System was necessary in 23 cases. Average procedure time was 23.2 ± 19.3 minutes. The risk of bleeding or trauma is reduced and the dilatation process can be performed with better adaptation to the stenosis. Usage of a guideewire is reasonable and necessary in special cases (i.e. very high grade-stenosis, usage of a pediatric gastroscope).

The BougieCap: a new method for endoscopic treatment of esophageal stenoses
Walter B, Schmidbaur S, Rahman I, Schumacher B, Albers D, Meining A.

RESECT+: presented studies on first (pre)-clinical data confirm beneficial effect of the additional working channel (AWC) and new injection solution (LiftUp®) for optimized endoscopic resection
EMR – new endoscopic resection technique for en-bloc resection of lesions up to 30 mm
B Meier et al. presented a preclinical study evaluating a new endoscopic resection technique, which allows en-bloc resection of large lesions. The endoscopic mucosal resection (EMR) is regarded as standard procedure for endoscopic resection of mucosal intestinal neoplasms. However, when the lesion size surpasses 20 mm, the en-bloc margins are below 40 %. For lesions ≥ 20 mm with urgent need of en-bloc/R0 resection, the endoscopic submucosal dissection is on hand, which albeit proves to be very sophisticated and time-consuming and is associated with a higher complication rate. Submucosal injection is a crucial part of both techniques, with longer duration of the intervention, however, the so created cushion is more and more absorbed. The authors reported on a new procedure technique (EMR+). For the EMR+ technique, a standard endoscope with additional working channel (AWC) is used. Through the working channel of the endoscope, a grasping anchor is conducted, a resection snare is passed through the working channel. The grasping anchor is led through the resection snare. For submucosal injection of the lesion, a new polymer injection solution (LiftUp®) is used. After injection the target lesion is lifted with the grasp anchor. The anastomotic line is grasped, the snare is conducted over the lesion and the tissue below the lesion is cut. For the preclinical study, EMR+ was performed in 2 sessions with 11 resections each in ex-vivo porcine models. The en-bloc specimen had an average size of 30 × 26 × 11 mm (maximum 40 × 33 × 14 mm). The overall procedure time was in average 6–7 minutes. Perforations did not occur. The authors rated the EMR+ as technically easy and fast technique for the en-bloc resection of lesions up to 30 mm in size.

New endoscopic dissection technique for en-bloc dissection of lesions up to 30 mm (EMR+)
The authors concluded, that the AWC makes en-bloc EMR possible. Advantages are the usability for ESD as well as EMR, the possibility of bi-manual working without 2-channel endoscope and the individual adjustment of the channel distance.

New multimodal endoskopische Behandlung von Ösophagusperforationen und postoperativen Anastomoseninsuffizienzen nach onkologischen Resektionen. Wiederholte endoskopische Therapie des sterilen Peritonitis. Was ist die Richtige Strategie? (Multimodal endoscopic treatment of esophageal perforation and post-surgical anastomosis insufficiency following oncolgical resection. Which is the right strategy?)

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Verwendung eines zusätzlichen externen Arbeitskanals (AWC) zur verbesserten endoskopischen Großflächenresektion (Usage of an additional external working channel (AWC) for improved endoscopic resection of large areas).

BougieCap – visually controlled dilation with the BougieCap is effective and prevents complications due to clipping
B Walter et al. presented a multicenter study (Ulm, Southampton and Essen) evaluating dilation of benign esophageal stenoses with the BougieCap. The BougieCap allows, in contrast to Savary bougies, direct visual control and re-traumatization are reduced and the dilatation was achieved. In 5 cases, continuity could not be restored. 2 of the patients died; 3 patients received a cervical drainage. The authors concluded that the group of patients examined was heterogeneous and showed complex disease courses. The concept of combination therapy using EndoVac, esophageal stent, OTSC and endoscopic debulking seems to be promising. Further large scale studies are necessary to reliably describe the efficacy of this approach.

Multimodale endoskopische Behandlung von Ösophagusperforationen und postoperativen Anastomoseninsuffizienzen nach onkologischen Resektionen. Wiederholte endoskopische Therapie des sterilen Peritonitis. Was ist die Richtige Strategie? (Multimodal endoscopic treatment of esophageal perforation and post-surgical anastomosis insufficiency following oncolgical resection. Which is the right strategy?)

remove System – endoscopic removal of OTSC and FTRD clips is effective and safe
M Schmidbaur et al presented a multimodal prospective registry data regarding application of the remove System. Data on 119 patients from 63 centers were submitted. Main indications for clip removal were: necessity of local re-therapy (62/119), local clip-associated complications (27/119), and ineffective clip placement (16/119). Cutting of the clip through both bows was successful in 89.1 % of cases, endoscopic retrieval of both clip fragments was possible in 82.4 %. Uncovering the clip from granulation tissue before application of the remove System was necessary in 23 cases. Average procedure time was 23.2 ± 19.3 minutes. The risk of bleeding or trauma is reduced and the dilatation process can be performed with better adaptation to the stenosis. Usage of a guideewire is reasonable and necessary in special cases (i.e. very high grade-stenosis, usage of a pediatric gastroscope).

The BougieCap: a new method for endoscopic treatment of esophageal stenoses with the BougieCap allows direct visual control of the dilation process and of beginning mucosal lacerations. Thus, in contrast to the conventional blind method, overdilatation and re-traumatization are reduced and the dilatation
throughout all cases. The authors concluded that the new device is safe and efficient and allows for rapid dissection of the submucosa due to its inherent design.

**Preliminary report of a new device for rapid endoscopic submucosal dissection (ESD)**


For questions and further information: Ovesco Endoscopy AG Scientific Information Service Dorfackerstraße 26 D-72074 Tübingen science@ovesco.com

**October 2018 | Successful application of OTSC® in GI bleeding under antithrombotic / anticoagulant therapy**

Lamberts R and colleagues, HELIOS Park-Hospital, Department II for Internal Medicine, Leipzig, Germany, conducted a retrospective study examining success rates in hemostasis of acute upper and lower gastrointestinal bleeding with the OTSC System as first or second line therapy in patients taking different regimens of antithrombotic and/or anticoagulant therapy.

Overall 75 consecutive patients (mean age 71.7 ± 5.5 years, 20 women) with active gastrointestinal bleeding were analysed. 34 patients (45.3%) were under antiplatelet monotherapy, 10 patients (13.3%) under dual antiplatelet therapy, 13 patients (17.3%) under inhibitors of plasmatic coagulation, and 18 patients (24.0%) no antithrombotic/anticoagulant therapy. OTSC was the first-line treatment in 45 (60%) patients, in 30 patients (40%) it was used in second line after preceding hemostasis attempts with conventional clips, adrenaline injection, fibrin glue and/or APC therapy. Key outcomes measured were: success rate with the OTSC therapy, rebleeding episodes, their management and the influence of antithrombotic or anticoagulant therapy.

Application of the OTSC resulted in immediate hemostasis in all 75 patients (100% primary success rate). In 28 patients (37.4%) a rebleeding episode was noted. In the group of first-line OTSC treatment the rebleeding rate was 28.9% (13/45) compared to 43.3% (13/30) in the group of second line OTSC treatment. In 23 patients rebleeding could be treated by further endoscopic interventions. Only 3 patients had to undergo radiological or surgical treatment because of failure of endoscopic management attempts. In the rebleeding group the use of antiplatelet therapies was higher (73.1% vs 48.9%).

The authors concluded that primary OTSC application should be the treatment of choice in this high-risk patient population. Repeated endoscopic treatments to achieve definitive hemostasis may be justified and show promising results.

**Use of over-the-scope clips (OTSC) for hemostasis in gastro-intestinal bleeding in patients under antiplatelet treatment**


**October 2018 | FTRD® offers endoscopic approach in the management of non-lifting and submucosal colorectal lesions and avoids surgical interventions**

Bauder M et al., Department of Gastroenterology and Oncology, Ludwigshurg Hospital, Ludwigshurg, Germany, presented a pilot study evaluating OTSC removal with the remOVE System.

OTSC (or FTRD) removal may be indicated when OTSC/FTRD-associated complications occur, when the clip was misplaced, re-therapy after full-thickness resection is needed or an OTSC-fixed stent has to be removed.

**The remOVE System is a bipolar grasping device with which short direct current (DC) impulses can be applied to cut the OTSC at two opposing sites. The DC impulses are delivered by a special electric generator connected to the grasping device. The bipolar grasper can be advanced through a 2.8 mm endoscope working channel. Its tip contains three electromagnetic coils in contact with the thinnest parts of the nitinol clip. Application of DC impulses then selectively heat up and melt the nitinol. As soon as the clip is cut or the contact to the nitinol is lost during the cutting process, an integrated safety feature automatically stops the current flow. In the next step, OTSC fragments are extracted with a standard forceps. For extraction, a plastic cap at the tip of the endoscope is used to avoid tissue damage.**

Data of all consecutive patients with indication for OTSC removal were collected and analysed retrospectively. Between 12/2012 and 02/2016, a total of 42 OTSC removals in the upper (n=25) and lower (n=17) gastrointestinal tract have been performed. Overall technical success, defined as cutting the OTSC at two opposing sites and extraction of both fragments, was achieved in 92.9% (39/42) of all cases. Successful fragmentation of the OTSC was achieved in 97.6% (41/42). Minor bleedings were rare and could be managed endoscopically in all cases. There were no perforations and/or delayed bleedings.

The authors concluded that endoscopic OTSC removal with the remOVE System is feasible, safe and effective. The technique can be applied in the upper and lower gastrointestinal tract.

**Endoscopic removal of over-the-scope clips: Clinical experience with a bipolar cutting device**


**August 2018 | Systematic review: leaks and fistulae after laparoscopic sleeve gastrectomy successfully closed by OTSC®**

A systematic literature review evaluating efficacy and safety of the OTSC System in the management of leak and fistula after laparoscopic sleeve gastrectomy (LSG) was published by Shoar S et al., Bariatric and Metabolic Institute, department of surgery, The Brooklyn Hospital Center, Icahn School of Medicine at Mount Sinai, Brooklyn, NY, USA. A total of 10 eligible studies including 195 patients with post-LSG leaks/fistulae were identified. The time interval between LSG and leak/fistula ranged from 1 day to 803 days. Most of the leaks/fistulae were located at the proximal staple line, and had a size from 3 to 20 mm. Time between diagnosis and OTSC clipping ranged from 0 to 271 days.

Details for endoscopic management of post-LSG leak/fistula by OTSC were available for nine studies (73 patients). Of the 73 patients with post-LSG leak treated with OTSC, 63 patients had an overall successful closure (86.3 %). Number of the deployed OTSC was reported by six studies (53 patients). Of these, 33/53 patients (63.5 %) required one clip for closure of the lesion, 14 patients (26.9 %) required one or more clips and 5 patients (9.6 %) required more than five clips.

Regarding OTSC-related complications, OTSC migration was reported in one patient (1.4 %), stenosis in one patient (1.4 %), and tear in one patient (1.4 %).

In conclusion, the authors stated that the OTSC System is a promising endoscopic approach for management of post-LSG leaks in appropriately selected patients. Unfortunately, most studies are series with a small sample size, short-term follow-up, and mixed data of concomitant procedures with OTSC. Further studies should distinguish the net efficacy of the OTSC system from other concomitant procedures in treatment of post-LSG leak.

**Efficacy and Safety of the Over-The-Scope Clip (OTSC) System in the Management of Leak and Fistula After Laparoscopic Sleeve Gastrectomy: A Systematic Review**


Obes Surg 2017 Sep;27(9):2410-2418.

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Ovesco Research Update | Research and clinical trials | Version 33 | 2019-12-20
August 2018 | Multicenter experience comparing simple suction and OTSC® Twin Grasper.
Kobayashi K and colleagues, Department of Gastroenterology and Neurology, Faculty of Medicine, Kagawa University, Kagawa, Japan performed a retrospective study examining 58 consecutive patients undergoing OTSC placement for gastrointestinal defect closure in 5 medical centers. The overall results of the technical success, clinical success, complications and procedure time were analysed as major outcomes. Subsequently, 56 patients, excluding 2 cases that used the Anchor device, were divided into two groups: 14 cases of simple suction (SS-group) and 42 cases using the OTSC® Twin Grasper. Secondary closure method was performed to clarify the performance of OTSC success. Overall clinical outcomes demonstrated efficacy and safety of the OTSC System and were as follows: technical success rate (TSR) 89.7 %, clinical success rate (CSR) 84.5 %, complications 1.8 %, and median procedure time 8 minutes (range 1-36 min).

Significant differences were observed between the two groups in terms of the mean procedure time (5.9 min vs 14.1 min). The clinical success rate of the SS- and TG-group were 83.3 % versus 95.2 % respectively. Complications and immediate or acute refractory bleeding was 100 %, which suggests that SS is a better method than TG in terms of time efficacy. The clinical success rate in the SS-group (78.6 %), despite the technical success of the SS method (100 %), tended to decrease due to delayed leakage compared to that in the TG group (TSR 88.1 %, CSR 88.1 %), indicating that the OTSC Twin Grasper may be desirable for leaks and fistulae with defects of the entire layer.

The authors concluded, that the OTSC System is a safe and effective therapeutic option for gastrointestinal defects. Individualization of the suction method based on particular clinical conditions may contribute to the improvement of OTSC success.

Outcomes of gastrointestinal defect closure with an over-the-scope clip system in a multicenter experience: An analysis of a successful suction method.
World J Gastroenterol 2017 Mar 7; 23(9): 1645-1656.

OTSC® Update 28
July 2018 | Closure of acute GI defects with OTSC® successful in more than 75 % of patients of an unselected cohort
Raihelt M and colleagues, Department of Medicine II, University Erlangen, Germany presented data from three tertiary referral centers with 24-h emergency endoscopy (Erlangen, Wuerzburg, Fuerth) on patients receiving OTSC placement for gastrointestinal defect closure in 5 medical centers. Unselected consecutive patients presenting with acute non-surgical perforations, postoperative anastomotic leaks or inadvertent postoperative perforations underwent attempted OTSC placement as primary closure method after interdisciplinary consensus. Their clinical data and intervention characteristics were evaluated in an intention to treat analysis during a 24-month period to assess closure rates, 30-day mortality, hospitalization and morbidity. In the study, 34 patients were included with 22 non-surgical perforations and 12 postoperative leaks or perforations. 5 GI defects were located in the oesophagus, 14 in the stomach, 4 in the duodenum, 2 in the jejunum, 1 in the ileum, 2 in the colon, and 6 in the rectum. Definitive closure of the defect and leak was achieved in 24 out of 34 patients (70.6 %). The closure rate among non-surgically caused perforations was 72.7 % and among acute postoperative GI wall defects 83.3 % in total. Successful closure of the GI wall defect resulted in a significantly shorter hospital stay (8 vs 22 days) compared to failure with OTSC closure, 6 of 8 patients (75 %) required immediate surgery. In the group with successful OTSC closure, morbidity rate was significantly higher (19/26 patients vs 4/8 patients in the group with OTSC failure; p = 0.005). Three deaths occurred in the group with successful OTSC closure due to morbidity, while one death in the OTSC failure group was related to a refractory perforation. Favourable indications and locations for a successful OTSC procedure were identified as PEG complications, and endoscopic or postoperative leaks of stomach, colon or rectum.

The authors concluded, that OTSC was effective for closure of acute GI wall defects in more than 75 % of patients in an unselected cohort.

Outcome, morbidity, hospitalization and 30-day mortality after closure of acute perforations and postoperative anastomotic leaks by the over-the-scope clip (OTSC) in an unselected cohort of patients.

July 2018 | Single center experience: OTSC® especially valuable in treating defects of the upper gastrointestinal tract
Mizrahi Y, Oryu M, AboEllail A, Kagawa, Japan performed a retrospective study examining 58 consecutive patients undergoing OTSC placement for gastrointestinal defect closure in 5 medical centers.

The authors concluded that the OTSC treatment is an effective and minimally invasive procedure with immediate high success rates with sustained clinical success at 30-day follow-up.

Establishment of Over-The-Scope-Clips (OTSC) in gastroenterology: a local endoscopic routine.

June 2018 | 100 % long-term success with OTSC® in acute GI defects, 73 % in chronic defects

June 2018 | Breaking news: Ovesco OTSC® Clip superior to standard hemostatic therapy in randomized-controlled trial
OTSC has long been described in the scientific literature as a highly effective device for the treatment of upper GI device at the institution, focusing on indications, anatomic site of OTSC deployment, complications, and immediate and 30-day success rates. Patient age ranged from 14 to 93 years with a median of 61 years. 51.5 % were male. Immediate success of OTSC treatment was observed in 87.1 % of all sessions (203/233). The success rates per indication were as follows: spontaneous bleeding 84.8 % (28/33); iatrogenic bleeding 100 % (20/20); acute perforation 90.3 % (65/72); prophylaxis for perforation 100 % (24/24); anastomotic leakage 61.1 % (11/18); fistulae 80.7 % (46/57); diameter reduction of the gastro-jejunal anastomosis 100 % (6/6); and stent fixation 100 % (3/3).

At 30-day follow-up, the overall success rate was 67.4 % (157/233). The success rates per indication were as follows: spontaneous bleeding 69.7 % (23/33); iatrogenic bleeding 90 % (18/20); acute perforation 88.1 % (62/72); prophylaxis for perforation 100 % (24/24); anastomotic leakage 33.3 % (6/18); fistula 29.8 % (17/57); diameter reduction of the gastro-jejunal anastomosis 83.3 % (5/6); and stent fixation 66 % (2/3).

The authors concluded that the treatment with an OTSC is simple and feasible in clinical routine, with high immediate success rates with sustained clinical success at 30-day follow-up.

Overall clinical outcomes demonstrated efficacy and safety of the OTSC System and were as follows: technical success rate (TSR) 89.7 %, clinical success rate (CSR) 84.5 %, complications 1.8 %, and median procedure time 8 minutes (range 1-36 min).

Increased success of OTSC® compared to simple suction in an unselected cohort of patients receiving OTSC for gastrointestinal defects.
Ikeda Y, Oryu M, AboEllail A, Mizrahi I, Eltawil R, Haim N, Chadi SA, Shen B, Erim T, Kagawa, Japan performed a retrospective study examining 58 consecutive patients undergoing OTSC placement for gastrointestinal defect closure in 5 medical centers.

The authors concluded that OTSC was effective for closure of acute GI wall defects in more than 75 % of patients in an unselected cohort.
hemorrhage. Now a randomized-controlled trial at 9 academic referral centers (in Germany, Switzerland, and Hong Kong) has proven OTSC to be superior to standard methods. The trial, published by Dr. Arthur Schmidt, Ludwigsburg, Germany, enrolled 86 patients with recurrent bleeding and randomized them to receive either OTSC treatment of Gastrointestinal bleeding (a combination of 2 methods from through the scope clipping, injection or electrical coagulation).

Persistent bleeding after per-proctor hemostasis was observed in 42.4% of patients in the standard therapy group and 6.0% in the OTSC group (P=0.01). Further bleeding occurred in 57.6% in the standard therapy group and 15.2% in the OTSC group (absolute difference, 42.4%; 95% CI 21.6-63.2; P=0.01).

Over the Scope Clips are More Effective Than Standard Endoscopic Therapy for Patients With Recurrent Bleeding of Peptic Ulcers.


1Department of Gastroenterology, Klinikum Ludwigsburg, Ludwigsburg, Germany. 2Department of Medicine II, Medical Center, Faculty of Medicine, University of Freiburg, Germany. 3Department of Gastroenterology, Klinikum Augsburg, Augsburg, Germany.

A double-blind, randomized, multicenter study to compare the efficiency of Over the Scope Clips (OTSC) and Endoclips (ECT) in the treatment of hemorrhagic peptic ulcers. The OTSC was superior to the ECT in terms of primary efficacy (bleeding cessation by the end of the procedure) in a 2:1 ratio (61.1% vs 40.2%) (P<0.001).

The authors conclude that OTSC with the colonic FTRD is suitable for surgical resection, submucosal lesions and the removal of gastrointestinal amyloidosis.

May 2018 | Single-center study confirms safety and efficacy of the FTRD® in the colorectum

Valli and colleagues, Division of Gastroenterology and Hepatology, Zurich University Hospital, Switzerland, reported on their data on the colonic FTRD® between June 2012 and October 2016. Full-thickness resection in the colorectum (52) and off-label use in the upper GI (8) were performed in 60 patients with the following indications: recurrent and primary non-fibrotic adenomas, combined polypoid neoplasms (EMR and EFR) in large polyps (non-lifting area), primary and re-resection of T1 tumors not suitable for surgical resection, submucosal lesions and adenomas at difficult locations (appendix base, diverticulum).

The overall technical success rate was 97% (58/60), the overall R0 and full-thickness resection rates were 79% and 88% respectively. Clinical success was shown to be even better (88%) based on follow-up histology. In median a procedure took 60 minutes with a mean resection size of 24 mm. The adenoma resection rate was 7%. One patient (2%) developed appendicitis after resection at the appendix base and needed surgical appendectomy. All other complications (mild bleeding, perforation due to accidental lack of clip deployment) were treated endoscopically. The data corresponds with the results of the Velit trial. The authors conclude that EFTR with the colonic FTRD is safe and feasible with respective prior training. It enables endoscopic resection of all gut layers with low risk of severe adverse events. EFTR with the FTRD shows also an alternative procedure to surgery for lesions that were previously not endoscopically resectable.

Safe and successful resection of difficult GI lesions using a novel single-step full-thickness resection device (FTRD).

Valli P.V., Mertens J., Bauerfeind P.


May 2018 | Conference Report

The 48th Congress of the German Society for Endoscopy and Imaging Procedures (DGE-BV) took place together with the learned societies of CAES, CATC, DEGEA, DEGUM, DGMBT, DDSG, OGHG and bgm on March 15 – 17, 2018 in Munich, Germany.

Ovesco products were presented in six workshops on two different topics (hemostasis techniques held by M. Mühlbeck, and S. Loefffer, respectively, and management of complications held by C. Hamperl and S. Loefffer, respectively). Additionally, several tables and posters discussed products of Ovesco.

FTRD® System

Diagnosis of amyloidosis with FTRD full-thickness rectal tissue sampling

A. Braun and H. Dawson.

Gastroenterology and Endoscopy, SFO Langenthal, Switzerland and Institute of Pathology, University of Bern, Switzerland, presented a study on amyloidosis diagnosis with FTRD. This is the first description of FTRD use in this indication. Amyloidosis is a heterogeneous group of diseases with accumulation of abnormal protein, known as amyloid fibrils, which build up in extracellular tissue, leading to manifold clinical problems. The GI tract is also affected. Diagnosis of amyloidosis with FTRD full-thickness resection in the rectum for gastrointestinal amyloidosis diagnosis. Between 2015 and 2017, full-thickness excision of rectal wall with the FTRD System was performed in 12 patients (5 female, median age 73 years (23-81)) with suspected amyloidosis. Sigmodoscopy was performed under light sedation in all patients. Biopsies were taken from the upper third of the rectum 18 cm ab ano. FTRD application and full-thickness resection was successful in all cases. Maximal procedure time was 60 minutes. No adverse events occurred and the clinical course was uneventful in all cases. Clear diagnosis was possible in all histological examinations. In 7 of the 12 patients (n=5, f=2) amyloid fibril accumulation was found in small submucosal vessels and in the muscularis propria layer, confirming the diagnosis of amyloidosis.

The authors conclude that FTRD application for diagnosis of gastrointestinal amyloidosis is a safe and very effective method and mitigates the diagnostic challenges that amyloidosis can pose.

Amyloidose-Diagnostik durch Full-Thickness Resection Device (FTRD).

Braun A, Langenthal and Dawson H, Bern.

Ovesco Research Update 33 | Research & clinical trials
appendicular cavity of the coecum. Histological examination yielded the diagnosis of a tubular adenoma without evidence of dysplasia. Submucosal injection and following resection by EMR was not successful due to the location of the polyp. A second attempt of resection by eFTR with the FTRD System was performed and succeeded. The resected specimen was sized 3x1x1 cm. Histological examination showed a partial appendix, at the appendical basis a 9 x 8 mm sized polyp with R0 resection status. The patient received peri-interventional antibiotic prophylaxis with Cefuroxim and Metronidazol. The post-interventional clinical course was uneventful, stepwise return to normal diet was tolerated without problems and the patient could be discharged after two days.

Erfolgreiche endoskopische Appendektomie mittels EFR.


OTSC® System

100 % hemostasis with OTSC reported for first-line emergency treatment of acute hemorrhage

A. Braun and S. Peter, SRO Langenthal, Switzerland, presented personal data on OTSC application for emergency treatment of acute hemorrhage. Between 2011 and 2017, 48 patients (29 female, median age 75.5 years (61-92)) each received one OTSC clip for first-line treatment of acute gastrointestinal hemorrhage. No adverse events occurred and the clinical course was uneventful in all cases. Maximal procedure time was 20 minutes. No relapse hemorrhage occurred. 26 patients (15 F, 9 F b) received follow-up examination day 1 to 4, which showed the clip in situ and no bleeding stigmata. The other 22 patients received no follow-up examination. The clinical course was uneventful in all cases.

The authors concluded that OTSC application for emergency hemorrhage is safe and very effective, and related to short procedural time.

Endoskopische Behandlung von akuten Blutungen mit einem over-the-scope clip (OTSC).


April 2018 | Diagnosis of amyloidosis with FTRD® full-thickness rectal tissue sampling

A. Braun and H. Dawson, Gastroenterology and Endoscopy, SRO Langenthal, Switzerland and Institute of Pathology, University of Bern, Switzerland, presented their study on amyloidosis diagnosis with the FTRD System at the 48th DGE-BV Conference (DGE-BV: German Society for Endoscopy and Imaging Procedures) in March 2018. This is the first description of FTRD use in this indication. Amyloidosis is a heterogeneous group of diseases with accumulation of abnormal protein, known as amyloid fibrils, which build up in interstitial tissue, leading to manifold clinical problems. The GI tract is also affected. Diagnosis of this disease is a diagnostic and clinical challenge.

The authors emphasize that deployment of the OTSC system while in 95/201 patients the t clip was simple yet very effective. The device was not only a rescue tool for hemostasis from a recurrent actively bleeding GDA pseudoaneurysm, but also for simultaneous perforation closure. The video can be viewed directly from the GIE website or by using the QR code below.

OTSC® System

February 2018 | OTSC® prevents rebounding in over 70 % of high-risk GI bleeding cases

J. Brandler and colleagues, Department of Internal Medicine, Mayo Clinic, Rochester, Minnesota, USA, performed a study on 67 patients with gastrointestinal hemorrhage. All patients had high-risk lesions who were treated with the OTSC System. The definition of high-risk lesions was lesions situated in the area of a major artery and larger than 2 mm in diameter and for a deep penetrating, encapsulated fibroptic ulcer with high-risk stigmata, in which perforation could not be ruled out or thermal therapy would cause perforation, or lesions that could not be treated by standard endoscopy (epinephrine injections, hemocigam, coagulation). Between 12/2011 and 02/2015, data from 67 patients with high-risk non-variceal gastrointestinal bleeding were collected. Of 49 received OTSCs as primary and 18 as rescue therapy, was prospectively collected and retrospectively analysed. Clinical severity was determined based on the Rockall score and a modified Blatchford score. Out of 67 patients, 47 (70.1 %) remained free of rebounding after OTSC placement. No difference was found in the proportion of patients with bleeding who received primary or rescue therapy (hazard ratio .639; 95 %C.I. 0.84 – 4.860; P=0.663). Only 9 rebounding events were linked clearly to OTSCs and required intervention, indicating an OTSC failure rate of 1.3%.

The authors concluded that OTSCs have a valuable role in managing and adverting high-risk radiologic or surgical interventions for non-variceal gastrointestinal bleeding, despite the presence of high risk of adverse outcome and severe diagnostic and therapeutic dilemmas.

Efficacy of Over-the-Scope Clips in Management of High-Risk Gastrointestinal Bleeding


November 2017 | 96 % hemostasis with OTSC® as first-line treatment in patients with gastrointestinal bleeding: an Italian multicentric study comprising 201 consecutive patients

Mangialfo S et al., Azienda Ospedaliero, University of Palermo, Italy, presented their study at the 25th UEG week (October 28 – November 1, 2017, Barcelona) data from 9 Italian tertiary referral centers comprising a large series of patients with non-variceal upper and lower gastrointestinal bleeding lesions in whom OTSC was used as first-line endoscopic therapy.

Over a period of three years (01/2014 - 01/2017), data on 201 consecutive patients (mean age 68 years, range 28-89 years), who underwent emergency endoscopy for severe acute nonvariceal gastrointestinal bleeding and were treated with OTSC as primary first-line therapy, was prospectively collected and analyzed. 100/201 patients were treated with the a version of the OTSC system while in 95/201 patients the t clip was applied.
preferred. Indications for OTSC treatment included duodenal-jejunal ulcer Forrest 1a (n=29) and Forrest 1b (n=35), gastric ulcer Forrest 1a (n=19) and Forrest 1b (n=28), Mallory Weiss (n=13), Deulafy’s lesion (n=9), post gastric-EED bleeding (n=14), post EMR bleeding (n=15), post ESD bleeding (n=12), traumatic rectal ulcer (n=2), colonic diverticulum (n=4), and surgical anastomosis bleeding (n=15).

Technical success was achieved in all cases (100%). Primary hemostasis was achieved in 193/201 patients (96%). In the remaining 8 patients hemostasis was obtained with angiographical vascular embolization (n=5) or surgery (n=3).

Early rebleeding (within the first 24 hours) occurred in 9/201 patients (4 %) and it was treated with epinephrine injection with or without use of the scope clips or radiological vascular embolization. No late rebleeding was observed in the series.

The authors concluded that the use of OTSC as first-line therapy in acute high-risk gastrointestinal bleeding is safe and highly effective.

High efficacy of OTSC as first-line endoscopic treatment in patients with gastrointestinal bleeding: an italian multicentric experience in a large cohort of patients.


November 2017 | Recommendation for OTSC® as first-line therapy in non-variceal upper gastrointestinal bleeding

Chan SM and Lau JYW, Prince of Wales Hospital, The Chinese University of Hong Kong, Hong Kong, China, published an editorial in Endoscopy International Open on the question: “Can we recommend OTSC as first-line therapy in case of non-variceal upper gastrointestinal bleeding?”

The authors explicate that 8 to 15 % of patients with non-variceal upper GI bleeding (NVUGIB) continue to bleed after endoscopic hemostasis and acid suppression therapy. Further bleeding remains one of the most important predictors of mortality. These facts make research on methods to improve endoscopic hemostasis so important. The authors list several limitations to conventional hemostatic methods such as the impossibility to consistently seal larger vessels with thromboagulation, the difficulty of tangential application of hemostatic clips, the frequent dislodgement of the clips and the difficulty of clip application in bile ducts with a fiberoptic scope. The authors argue that the Over-the-Scope-Clip, with a wider jaw and greater strength, has the advantages of a firm grip over a larger amount of tissue. Clip retention is almost universal. The editorial names the study from Wedi et al with 100 patients with NVUGIB and first-line OTSC management and a reported 94 % success rate for primary hemostasis. Besides, the study of Richter-Schrag et al is cited, including 100 patients with both NVUGIB and lower GI bleeding and showing similar results.

However, the paper also names problems that can lower the success rates of OTSC hemostasis, namely tangential application or OTSC deployment with scope in retroflexion (when ulcers are located in the lesser curve or the posterior wall of the duodenal bulb). The text offers a solution to this problem: usage of a smaller OTSC and an anchoring device to puncture near the bleeding site to guide the OTSC. Second, pretreatment with adrenaline injection is recommended to improve visualization in case of actively bleeding ulcers. The authors narrate to eagerly await the publication of the first large series of OTSC in patients with hemorrhagic instability, coromobious illness, with active bleeding ulcers, large ulcers and ulcers at posterior duodenum and lesser curve. The authors speculate that the added cost in managing further bleeding after standard treatment likely outweighs the cost of OTSC. Can we now recommend OTSC as first-line therapy in case of non-variceal upper gastrointestinal bleeding? Chan SM, Lau JYW

Endoscopy International Open 2017; 05: E883–E885

September 2017 | Prospective multicenter study confirms efficacy and safety of the FTRD® device for difficult-to-resect colorectal lesions

Schmidt A, Beyna T, Schumacher B et al., affiliated to different German hospitals (Ludwigsburg, Freiburg, Dusseldorf, Essen, Ulm, Augsburg, Dortmund, Krefeld and Tuebingen) published a prospective multicenter study which evaluates efficacy and safety of the FTRD device for resection of colorectal difficult adenomas (non-lifting and/or at difficult locations), early cancers and subepithelial tumours (SET). Hitherto, small retrospective studies had shown feasibility of the EFTR technique in the before-mentioned indications.

In total, 113 patients were recruited. The overall technical success rate was 90.5 %, the overall R0 resection rate 76.9 %. In 127 patients with difficult adenomas and benign histology, R0 resection rate was 77.7 %. In 14 cases, lesions harboured unsuspected cancer, another 15 lesions were primarily known as cancers. Of these 26 cases, R0 resection was achieved in 72.4 %; 8 further cases had deep submucosal infiltration >1000 μm. Therefore, curative resection could only be achieved in 13/29 (44.6 %).

In the subgroup with SET (n=23), R0 resection rate was 87.0 %. In general, R0 resection was higher with lesions equal or smaller to 2 cm vs >2 cm (51.2 % vs 58.1 %, p=0.038). Adverse event rate was 9.9 % with a 2.2 % rate of emergency surgery. Three month follow-up was available from 154 cases and recurrent/residual tumour was evident in 5 cases. In summary, this first prospective multicenter study on the FTRD System demonstrates its efficacy for colorectal lesions that otherwise would have required more invasive techniques (mainly surgery), especially in lesions equal or smaller to 2 cm with acceptable complication rates. The authors state that the curative resection rate for early cancers was too low though to recommend its primary use in this indication for now. They state that further comparative studies will show the clinical value and the longterm outcome in such lesions.

Colonic neoplasms: high risk resection using an over-the-scope device: a prospective multicentre study in various indications


Gut 2017;1:1–10. doi:10.1136/gutjnl-2016-313677

July 2017 | Video case report: OTSC® hemostasis in patients with refractory bleeding due to chronic peptic ulcer

Xiao X and Lau JY, Department of Surgery, Chinese University of Hong Kong, Hong Kong, China, published an article on VideoGIE, the official video journal of the American Society of Gastrointestinal Endoscopy, showing OTSC treatment in two patients with refractory peptic ulcer bleeding.

The first patient was an 89-year-old woman admitted with fresh hematemesis and a haemoglobin of 4.8 g/dl. Endoscopy revealed bleeding from a 2-cm chronic bulbar ulcer. She was treated by angiographic embolization to her right gastroduodenal artery (GDA). Three days later, she again experienced massive bleeding. A pulsatile vessel at the ulcer base was treated with an OTSC clip induced. The cap was adjusted to encompass the vessel, and a trip string was pulled to deploy the OTSC. The patient was discharged 4 days later without further bleeding.

Patient two was a 76 year old man presenting with fresh melena and a haemoglobin of 7.5 g/dl. He reported a history of recurrent bleeding from a chronic gastric ulcer. Additionally, he had previously been on warfarin therapy for the treatment of deep vein thrombosis complicated by pulmonary embolism. Endoscopy revealed bleeding from a chronic ulcer at the antral incisura of the stomach. The first attempt to stop the bleeding with heaterprobe and hot saline failed. Then an OTSC anchor device was used to target the ulcer base and deploy an OTSC clip without suction. Complete hemostasis was achieved and the patient had an uneventful recovery.

The authors concluded that OTSC is useful in the treatment of chronic peptic ulcerations with refractory bleeding. The anchor device was rated a helpful tool, which allows accurate targeting of the bleeding artery.

October-over-the-scope clip treatment of refractory peptic ulcer bleeding

Yin XM, Lau JY (2016)


https://www.youtube.com/watch?v=66u_szN_Yqc&feature=youtu.be

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June 2017 | 80 % success in endoscopic closure of post-surgical gastrointestinal leaks


Gastroenterology 2015; 148 (1): 110-116

Eleven endoscopic series were compared to define the role of OTSC in the treatment of post-surgical gastrointestinal leaks in different locations and different levels of evidence. Without a doubt, OTSC in the hands of the best endoscopists could represent a valid therapeutic option in selected cases of persistent leaks. However, currently, the evidence is not sufficient to recommend OTSC as the primary therapy in the management of post-surgical gastrointestinal leaks.

Month 2017 | High-risk GI bleeding: primary hemostasis in first-line OTSC® treatment in 95 %

HJ Richter-Schrag and colleagues, Center of Interdisciplinary Gastrointestinal Endoscopy and Department of General and Visceral Surgery, University of Freiburg, Germany, performed a retrospective study evaluating rebleeding, primary failure and mortality of patients, in whom OTSCs were used as first-line and second-line endoscopic treatment (FLET, SLET) of upper gastrointestinal bleeding (GIB). All patients with upper and lower GIB who underwent FLET and SLET with OTSCs between 04/2012 and 05/2016 were included. In addition, patients with upper GIB were categorized by complete Rockall risk score, and the data
were used to calculate predictors of OTSC success and mortality. A total of 93 patients (58 males, median age 72, range 19-98) with altogether 100 severe acute GI blebs fulfilled the inclusion criteria. One patient had 3 OTSC applications, and five other patients had 2 OTSCs on different lesions. Finally, 39 patients were included (in treated in 51 cases), and second line OTSC treatment in 42 cases. The mean hospital stay was 19.8 d (range 1-79). Primary hemostasis was achieved in 85 % of cases (80/100). Clinical success (no in-hospital rebleeding) was achieved in 78 % of cases (78/100). Secondary failure was significantly lower when the OTSCs were applied as FLET compared to SLET (4.9 % vs 23 %, P= 0.0008). Patients with Rockall scores ≥ 4 had a significantly higher in-hospital mortality compared to those with scores < 7 (55% vs 10 %, P=0.034). No significant differences were observed in patients with scores < or ≥ 7 in rebleeding and rebleeding-associated mortality. The authors concluded that the reduction of primary failure in endoscopic treatment of severe acute gastrointestinal bleeding was best achieved when OTSC was used for first line treatment. In this series, first line OTSC treatment seemed to be a predictor of successful reduction of rebleeding rates.


December 2016 | Experience with the FTRD® System in Halle, Germany: FTRD® broadens endoscopic therapeutic spectrum and reduces surgery rate. The 23rd Congress of the Society for Internal Medicine in Sachsen-Anhalt (25. Jahrestagung der Gesellschaft für Innere Medizin Sachsen-Anhalt) took place on November 18-19, 2016 in Halle (Saale), Germany. Ohse C et al., hospital Martha-Maria Halle-Doelau, Germany, presented in a poster their experience with the FTRD device. This poster received the Poster Champ Award at the meeting. The FTRD System is used at the hospital since January 2015. Until October 2016, 31 endoscopic full-thickness resections with the FTRD in 30 patients were performed. For the first time, a lifting and clipping only (n=9), subepithelial tumor (n=7), adenoma at appendiceal orifice (n=1), adenoma at appendiceal orifice after Stapler-appendectomy (n=1), hybrid EMR-ETFR in large adenoma with non-lifting parts (n=2), follow-up resection of a cancer with lifting sign (n=1), EMR-ETFR in cancer (n=2), T1sm1 cancer (n=2), T1sm2 cancer (n=1), T1sm3 cancer (n=3), T2 cancer (n=2). The lesions were located in the rectum (n=10), sigmoidal colon (n=3), right flexure (n=2), transverse colon (n=3), right flexure (n=3), and cecum (n=6). The median size of the resected specimen was 19 mm (range 13-35 mm) Resection of the lesions with the FTRD succeeded in 100 % (31/31). En-bloc-R0-resection was achieved in 94 % (29/31). One patient (3.2 %) suffered a post-polypectomy syndrome after resection of an appendiceal orifice adenoma. Since the appendiceal orifice had a very small remnant complication could be managed conservatively. No other complications occurred. In 5 patients, correct oncological follow-up resection was undertaken due to the T-stage (3TxT1m3, 2Tx2). During 3-months follow-up, which could be concluded in 26 patients, a relapse adenoma cases was found in one patient and treated with a second EFR. The authors concluded that EFR with the FTRD System broadens the therapeutic spectrum of lesions in the lower gastrointestinal tract and helps to avoid surgery in selected patients.


November 2016 | Large single-center experience with 101 OTSC® applications in patients with severe hemorrhage, perforations and fistulas: 89 % overall primary clinical success Wedi E and colleagues, Strasbourg University Hospitals, Strasbourg, France and St. Bernward Academic Teaching Hospital, Hildesheim, Germany, and Ioahn School of Medicine, New York, United States, and Boston Children’s Hospital, Boston, United States, conducted a retrospective study to investigate efficacy and clinical outcome of patients treated with an OTSC clip for gastrointestinal (GI) emergencies and complications. From 02/2010 to 10/2012, 94 patients were treated with 101 OTSC clips. 41 patients (48.8 %) presented with severe upper-GI bleeding, 3 (3.6 %) patients with lower-GI bleeding, 7 patients (8.3 %) underwent perforation closure, 18 patients (21.4 %) had prevention of secondary perforation, 12 patients (14.3 %) had control of secondary bleeding after endoscopic clipping, and five other patients had 2 OTSCs on different lesions. The clinical success in 35/41 (85.36 %) patients with upper GI bleeding and in 3/3 patients with lower GI bleeding. Technical success of perforation closure was 100 % while clinical success was seen in 4/7 cases (57.14 %) due to attendant circumstances unrelated to the OTSC. Technical and clinical success was achieved in 18/18 (100 %) patients for the prevention of bleeding or perforation after endoscopic mucosal resection and in 5/5 cases (100 %) patients with upper GI bleeding and in 3/3 patients with lower GI bleeding. The authors concluded that the reduction of primary failure in endoscopic treatment of severe acute gastrointestinal bleeding was best achieved when OTSC was used for first line treatment. In this series, first line OTSC treatment seemed to be a predictor of successful reduction of rebleeding rates.


October 2016 | New patient series with the FTRD® System in Switzerland: EFTFR efficacious and safe The annual congress of the Swiss Society for Gastroenterology (SSG) this year took place in Interlaken, Switzerland on September 22-23, 2016. Clinical experience with the FTRD System in two tertiary referral centers in Switzerland was presented by P. Aspi and colleagues, canton hospitals of Luzerne and St. Gallen, Switzerland. Nineteen consecutive patients with colorectal polyps were treated with the FTRD during a one-year period (05/15 - 05/16). Thirteen procedures were performed in the colon and 6 in the rectum. Indications were adenoma recurrence or residual adenoma with non-lifting sign after previous polypectomy or the presence of an appendiceal orifice polyp. Management of the appendiceal orifice complication could be managed conservatively. No other complications occurred. In 5 patients, correct oncological follow-up resection was undertaken due to the T-stage (3TxT1m3, 2Tx2). During 3-months follow-up, which could be concluded in 26 patients, a relapse adenoma cases was found in one patient and treated with a second EFR. The authors concluded that EFR with the FTRD System broadens the therapeutic spectrum of lesions in the lower gastrointestinal tract and helps to avoid surgery in selected patients.

September 2016 | Endoscopic full-thickness resection of gastric submucosal tumors: Use of OTSC® significantly associated with shorter hospital stays Yang F et al., Endoscopic Center, Shengjing Hospital of China Medical University, Shenyang, China, conducted a retrospective cohort study to identify factors that impact the procedure and treatment outcomes for endoscopic full-thickness resection (EFTFR) of gastric submucosal tumors (SMTs). Gastric SMTs include gastrointestinal stromal tumors (GISTs), leiomyomas, schwannomas, malignant lymphomas, lipomas, carcinoids, lymphangiomias, and hemangiomas. They are usually detected incidentally during upper gastrointestinal endoscopy, and have an estimated prevalence of 0.4%. Further, the medical records of all patients with gastric SMTs who underwent EFTFR procedures in Shengjing Hospital between June 2012 and April 2014 were reviewed. EFTFR procedures had been performed as follows: the
tumor was completely removed endoscopically, including surrounding mucosa, muscularis propria, and serosa, without injury to the tumor capsule. The post-resection gastric defect was closed immediately using metallic clips or an OTSC system.

In total, 41 patients (13 males and 28 females, mean age 53.3 ± 14.2 years; 17 patients were reoperated). All patients underwent endoscopic ultrasound (EUS) before EFTR, the mean tumor size based on EUS was 16.3 ± 5.9 mm. Of the 41 SMTs, 1 was located in the anterior wall of the antrum, 2 in the greater curvature of the antrum, 6 in the anterior wall of the corpus, 8 in the greater curvature of the corpus, 3 in the lesser curvature of the corpus, 9 in the posterior wall of the corpus and 13 in the fundus of the stomach. EFTR of the gastric SMTs was successfully performed in all 41 patients. The final pathologic analyses revealed R0 Resection in all cases. An OTSC system was used in 6 patients, metal clips were used in 35 patients. Maximum tumor size on EUS and tumor location in the greater curvature were significantly associated with the length of the procedure (P=0.000 and P=0.026, respectively). A pneumoperitoneum occurred in 26 patients during EFTR. There were no cases of bleeding, perforation, or other postoperative complications. A pneumoperitoneum was more likely to occur during EFTR in tumors with a larger EUS size (P=0.017). The use of the OTSC system was significantly associated with shorter hospital stays (P=0.048) and less time for surgery (P=0.001). The authors conclude that endoscopic full-thickness resection is an effective and safe treatment for patients with gastric submucosal tumors.

Factors associated with endoscopic full-thickness resection of gastric submucosal tumors


August 2016 | Post-ESD duodenal ulcer closure with OTSC® vs conventional clips: Significantly less adverse events and shorter closure times with OTSC®

Mori H and colleagues, Departments of Gastroenterology and Neurology, Faculty of Medicine, Kagawa University, Japan, compared in a retrospective study safety of closure methods, closure times and medical costs between two groups of patients who had post-endoscopic resection (ER) artificial ulcers in the duodenum.

Nineteen patients with duodenal adenoma, early duodenal cancer, and subepithelial tumors underwent resection of the lesion by endoscopic submucosal dissection (ESD) between 2009 and 2014. Ulcer floor closure was achieved either by conventional clips (in 12 patients) or over-the-scope clip (OTSC® in 7 patients). The closure method was selected at the discretion of each operator (i.e. three endoscopists, each having performed > 100 cases of gastric ESD).

Delayed bleeding was observed in three patients from the conventional clip group, in the OTSC group no delayed bleeding occurred (p=0.049). No perforations were observed in either group. The mean procedure time for ulcer closure was 33.26 ± 2.57 min with conventional clips and 9.71 ± 2.92 min with OTSC clips (p=0.0001). The resection diameters were 18.8 ± 1.30 mm and 22.9 ± 1.21 mm in the conventional clip group and the OTSC group, respectively (p=0.039).

In conclusion, the authors state that if the post-endoscopic resection ulcer is over 20 mm, the OTSC closure should be selected with regard to safety and reliable closure.

Suitable closure for post-duodenal endoscopic resection taking medical costs into consideration

World J Gastroenterol 2015; 21 (17): 5281-5286. ISSN 1007-3736 (print) ISSN 2215-2240 (online)

August 2016 | OTSC® safe and effective for closure of gastric access in NOTES appendectomy and other procedures

In NOTES (natural orifice transluminal endoscopic surgery), surgical procedures in the abdominal cavity are performed through a natural oriﬁce in order to avoid abdominal incisions. Only patients with refractory anal fistulae were included, in which alternative surgical approaches had failed or were not feasible any more, e.g. due to scarring. By this policy, only the most problematic and refractory anal fistulae were selected.

Between 2010/12 and 06/2014, five male and female patients, with a median age of 41 years (range 26-69 years) met the inclusion criteria. The etiology of the fistula was cryptoglandular in four patients, and perianal Crohn’s disease in six patients (including one patient with an anovaginal fistula).

The surgical procedure was technically successful in all patients. There were no intraoperative or postoperative complications. Permanent fistula closure was achieved in seven out of ten patients (70%) within a median time of 72 days (range 3-106 days). Median total follow-up time was 86 months (range 18-144 months). There were three failures (30%), including two cryptoglandular and one Crohn’s disease-associated fistula. In all three cases, the OTSC was lost spontaneously on days 22, 23, and 40, respectively, and persistence of the fistula was diagnosed thereafter. In three of the seven patients with successful closure, the OTSC was removed after complete healing of the fistula, because of slight anal discomfort or soiling. These symptoms disappeared completely after clip removal. There was no postoperative incontinence.

The authors conclude that the OTSC Proctology system is a safe and effective method for the closure of even complex and recurrent fistulae. It will compete with established surgical procedures in the management of transperineal or suprasphincteric fistulae.

OTSC® proctology clip system for the closure of refractory anal fistulas


June 2016 | OTSC® vs. cSEMS for intestinal leakage: clamping associated with significantly higher clinical success rates

A retrospective study comparing over-the-scope clips (OTSC) and covered self-expanding metal stents (cSEMS) for upper gastrointestinal perforation or leakage was conducted by Prof. Dr. med. H. Famik, university hospital Frankfurt am Main, and colleagues in four German tertiary endoscopic centers (Frankfurt, Tübingen, Jena, Dortmund).

Technical success, outcome (e.g. duration of hospitalization, in-hospital mortality), and complications were assessed and analyzed with respect to etiology, size and location of leakage.

Between 2006 and 2013, overall 106 patients underwent endoscopic treatment for postoperative leakage, endoscopic perforation or spontaneous rupture of the upper gastrointestinal tract. Of these, 72 (69%) were treated by over-the-scope clips (OTSC) and covered self-expanding metal stents (cSEMS). OTSC was preferred in small-sized lesions and in perforation caused by endoscopic interventions, cSEMS in patients with concomitant local infection or abscess. For cSEMS vs. OTSC, mean treatment duration was 41.3 ± 26.0 days (range 0-149 days) vs. 39.7 ± 21.7 days (range 3-144 days), respectively.

Clinical success for primary interventional treatment was observed in 29/72 (40.3%) vs. 29/44 (65.9%) for OTSC vs. cSEMS (p = 0.034).

In conclusion, cSEMS and OTSC are rather complementary means than to be mutually exchangeable. The authors suggest, that due to its low complication profile and high

July 2016 | OTSC® Proctology: 70% closure rate in recurrent complex anal fistulae in retrospective analysis

R. Magenhan, et al., Department of General and Visceral Surgery, University Hospital Muenster, Germany, conducted a retrospective study to evaluate the efficacy of the OTSC Proctology in patients with multiple previous fistula operations, Crohn’s disease, or anovaginal fistulae.

Only patients with refractory anal fistulae were included, in which alternative surgical approaches had failed or were not feasible any more, e.g. due to scarring. By this policy, only the most problematic and refractory anal fistulae were selected.

Between 2010/12 and 06/2014, five male and female patients, with a median age of 41 years (range 26-69 years) met the inclusion criteria. The etiology of the fistula was cryptoglandular in four patients, and perianal Crohn’s disease in six patients (including one patient with an anovaginal fistula).

The surgical procedure was technically successful in all patients. There were no intraoperative or postoperative complications. Permanent fistula closure was achieved in seven out of ten patients (70%) within a median time of 72 days (range 3-106 days). Median total follow-up time was 86 months (range 18-144 months). There were three failures (30%), including two cryptoglandular and one Crohn’s disease-associated fistula. In all three cases, the OTSC was lost spontaneously on days 22, 23, and 40, respectively, and persistence of the fistula was diagnosed thereafter. In three of the seven patients with successful closure, the OTSC was removed after complete healing of the fistula, because of slight anal discomfort or soiling. These symptoms disappeared completely after clip removal. There was no postoperative incontinence.

The authors conclude that the OTSC Proctology system is a safe and effective method for the closure of even complex and recurrent fistulae. It will compete with established surgical procedures in the management of transperineal or suprasphincteric fistulae.

OTSC® proctology clip system for the closure of refractory anal fistulas

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In conclusion, cSEMS and OTSC are rather complementary means than to be mutually exchangeable. The authors suggest, that due to its low complication profile and high

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effectively rates, the OTSC should be the first choice in all cases when it is technically feasible and the diameter of the lesion is not too large. In patients with larger defects and already infection accompanying the leak, cSEMS placement might be preferred.

Indication for ‘Over the Scope’ (OTS)-Clip vs. Covered Self-Expanding Metal Stent (cSEMS) is Unequal in Upper Gastrointestinal Leakage: Results from a Retrospective Head-to-Head Comparison


May 2016 | 100 % defect closure rates with OTSC® after EFTR of gastric tumors and no complications

Guo J and colleagues, Shengjing Hospital of China Medical University, Shenyang, China, reported on their experience of defect closure with OTSC after endoscopic full-thickness resection (EFTR) of gastric subepithelial tumors. Between October 2013 and March 2014, 23 patients underwent EFTR of a gastric subepithelial tumor ≤ 2cm originating in the muscularis propria by full-thickness transaction of the gastric wall. Defect closure was achieved by tissue approximation with an OTSC clip. Endoscopic follow-up was performed at 1 week, 1 month and 6 months after operation to check OTSC closure. The full-thickness resection rate was 100 % (23/23), the success rate of defect closure was also 100 % (23/23), and the average time of defect closure was 4.9 min (range 2-12 min). No post-operative complications such as bleeding and perforation were seen, and no premature OTSC detachment was found. The authors conclude that OTSC placement is a simple, convenient, safe and effective way of defect closure after EFTR of gastric subepithelial tumors.

Endoscopic full-thickness resection with defect closure using an over-the-scope clip for gastric subepithelial tumors originating from the muscularis propria


April 2016 | Technical success rates and long-term clinical outcomes of fistula closure with OTSC®

Dr. S. Irani, Digestive Disease Institute, Virginia Mason Medical Center, Seattle, WA, USA and Dr. T.H. Baron, Division of Gastroenterology and Hepatology, University of North Carolina at Chapel Hill, NC, USA investigated long-term clinical outcomes of fistula closure with OTSC.

The authors note that most of the literature focuses on short-term success, so they conducted a two-center, review of all patients at Mayo Clinic, Rochester and Virginia Mason Medical Center, Seattle, WA. This prospective study included 17 patients with OTSC for closure of chronic fistulas from October 2011 to September 2012. The retrospective study includes 47 unique patients (24 men, 23 women) at a mean age of 57 years. Fistula locations were the small bowel (18), stomach (16), colon (10) and esophagus (3). Previous percutaneous endoscopy gastrostomy/ejunostomy and prior bariatric surgery were the cause of these fistulas in 10 cases respectively. Patients were treated with the gastric (gastrotomy) OTSC clip for gastric indications and (tracheal) clips for tracheo-oesophageal peristaltic events. The prospective, multicentric CLIPPER - study comprises 36 patients with gastrointestinal perforations < 30 mm. Technical and clinical success rates reached 92 and 89 %, respectively. A systematic review conducted by Welland et al. in 2013 reports on a technical success rate of 83-100 % and a clinical success rate of 60-100 %. Authors of recently published retrospective multicentre studies with 106 and 48 patients report similar results. Based on the named results the occlusion with OTSC-clips in stomach and colon found entry into the recommendations of the current technology paper of the European Society of Gastrointestinal Endoscopy (ESGE).

The endoscopic treatment of iatrogenic gastrointestinal perforation


March 2016 | Use of OTSC® is safe and efficient in endoscopic full-thickness-resection in the upper and lower digestive tract

Use of OTSC system is safe and efficient in endoscopic full-thickness-resection in the upper and lower digestive tract

Fähnrich M, Schindhelm M and Sandmann M, Department of Gastroenterology, Klinikum Dortmund, report about a study to evaluate the efficacy and safety of the over-the-scope-clip (OTSC) system for endoscopic full-thickness-resection (EFTR) of endoluminal gastrointestinal tumours. The retrospective, observational, open-label, single-arm, consecutive case study from May 2010 to May 2014 included 17 patients (8 men and 9 women with a median age of 57.65 years). Six patients suffered from carcinoids, located in stomach, duodenum or rectum, seven patients had tubo-ovarian lesions and five patients underwent endoscopic polyectomy with low risk for colorectal cancer of the colon, three from adenoma relapses in the colon and one patient from a submucosal lesion of the stomach. The mean diameter of the lesions was 22.7 mm with a range of 10 - 25 mm. The prospective study included 14 patients (May 2012 - April 2016). In 16 cases, a combination of the OTSC System and the Inoue Cap for EFTR was used and in one case a new, dedicated full-thickness resection device (FTRD). All cases were performed using OTSCs (12 | 8rg or 14/6g) or FTRD device.

The application of the clips was successful in 16/17 cases, only in one case the clip did not deploy correctly. An endoscopic successful resection was accomplished in all remaining patients (16/16, 100 %).

In a final study, a full-thickness resection was achieved in 69 % (11/16) and a deep muscle margin of resected specimen (OMR) was accomplished in the remaining 31 % (5/16). Also a Complete resection (RO) was achieved in all patients.

The authors discuss that the OTSC System is safe and feasible for EFTR and dDMR of gastrointestinal lesions up to 25 mm in diameter. In their opinion the technique does not replace existing methods but may become a useful addition of the interventional endoscopy and an effective and valid alternative to surgical resection. As another advantage of OTSC, the article describes that the dynamic clip does not induce strangulation necrosis (like endoloops may do).

The report concludes that the use of the over-the-scope clip system in endoscopic full-thickness-resection is a safe and effective addition for patients and endoscopists. Endoscopic full-thickness resection for gastrointestinal lesions using the over-the-scope clip system: a case series


February 2016 | Complete closure of artifical gastric ulcer after endoscopic submucosal dissection by combined use of a single over-the-scope-clip and through the scope clips

Maekawa S, Nomura R, Murase T, Nakamura, Y and Harada M from the Department of Gastroenterological Medicine, Faculty of Medicine, School of Medicine, Juntendo University, Tokyo, Japan, reported about a prospective study to evaluate the combined use of a single OTSC and multiple TTSCs in closure of artificial gastric ulcer after ESD. From June 2013 to March 2014 nine patients were included with early gastric cancer and three patients with gastric adenoma with a mean age of 71.8 ± 12 years. The tumors were 3 cm or less in diameter and did not involve the cardiac or pyloric region. Mean size of the artificial ulcer after ESD was 54.6 mm. The average operating time of post-ESD artificial gastric ulcer was 15.1 minutes. 1 OTSC and a mean of 5.8 TTSCs were used per patient.

The success rate of complete defect closure was 91.7 % (11/12). No complications like delayed perforation, postoperative bleeding or gastric stenosis occurred. The OTSC dropout rate was 0 % on the day following ESD and 3 months later.

The authors argue that ESD-associated complications are common in the treatment of gastrointestinal tract tumors. Studies have shown that postoperative bleeding occurs in 6-16 % of patients after gastric ESD. Maekawa et al. see an advantage of the OTSC system at this point. Besides the closure of fistulas, perforation sites, leaks and severe bleeding of the GI tract the OTSC could improve therapeutic options in endoscopy. Often it has been difficult to close large artificial ulcers only with TTSCs. But the combined use of a single OTSC with its closure power and easy handling showed excellent results in this study. The new closure technique allowed the authors to discharge their patients
from hospital after only 2 days instead of the traditional 5-7 days.

In conclusion, Maekawa and colleagues consider this new closure method of artificial gastric ulcers after ESD safe and feasible. It is useful for shortening the period of hospitalization and reducing treatment cost compared to traditional treatments for bleeding ulcers.

Complete closure of artificial gastric ulcer after endoscopic submucosal dissection by combined use of a single over-the-scope clip and through the scope clips


February 2016 | OTSC® as successful last resort before surgery for challenging bleeding lesions

Endoscopy, the official blog of “GIE: Gastrointestinal Endoscopy” recently published a video on OTSC use by Dr. James Y. W. Lau. The video, called “Over-the-scope clip treatment of refractory peptic ulcer bleeding”, presented two cases in which OTSC was used to treat chronic peptic ulcerations with refractory bleeding after failed angiographic embolization and endoscopic treatment. Dr. Lau concluded that, “Endoscopists should consider the use of OTSC when tackling challenging bleeding lesions especially when other standard treatments have failed and certainly before referring your patients to surgery.”

February 2016 | Use of Over-The-Scope Clip for treatment of refractory upper gastrointestinal bleeding: high technical and clinical success rates reported

Chan SM, Chiu PWY, Tech YB and Lau JYW from the Department of Surgery, Institute of Digestive Disease, Prince of Wales Hospital, Chinese University of Hong Kong, China, reported about a prospective case series to evaluate the safety and efficacy of the Over-The-Scope Clip in patients with refractory GI bleeding. The case series included nine patients (5 men, 4 women) with a median age of 72.5 years (range 39 - 91 years), suffering from bleeding gastric ulcers (n=2), bleeding duodenal ulcers (n=5), bleeding gastrointestinal stromal tumor in the stomach (n=1), and bleeding from ulcerative carcinoma of the pancreas (n=1). Median diameter of the ulcers was 2.5 cm (1-4 cm). Six of the nine patients underwent previous endoscopic hemostasis attempts. A total of 10 OTSCs were applied in the nine patients. The technical success rate of OTSC was 100% (10/10). Endoscopic hemostasis was achieved in all patients. No local complications occurred. The clinical effectiveness was 77.8% (7/9), while two patients with specific conditions developed rebleeding after OTSC application due to chronically fibrotic ulcers because of residual tumor infiltration and previous radiotherapy.

Chan and colleagues discuss that in 8/10 patients, the bleeding was located in difficult positions, where application of conventional clips would have been complicated as the endoscopic approach to the ulcer would have been at a steep angle. The OTSCs allowed a larger amount of tissue to be captured for compression compared to common clips while avoiding the possibility of thermal injury with its high risk of perforation, as can happen with thermal hemostasis methods.


January 2016 | OTSC® as successful treatment of massively bleeding jejunal varix, which had resisted previous interventions

S Kothari, T Kothari and V Kaul of the Center for Advanced Therapeutic Endoscopy, Division of Gastroenterology and Hepatology at the University of Rochester/Strong Memorial Hospital in Rochester, NY, USA presented a case of successful treatment of massive gastrointestinal bleeding from a jejunal varix with OTSC after several other treatment options had failed. The 67-year old male patient had a medical history of hypertension disease, chronic renal insufficiency and Laennec’s cirrhosis before he was admitted for a laparoscopic left radical nephrectomy for renal cell carcinoma. Afterwards, the patient suffered from several complications, including superior mesenteric vein thrombosis, portal hypertensive drop in hematocrit and clinical signs of bleeding, which led to identification and unsuccessful treatment of several possible bleeding sites. The patient underwent anticoagulation, a tagged red blood cell scan, angiography, coil-embolization, repeat mesenteric angiography and repeat (push) endoscopy. The patient also received a total of 38 units of packed red cells, 13 units of thawed plasma, 9 units of fresh frozen plasma, 3 units of platelets and 2 units of cryoprecipitate. Due to multiple comorbidities, he was deemed as a high-risk patient unfit for surgery.

Finally, a tortuous, varix-like, prominent blood vessel with a central small ulceration, bleeding actively, was identified in the proximal jejunum. Ethanolamine injection into the varix did not achieve hemostasis. Finally, a size 12/6t OTSC clip was applied over the actively bleeding jejunal varix using a pediatric colonoscope. The clip was successfully deployed and complete hemostasis was achieved with this single clip. No additional transfusions were required and his hematocrit stabilized over the next few days. Due to his overall poor prognosis and multiple comorbidities, the patient’s family opted for “comfort care” which meant that he died four days later.

The authors emphasize the fact that they were able to quickly and effectively treat a massively bleeding jejunal varix, which had resisted multiple evaluations and courses of treatment. They deem the OTSC device a major advance in the endoscopic management of high-risk patients in a variety of challenging clinical settings, especially in case of poor candidates for surgical intervention. They also note that endoscopic perforation management with the OTSC clip may avoid the cost and ordbility of surgery and other interventions. Statement by Ovesco Endoscopy: the treatment of jejunal varix hemorrhage is not a common indication for the use of OTSC and there is limited experience with such application.

January 2016 | Novel remOVE DC ClipCutter for endoscopic removal of OTSC®: a retrospective case series


November 2015 | Promising case series on novel OTSC® removal device

Bonnin MA, Verra M, Salahi A, Bullano A, Rapetti L, Areszo A and Morino M (2014) 20th National Congress of Digestive Diseases, Napoli, Italy, March 19th-22nd 2014, about a prospective study including 26 patients treated with OTSC for postvascular and fistulas of the colorectum. Anastomotic leakage is a feared and serious complication in colorectal surgery associated with increased morbidity and mortality. The prevalence in literature ranges from 1 to 39 %, whereas clinically relevant leukomas commonly occur in 3-6 %.

Out of 26 consecutive patients treated with OTSC in this study, 10 patients suffered from acute and 16 patients from chronic fistulas (fistulas in situ). The OTSC series included 15 mm. 14 cases were complicated by recto-vaginal, recto-vesical or colo-cutaneous fistulae. In 3 cases OTSC was used to complete endoscopic vacuum-assisted closure of large defects.

The overall success rate was 77 % (20/26); 90 % (9/10) in acute and 69 % (11/16) in chronic cases. No OTSC-related complications occurred in the study. Further surgery was required in two cases.

The authors conclude that the endoscopic OTSC closure of colorectal postvascular leaks is a safe technique with high success rate in acute and chronic cases, including the treatment of fistulas.

Efficacy of the Over-the-Scope Clip (OTSC) for treatment of colorectal peristomal and fistulas.


November 2015 | Promising case series on novel OTSC® removal device


December 2015 | OTSC® is a safe and efficient technique in treatment of colorectal postvascular posttests and fistulas

Bonin MA, Verra M, Salahi A, Bullano A, Rapetti L, Arrezò A and Morino M, Department of Surgical Sciences, University of Turin, Italy, reported at the 20th National Congress of Digestive Diseases in Napoli, Italy, March 19th-22nd 2014, about a prospective study including 26 patients treated with OTSC for postvascular and fistulas of the colorectum. Anastomotic leakage is a feared and serious complication in colorectal surgery associated with increased morbidity and mortality. The prevalence in literature ranges from 1 to 39 %, whereas clinically relevant leukomas commonly occur in 3-6 %.

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The authors conclude that the endoscopic OTSC closure of colorectal postvascular leaks is a safe technique with high success rate in acute and chronic cases, including the treatment of fistulas.
of tissue grasped. Since OTSC clips are fully biocompatible, they may stay in place indefinitely. However, there are a few situations which call for active removal. In these situations, clinicians have to rely on techniques that lack proof of safety and efficacy. In the case series, the prototype of a specifically developed bipolar cut-on-tissue cap was used. A total of 11 patients (male: 7, female: 4) between 43 and 73 (median age: 62) were treated with the device under the “compassionate use” statute. Average procedure time was 47 minutes (range: 35-75 minutes) and cutting of the clip was successful in all cases (100% success rate). Fragments were removed successfully in all but one case (91%), where a fragment was deeply grown into the duodenal wall. In a follow-up after 3 months, this fragment had not caused any complications. Indications for clip removal included intermittent epigastric/abdominal pain, need for a repeat biopsy at the resection site and patients wishes. The cutting device consists of a grasper connected to a generator. Two electrodes in the grasper tips conduct a direct current impulse, which heats up the clip and thermally cuts the tissue material. The current has a maximum strength of 140 amps and maximum duration of 100 milliseconds. After successful cutting, the device stops automatically, and there is no relevant current pathway through the patient’s tissue.

During the procedures, the clip was grasped at its thinnest visible part and cut by applying 1 to 4 direct current impulses. Then the clip was cut again at the opposite site, creating two clip fragments, which were then removed from the tissue with standard forceps. To avoid tissue damage during extraction of sharp fragments, a soft clear plastic cap was used (prototype accessory, courtesy of Ovesco). After removal of all fragments, the OTSC site was inspected for bleeding or perforation. Minor bleeding was observed in two patients and treated immediately. One patient had a suppurative bleed with minor bleeding in the lesser curvature, caused by fragment removal without the use of a cap. In all subsequent patients, the cap was used for fragment extraction.

The authors stress that the removal of an OTSC clip is only necessary in a minority of cases. Even if it does not fall off on its own, the clip is designed as a durable implant. The few indications for endoscopic clip removal include wrongly placed clips, accidental clipping of the retraction device to the tissue, local complications due to the clip (e.g. luminal obstruction, minor ulcerations), scheduled removal of fragments fixed with an OTSC, and the need for a repeat biopsy of the OTSC site. Additionally, patients may insist that symptoms are caused by the clip’s presence. According to the group, recommended removal times have yet to be established. However, they assume that for repeat biopsies performed within 3 months, while for example for stent removal they favor 6-8 weeks. Longer periods of time are correlated with deep ingrowth into the intestinal wall, which impedes removal. They also caution that clips placed for perforation closure may not be removed too early to prevent re-perforation. In the case series, clips had been placed at least 4 weeks prior, while the clip in-situ for the longest time (15 months) was difficult to remove and had the longest procedure time (75 minutes).

Overall, the authors see the new device for OTSC clip removal as an indispensable addition to the clinician’s repertoire since it proved safe and effective in all treated patients. Endoscopic removal of over-the-scope clips using a novel cutting device: a retrospective case series. Schirmer A, Rehder B, Damvroullari, Caluwyk O, Bauder M, Casca M. Endoscopy. 2014 Sep;46(9):762-6. doi: 10.1055/s-0034-1365493. 182

September 2015 | OTSC® as effective treatment of GI fistulae: absence drainage increases healing rates to 88 %
Dr. T. Atzmüller, Dr. J. M. Kossakowski, Dr. E. A. Bonin, Dr. D. Emungania, Dr. J. Brunet, Dr. J.-C. Giraud, and Dr. M. Barthet of the Departments of Gastroenterology and Digestive Surgery, North Hospital, Mediterannée University, Marseille, France, presented the results of a retrospective study in two teaching hospital centers. The study encompassed 30 patients (12 male, 18 female) of 23 to 75 years of age (mean age: 48) suffering from GI fistulae (upper GI: 24; lower GI: 6). 60 % of fistulae (18 patients) occurred after laparoscopic sleeve gastrectomy (LSG), the other 40% of fistulae resulted from fistula at mixing or draining locations (rectovaginal, ureterorectal, rectovesical, gastrogastric, gastrocuteaneous, esophagojejunal fistulae and one colorectal anastomotic leak). Fistula orifice sizes ranged from 3 mm to 20 mm (mean: 7.2 mm) and mean time between treatment and OTSC placement was 12.4 months (8 days to 10 years). 18 patients (60 %) had previously undergone endoscopic or surgical treatment attempts of their fistula in another center. The OTSC clip was placed successfully in all cases, and 16 patients (89 %) had not caused any complications. Indications for fistula removal as an indispensable addition to the clinician’s repertoire since it proved successful in cases of treatment method, due to insufficient circulation in scarred and calloused tissue, remain a challenge, even with OTSC. Caution is also in order when closing no longer fresh postoperative leakage or other indications since these may require sufficient external drainage.

Klinische Erfahrungen mit dem Over-the-Scope Clip (OTSC)
Wolfgang E. Hochberger (2014)
Endo-Praxis. 2014, 30, 14.
dx.doi.org/10.1055/s-0034-1370894 179

June 2015 | Prophylactic OTSC® application for prevention of complications after colorectal ESD
A team from Kagawa University, Japan, around Dr. S. Fujihara, Department of Gastroenterology and Neurology, together with Dr. Kazi Rafiq, Department of Pharmacology, conducted a study exploring prophylactic closure after colorectal endoscopic submucosal dissection (ESD) using the OTSC clip as a preventative measure.

The authors note that in spite of ESD’s increasing prevalence, the technique is not widely used in treatment of large superficial colorectal neoplasms. They assume that this is due to the technical skill required and higher incidence of complications, like inflammation and especially perforation (reported at a 1.4–10.4 % incidence in previous studies) as well as postpolypectomy syndrome and transmural burn syndrome. They also note the risk of delayed perforation after ESD, possibly linked to excessive coagulation in the muscular layer, which sometimes even requires emergency surgery (incidence at 0.3–0.7 % in previous studies).

The study included 68 patients (39 male, 29 female) whose colorectal tumors (mean tumor size 35.4 mm) were treated with ESD. Prophylactic closure was performed on patients with excessive coagulation in the muscularis propria or larger resection size (n=27). Closure was performed either with conventional clips (n=23) or OTSC® (n=45). OTSC® was used for large mucosal defects (>30 mm), in case of flexure or sigmoid of the colon, excessive coagulation in the muscularis propria and when closure could not be achieved with conventional clips. OTSC closure required more time than conventional closure since in 5 cases tumors were located at a sharp bend in the sigmoid colon and required the use of the Twin Grasper. The median of clips needed was 8 for conventional clips (range 4–12) and 1 (range 1–3) for OTSC. The study showed the efficacy of endoscopic closure after ESD in preventing local peritoneal inflammation and post-polypectomy symptoms without any adverse effects. It did, however, not demonstrate a reduction of perforation and post-operative bleeding. The authors point out the limited sample size of their study and lack of randomization. They call for more randomized prospective studies with more focus on confirming or refuting the results.

Efficacy and safety of over-the-scope clipping system for closing digestive fistulas.

OTSC Update 20

August 2015 | Clinical experience with OTSC® shows high success rate for recurrent bleeding and complex resections
E. Wedi and J. Hochberger of the Department of Hepato-Gastroenterology at the University Hospital of Strasbourg, France, reported on clinical experiences with the over-the-scope clip system and its application aids such as the OTSC Twin Grasper and OTSC anchor for coarse tissue. They present a review of 14 clinical studies on OTSC use and add their own experiences with 84 patients (101 OTSC applications). All Strasbourg patients suffered from recurrent gastrointestinal bleeding and fistulae or post-operative leakage. 78 out of 84 cases (92.5 %) could be treated successfully.

The report notes that misapplication and complications are rare (<3 % according to the literature) when using OTSC. If they occur, they include narrowing of the organ lumen in case of small passageways and comprehensive aspiration of tissue. The authors remark that this should be kept in mind, especially in narrow sections of the esophagus or bowel.

They also maintain, however, that OTSC is often a good option for achieving quick closure in case of acute perforation or severe bleeding. Possible complications might then be compensated in a subsequent procedure, e.g. through dilation of a stenosis. They also report isolated cases of a grasper getting caught in the OTSC clip. However, if the clip is deployed before the grasper is pulled back fully into the cylinder, this complication is extremely unlikely in clinical practice.

The authors report that a device for cutting the clip for later removal as well as other instruments based on the OTSC concept show promising results in experiments. The paper concludes that OTSC is an asset in interventional endoscopy, especially in case of complex endoluminal interventions. According to the authors, OTSC is especially useful for closure of perforations of up to 1.3 cm (and much larger in individual cases) and bleeding lesions with a high risk of recession bleeding, e.g. in anti-coagulated patients or treatment of acute Forrest Ia/b hemorrhage.

Chronic fistulae, which have limited chances of successful treatment, regardless of treatment method, due to insufficient circulation in scarred and calloused tissue, remain a challenge, even with OTSC. Caution is also in order when closing no longer fresh postoperative leakage or other indications since these may require sufficient external drainage.

Conference Report: German Society for Endoscopy and imaging Procedures (DGEV)
The conference, held from March 26–28, 2015 in Munich, featured papers on fistula closure and perforation management (even after EVT or stent therapy) with OTSC®.
full-thickness resection with FTRD® at success rates of well over 80% treatment of therapy-resistant complicated fistulae with OTSC® Proctology, and one presentation on the new remOVE System for OTSC clip removal (currently in development)
Conference Report | talks, posters and videos 10° Conference of the German Society for Endoscopy and Imaging Procedures (DGE-BV)
Munich, Germany, March 26 – 28, 2015
Deutschen Gesellschaft für Endoskopie und Bildgebende Verfahren e.V.
Chairman: Prof. Dr. Hans-Dieter Allescher, Garmisch-Partenkirchen
Ovesco products were presented in four workshops on two different topics (hemostasis techniques, held by E. Wedi and A. Nägeli respectively, and management of complications led by T. Lankisch and J. Bernhardt respectively). Additionally, several talks, posters and videos discussed products by Ovesco.

OTSC System
Improved fistula closure with OTSC: treatment of fistulae and fibrotic lesions
A. Meining, University Hospital Ulm, together with M. Bajbouj, Technical University Munich, well as H. Feußner and D. Wilhelm. Technical University Munich, presented a video of a 41-year-old female patient who had developed a large fistula into the bronchial system after resection of the esophagus with gastric interposition due to dye ingestion. Because of coarse, scarred mucosa at the fistula opening in the gastro-esophageal juncture it was impossible to permanently and securely anchor an endoscopic clip. Overstaining treatment was also unsuccessful, and the patient had to be tube fed for several weeks. In order to ensure secure anchoring of the OTSC clip, the mucosa around the fistula opening was incised in a diameter of about 15 mm (corresponding to the opening of the OTSC applicator) with an HF knife. In the uncovered submucosa, the clip could be securely fastened and applied around the fistula with the mobilized mucosal edges covering the opening of the fistula. Administration of a contrast agent confirmed fistula closure, the patient suffered no more aspirations, and endoscopic follow-up after three months confirmed treatment success. The group recommends incision of the mucosa before application of the OTSC clip in case of coarse and chronically indurated mucosal tissue in order to improve clip anchoring.

Förderlicher Verschluss einer großen ösophago- bronchialen Fistel durch Mukosale Inzision vor OTSC®
A. Meining, Ulm; M. Bajbouj, H. Feußner, D. Wilhelm, München

OTSC as treatment option for fistulae, even after EVT or stent therapy
M. Lautkötter, T. Vowinkel, D. Palmes, N. Senninger and R. Menningen, University Hospital Münster, presented two cases in which patients suffered from leaking anastomoses after sleeve gastrectomy. In the first case, three separate insufficiencies with abscess formation manifested along the staple line in a 50-year-old male. He was treated with endoscopic vacuum therapy (EVT) and a total of 25 polyurethane sponges. The group contrasted this with the case of a 45-year-old woman, who had been unsuccessfully treated with stents after an anastomosis fistula. After the stent had been extracted, one OTSC clip was applied. Treatment duration was eight days. In both cases, no complications occurred during or after treatment and was successful. The group recommends the OTSC system for fistulae in fresh lesions free from inflammation as well as for rescue treatment after EVT or stent therapy failed.
Endoskopisches Komplikationsmanagement nach Sleeve-Magen-Resektion.
M. Lautkötter, T. Vowinkel, D. Palmes, N. Senninger and R. Menningen, Münster

OTSC as important treatment option for management of perforations
A. Meining, University Hospital Ulm, emphasized the important role of timing (acute or chronic), pathogenesis and...
In a retrospective study of 13 patients, Dr. Irani, Dr. Gluck, Dr. Gan, Dr. Ross and Dr. Kozarek of the Department of Gastroenterology, Virginia Mason Medical Center, Seattle, Washington, concluded that an important role of gastroenterology and Hepatology, University of Alabama at Birmingham, Division of Gastroenterology, Endoscopy International Open 2014; 02: E37–E40 171

March 2015 | JFHOD Congress, France: OTSC in hemostasis – high success rate in anti-coagulated patients
Paris, March 15–22: The JFHOD congress – Journées Francophones d’Hépatos-Gastroentérologie et d’OncoLOGie Digestive 2015 – the major French clinical congress on gastroenterology, hepatology and GI oncology was held under the presidency of Prof. Jean-Christophe Saurin. The group around Prof. J. Hochberger presented their data on OTSC in the treatment of severe gastrointestinal hemorrhage. Dr. E. Weid, Dept. of Gastroenterology and Endoscopy, University Hospital, Strasbourg, France summarized cases admitted to emergency care due to severe GI bleeding. All patients had Hb <7g/dl upon admission. Median age 73 years (29–97), 80 % were under concomitant anticoagulation or antiplatelet therapy. In 87.2 % (48/55) bleeding was due to a gastrointestinal peptic ulcer, and the remaining from various other causes. OTSC clips were placed. The overall clinical success rate without recurrence was 83.6 % (46/55). In 32.7 % OTSC was placed as a salvage treatment due to prior ineffectiveness of other techniques. 12.7 % (n=7) had to undergo surgical treatment. Out of these 7 patients 4 died, giving a total mortality rate of 7.2 % in this highly challenging case series. The report by Wedi et al. underlines that patients with a high Rockall score can profit from OTSC treatment, especially patients with anticoagulative or antiplatelet therapy.

March 2015 | German Congress of Coloproctology: further clinical data on OTSC®
Munich, March 12–14, 2015: The annual congress of the German Society for Coloproctology took place in Munich under the presidency of Prof. Dr. h. c. W. Hohenberger, Erlangen. Dr. L. Duschka and colleagues from the department of colorectal surgery and proctology, DKD Helios hospital, Wiesbaden reported in a plenary lecture about their clinical experience in the use of OTSC Proctology. In their abstract (Coloproctology; 2015; 1:76) they summarized the data of 22 patients, treated between March and August 2014. The majority had trans-sphincteric fistulas (n=16), followed by inter-sphincteric, rectal, recto-vaginal and psoas fistula (one case each). 13 patients had prior fistula surgery and 8 patients suffered from IBD. Post-surgical follow-up was 3–8 months. 68 % of the patients had healing of their fistula, 32 % had recurrence. The authors found that patients without prior history of fistula surgery had a higher probability for healing. They conclude that selection of patients is important to achieve high success rates.

OTSC® Update 19
February 2014 | Two Studies show efficacy of anchoring esophageal SEMS (self-expanding metal stents) with OTSC®
In a retrospective study of 13 patients, Dr. Irani, Dr. Gluck, Dr. Gan, Dr. Ross and Dr. Kozarek of the Department of Gastroenterology, Virginia Mason Medical Center, Seattle, Washington, concluded that an important role of gastroenterology and Hepatology, University of Alabama at Birmingham, Division of Gastroenterology, Endoscopy International Open 2014; 02: E37–E40 171

April 2015 | Study identifies OTSC® as effective and safe endoscopic therapy for acute gastrointestinal bleeding
In an observational retrospective case series, Dr. Matthew Skinner, Dr. Juan P. Gutierrez, Dr. Helmut Neumann, Dr. C. Melani Parola, Dr. F. Burski, Klaus Mönch and the Basel I. Hirschwort Endoscopic Center of Excellence, Department of Gastroenterology, University of Alabama, Birmingham, USA, evaluated the efficacy and safety of OTSC clip placement in patients with upper gastrointestinal bleeding after traditional endoscopic methods had failed. The study was conducted at a large tertiary care hospital, comprising 12 patients (8 male, 4 female), mean age of 59 (range: 28–86) with ongoing upper gastrointestinal bleeding despite two or three previous sessions of endoscopic therapy. Of the 12 patients, 9 (range: 2–4), mean hemoglobin of 7.2 g/dl, (range: 5.2–9.1), and shock was present in 75 % of patients. They had all received packed red blood cells (mean 5.1 units, range 2–12). Bleeding was due to duodenal ulcer (6), gastric ulcer (2), Duodenal fistula (2), Mallory-Weiss tear (1). Hemostasis was achieved in all patients, but rebleeding occurred in two patients 1 day and 7 days after OTSC place- ment. There were no complications associated with OTSC application. The OTSC System was loaded onto a standard gastro- scope and introduced into the upper gastrointestinal tract under standard direct visualization. The bleeding lesion was located and the gastroscope was maneuvered towards it. Once the OTSC clip was positioned on top of the lesion, full suction was applied to tissue, so that the lesion was fully engulfed inside the transparent cap before the clip was released. In two patients with post-bulbar ulcers, a wire or a wire placed inside a feeding tube was advanced into the distal duodenum and the scope advanced alongside the wire. This means to an attempt to prevent small-bowel luminal occlusion, which has previously been reported as a major adverse event. The authors conclude that the OTSC System provides tis- sue apposition far superior to traditional clipping and can function as a ‘rescue therapy’ in patients with severe non- variceal upper gastrointestinal bleeding in whom prior endo- scopic therapies have failed, avoiding more invasive proce- dures such as embolization or surgery. They point out that the OTSC System appears promising for the treatment of bleeding lesions with large-diameter visible vessels or those located in awkward positions, such as the greater curvature of the stomach or the posterior duodenal wall, which may not always be amenable to treatment with standard endo- scopes and endoscopic devices. Any bleeding occurring more than 72 hours after therapy is usually regarded as a new incident. Over-the-scope clip placement is effective rescue therapy for severe acute upper gastrointestinal bleeding Skinner M, Gutierrez JP, Neumann H, Wilczek C, Burski C, Mönchmüller K. Endoscopy International Open 2014; 02: E37–E40 171

In a retrospective study of 13 patients, Dr. Irani, Dr. Gluck, Dr. Gan, Dr. Ross and Dr. Kozarek of the Department of Gastroenterology, Virginia Mason Medical Center, Seattle, Washington, concluded that an important role of gastroenterology and Hepatology, University of Alabama at Birmingham, Division of Gastroenterology, Endoscopy International Open 2014; 02: E37–E40 171

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successful in all cases, in two cases clip dislodgment and subsequent stent migration was documented during follow-up. After complete healing, stent and clip were removed in six patients, while the stent was left indefinitely in four patients to treat their underlying condition. The authors emphasize the potential to significantly reduce stent migration rates, leading to a possible reduction of 8 to 40 percent in stent migration placement by using OTSC as an anchoring device. The inject-and-resect technique used for removal was successful in all cases in which the underlying condition had been healed, although the authors caution that a possible risk of perforation is connected with anchoring the clip to deeper tissue. While the group believes benefit to be greater for nonstenosing diseases, they point out that patients with malignant stricture receiving chemo-radiation may also benefit from clipping, as a reduction in the size of the tumor may also lead to stent migration. They also mention ex vivo trials showing that sutures are most resistant to tensile forces (average of 20.4 newton needed for stent removal) compared to clip-anchored stents (16 newton on average) and unanchored stents at 4.0 to 5.6 newton. The paper identifies clips as the least expensive device, but advises that costs associated with the possible use of multiple clips or stent migration should also be taken into account.

In conclusion, the authors evaluate the use of OTSC for anchoring of fully covered SEMSs as a safe and easy alternative to stent placement. The potential to significantly reduce stent migration rates and call for further studies to assess and refine the fixations.

* The fixation of stents is not a common indication for the OTSC System and there is only very limited experience.

**Preventing migration of fully covered esophageal stents with an over-the-scope clip device (with videos).**

**Epub 2014 Jan 25** 166

**Anchoring of self-expanding metal stents using the over-the-scope clip, and a technique for subsequent removal.**

**Epub 2014 Sep 30** 210

January 2015 | OTSC® clip for closure of pancreatico-colonic fistulas – new case studies
K. Ito, Y. Igarashi, T. Mimura et al., Division of Gastroenterology and Hepatology, Toho University Omori Medical Center, Tokyo, Japan, published a case study on the successful OTSC closure of a colonic fistula complicating severe pancreatitis. Dr. E.C. Gorospe, Dr. S. Desai, Dr. B. Al-Bawardi et al., Division of Gastroenterology and Hepatology, Mayo Clinic, Rochester, Minnesota, USA, describe the clip closure of a pancreatico-colonic fistula caused by severe necrotizing pancreatitis. Y. Koike, T. Kudo, et al., Division of Gastroenterology, Sapporo City General Hospital, Sapporo, Japan, presented the closure of a colonic fistula complicating a pancreatic pseudocyst. The Tokyo case was a 44-year-old male with hyperlipidemic alcoholic pancreatitis including an abscess in the left abdominal cavity and immense peripancreatic fluid collection. Conservative treatment resulted in middling success. A disruption on the tail of the main pancreatic duct was suspected and confirmed after 90 days and treated with an ENBP tube and a pancreatic stent, which proved ineffective. After conservative management options had been exhausted, surgical therapy was considered, but postponed due to presence of E. coli and MRSA in abscess culture. Finally, an OTSC clip was used on day 148 to endoscopically seal the fistula. A following endoscopic complete sealing of the leak and improved healing. After the patient had been upgraded to a full diet, an endoscopic pancreatic stent was placed to deal with increased pancreatico-duodenal drainage. Several follow-ups showed the success of the procedure with improvement of the abscess, clip in situ and healed perforation site with no signs of inflammation, ulceration or pancreatic duct disruption. Patient is well and now receives outpatient care for hyperlipidemia. The Mayo Clinic reported the case of a 95-year-old female who had had 3 previous transgastric necroses when she was hospitalized 3 weeks after her last necrosectomy, there was reflux of fecal-like material into the debrided cavity as well as a sigmoid structure, likely caused by pancreatic necrosis and disruption of the main pancreatic duct. Two fistulae were located and closed from a colonic approach using OTSC clips. Closure was confirmed fluoroscopically and endoscopically. After 7 months, the patient remained asymptomatic.

The team from Sapporo City General Hospital reported the case of a 53-year-old man with a history of alcohol-induced chronic pancreatitis. A fistula between a pancreatic pseudocyst and descending colon did not respond well to traditional endoscopic drainage and was reinjected. It was also believed to be the cause of repeated cyst infections. The fistula was finally closed using the OTSC clip and closure was confirmed via radiographic imaging. The patient’s pancreatic pseudocyst has decreased in size with no signs of re-infection. In cases where endoscopic drainage was used, home care of the colonic fistula closure, the OTSC System is an interesting treatment option since it is less invasive than surgery.

Severe Acute Pancreatitis with Complicating Colonic Fistula Successfully Closed Using the Over-the-Scope Clip System

**Print 2015 May** 134

Over-the-scope clip closure of pancreaticocolonic fistula with OTSC device: a case report

**Epub 2013 Dec 12** 158

Pansicnic pseudocyst with complicating colonic fistula successfully closed using the over-the-scope clip system

**Epub 2014 Apr 22** 191

January 2015 | ASGE: Over-The-Scope Clipping device is safe and effective for management of GI defects
ASGE – The American Society for Gastrointestinal Endoscopy issued a press release concerning a publication in its GIE-Gastrointestinal Endoscopy journal. "An international multicenter study reports that over-the-scope clip (OTSC) placement is a safe and effective therapy for the closure of gastrointestinal (GI) defects, which includes anastomotic leaks, fistulae and perforations. Clinical success was best achieved in patients undergoing closure of perforations or leaks when OTSC placement was used as the primary therapy (91.3 percent) and leaks (73.3 percent) was significantly higher than that of fistulae (42.9 percent). Long-term success was significantly higher when OTSCs were applied as a primary therapy."

**Methods** A retrospective review of consecutive patients who underwent attempted OTSC placement (either as primary or rescue therapy) for the indication of GI leak, fistula or perforation at 16 academic centers in the United States, The Netherlands, Germany, Italy, and Chile was conducted between May 2006 and November 2012. Patients were identified by using endoscopic databases at each institution. Anastomotic leak was defined as disruption at a surgical anastomosis resulting in a fluid collection with or without evidence of extravasation of contrast medium on radiologic evaluation. Fistula was defined as abnormal communication between two epithelialized surfaces. Perforation was defined as an unintentional, acute communication bet...
mainstream endoscopy is promising. It is arguable that these clips should be available in every well-stocked unit, and because application and deployment are similar to those of a standard ligature bander, it would be appropriate for implementation into training and clinical practice in gastroenterology.

December 2014 | Full-thickness r section of adenoma in colonic diverticulum using Ovesco FTRD® System

PV Vall, M Kaufmann and P Bauerfeind, Dept of Gastroenterology and Hepatology, University Hospital Zurich and B Vrugt, Institute of Pathology, University Hospital Zurich in Switzerland published the first case where colonic adenomas were resected through diverticulum. Diverticulosis revealed a 10 mm lesion (pathological size: 13 mm) inside a diverticulum in the ascending colon. Using a standard colonoscope with Indian ink injection and a hemoclip, the diverticulum was marked before a therapeutic colonoscopy, fitted with the FTRD System, was introduced and advanced to the adenoma, located 10 cm proximal to the hepatic flexure. Adenoma and diverticolitis were mobilized into the cap of the FTRD with grasping forceps and additional suction before the FTRD clip was placed. The patient survived the procedure with no sign of leakage of bowel content into the peritoneal cavity and was discharged the next day, and no signs of complication arose over a 3 month follow-up period. The authors consider the Ovesco FTRD System as a novel treatment option for the resection of high-risk polyps without the risk of leakage of bowel content into the peritoneal cavity and potential for use in an outpatient setting. To watch a video of the procedure, please visit the website of Gastroenterology journal at www.viszeralmedizin.com.

November 2014 | Clinical presentations confirm efficacy of OTSC® clipping at German Congress of Visceral Medicine in Leipzig

PV Vall, M Kaufmann, V Vrugt, B Bauerfeind P gastroenterology 2014, 147:5:969-71

Clinical presentations at German Congress on Visceral Medicine confirm efficacy of OTSC clipping and show clinical data on novel Ovesco products FTRD and remOVE Leipzig, September 17–20, 2014. The 69th annual congress of the German society for gastroenterology, digestive and metabolic diseases, DGVS, was held under the presidency of Prof. Dr. med. Peter R. Galle. A significant number of presentations provided clinical evidence and confirmed efficacy and safety in the primary indications of the product, hemostasis, closure of acute lesions/perforations and closure of chronic lesions/l Fistulae (source: www.viszeralmedizin.com).

Conference report

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Ovesco Research Update 33 | Research & clinical trials 30

Reports on Ovesco OTSC

OTSC proves to be better treatment option for several indications.

Giltach A, Schreiber A, Boldt J, Keßler W, and Mayerle J, Greifswald, reported about a cohort of 46 patients treated with OTSC clips. The indications include postoperative anastomotic insufficiency (n=13), bleeding (n=7), perforations (n=4), and recurrent bronchial fistulae in the colon (n=4), fistulae in patients with inflammatory bowel disease (n=5) and OTSC use after ESD (n=2). Successful closure and complete healing was achieved for all but one indication. In the case of postoperative anastomotic insufficiencies 3 out of 13 insufficiencies were closed successfully (76.93 % success rate). These patients had to undergo further laparoscopic treatment. In all other cases (n=43), no complications were observed and thus no further treatment was necessary. The authors declare OTSC to be a procedure with significantly lower morbidity and mortality in comparison to conventional treatment options and emphasize that it spares patients elaborate and more complication-prone methods of treatment.

Retrospective Auswertung der OTSC Anwendung an der Universitätsklinik Leipzig


Braun A, Freiburg, and Kirchmair A, Tübingen, presented data about a total of 16 patients (median age=75.5 years, F=13, M=3, age range=57–92 years) with acute bleeding, who were treated with OTSC application during emergency endoscopy. 8 procedures were performed in the upper and 8 in the lower gastrointestinal tract. Patients with upper GI bleeding were given a highly dosed proton pump inhibitor (80mg l.v. Bolus, 320 mg i.v./24h). Hemorrhages were classified as follows: Forrest I (n=7), Forrest II (n=7), and Forrest III (n=2). All patients suffered an acute drop in hemoglobin and showed definite signs of bleeding. No further local therapies were administered. All OTSC applications were performed by the same clinician and took 20 minutes or less. OTSC application and thus primary hemostasis was successful in all cases. None of the patient suffered recurrent gastrointestinal bleeding. 6 patients (4 F, 1 Fb, 1 Fia) had a follow-up endoscopy between day 1 and 7; all clips were in situ with no signs of bleeding. The other 7 patients were not reexamined due to good response to treatment. The authors see OTSC as a safe and very effective treatment option in emergency endoscopy. Primary hemostasis is possible for a large percentage of patients, which improves lethality, and examination time is low.

Endoskopische Behandlung von akuten Blutungen mit einem Over-The-Scope Clip (OTSC)

Braun A, Kirchmair A

Interdisciplinary treatment regimen for thoracic anastomotic insufficiencies.

Pauthner M, May A, Lorenz D, and El C, Offenbach, introduced the complication management regimen for thoracic anastomosis insufficiencies (AI) at HS Wiesbaden hospital. From 07/2000 to 12/2013, they counted 632 cases of resections on the esophagus, 557 of which included thoracic anastomoses. In 49 of these 557 patients (8.8 %) suffered from confirmed AI. Of these cases, 13 (26.5 %) were treated conservatively with a tracheal feeding and gastric decompression tube (TTL), 14 (26.8 %) were treated with a primary stent, in 7 patients an OTSC clip was placed endoscopically (14.3 %) and 2 (4.1 %) received transluminal vacuum therapy. 12 patients (26.5 %) had to undergo repeated OTSC clipping and 1 patient placed another OTSC clip during the procedure (14.3 %). Hospital lethality after all esophageal resections was 3.6 %, with only 2.3 % in the last 4 years. If gastric stasis shows good blood circulation and the AI is small, either a clip or a TTL is placed. Routine check after 24-48h, larger Al are treated with stents; routine check after 24 h confirms the TTL to protect stent from bile. If pleural empyema occurs, a repeat thoracotomy is performed, including decortication and sewing-over of the AI as well as stent placement; stent is fixed with an absorbable suture. The authors report that this indicationspecific, standardized complication management regimen reduced lethal reduction after occurrence of thoracic AI from 14.3 % to 3.1 %. Therapie der Anastomoseninsuffizienz nach Ösophagus-Resektion – die viszeralmedizinische Herausforderung

Pauthner M, May A, Lorenz D, El C

New treatment option for chronic, therapy-resistant esophageal-bronchial fistulae.

Wedi E, Sports A, and Hochberger J, Strasbourg, France, presented the case of a 68-year-old patient with a chronic esophageal-bronchial fistula. In early 2010 he presented with dysphagia and weight loss and was initially pulmonological. Examination of the mediastinum and subsequent exploratory thoracotomy showed giant-cell granuloma with no indication of malignancy. In December 2011 patient reported repeated incidents of coughing during food intake with recurrent broncho-pulmonary infections, and an esophageal-bronchial fistula was diagnosed. Initial treatment included a fully covered Nitinol stent (23/18 mm wide, 12 cm long), which dislocated two days after food was reintroduced. In the following 1.5 years, a variety of endoscopic treatments (stent, clips, OTSC) were implemented. Furthermore, bronchoscopic clipping and show further local therapies were performed. Finally, the fistula tract was closed with a 17.5 mm OTSC macro clip. Preliminary endoscopic re-exploration for up to 4 months patients shown no recurrence. The authors conclude that excision of the fistula and subsequent closure with an OTSC macro clip is a promising new treatment option, which should be further evaluated.

Therapie-refraktäre ösophago-bronchiale Fistel – Was tun, wenn alle Therapieoptionen versagen?

Wedi E, Sports A, Hochberger J

Report on Ovesco FTRD (Full-Thickness Resection Device), newly launched by Ovesco

Preliminary clinical experience with the FTRD system in the lower gastrointestinal tract.

Schmidt A, Damm M and Caca K, Ludwigburg, together with Gubler C and Bauerfeind P, Zurich, Switzerland, reported their experience with endoscopic full-thickness resections in the lower GI tract in May 2011 patient from July 2011 to March 2014. Resection was always performed using the FTRD system mounted on a standard endoscope. Indications included recurrent or incompletely resected adenoma with non-lifting sign (n=9), adenoma with high-grade prostate intraprostatic neoplasia (HPGN) (n=1), adenoma on base of appendix (n=3), benign adenoma in patient with coagulation disorder (n=1), diagnostic (re-)resection in patients with T1 carcinoma (n=3), adenoma on diverticulum (n=1), a submucosal tumor (n=2), a diagnostic FTR for a patient with suspected Hirschsprung’s disease (n=1), lesions were located in the cecum (3), ascending colon (4), transverse colon (2), descending colon (4), sigma (2), recto-sigmoid (3), and rectum (3). Navigation to target lesion with FTRD mounted onto endoscope was possible in all but one case (95.2 % success rate).

Once the lesion was reached, resection was technically successful in all cases and macroscopically complete in 19 out of 20. Histological findings confirmed complete full-thickness resection in 17/20 cases (85%). No perforations or bleeding complications during the procedure were observed in 17/20 patients (85%); bleeding or perforations were observed in 3/20 patients (15%). Two patients developed postpolypectomy syndrome (PPCS) after resection in the cecum, which was treated conservatively and with success. The authors conclude that endoscopic full-thickness resection in the lower GI tract with the FTRD system is technically feasible, effective and safe. Larger studies are necessary for further evaluation of this new device.

Endoskopische Vollwandresektion im unteren GI-Trakt mit dem FTRD® System: eine retrospektive Studie

Schmidt A, Damm M, Gubler C, Caca K, Bauerfeind P

Ovesco Research Update | Research and clinical trials | Version 33 | 2019-12-20
Report on OTSC Proctology

Prospective study deems OTSC Proctology a very promising method for anorectal fistula closure.

Prost R presented the experiences of a prospective pilot study at St. Anna hospital, Stuttgart, and etz center of excellence in proctology, Mannheim, regarding the use of OTSC Proctology. The study included 20 patients (14 male, 6 female), aged 56.1 years on average (R 25–73 years). There were 14 transsphincteric and 6 suprasphincteric anorectal fistulas. Average procedure time for clipping of fistulae was 32 minutes (R 17 to 66 minutes). There were no intraoperative complications. Follow-up endoscopy after six months or more showed proper healing in 18 of 20 cases (90 % success rate). The clip had remained in-situ in 13 patients. The clips fell off spontaneously (10 to 4 days post-op) in three patients. The clip was surgically removed in two patients, once due to acute perineal pain and the other due to leakage. The fistula persisted/recurred in two of 20 cases (10 %). Reasons were spontaneous clip displacement on day 3 post-op and failure to heal. In the second case, the clip was removed and another loop was placed.

The author pointed out that, since this is a new method, clinical experience is limited and efficiency with regards to ano-/recto-vaginal fistulae is unclear. The report claimed OTSC Proctology to be a very promising new treatment option with lower morbidity and fewer complications than established methods. It prevents traumatizing the sphincter, eliminating acute and chronic incontinence, and does not impede further treatment options. Additionally, patient satisfaction is high and the instrument is easy to use.

OTSC without Endoskop: Anorektaler Fistelverschluss mittels OTSC Proctology


Report on remOVE System

(product approval in Europe pending)

Early clinical data on new bipolar DC cutting instrument for OTSC clips show efficacy and safety. Rische S, Schmitz A, Damm M, Cahyadi O, Bauder M, and Caca K, Ludwigswigsum, summarized a retrospective study of compassionate use cases, which used a prototype of the remOVE System to remove OTSC clips in 13 patients. Clips remained in the upper and lower gastrointestinal tract for an average of 70 days (R 7–469 days). Fragmentation of clip was successful in all cases. Mean procedure time was 45 minutes (R 35–75 minutes). Endoscopic removal of clip fragments was possible in all but one case (92.31 % success rate). No serious complications were observed. The authors conclude that clip removal with the remOVE System prototype is easy, fast and safe, and is thus suitable for elective procedures as well as endoscopic emergencies.

Endoskopische Entfernung von Over-The-Scope Clips (OTSC) mit Hilfe eines bipolaren Schneideinstruments (DC ClipCutter); retrospektive Fallserie von 13 Patienten

Rische S, Schmidt A, Damm M, Cahyadi O, Bauder M, Caca K


Under the lead of GA Paspatis, Gastroenterology Department, Benizelion General Hospital, Heraklion, Crete, Greece, a group of experts analysed best clinical practice in the treatment of iatrogenic endoscopic perforations. Iatrogenic perforation of the gastrointestinal tract related to diagnostic or therapeutic endoscopy is a severe adverse event, associated with significant morbidity and mortality. In the Position Statement, ESGE aimed to define the main risk factors for the development of perforations as well as clear diagnostic and therapeutic algorithms for their management.

The authors allude to the OTSC Clip by Ovesco Endoscopy as a first line therapy for the use in different GI organs. For esophageal perforations that are associated with particularly high risk of secondary complications OTSC is recommended for lesions between 1 and 2 cm. In gastric perforations the authors cite the high therapeutic efficacy of OTSC published in the literature. OTSC is the device of choice for closing gastric defects larger than 10 mm. The use of conventional clips is not recommended in such lesions. Also combinations of such clips and endolops is only appropriate in case no OTSC clip should be available. For colonic perforations the guideline states that OTSC is the first line therapy in the preference of the authors. Only small holes can be treated with conventional clips.

For the complete list of recommendations by ESGE please check the resources linked at the bottom of this news message.

The position paper is an official statement of the European Society of Gastrointestinal Endoscopy. ESGE guidelines are intended to be an educational device to provide information that may assist endoscopists in providing best care to patients.

Diagnosis and management of iatrogenic endoscopic perforations: European Society of Gastrointestinal Endoscopy (ESGE) Position Statement


September 2014 | OTSC® clip for closure – new case studies on alimentary tract fistulas

K, D, H, T. Department of Gastroenterology, Lenox Hill Hospital, New York, USA published a three-case series on closure of fistulas in the alimentary tract, while Dr. T. Meister, Dr. J. Kuhlrat and Dr. M. Floer, Helios-Albert-Schweitzer-Klinik, Northeim, Germany published a case report on closure of a postoperative enterocutaneous fistula.

The first New York case was an 80-year-old female with dysphagia, history of aortic valve regurgitation, esophageal perforation due to TEE, repair with feeding jejunostomy and venting gastrostomy. Healing resulted in a gastrointestinal fistula, which persisted for 9 months despite PPI therapy. Tissue was grasped with OTSC Anchor and pulled into the clip, then an OTSC clip was successfully deployed. Follow-up after 3 months showed that the fistula had fully healed. The second case was a 36-year-old female with a history of diverticulitis in the lower alimentary tract. She underwent a colostomy and closure of a rectovaginal fistula from her vaginal canal and recurrent urinary tract infections. CT scan revealed a fistula between sigmoid colon and vagina, but locating it gastroscopically was difficult. The OTSC clip was deployed, resulting in tissue entrapment. The patient was fistula-free for several weeks. When symptoms recurred, surgery revealed an abscess communicating with the colovelar, which prevented healing.

The third case was a 41-year-old female with colonic interposition after lye ingestion and PEG tube placement. After the tube was removed, gastrostomy tract did not close for several months and conventional methods of closure failed. The fistula tract presented with some exudate at the gastric orifice. After several attempts to draw sufficient tissue to the clip with the OTSC Anchor, the OTSC clip was successfully deployed. After a few weeks, patient started having secretions. It was hypothesized that the diameter of the fistula (>1 cm) was to blame for inefficient healing. The German case report was about a 48-year-old female suffering from a perforation at the gastric orifice, the OTSC clip was deployed and was successfully deployed. After a few weeks, patient started having secretions. It was hypothesized that the diameter of the fistula (>1 cm) was to blame for inefficient healing.

The German case report was about a 48-year-old female suffering from a perforation at the gastric orifice, the OTSC clip was deployed and was successfully deployed. After a few weeks, patient started having secretions. It was hypothesized that the diameter of the fistula (>1 cm) was to blame for inefficient healing.

The other patient (71 years old) who had an Ivor-Lewis esophagectomy due to esophageal carcinoma. After the development of chest pain 6 days later a CT scan revealed an anastomotic dehiscence. During an emergency laparotomy was done, the patient found 10 days later by a CT. An additional stent was placed overlapping the first stent. Because of a continued leakage another EGD was performed demonstrating a gastric conduit fistula. After application of conventional endoscopic clips the patient was discharged but presented with worsening symptoms. Another EGD showed a persistent fistula that was finally closed with an OTSC clip resulting in a complete healing.

The other patient (71-year-old woman) presented with hypotension, melena and low hemoglobin level 3 weeks after esophageal (gastrointestinal) anastomosis. EGD showed an oozing bleeding and as well as a defect at the anastomosis. In this case the dehiscence extended over half the circumference of the anastomosis. Since other techniques seemed inappropriate due too large leak, massive bleeding and clot, a clipping position was decided to use the Twin Grasper and an OTSC clip to close the defect. Complete closure was confirmed by a subsequent endoscopic examination. According to the authors, the OTSC clip should be considered as the first choice for sealing of intermediate leaks.

Successful over-the-scope clip (OTSC) treatment for severe bleeding due to anastomotic dehiscence

July 2014 | Retrospective study confirms safety and effectiveness of OTSC® in the endoscopic treatment of GI bleeding, perforation and fistula

Dr. Vijay Jayaraman and colleagues, Cedars Sinai Medical Center, Los Angeles, recently presented a retrospective study on their experience with the OTSC System in the treatment of GI bleeding, fistula and perforation. Their case series consisted of 24 consecutive patients treated between January 2011 and April 2012 (mean age 70 years) included the following indications for OTSC placement (28 clips): post-surgical enterocutaneous fistula (n=10), spontaneous perforation (n=1), anastomotic leak (n=4), perforation after mucosal resection (n=3), prophylactic closure of mesocolic defect after EMR (n=1), postpolypectomy bleeding (n=2), postendoscopic perforation (n=2), tranchoesophageal fistula (n=1) and leakage from a percutaneous jejunalostomy site (n=1). Instruments or modalities used to grasp the tissue were dedicated devices (OTSC Twin Grasper and OTSC device with endoloops) in 70 %, non-dedicated devices (rat tooth/valvuliter apex forceps or suction alone) in 30 %. Median follow-up time was 2.9 months; mean defect size 10 mm (range 5–22 mm). The overall success rate was 61 %. In their experience the success rate of closure of an acute (ruptured) mesocolic defect or a mesocolic perforation where 24 lesions were chronic (>1 month) in this series which might explain the lower overall success rate in comparison to the literature (72–100 %).

Furthermore, a trend towards higher success rate was noted in defects <10 mm compared to defects >10 mm. No death was reported, any complications associated with OTSC placement.

Endoscopic therapy is still the initial choice before any surgical intervention to manage GI bleeding, fistulae, perforations and leaks. As the scope of clips are
limited by their smaller wing span and low force of closure leading to suboptimal results, the OTSC clip provides a safe and effective endoscopic alternative.

Clinical Application and Outcomes of Over the Scope Clip Device: Initial US Experience in Humans
Jayaraman V, Hammerle C, Lo SK, Jamil L, Gupta K
Diagn Ther Endosc. 2013;2013:38173

June 2014 | Spanish researchers receive award for successful OTSC® case presented at the National Digestive Congress Spain, June 14–16, 2014 in Valencia
D. López Peñas and colleagues, Servicios de A. Digestivo, Dotoirnolaringología y Oncología médica, Hospital de Llerena, Spain received an award for their presentation at the Semana de las Enfermedades Digestivas (SED 2014) in Valencia.

The researchers report on a successful closure of a pharyngo-cutaneous fistula after total laringectomy in a 58-year-old patient. The 3-stage treatment of dilatation, subsequent percutaneous gastrostomy and closure with an OTSC® clip indicated a substantial improvement of food supply and quality of life.

Here you can see the presentation (in Spanish):

June 2014 | Three case reports on surgery-sparing uses of the OTSC® clip in multiple indications
Three different case reports lately published by Dr. V. Gómez et al., Dept. of Gastroenterology and Hepatology, Mayo Clinic, Jacksonville, USA, Dr. S. Singh et al., Div. of Gastroenterology, The Brooklyn Hospital Center, New York, USA and Dr. J. Albert, Center of Internal Medicine, Johann Wolfgang Goethe University Hospital, Frankfurt/Main, Germany illustrate the broad spectrum of indications for which placement of OTSC clips can be useful.

The first case report describes the use of the OTSC System in the management of a Dieulafoy lesion. A 74-year-old man suffered from a recurrent, obscure, life-threatening gastrointestinal bleeding. EGD revealed a non-bleeding Dieulafoy lesion at the lesser gastric curve. Due to the large size and difficult position of the lesion, conventional through-the-scope clips were not used, but an OTSC clip was placed on the stump in another case report a 61-year-old woman presented for EGD for evaluation of dysphagia. Four arteriovenous malformations were found in the duodenum, which were cauterized. On withdrawing the endoscope, a 2-cm gastric perforation was identified on the lesser curvature. Using the suction technique an OTSC clip was applied to close the defect.

The third paper presents the case of a patient with severe bleeding from a duodenal ulcer that could not be controlled by conventional clips and injection of fibrin glue. Angiographic placement of coils into the afferent vessel then stopped the bleeding. After 3 days a fistula penetrated into the dorsal duodenum leading to a peritoneal leakage. Successful closure of the fistula was achieved with an OTSC clip. All the authors agree that the OTSC System is an effective tool for endoscopic control of bleedings, perforations and fistulas.

June 2014 | Prophylactic closure of large mucosal defects after colorectal ESD significantly reduces the inflammatory reaction and abdominal symptoms of patients with neoplasms
Fujiura et al., Department of Gastroenterology and Neurology, Faculty of Medicine, Kagawa University, Kagawa, Japan, assessed the efficacy and safety of a prophylactic closure for large mucosal defects after colorectal ESD.

From April 2010 to December 2012, 68 patients with colorectal tumors were treated with ESD. The prophylactic closure using a conventional clip and the over-the-scope clip (OTSC) system was indicated for patients with excessive coagulation in the musculis propria or larger resection size. The closure aimed at reducing inflammatory reaction and abdominal symptoms without increasing complications.

The closure group also had a significantly lower WBC count (post operative day 1), CRP (post operative day 4) and abdominal pain after colorectal ESD compared to the non-closure group. Perforation occurred in 1 case, and postoperative bleeding in 2 cases, with only 1 bleeding case needing an emergency endoscopy in the non-closure group. One perforation case needed emergency surgery because the endoscopic treatment was ineffective. Without incurring adverse effects, the prophylactic closure efficiently reduced the inflammatory reaction and abdominal symptoms of colorectal ESD in patients with large superficial colorectal neoplasms.

The efficacy and safety of prophylactic closure for a large mucosal defect after colorectal endoscopic submucosal dissection
Fujiara S, Mori H, Kobara H, Nishiyama N, Kobayashi M, Rafiq K, Masaki T

May 2014 | Sleeve gastrostomy leaks: Closure with the OTSC® System
Sleeve gastrostomy is increasing in popularity for the treatment of morbid obesity. The most serious and dreaded complication of this procedure is an anastomotic leak typically at the gastroesophageal junction.

Dr. Ahmad Aly and colleagues, Upper GI & Bariatric Unit, Austin Hospital, Heidelberg, Australia present two case reports on managing a sleeve leak with the OTSC System. A 58-year-old woman with a BMI of 45 underwent sleeve gastrectomy without intraoperative incident. In the case of a 44-year-old woman a conversion from laparoscopic adjustable gastric band to a sleeve gastrectomy was performed.

To prevent leakage from the resection line, Sealguard®, a staple line reinforcement product was used in both cases. After initial recovery both patients presented with abdominal discharge and inflammatory markers remained normal. As spontaneous closure of a gastric staple line fistula is rare, many patients require further complex surgery for definitive closure. The OTSC System has the potential to significantly simplify the management of leaks after sleeve gastrectomy by offering a simple and easy solution.

The use of over the scope clip (OTSC) device for sleeve gastrectomy leak
Aly A, Lim HK
J Gastrointest Surg. 2013 Mar;17(3):606-8

April 2014 | Multipurpose use of the OTSC® System to treat endoluminal gastrointestinal disorders
Recently Mönkemüller et al. from Birmingham, AL, USA report the analysis of an observational retrospective case series of 16 patients (median age 65.8 years) with mixed indications for the treatment with the OTSC System. The overall success rate of 75 % is well in line with other reports and with the meta-analyses of Weiland et al. with a 71 % success rate in fistulas and anastomotic leaks, 79 % in acute perforations, and 88 % in acute GI hemorrhages.

The range of indications included leak management after pyloroplasty (n=6), gastrectomy (n=3), esophagotracheal and/or esophagopleural fistulae (n=3), resection of submucosal tumor (n=2), stent fixation (n=1), and anastomotic leak after esophagectomy (n=1). The overall per-lesion success rate was 70 % (14 of 20 applications).

Mean follow-up was 10 months (range 1–10). There were no complications (0 %) related to endoscopy, sedation or application of the clipping device.

The authors pointed out in the discussion that OTSC allows for the entrapment of a larger amount of tissue, allowing closure of fistula holes and, as shown in these cases, hemostasis superior to other devices. In their critical remarks they also discuss situations where they experienced certain limitations to the system such as the tubular structure of the esophagus which at times might need an adequate preparation of the device.

Comment Ovesco: especially in cases where the apposition of the OTSC System might seem difficult, the OTSC Anchor is usually a very useful device to facilitate the successful application of a clip with the Anchor functioning as a guide wire for both scope and System (e.g. esophagus, cardia, postpyloric duodenum).

In essence the authors draw a very positive conclusion stating that “the OTSC device is ideally suited to treat soft tissue leaks or fistulizing lesions and high-risk bleeding lesions such as ulcers in the posterior duodenum or Dieulafoy’s lesions with the main underlying mechanism being compressing the surrounding tissue around the vessel. They continue “…the OTSC device may become a standard device to treat ulcers located in difficult positions because of its barrel-shaped transparent cap design which allows it to suction the bleeding lesion. It is well known that these bleeding ulcers and lesions are of a higher risk and also more difficult to treat because of their awkward location and/or position…”.

This statement is followed by an elaborate discussion of the shortcomings of alternative devices. It is important to underline also that the authors support “…multiple OTSC applications in a single session...” as sometimes being useful and allowing “application of tissue layer by layer in a submucosal plane. “Interestingly, the device does not treat tissue, as it snaps it together. So far, there have been no reports of GI wall tearing…”.

Finally the authors discuss the issue that once OTSC is deployed it cannot be removed easily, and report of two methods they have been using in this case: the “wire technique” as described by Mönkemüller et al., and the use of an Nd-YAG laser, as described by Fährndich et al. earlier.

Comment Ovesco: we are aware of this issue and are currently finalizing the development of an own, easy to use clip cutter.

Multipurpose use of the ‘bear claw’ (over-the-scope clip) system to treat endoluminal gastrointestinal disorders Mönkemüller K, Peter S, Tradernw J, Popa D, Zabieński M, Stahl RD, Ramesh J, Wilcox CM
Dig Endosc. 2014 May;26(3):350–7

April 2014 | Conference report | 44° DGE-BV Congress, Hamburg
The 44th DGE-BV Congress of the German Society for Endoscopy and Imaging Procedures/Diagnostics was held in Hamburg, April 3–5, 2014 under the presidency of Prof. Dr. Thomas Rösch.

Again a significant number of both oral presentations and posters have been featured at this year’s event. In summary they all reported their mostly positive experiences with the OTSC System in all main indications. In addition, our products were featured in several hands-on courses and debates at the conference (Chung Hoong J, Mönkemüller K, Kraus F.). Ovesco presented their new products, the DC Clip Cutter and the FTRD® device which are both due to be launched later this year. The reaction of the medical world was more than promising.
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• New Clips for Blutung und Verschlusstechniken
Caca K, Ludwigshafen, Germany

K. Caca gave a talk on “New tools for the treatment of Gl- hemorrhage and perforation”. Even though also mentioning other devices he mainly elaborated on the OTSC System. In his summary of clinical cases his take home message was that the OTSC device is a very important tool for removing the OTSC which will be launched later this year.

• Update Endoskopie – meine Top papers
Häfler M, Vienna, Austria

M. Häfler updated the plenary session on important papers on GI hemorrhage. There he cited two papers by Manta et al. (2013) and Chan et al. (2014) where OTSC had proven to be safe, effective and also in severe bleeding when other procedures had already failed.

Over-the-scope clip (OTSC) represents an effective endoscopic treatment for acute GI bleeding after failure of conventional techniques

consecutive patients were included into the trial. The authors conclude that OTSC is a safe and effective procedure for closing recurrent anal fistulae even in more complex cases with Crohn’s disease or multiple surgical pretreatments.

Verschluss analer Rezidivfisteln mit dem OTSC System
R. Menningen, M. Laukoetter, N. Senninger, E. Fijten
Klinik für Allgemein- und Viszeralchirurgie, University Hospital, Muenster
For more detailed information on the study see reports in a pdf file on: www.oversco.com

April 2014 | The OTSC® System: a surgery-sparing device for the management of iatrogenic duodenal perforation during endoscopic ultrasound
Duodenal perforations are a rare but serious complication during endoscopic ultrasound examinations. The closure of these perforations with the OTSC System can be a surgery-sparing approach. Three case studies published by Dr. Silvia Sardor et al., Dept. of Digestive Disease, University Hospital, Barcelona, Spain and by Dr. Gianfranco Donatelli and colleagues, Endoscopy Unit, Hôpital Privé des Peyregues, Paris, France demonstrate the successful use of the OTSC System in case of iatrogenic duodenal perforation. Two patients (aged 88 and 67) presented with cholangitis, one 74-year-old woman with obstructive jaundice. In all three cases perforations occurred during endoscopic ultrasound procedures. Two perforations were located in the duodenal bulb, one at the superior duodenal flexure. By deploying an OTSC clip successful closure was achieved in all cases, no further surgical interventions were required. The two patients with cholangitis underwent therapeutic endoscopic retrograde cholangiography (ERC) afterwards without any complications. Oral food intake was restarted after 2 or 5 days, respectively.

Endoscopic closure of duodenal perforation with an over-the-scope clip during endoscopic ultrasound guided cholangiopancreatography
Salord S, Gornals JB, Maisterra S, Pons C, Busquets J, Fabregat J
Rev Esp Enferm Dig. 2012 Sep;104(9):489-90 98
Closure with an over-the-scope clip allows therapeutic ERC and endoscopic treatment of duodenal perforation during diagnostic endoscopic ultrasound Donatelli G, Vergeau BM, Drittas S, Dumont JL, Tuzuyuki T, Meduri B
Endoscopy. 2013 Nov;45 Suppl 2 UCTN:E392-3 151

March 2014 | OTSC®FISMD, Naples, Italy: 77 % success in anastomotic leak treatment
At the 20th National Congress of Digestive Diseases, Naples, Italy, March 19-22, MA Bonino and colleagues, Department of Surgery, Turin University reported about a consecutive series of 26 patients treated with OTSC for post-surgical colorectal leakage.
The median defect size was 8.7 mm, in 10 cases there were acute and in 16 cases chronic leaks (fistula), 4 cases were complicated by recto-vaginal, 3 by recto-vesical and 7 by colo-cutaneous fistula. In 3 cases OTSC was used to complete earlier vacuum sponge therapy. The overall success rates were 77.2% (20/26), 90% in acute (9/10) and 69% (11/16) in chronic cases. There were no OTSC-related complications, additional surgery was needed in 2 cases. Anastomotic leakage is a serious and non infrequent complication in colorectal surgery. Incidence rates in the literature range from 1 to 39 %. Clinically relevant leaks are commonly seen in 3-6 % of the cases. OTSC closure of colorectal post-surgical leaks and fistula is a safe technique with a high success rate.

Efficacia della clip OTSC per il trattamento del deiscenze e fistole di origine chirurgica
Efficacy of the Over-The-Scope Clip (OTSC) for treatment of colorectal post-surgical leaks and fistulas
Bonino MA, Verna M, Salvia A, Bullano A, Rapetti L, Azzeroz A, Morino M

March 2014 | Management of esophageal perforation with the OTSC® System – four new case studies by different authors report favourable results
Spontaneous or traumatic esophageal perforation is a life-threatening condition that can lead to severe mediastinitis, sepsis and multiple organ failure. Endoscopic management has contributed to the decrease of morbidity and mortality associated with surgical repair. Four different case reports lately published by Dr. Alexander Braun et al., Div. of General Surgery, University of Freiburg, Germany, Dr. Davide Bona et al., Div. of General Surgery, University of Milan, Italy and Dr. Alexandre Ferrera, Dept. of Gastroenterology and Hepatology, Hospital de Sant Maria, Barcelona, Spain and Dr. Clement Vergeau in Paris, France demonstrate the successful closure of esophageal perforations with the OTSC System.
Two patients presented with Boerhaave’s syndrome, one patient had an iatrogenic perforation and one patient suffered from a perforation caused by a fishbone. In all four cases a minimally invasive approach with the OTSC System was chosen. Two patients were treated with the OTSC clip within 12 hours. Although the two other patients were admitted to hospital not until after 48 h after an episode of vomiting, late management of the esophageal perforation with the OTSC System was performed, and complete closure of the defect, all patients were kept on antibiotic therapy and were discharged in stable condition after 10 days (patient with iatrogenic perforation), 21 days (patient with perforation caused by a fishbone) and 20 or 28 days respectively (patients with Boerhaave’s syndrome).
3-month follow-up revealed a free esophageal passage and correct placement of the OTSC clip. The OTSC clip is a new, safe and effective treatment alternative for the management of esophageal perforation. Due to the endoscopic approach and shorter hospital stay, the procedure is more cost effective than the alternative procedures.

Endoskopischer Verschluss von distalén Ösophagus-Perforationen mit einem Over-The-Scope-Clip (OTSC)
Braun A, Hopf UT, Richter-Schrag HJ
Endo heute 2013 131
Management of Boerhaave's syndrome with an over-the-scope clip
Bona D, Alold A, Rausa E, Bonavina L
Snapper fishbone esophageal perforation closed with in-over-the-scope endoscopic surgical procedures
Ferrera AO, Lopes J, Velosa J

March 2014 | OTSC: easy to use with good results, decreasing morbidity and mortality in diagnostic and therapeutic endoscopy
In the quest to describe the use and the clinical applications of OTSC System in an environment where endoscopic and surgical techniques are increasingly more complex and frequent Singhal et al. have searched and analysed the literature using the key words “endoscopy” and “over-the-scope” in order to identify human studies evaluating the application of OTSC from January 2001 to August 2012.
The indication, efficacy, complications, and limitations were recorded. The overall success rates of OTSC based on the literature were in the range of 75 % to 100 % for closure of iatrogenic gastrointestinal perforations, 38 % to 100 % for closure of gastrointestinal fistulas, 50 % to 100 % for anastomotic leaks, and 71 % to 100 % for bleeding lesions. OTSC has shown 100 % success rates in managing postbariatric surgery weight gain secondary to dislocation of the gastric-jejunostomy.
The authors conclude that OTSC is easy to use with good results, decreasing morbidity and mortality associated with complications secondary to both diagnostic and therapeutic endoscopy and avoiding surgery in many situations.

Over-the-Scope-Clip: Technique and Expanding Clinical Applications
Further reviews by Weiland et al.: Performance of the OTSC System in the endoscopic closure of iatrogenic gastrointestinal perforations: a systematic review
Weiland T, Fehlmer M, Gottwald T, Schuur MO
Performance of the OTSC System in the endoscopic closure of gastrointestinal fistulae – a meta-analysis
Weiland T, Fehlmer M, Gottwald T, Schuur MO

February 2014 | New case series on use of OTSC® for treatment of refractory upper GI bleeding
Apart from using the OTSC System in acute and chronic perforation, i.e. perforation caused by perforating ulcers, the authors of the renowned Institute of Digestive Disease, Department of Surgery, Chinese University of Hong Kong are reporting of patients in whom OTSC was used for endoscopic control of refractory or major upper gastrointestinal bleeding from lesions in the gastrointestinal tract between 1. July and 31 December 2012. Nine patients were included (median age 72.5 years, range 39-91 with bleeding gastric ulcers (n=2), bleeding duodenal ulcers (n=5), bleeding gastrointestinal stromal tumor in the stomach (n=1) and usual rectal carcinoma of the pancreas (n=1)). The median size of the ulcers was 2.5 cm (range 1-4). Six of the nine patients had undergone previous endoscopic hemostasis. Technical success (defined as hemostasis achieved at index endoscopy) was achieved in all patients and the clinical effectiveness was 77.8 % (defined as technical success with no rebleeding). All procedures were carried out by two experienced endoscopists. Those two patients that experienced rebleeding suffered from complex duodenal ulcer. One of them had been treated with radiotherapy for residual disease before resection of common bile duct cholangiocarcinoma. After several additional EGDs, arteriotal embolization, and one surgical intervention which all failed to stop the bleeding, the patient died eventually. The second patient bled from the inferior pancreaticoduodenal artery and needed arterial embolization as well.
The authors discuss a meta-analysis of 1156 patients in 15 randomized trials where endoclips were shown to be superior to injection alone, and as effective as heater probe treatment. The overall rate of rebleeding in those conventionally treated patients ranged between 7.1 % and 9.5 % though. Since rebleeding correlates with the adverse outcome of this indication they speculate that control of bleeding would have a positive impact on patient outcome. Even though the study was carried out in patients with conventional bleeding ulcer and patients with miscellaneous ulcer site, the authors conclude that the technical success rate of OTSC was 100 %. They also point out that usually in cases like these the application of conventional clips is difficult; the repeated application of heater probe being associated with a higher risk of perforation. Whereas the application of OTSC allows for larger amounts of tissue and constitutes a quite durable treatment (OTSC in situ after a median of 28 days in this study).
The authors conclude that the use of OTSC is a safe and effective method of endoscopic hemostasis for major bleeding of miscellaneous ulcer site and should be considered in refractory bleeding after conventional endoscopic hemostasis, before surgery or angiography.

Comment by Ovesco: a prospective controlled multicenter trial to compare upper GI bleeding in recruiting in Germany (Endoscopic Treatment of Recurrent Upper GI Bleeding: OTSC [Over the Scope Clip] Versus Standard Therapy (STING). ClinicalTrials.gov Identi- flier: NCT01836900)
Use of Over-The-Scope Clip for treatment of refractory upper gastrointestinal bleeding: a case series
Cham SM, Chiu PW, Teh AY, Lau JY
Endoscopy. 2014 Feb 6. [Epub ahead of print] 162

February 2014 | Retrospective study on efficacy and safety of the OTSC® System in the treatment of GI bleeding, fistula and
perforation: primary technical success rate 91.3 %, durable clinical success rate 82.6 %

Dr. Nishiyama and colleagues. Dept. of Gastroenterology and Neurology, Kagawa University, Japan, recently presented their retrospective study on efficacy and safety of the OTSC System in endoscopic closure of gastrointestinal bleeding, fistulas and perforations. The OTSC System is a highly useful device that can safely be utilized for these indications.

Their case series consisted of 23 consecutive patients treated between November 2011 and September 2012 (mean age 77 years) including the following indications for OTSC placement: stopping Gl bleeding (n=9), closing perforations (n=7), closure of a gastrointestinal fistula (n=4) and prevention of post endoscopic submucosal dissection (ESD) duodenal artificial ulcer perforation (n=1). One patient had a perforation that formed a fistula. Lesions were located in the esophagus (n=1), the stomach (n=10), the duodenum (n=5), the sigmoid colon (n=3) and in the rectum (n=4). In 8 patients other therapies preceded OTSC application (e.g. conventional hemostatic clips, local injections, hemostatic coagulation forceps). Median follow-up time was 67 days.

The primary technical success rate (complete closure by using only OTSC clips) was 82.6 %. Major contributing factors for OTSC failure were a large lesion size (greater than 20 mm) and a delayed diagnosis (more than 1 week). Three patients reported anemia that was associated with OTSC placement. In conclusion, the OTSC is an interesting and novel device that enhances the armamentarium of therapeutic gastroenterologists.

Efficacy and safety of over-the-scope clip: including comparison with conventional hemostatic or submucosal dissection

Distinguished authors

Dr. Shehab presents the case of a 36-year old woman who was admitted with a history of regurgitation and vomiting. A CT scan showed a fluid collection in the region of the right liver lobe, free peritoneal air, fever and abdominal pain. A barium contrast study confirmed a hiatal hernia. A gastroscopy confirmed a hiatal hernia. Dr. Shehab describes the use of the OTSC Twin Grasper to close the esophageal stent was applied. A second stent had to be deployed to bridge the anterior orifice of the stent. Since there was no improvement of the stent, the stents were again removed.

As an initial treatment of the perforation. With the advent of the larger and more power-ful OTSC clips, surgery can be avoided and perforations managed in a minimally invasive, endoscopic way. For that purpose, the OTSC System should be available to all endoscopy units as a bail-out device.

A novel system for endoscopic closure of gastroduodenal perforations using the OTSC® clip and omental patch


January 2014 | Closure of gastric fistulas after bariatric surgery with the OTSC® System – Two case studies

Iatrogenic gastric fistulas after bariatric surgery are a potentially dangerous situation as they can lead to severe complications, such as peritonits and abscess formation.

Two case reports recently published by Dr. Victoria Gómez and colleagues, Dept. of Gastroenterology and Hepatology, Mayo Clinic, Scottsdale, Arizona, USA, and Dr. Shehab et al, Dept. of Gastroenterology, Dar Al Fouad Hospital Giza, Egypt, respectively, describe the closure of gastric fistulas with the OTSC System after laparoscopic bariatric surgery.

Dr. Gómez reports on a 45-year old woman who was hospitalized for management of complications from a prior sleeve gastrectomy. Postoperatively the patient developed fever and abdominal pain. A CT scan showed a fluid collection in the region of the right liver lobe, free intraperitoneal air and an abscess in the post-surgical bed of the stomach. The results of a barium contrast study were consistent with a significant leak in the proximal third of the gastric sleeve. EGD revealed a gastric fistula 4 centimeters below the esophago-gastric junction. As an initial treatment with an esophageal stent and abdominal drains had to be deployed to bridge the prior stent. Since there was no improvement of the stent, the stents were again removed.

As next treatment approach the fistula was grasped with the OTSC Twin Grasper and closed by application of an OTSC clip. A follow-up radiograph showed no extravasation of contrast.

Dr. Shehab presents the case of a 36-year old man who had undergone a Roux-en-Y gastric bypass for morbid obesity. Postoperatively an anastomotic leak was found. Two attempts of surgical repair failed as well as a conservative endoscopic approach (e.g. application of the OTSC® clip. It was decided to close the fistula by OTSC clipping. To remove the epithelium at the fistula orifice, argon plasma coagulation was applied to the proximal lumen of the fistula.

Then the OTSC Twin Grasper was used to approximate the edges of the fistula orifice followed by the application of the OTSC clip. After 10 months there was no evidence of a fistula recurrence.

Since a surgical intervention for postoperative fistulas in an obese patient with recent bariatric surgery is most often not feasible, an endoscopically based approach with the OTSC System is an attractive treatment option. In comparison to conventional clips that are only suitable for small fistulas and only attach to the superficial mucosal layer, the OTSC clip offers a deeper grasp of the tissue and as such, it is sturdier.

Closures of iatrogenic bariatric gastric fistula with an over-the-scope-clip

Gómez V, Lukens FJ, Woodward TA

doi: 10.1016/j.soard.2012.09.004

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Combined endoscopic techniques for closure of a chronic post-surgical gastrocutaneous fistula: case report and review of the literature (with video)

Shehab HM, Elasmar HM


December 2013 | First report on successful management of delayed presentation of Boerhaave’s syndrome

Current guidance has advocated surgery for delayed presentations of Boerhaave’s syndrome with evidence of loculated mediastinal contamination. However, in 2010, Dr. Eamon Ramsay and colleagues, Dept. of General Surgery, University Hospital Coventry and Warwickshire, UK, present the successful management of Boerhaave’s syndrome in a 69-year-old man by means of the OTSC System, sparing the patient surgery and possible associated complications.

The patient presented to hospital with an episode of forceful vomiting. A chest radiograph was performed revealing a pleural effusion. After several days without improvement a CT chest showed an oesophageal perforation with mediastinitis. Because of the size of the defect and the delay in presentation, it was decided not to perform surgery, but to apply the OTSC clip for endoscopic repair. A CT scan confirmed the correct placement of the clip and the successful closure of the leak. After a total parenteral nutrition for 3 days, the patient was fed via a nasojejunal tube. In a follow-up visit, the stoma was noted to be closed, and a stoma dressing was placed over a resolving mediastinal abscess. The whole procedure resulted in a favourable outcome without the need for surgery.

The authors conclude that the OTSC can be used to manage patients with delayed presentation of Boerhaave’s syndrome. They further state that further evaluation is needed to define the indications for minimally invasive techniques like the OTSC System.

A delayed presentation of Boerhaave’s syndrome with mediastinitis managed using the over-the-scope-clip.

Ramhamady E, Mohamed S, Jaouss S, Baker T, Mannah J, Harding J, Menon V


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December 2013 | Management of postoperative gastrointestinal leakages and fistulas with the OTSC® System: long-term success rate of 79 %

Dr. Rudolf Menninger and colleagues, Dept. of General and Visceral Surgery, University Hospital of Muenster, Germany, recently presented a study on efficacy and safety of the OTSC System in endoscopic closure of postoperative gastrointestinal leakages and fistulas, concluding that the OTSC System dramatically increases the possibilities of defect closure by endoscopic clipping as opposed to surgical intervention.

Their case series of 14 consecutive patients (May 2011–November 2012) included patients with anastomotic leakage (n=6) e.g. after gastrectomy, perforation after fundoplication (n=1) and post-operative fistulas (n=7, e.g. enterocutaneous, jejuno-jejunal, rectourethral, recirculectaneus, gastropleureal). 11 of the 14 lesions were chronic (treated by OTSC later than postoperative day 14) and in 9 patients other therapies preceded OTSC application (e.g. covered stent application, fibrin glue injection). Median follow-up time was 5.5 months.
The primary procedural success rate was 100%, 3/3 patients (100%) required further treatment during follow-up. Reasons for OTSC failure were massive fibrosis of the fistula and application in an actively inflamed bowel segment in Crohn’s disease. However, unsuccessful OTSC treatment did not impair subsequent surgical therapies. Conversion and clinical and radiological closure of both defects was achieved in 79%, indicating from the authors’ point of view that the OTSC will play an important role in the therapy of postoperative leakages.

Endoscopic closure of postoperative gastrointestinal leakages and fistulas with the Over-the-Scope Clip (OTSC)

Mengien R, Colombo-Benkmann M, Senninger N, Laukötter M

November 2013 | OTSC® in endoscopic treatment of acute GI bleeding after failure of conventional techniques: primary hemostasis of 97% The OTSC System can overcome the limitations of conventional clips in the treatment of patients with acute GI bleeding by providing compression of large amounts of tissue, leading to a more efficient hemostasis. Dr. R. Manta and colleagues, Department of General, Gastroenterological, and New S. Agostino Hospital, Modena, Italy draw this conclusion on the basis of a retrospective analysis of a consecutive case series of 30 patients with severe acute GI bleeding treated with the OTSC System after failure of conventional techniques. Data were collected from six high-volume endoscopy units in a period between December 2011 and September 2012. All 30 patients suffered from bleeding lesions unresponsive to saline/adrenaline injection and through-the-scope clipping located in the upper and lower GI tract in 23 and 7 cases, respectively. Bleeding lesions included duodenal ulcer (n=12), gastric ulcer (n=6), Mallory-Weiss (n=2), Dieulafoy (n=2) and surgical anastomosis (n=1) in the upper GI tract and endoscopic mucosal resection (n=5), endoscopic submucosal dissection (n=1) and colonic diverticulum (n=1) in the lower GI tract. Primary hemostasis with OTSC was achieved in 29 of 30 cases (97%). Rebleeding in two cases was successfully treated with injection of saline and adrenaline. Endoscopic follow-up after 2–4 days and 1 month revealed correct placement of the OTSC clip and no post-treatment complications. Thus, the OTSC is an effective and safe device for treatment of acute GI bleeding and represents a useful adjunct to the therapeutic armamentarium in endoscopic emergencies.

Overview of OTSC® clip OTSC represents an effective endoscopic treatment for acute GI bleeding after failure of conventional techniques

Surg Endosc. 2013 Sep;27(9):3162-4

October 2013 | OTSC® System: Effective closure of esophageal fistula following total gastrectomy

Postoperative leaks after total gastrectomy are among the most common early complications. Dr. C. N. Ferreira and colleagues, Serviço de Gastroenterologia e Hepatologia, Hospital de Santa Maria, Lisbon, Portugal report on a 78-year-old woman presenting with melena. She was diagnosed with gastric adenocarcinoma and treated with total gastrectomy and esophageojugular Roux-en-Y anastomosis. On the fifth postoperative day she developed a septic condition caused by a fistulous orifice just above the jejunostomy. Due to her poor general condition a surgical intervention was unfeasible. Thus, it was decided to treat the fistula endoscopically by means of the OTSC clip. By using the OTSC Twin Grasper to approximate the edges of the fistula and application of an OTSC clip the orifice was effectively closed. The patient was discharged in stable condition two weeks later. In a commentary to this publication Dr. David Robbins, Assistant Editor of the Journal Gastrointestinal Endoscopy emphasizes the significantly higher strength of the OTSC clip for hemostasis and closure of GI tract wall in comparison to conventional endoscopic clips. Total gastrectomy in an elderly patient complicated by esophageal fistula: rescue by the over-the-scope clip

Gastrointest Endosc. 2013 Mar;77(3):497-8; [Epub 2013 Jan 4]

October 2013 | Efficacious OTSC® hemostasis in Dieulafoy’s gastric lesion resistant to conventional endoscopic treatment

Dr. B. Mangiavillano and colleagues, Gastrointestinal Endoscopy, Azienda Ospedaliera San Paolo University Hospital, University of Milan, Italy, present a case study of a 99-year-old patient suffering from a large Dieulafoy’s lesion on the gastric antrum. EGD showed a Dieulafoy’s bleeding lesion in the proximal third of the posterior wall of the stomach. The lesion was treated with an epinephrine injection and application of two conventional working-channel delivered metallic clips and the patient was discharged two days later. After three days the patient again presented with melena. Blood transfusions were necessary. An EGD was performed, showing no sign of an actively bleeding ulcer. The patient was admitted to hospital and suffered from another episode of melena with hematemesis. EGD revealed a new, actively bleeding Dieulafoy’s lesion was then treated with an OTSC clip, stopping the hemorrhage completely and persistently. Endoscopic follow-up after 30 days displayed correct placement to the OTSC and no signs of further bleeding.

Successful treatment with an over-the-scope clip of Dieulafoy’s lesion resistant to conventional endoscopic treatment

Mangiavillano B, Arena M, Morandi E, Viaggi P, Maselli E
Endoscopy. 2012;44 Suppl 2 UCTN:E387

OTSC Update 15 EXTRA

October 2013 | OTSC® successful in providing hemostasis in posterior duodenal ulcer bleeding after failure of conventional clips

Ulcer bleeding is one of the key indications for the OTSC System. In a recently published case series (n=4), Prof. Klaus Mönkemüller and colleagues, Dept. of Internal Medicine, Gastroenterology and Infectious Diseases, Marienhospital Bottrop, Germany add to the growing clinical experience in using the OTSC System to control massive bleedings and achieve lifetime saving hemostasis. All four patients (mean age 84.5) presented with hypotension and mean hemoglobin of 9 g/dL. After initial fluid resuscitation an emergent EGD displayed actively oozing ulcers in the posterior duodenum. As an initial therapy with injection of epinephrine saline solution and standard clip placement failed the patient suffered from rebleeding, the decision to apply the OTSC System was made. Hemostasis was attained successfully and all patients discharged in stable conditions. Even in difficult located ulcers in the posterior duodenum the placement of the OTSC is easy and effective to obliterate bleeding vessels resulting in life-saving hemostasis.

Utility of the „bear claw“, or over-the-scope clip (OTSC) system, to provide endoscopic hemostasis for bleeding posterior duodenal ulcers

Mönkemüller K, Toshniwal E, Zabelski M, Vormbrock K, Neumann H

September 2013 | OTSC® in post-surgical complications: retrospective case review confirms high clinical efficacy

Dr. Alisa Coker and colleagues, Department of Surgery, University of California San Diego, USA, report on their experience with the OTSC System in a retrospective review of all cases treated between August 2011 and March 2012. All 10 patients had clinically significant gastrointestinal post-surgical complications. Indications included: gastric leaks after sleeve gastrectomy (n=4), postoperative colonic leak following extended ileocolicectomy and palliative debulking (n=1), gastric-gastro fistula following Roux-en-Y gastric by-pass (n=2), esophageal perforation (n=3). Three of the four patients with gastric leaks had undergone previous unsuccessful attempts at endoscopic repair (stenting, fibrin glue application, traditional clipping, endoscopic suturing). The overall clinical success rate was 70%. Re-surgery was needed in the two cases of gastro-gastric fistula. In the colonic leak patient the clip placement procedure was aborted due to a fixed tortuous sigmoid colon as a result of the metastatic disease and adhesions, limiting endoscope passage. For the subgroup of seven patients treated for leaks and perforations a success rate of 87.5% with complete resolution was achieved. The mean follow-up period was 83 days. No complications occurred. The authors conclude that the OTSC System is simple to use, safe and effective with a great potential for success in a broad number of applications. For the treatment of gastric leaks following sleeve gastroectomy the OTSC System is their first-line treatment.

Initial Experience with an Innovative Endoscopic Clipping System

Coker A, Jacobson GR, Acosta G, Talalamin MA, Savides TJ, Horgan S

September 2013 | Preventive closure of duodenal ulcer after endoscopic submucosal dissection with the OTSC® System to obviate delayed perforation

Two recently published reports, published in the journal Digestive Endoscopy by Dr. Hirohito Mori and his colleagues, Dept. of Gastroenterology and Neurology, Faculty of Medicine, Kagawa University, Japan illustrate the complete closure of secondary duodenal ulcers after endoscopic submucosal dissection (ESD) with the OTSC System without any complications.

Two elderly patients were diagnosed with early duodenal cancer. ESD was carried out successfully removing the lesions en bloc. In one case the muscle layer was slightly injured but not perforated. Because of the exposure to bile and pancreatic juices the risk of post-ESD delayed perforation is much higher in the duodenum than in other parts of the gastrointestinal tract. As conventional clips are less suitable due to small size and insufficient grasping power, Dr. Mori and his team used the OTSC System to clasp the ulcers completely without any complications. The ulcer closure procedure time was 7 resp. 10 min. In both cases control endoscopy revealed a complete healing of the ulcer after 30 days.

Dr. Mori and his colleagues consider the OTSC System to be one of the most effective devices to prevent delayed perforations in post-ESD ulcer.

Successful closure of duodenal ulcer after endoscopic submucosal dissection with over-the-scope clip to prevent delayed perforation


September 2013 | First two publications of endoscopic closure of gastric fistula using the OTSC® System

Dr. Alberto Munro, Wolfson Unit for Endoscopy, St Mark’s Hospital, London, UK, and his colleagues report on a successfully treated gastric fistula using the OTSC System. A migrated PEG tube caused a gastric fistula in the transverse colon in a 41 y/o male with cerebral palsy. The fistula led to extensive diarrhea and mouth odor. The CT showed an involvement of the greater curvature of the stomach. By using the OTSC Anchor to approximate the tissue the OTSC clip was released precisely closing the fistula orifice completely. Diarrhea and mouth odor were stopped. The 3 months’ follow-up revealed a complete healing of the gastric fistula.

The second case report published in the World Journal of Gastrointestinal Endoscopy by Prof. Klaus Mönkemüller and colleagues, Division of Gastroenterology and Neurology, Faculty of Medicine, University of Regensburg, Germany illustrate the complete closure of a jejunal enterotomy using the OTSC System, without any post-endoscopic complications.
Hepatology, Basil Hirschowitz Endoscopic Center of Excellence, University of Alabama, Birmingham, USA, describes the effective endoscopic closure of a large gastrointestinal fistula with the OTSC System in an extremely malnourished patient with complex post-surgical GI anatomy. The 47 y/o man presented with chronic diarrhea and emaciation 1-1.5 years after a 1-year period. He had a history of chronic pancreatitis, alcoholism and Biliroth II gastrectomy due to a perforated peptic ulcer. Endoscopy showed a clear based ulceration at the gastrocolic fistula measured about 10–12 mm. Because of the patient’s poor clinical status he could not benefit from a surgical intervention so an endoscopic procedure using the OTSC System was chosen. To ensure a definitive closure of the fistula the OTSC Twin Grasper was used to approximate the edges of the fistula. The application of the OTSC led to a complete closure of the gastrointestinal fistula which was confirmed by an endoscopy.

For Prof. Mönkemüller this case adds to the growing evidence that the OTSC System is a useful device to treat clinical significant endoluminal GI defects. He believes that "this device is a major breakthrough for the management of various types of discontinuity defects or fistulas of the GI tract [...] and that ‘the OTSC System should be incorporated into the therapeutic armamentarium of the advanced endoscopist.”


Gastrointest Endosc. 2012 Apr;75(4):833; discussion 834

Endoscopic closure of a gastrocolic fistula using the over-the-scope clip system Mönkemüller K, Peter S, Allkundi B, Rameish J, Popa O, Wibix C.

World J Gastrointest Endosc. 2013 Aug;16(58):402-6

July 2013 | The interesting case: OTSC® closure of esophagobronchial fistula

Dr. E. Zolotarevsky and colleagues from the Department of Gastroenterology and Nutrition Service at Memorial Sloan-Kettering Cancer Center, New York City report about an interesting case in which OTSC clipping was used for closing an esophagobronchial fistula.

An 83 y/o woman presented with a symptomatic fistula arising from an esophageal and submucosal pulmonary lesion. Placing a covered self-expanding metal stent was not believed to result in adequate seal of the chronic lesion. The placement of a percutaneous gastrostomy tube was refused by the patient. Also bronchial stenting and surgery were not considered as good options in this case.

In this situation closure of the fistula with the OTSC clip was decided. A 12/6 clip was placed under endoscopic control and with the aid of the OTSC Anchor for better manipulation and targeting of the fistula orifice. Immediate technical success was achieved and verified by chest X-ray about 2 days later. The patient was discharged from the hospital after 1 week in stable condition. The clip was still found in place at 1 month follow-up by chest X-ray but passed spontaneously and uneventfully as seen in CAT scan 10 days after the procedure. Final follow-up at 3 months revealed no recurrence or postprandial cough.

Esophagobronchial fistula closure using a novel endoscopic over-the-scope clip Zolotarevsky E, Kwon Y, Bains M, Schattner M.

Ann Thorac Surg. 2012 Sep;94(3):859-70. 96

July 2013 | OTSC® effective in emergency closure of iatrogenic GI perforations instead of abdominal surgery

Dr. Hagel and colleagues, Dept. of Gastroenterology, University of Erlangen-Nuremberg, Germany reported about a consecutive series of 17 cases with perforations of the digestive tract, treated with OTSC clipping. All cases were considered as being candidates for abdominal surgery for closing the perforation. In 11 cases perforation closure with OTSC was immediately successful, thus avoiding surgery in 64.7 %. In 6 cases surgical closure was done. The area size of perforation in the successful cases was 21.1 ± 9.1 sqmm; in the unsuccessful group the area size was 57.6 ± 149 sqmm. Unsuccesful cases had on average a larger size, necrotic margins and required more OTSC clips during closure attempts (2.3 ± 0.5, p=0.018).

The authors conclude: “OTSC application yields a high rate of endoscopic perforation closure in patients with macroscopic gastrointestinal perforation, even in an emergency setting, mostly representing an alternative to surgery, especially when the size of the lesion is not too large and when vital or solid perforation margins are expected.”

Over-the-Scope Clip Application Yields a High Rate of Closure in Gastrointestinal Perforations and May Reduce the Need for Surgery Hagel AF, Naegel A, Lindner AS, Kessler H, Matzel K, Dauth W, Neurath MF, Raithel M


OTSC Update 14: July 2013 | OTSC® System in transgastric appendicectomy

Kaelher E and colleagues report about the results of their first 15 patients in a prospective trial on “Transgastric appendicectomy” which now already recruited 30 patients who are currently under follow-up.

From April 2010 the Mannheim group offered to their patients a transgastric appendicectomy for ordinary appendicitis and patients with generalised peritonitis and/or local contraindications for a surgical intervention (the success rate was close to 93 %). The Mannheim group now already recruited 30 patients who are currently under endoscopic treatment.


World J Gastrointest Endosc. 2013 Aug 16;58(5):402-6

July 2013 | Recommendation of OTSC® System in complex GI bleeding

In an overview article the authors are referring to the current guideline therapies available and new developments. They report that other new three-dimensional clips seem to be more efficient than normal hemoclips. Thus, the authors conclude that obviously one of the key elements to successful hemostasis is the strength of the jaws of a clip and the amount of tissue captured. They state that this is obviously fulfilled by the design of the OTSC System which allows for the capture of a large amount of tissue and is more secure than other clips in the experimental setting.

Thus the OTSC System is being recommended and used in complex GI bleeding. According to Leung & Lau a single clip suffices for most circumstances and therefore the procedure is shorter when compared to multiple applications of hemoclips.

Comment by Ovesco: In a recently published series of 83 patients with severe and complicated GI bleedings (e.g. relapses after conventional endoscopic hemostasis or indication for a surgical intervention) the success rate was close to 93 % with OTSC (Kraut T et al., Poster DGE-BV meeting, Munich 3/2013)


June 2013 | Report on successful removal of an OTSC® Clip

Prof. Mönkemüller and colleagues presented a clip removal case in a letter to the editor of Gastrointestinal Endoscopy.

Ten days after treating an anastomotic leak with the OTSC System, there was still a leak due to misplacement of the clip. The clip had to be removed to place another OTSC onto the leak. At first clip rising was accomplished by injecting saline solution below the OTSC. A snare was positioned around the clip, slowly closed and retracted. The clip was dissected and was retrieved carefully without injury by catching it with the snare and keeping it close to the distal end of the endoscope. The anastomotic leak was thereafter closed successfully with a new OTSC.

Endoscopic removal of an over-the-scope clip (‘bear claw’)

Mönkemüller K, Tostniwal J, Zabiejcki M

Gastrointest Endosc. 2012 Nov;76(5):1077-8

June 2013 | German surgical periodical alludes to OTSC® Proctology as a novel therapy for anal fistula

In the German surgical periodical "Chirurgische Allgemeine" Prof. Dr. A. Herold, German Center for the Anorectum (EDZ), Mannheim, Germany, gave an overview on new treatments and devices for anorectal fistula. Prof. Herold is the General Secretary of the German Society for Coloproctology (DGK). In his paper he refers to OTSC Proctology as a new therapeutic alternative.

Neue Techniken bei der Therapie der Analfistel Herold A, Chirurgische Allgemeine (2013); 14: 99–102

May 2013 | Ovesco’s Full Thickness Resection Device (FTRD®) presented in live endoscopy at Endo-Update meeting

During clinical live demonstrations at endo-update which took place under the presidency of Prof. Dr. H. Messmann and Prof. Dr. H.-D. Allescher in Augsburg, Germany, a neuro-endocrine tumor (NET) in the rectum was resected with the new Full-Thickness Resection Device of Ovesco called the FTRD. Also resected was a submucosal tumor of about 9 mm diameter. Biopsy revealed a neuroendocrine tumor. Prof. Dr. Thomas Rösch (University Hospital Hamburg-Eppendorf) used the FTRD to resect the lesion. The FTRD consists of an elongated OTSC (University of Munich) premounted with a specially designed, derivative OTSC clip and the cap incorporates a resection snare. Prof. Rösch grasped the lesion with a grasping forceps and pulled the target tissue into the cap in a full thickness fashion. After mobilizing the tissue into the cap, the clip was retracted to seal the resected tissue before resection. Right afterwards the snare was closed and the tissue resected with HF current. The resection specimen included the full thickness of the wall carrying the NET, with a safety margin. The serosa was seen in histology, confirming that the specimen was a full-thickness resection.

The FTRD device is not yet commercially available. endo-update 2012 | 30.11.-01.12.2012

Venue: Klinikum Augsburg, Augsburg, Germany

May 2013 | Iatrogenic digestive tract perforations: OTSC® closure as preferred method

Dr. G. Dieler and Prof. P. Bauerfeld, Dept. of Gastroenterology, Zurich University Hospital, Switzerland, report about the use of the OTSC clip for endoscopic closure of iatrogenic organ perforations. In a consecutive patient series (n=14) they investigated technically successful closure of perforations as a result of an endoscopic intervention. All patients were followed clinically for 24 hrs. Endoscopic closure was achieved in 13 of the 14 cases (92.8 %). In 3 patients abdominal pain led to evaluation of the closure site by laparoscopy as a precaution. All 3 OTSC closure sites were found intact and no segmental resection of the bowel was needed. One OTSC gastric closure patient had gastric resection after histology revealed gastric adenocarcinoma after endoscopic mucosal resection. The authors conclude that GI perforations up to 35 mm diameter, observed during endoscopy should be treated with endo- scopic OTSC clip closure.

Ovesco Research Update 33 | Research & clinical trials | Version 33 | 2019-12-20
Endoscopic closure of iatrogenic gastrointestinal tract perforations with the over-the-scope clip

Guberl C, Bauerdorf P
Dignosis. 2012;85(4):302-7
Epub 2012 May 17 81

October Update 13

April 2013 | OTSC® System found safe and appropriate for closure of acute perforations in the stomach

In this first trial from China (after compassionate use cases in previous studies) the authors investigated the feasibility of the OTSC System for the closure of gastric perforations in the fundus. This location is of special interest since the handling of a flexible scope in the retroflex position is sometimes quite challenging. The investigation was done in a dog model. The perforation was performed with electrocautery and a needle knife in seven dogs. Closure was performed with one OTSC clip each. The closure was performed in 18.5 +/- 6.4 minutes (team without prior experience). The following leak pressure test with maximum air insufflation of the stomach with the methyl blue solution resulted in one minor leak (laparoscopic control) without clinical consequences though. The authors conclude that the OTSC System is safe and appropriate for the closure of acute perforations in the stomach despite the well known difficulties with the J-oscilatore.

Feasibility study of secure closure of gastric fundus perforation using over-the-scope clips (OTSC) in a dog model

Zhang XL, Ju JH, Sun G, Tang P, Yang YS

April 2013 | Conference report | OTSC® at German Endoscopy Conference (DGE-BV 2013 in Munich)

OTSC was well-covered in the scientific programme of this year’s German Endoscopy Conference in Munich. Clinical presentations confirm efficacy of OTSC clipping in a range of indications

March 14 – 16, 2013. The 43rd German Endoscopy Congress, DGE-BV, was held under the presidency of Prof. Dr. Christoph F. Dietrich. A significant number of presentations had clinical data of OTSC clipping as their topic and confirmed clinical efficacy and safety. The primary indications of the procedure were hemostasis, closure of acute lesions/perforations and closure of chronic lesions/fistula (source: www.dge-bv.de).

Large single center OTSC cohort with hemostatic and organ wall closure indications

Weid E, Menke D, and Hochberger J, Strasbourg (France) reported about a cohort of 84 patients with OTSC clipping for GI bleeding, fistula and GI wall insufficiency. 101 OTSC clips have been used in this cohort, or 1.2 clips per patient. Indications included mainly severe upper GI peptic ulcer hemorrhage (n=38) and preventive clipping to avoid rebleeding (n=12) or secondary perforation (n=18) after large area ESD. The clinical success rate in peptic ulcer hemorrhage (n=38) and preventive clipping to avoid migration of covered, self-expandable stents. Stent migration has an incidence of up to 30% and represents a significant clinical challenge. To prevent stent migration, the authors used OTSC to fix the stent temporarily to the neighboring GI wall. In 24 cases with benign indication for stent placement OTSC fixation was carried out in the following locations: esophagus, small bowel and colon. After 5–8 weeks the OTSC clips were removed by No.YAG laser cutting to intentionally remove the stent. In this group of cases the procedure was technically successful. In 1 patient an undesired stent migration before intentional removal was observed. In another case the stent had to be removed after a few days due to intolerance by the patient in a location close to the upper esophageal sphincter. The authors conclude that OTSC clipping was found to be a safe and practical technique and has prevented stent migration in 96% of the cases studied.

Verwendung des Ovesco-Clips zur Verhinderung der Migration bei vollgecoaten selbstexpandierenden Stententen

Fähndrich M, Pohl T, Rolffs S, Sandmann M, and Heike M

Hospitalisation time and 30 days mortality in GI perforations after technically successful and unsuccessful OTSC closure

Hagel A, Näge 1, Rahfel S, Diebel H, Neurath M, and Raithel M, Erlangen, showed data on the management of GI perforations with OTSC clips. They studied 19 patients with apparent perforation of a digestive organ wall in various anatomical locations. In 13 patients the perforation could be closed with OTSC (“O+”) to avoid emergency surgery. In 6 patients OTSC closure was technically unsuccessful and emergency surgery was needed (“O–”). In the O+ group the duration of hospitalisation was 10.7 +/- 10 days, no mortality. 2 patients in this group had co-morbidities unrelated to clip closure, leading to a prolonged hospital stay; excluding these 2 patients, hospitalisation was 5.8 +/- 2 days. In the O- group hospital stay was 12.1 +/- 7 days, one patient with esophageal perforation died after emergency surgery was not able to prevent fatal mediastinist. The authors draw the conclusion that OTSC treatment can significantly reduce morbidity and mortality in GI perforation.

OTSC-Anwendung bei manifest Perforation: 30-Tages-Mortalität, Hospitalisationsdauer und Out-come nach endoskopisch erfolgreichem und nicht-erfolgreichem Perforationsverschluss

Hagel A, Näge 1, Rahfel S, Diebel H, Neurath M, and Raithel, Erlangen

Monocentric case experience with OTSC in a broad range of wall closure indication: safe transmural closure

Nietisch H, Hammelmann F, and Asperger W, Halle, summarized their initial experience with OTSC in endoscopic closure of the GI organ wall in 10 consecutive applications. Indications included: post-surgical rectal anastomotic leak (n=2), rectal ESD perforation (n=1), gastric ESD perforation (n=1), gastric ulcer (n=2), and upper GI perforation (n=1) after balloon dilation (n=1), Mallory-Weiss tear (n=1), perforated gastric ulcer (n=1), post-surgical duodenal leak (n=1) and post-surgical bariatric suture line leak. All cases were successful. The authors conclude: OTSC enables a safe transmural closure of spontaneous and iatrogenic perforations. In a majority of cases target tissue handling is possible with suction only and does not require additional instruments. In well-trained endoscopy centers the learning curve for OTSC is short.

Herz- und Blutungsübersicht: den ersten 10 Anwendungen des endoskopischen OTSC-Clipsystems

H. Nietisch, F. Hammelmann, and W. Asperger, Halle

OTSC for closure of distal esophageal perforation

Braun A, Richter-Schrang H, Hopt U, Fischer A, Freiburg, showed data on OTSC in the treatment of distal esophageal perforation after endoscopy (Boerhaave, n=1) and iatrogenic injury. Esophageal perforation is a life-threatening situation with a high complication and mortality rate. In both cases endoscopic closure of the esophagus was achieved within 12 hrs after the lesion. Both patients received bilateral thorax drainage and antibiotic therapy. No patient showed clinical problems though. Control endoscopy after 3 months revealed no stenosis and both clips were found in place. The authors summarize that the closure of esophageal perforations with OTSC is a safe and effective method and is significantly more economic than common surgical therapy requiring longer hospital stays.

Endoskopischer Verschluss von distalen Ösophagus-Perforationen mit einem Over-The-Scope Clip (OTSC) A. Braun, H. Richter-Schrang, U. Hopt, A. Fischer, Freiburg

Consecutive case series of OTSC application in the endoscopic management of complications and diseases

Thomsen T, Berthold B, Khiabanchian M, and Trabandt I, Neubrandenburg, presented data of a case series (n=11). Indications included upper and lower GI bleeding, PEG-fistula closure, rectal-fistula closure, sigmoid and anal fistula. All patients were treated endoscopically. One patient required emergency surgery. The overall clinical success rate in the mixed case series was 82 %. No procedure took more than 30 min. As complications 1 fistula recurrence (required second OTSC treatment) and 1 remaining perforation was seen. The authors summarize that OTSC clipping is a fast procedure with a high primary success rate and is quick to learn.

Endoskopische Interventionen mit dem OTSC-System am Klinikum Neubrandenburg

T. Thomsen, B. Berthold, M. Khiabanchian, and I. Trabandt, Neubrandenburg

OTSC for stopping gastroduodenal artery bleeding in duodenal ulcer

Krat T, Sücker D, Kirschknik A, Heininge A, Wietek B, Königshoff J. Tübingen, showed a case series (n=7) in which OTSC was used for an upper GI perforation to stop bleeding from the gastroduodenal artery. Gastrroduodenal artery bleeding is besides aortoduodenal fistula considered the most severe bleeding complication in the digestive tract, associated with high morbidity and mortality. In many cases surgery or emergency perforation is inevitable.

In all cases reported here the gastroduodenal artery was verified as the bleeding source by angiography after successful endoscopic treatment. In all 7 patients the acute bleeding from an ulcer at the posterior duodenal wall was successfully controlled with OTSC, in 4 cases fibrin glue was additionally applied. After the initial 72 hrs, 3 patients suffered from rebleeding, which was then controlled surgically. No mortality was encountered in this case series. The authors draw the conclusion that OTSC is effective in emergency management of gastroduodenal artery bleeding. In more than half of the cases endoscopic management was
the only therapy. In the other patients OTSC was a successful "bridge to surgery" and allowed stabilizing the patient before the operation.

OTSC-basierte Notfall-Hämostase der lebensbedrohlichen A. gastrudodenalisis Ulkus-Arrosionsblutung: alleingelegene endoskopische Therapie oder "bridge to surgery"?


Report on Ovesco FTRD (pre-commercial device)

T. Kratt, T. Stüker, G. Gräpler, F. Schenk, M. Adam, and Königraiper A, Tübingen, presented data of their first 8 cases with FTRD, a device of Ovesco Endoscopy, not yet commercially available. It combines modified OTSC clipping with tissue resection. In 7 of the 8 cases the procedure was technically feasible; in 1 case the target lesion could not be reached. The cases treated included various indications in which FTRD was used as a device for full-thickness tissue retrieval with the primary purpose of enhanced histological examination of an in-loto full thickness specimen. The target lesions were in the upper GI tract, melanoma metastasis (n=3), GIST (n=1) or in the lower GI tract (adenoma or early colorectal cancer, low risk histology; n=4). The presentation gave a detailed case history of an elderly patient with recurrent adenoma (high grade dysplasia, partially adenocarcinoma-) of the rectum. The patient had full thickness resection with FTRD under single-shot antibiosis and was discharged the following day. As histology demonstrated complete removal of the lesion, no further therapy was done. Follow-up was uncomplicated. After 14 weeks control endoscopy revealed that the clip had detached from the tissue, normal scar formation was seen at the resection site and no signs of residual lesion or new recurrence were found.

Klinische Evaluation eines neuen endoskopischen GI-Trakt-Vollwandresektionssystems: das OTSC-basierte "full thickness resection device" (FTRD)

T. Kratt, D. Stüker, F. Gräpler, M. Schneek, P. Adam, and A. Königraiper, Tübingen

FTRD is not yet commercially available.

March 2013 | Dr. Thomas Kratt, University of Tuebingen, Germany, wins award for this device of Ovesco’s FTRD®

Dr. Thomas Kratt, Interdisciplinary Endoscopy, University Hospital, Tuebingen, Germany, received an award for this presentation of clinical research in the field of full-thickness resection at the 43rd Congress of the German Society for Endoscopy and Imaging (DGE-BV), held in Munich, March 14–16, 2013.

Dr. Kratt presented data of his first 8 cases with FTRD, a device of Ovesco Endoscopy, not yet commercially available. It combines modified OTSC clipping with tissue resection. In 7 of the 8 cases the procedure was technically feasible; in 1 case the target lesion could not be reached. The cases treated included various indications in which FTRD was used as a device for full-thickness tissue retrieval with the primary purpose of enhanced histological examination of an in toto full-thickness specimen. The target lesions were in the upper GI tract, melanoma metastasis (n=3), GIST (n=1) or in the lower GI tract (adenoma or early colorectal cancer, low risk histology; n=4).

The presentation of Dr. Kratt gave a detailed case history of an elderly patient with recurrent adenoma (high grade dysplasia, partially adenocarcinoma-) of the rectum. The patient had full thickness resection with FTRD under single-shot antibiosis and was discharged the following day. As histology demonstrated complete removal of the lesion, no further therapy was done. Follow-up was uncomplicated. After 14 weeks control endoscopy revealed that the clip had detached from the tissue, normal scar formation was seen at the resection site and no signs of residual lesion or new recurrence were found.

March 2013 | Prospective trial on OTSC® Proctology in anal fistula treatment first data

Munich, March 8, 2013. The annual conference of the German Society for ColoProctology (DGK) was held in Munich, March 8 and 9, 2013. At the conference first data were presented from an investigator initiated multicentric prospective observational clinical trial on the use of OTSC Proctology in the treatment of anal fistula. The two participating trial sites are the Stuttgart Institute of Proctology (led by Dr. W. Ehn), Stuttgart and the German Anorectal Center (EDZ) (Dr. A. Joos, Prof. Dr. A. Herold, PD Dr. D. Bussen), Mannheim.

The trial presented an interim analysis on the first 14 weeks of follow-up. All patients included criteria are supra-, extra- or high trans-sphincteric anal fistula, including first recurrence but excluding patients with IBD.

Mean follow-up was 6.9 months (1–15 months) after OTSC placement. 8 patients had already completed follow-up (6 months), 7 patients were still followed. In patients who had already completed the trial, mean follow-up was 10.8 months (6–15 months).

In these patients the healing rate, defined as post-surgical closure of the fistula, absence of drainage from the fistula and absence of recurrence after 6 months was 88 %.

In his presentation PD Dr. R. Prosst, Stuttgart, coordinator of the trial, summarized that data were encouraging but clinical trials | Version 3 | 2012-03-01

February 2013 | Retrospective multicentric review of early OTSC® patients in the US: overall clinical success rate of 71 %

Dr. Todd H. Baron and colleagues, Division of Gastroenterology & Hepatology, Mayo Clinic, Rochester MN, USA reported about their experience with 45 patients and 48 OTSC clip placements from March 2011 to January 2012. Median follow-up time in this mixed cohort was 77 days (30–330 days). Indication breakdown included hemostasis (n=7), closure of chronic fistula (n=28), closure of iatrogenic perforations (n=5), closure of post-esophagectomy anastomotic leakage (n=3) and miscellaneous indications (n=2).

Before OTSC placement 49 % of the patients had undergone other therapies for their condition that had failed. The overall clinical success rate was 71 %. Hemostasis was achieved in 100 % of cases. Anastomotic leakage and fistula was closed in 65 %. Also one case of OTSC clip removal by means of APC-cutting of a clip hinge is described:

The authors conclude that the OTSC clip appears clinically effective and is a welcome addition to the therapeutic armamentarium in the closure of leaks, fistula, perforations and other benign conditions.

Use of an over-the-scope clipping device: multicenter retrospective results of the first U.S. experience


January 2013 | Combined use of OTSC® System and stent to close large EMR-related perforations

Treatment of large EMR-caused perforations with a combined use of OTSC and stenting is reported by Hadj Amor et al.

One patient with a 20-mm esophageal perforation was treated with an OTSC, several other clips and an endoloop. A fully covered stent was placed on top to bypass the perforation. The large duodenal perforation in the other patient was initially unsuccessfully treated with a fully covered stent and several clips to avoid migration. After removal of the stent an OTSC and two other clips were used to close the perforation completely. The perforation was bridged by another fully covered stent that was placed over the closed perforation without fixation. In both patients the stents were removed after several weeks and both sites showed healing of the perforation.

Successful endoscopic management of large upper gastrointestinal perforations following EMR using over-the-scope clipping combined with stenting


April 2012 | OTSC® Use in the Treatment of an Anorectal fistula

Tosniwal J et al. report about the use of the OTSC System to anchor a fully covered self-expanding metal stent to prevent stent migration. The patient underwent distal esophagostomy with gastric pull-up. The stent was placed over an alternative anastomotic site after anastomosis. However, the stent partially migrated into the stomach. The stent was then repositioned onto the leak. The OTSC System was placed using the OTSC Twin Grasper to grasp the stent edge and suction. After application the OTSC clip fixed the stent to the esophageal wall. Follow-up showed successful closure of the anastomotic leak.

Ovesco Research Update 12 | January 2013 | OTSC® used to prevent stent migration in the treatment of anastomotic leak

Ovesco Research Update 33 | Research & clinical trials | Version 39 | 2012-12-20
December 2012 | Closure of anastomotic leaks and chronic fistulas in the digestive tract: best results in earlier treatment cases
Dr. Selouk Digibeyaz and co-workers, Department of Gastroenterology of Turkey Isihias Hospital, Ankara, report about their case series of 9 patients (age 22–65 years). Anastomotic leakage from GI surgical anastomosis was present in 5, fistula in 3 and acute perforation in 1 patient. Type “a” clips were placed in all cases. In 4 cases clip deployment was not undertaken, due to strong tissue fibrosis. In the other 5 patients the clip was successfully deployed and closed the defect without the need for further treatment. The median time between diagnosis of the defect and OTSC clip placement was 35 (20–80 days) days in the cases with successful placement and 70 days (58–94 days) in the unsuccessful cases. The median defect size was 15 mm (5–20 mm). In 4 cases clip deployment was not undertaken, due to strong tissue fibrosis. No clip-related complications were encountered.

Endoscopic closure of gastrointestinal defects with an over-the-scope clip device. A case series and review of the literature
Digibeyaz S, Köksal AS, Parlat E, Torun S, Sayınaz M
[Epub 2012 Jun 14]

December 2012 | OTSC® effective in closure of chronic esophagojejunal anastomotic leaks after total gastrectomy
Prof. Dr. Gennaro Galizia and co-workers from the Second University of Naples, Italy, recently described the application of OTSC clips in the treatment of postsurgical anastomotic failure after total gastrectomy. In a case series of 3 patients, that developed anastomotic leaks after gastrectomy and Roux-en-Y jejunal transposition and esophago-jejunoanastomosis were endoscopically treated with OTSC clipping. The case series was published in the Journal of Gastrointestinal Surgery.

In all patients clip closure of the leak was technically simple, clinically effective and did not result in complications. The authors conclude that the OTSC System may represent a new option in the management of postoperative esophago-jejunal leaks. The incidence of anastomotic leaks ranges from 4 to 27 % after total gastrectomy and is a not infrequent challenge in such patients.

The Over-The-Scope Clip (OTSC) System is effective in the treatment of chronic esophago-jejunal anastomotic leakage

December 2012 | The interesting case: ERCP-related jejunal perforation managed by OTSC® clipping
In a recent case of Gastrointestinal Endoscopy Dr. F. Buffoli and colleagues, Digestive Endoscopy and Gastroenterology Unit of the Hospital Institutes, Cremona, Italy, presented an interesting case report on OTSC clipping for jejunal perforation closure: An 84-year-old man with bile obstruction due to pancreatic cancer presented with jaundice. The patient had Billroth II anatomy from gastric resection due to a peptic ulcer 35 years in the past. Cholangiography showed a bile duct stricture. An endoscope-related perforation of the jejunum with a size of about 20 mm was visualized distally of the papilla. After placing a covered self-expanding stent along the biliary duct structure it was decided to close the perforation of the bowel with an OTSC clip. The patient was considered inoperable due to age and comorbidities. Closure of the jejunum was successful. Retropertoneal fatty tissue was additionally pulled into the cap by suction and created a “retroperitoneal fat patch”. A median CT revealed retropertoneal air but no free liquids. The patient received parenteral nutrition and antibiotic treatment. The patient remained symptom-free and the jaundice disappeared. Control CT after 20 days demonstrated complete absorption of the air and the patient was discharged.

ERCPC has a perforation rate of approx. 0.3 to 1.3 %, as described in the clinical literature. The authors conclude that for the endoscopic closure of large ERCP-related perforations, the OTSC may be considered as a possible treatment.

Endoscopic “retroperitoneal fatpatch” of a large ERCP-related jejunal perforation by using a new over-the-scope clip device in Billroth II anastomosis (with video)
Gastrointest Endosc. 2012 May;75(5):1115-7 [Epub 2011 Aug 5]

November 2012 | First publication of Japanese experience with OTSC®
In the recent issue of the World Journal of Gastroenterology published by Dr. Hiroshi Ohno, published first Japanese experiences with the OTSC System.

Two elderly patients who had suffered iatrogenic lesions in the rectum (one large rectal perforation with abscess formation and one recto-vesical fistula), both patients were not subject to a surgical intervention for poor general condition, and thus were successfully treated with one OTSC clip each. Both interventions resulted in a dramatic improvement of the patients’ status. It should be noted that both patients underwent direct endoscopic lavage before closure. This is noteworthy especially in the case with the rectovesical fistula where the “retroperitoneal fatpatch” was created a “retroperitoneal fat patch”. The authors state: ‘The endoscopic closure of perforations and fistulae with OTSC is a simple and minimally invasive technique. Given the complete closure and healing of large fistulae with OTSC in our two cases, this approach may be less expensive and more advantageous than surgical closure.’

Rectal perforations and fistulae secondary to a glycercin enema: Closure by over-the-scope clip
Mori H, Kobasa H, Fujihara N, Nishiyama N, Morino M

October 2012 | The success rates for hemostasis in severe GI bleeding, perforation closure and chronic fistula closure are 88 %, 79 % and 73 %, respectively
The OTSC System has been described in more than 40 clinical papers in the scientific literature covering a range of indications. In order to summarize the clinical data published so far and to evaluate the overall clinical efficacy, Ovesco Endoscopy has commissioned systematic literature research on the OTSC System.

The results limited to the clinical publications and covered the key applications of the OTSC System, hemostasis, closure of acute GI lesions (perforations) and chronic GI lesions (fistula). Only clinical reports with >4 patients were included into the survey, that was carried out by Dr. Timo Weiland, novineon CRO, a specialized contract research organization for the medical device industry (www.novineon.com). The success rates defined as permanent achievement of the therapeutic goal for hemostasis in severe GI bleeding, perforation closure (in acute anastomotic stump line failure) and chronic fistula closure are 88 %, 79 % and 73 %, respectively. The OTSC System compares to the effectiveness of a surgical intervention in the respective indications or offers a new therapeutic option in situations where surgery is not recommended.

OTSC System_clinical_data_eng_Rev01_2012.pdf

October 2012 | Hemostasis in large gastric ulcer with the OTSC® System
Vombrook et al. report a successful treatment of gastric ulcer bleeding with the OTSC System.

In an emergency EGD removal of clots and fresh blood revealed an ulcer with a 2-mm thick pulsating vessel. Bleeding was difficult due to the fibrotic tissue. Thus OTSC placement was decided. To mobilize the target tissue into the cap, two edges of the ulcer were grabbed by each of the two jaws of the OTSC Twin Grasper. After retraction of the grasper and additional suction the OTSC was applied and immediate hemostasis was achieved. The authors conclude that the OTSC was effective for hemostasis in this fibrotic ulcer which was very hard to treat with other endoscopic methods. They state that the placement of OTSC was quick and easy resulting in a potentially life-saving hemostasis. Use of the “bear claw” (over-the-scope clip) to achieve hemostasis of a large gastric ulcer with bleeding visible

Arrozo A, Verra M, Reddavid R, Cravero F, Bonino MA, Monno M

November 2012 | Performance of the OTSC® System in the endoscopic closure of gastrointestinal fistulae – a meta-analysis
The recent issue of ‘Minimally Invasive Therapy & Allied Technologies’ publishes a systematic review and meta-analysis on the challenging field of closing gastrointestinal fistulae by means of the OTSC System. The paper provides an extensive overview of relevant primary clinical research, case reports and conference abstracts published on this topic. The statistical evaluation of all, 19 examined articles revealed a high rate of procedural success (mean 84.6 %, 95 % confidence interval 66.6 % to 93.8 %) and durable clinical success (mean 69.0 %, 95 % confidence interval 51.8 % to 82.2 %) in OTSC-mediated closing of GI fistulae.

In summary, the authors rate endoscopic closure of gastrointestinal fistulae by means of the OTSC System as a safe and effective method.

Performance of the OTSC System in the endoscopic closure of gastrointestinal fistulae – a meta-analysis

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October 2012 | Postsurgical colorectal anastomotic leaks: OTSC® clip recommended as treatment of choice at SMIT conference

Barcelona, September 21st 2012: The 24th conference of the Society for Minimally Invasive Therapy (SMIT) was held in Barcelona, Spain, under the presidency of Dr. Enric Laporte.

Prof. Dr. Alberto Arezzo and colleagues, 2nd Dept of General Surgery, University of Turin, Italy, presented latest data of 25 clinical cases with postsurgical anastomotic leaks or fistula after colorectal surgery.

In the general literature anastomotic leaks have an incidence of about 7–9% after laparoscopic or open colorectal surgery. In the 25 cases prospectively collected in Turin, 21 were successfully treated with endoscopic OTSC clipping alone. This is a success rate of 84%. In 3 patients the fistula did not heal, and in 1 patient additional surgery was needed to close the defect.

In conclusion the authors recommend the use of endoscopic OTSC clipping for lesions up to 12 mm in size as the primary treatment for patients with postsurgical leaks and fistula after colorectal surgery.

Efficacy of the over-the-scope clip (OTSC®) for treatment of colorectal postsurgical leaks and fistula

Arezzo A, Verra M, Reddavid R, Cravero F, Bonino MA, Morino M