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

EFT of duodenal lesions in 20 patients showed technical success in 17/20 (85.0 %), a 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.

Bauder M et al., Department of Gastroenterology and Oncology, Ludwigshurg Hospital, Ludwigshurg, Germany, performed a study investigating the safety and efficacy of FTRD endoscopic treatment of 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 dilatation. 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. All bleeding stopping procedures were considered as high-risk. Bleeding lesions 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 which were considered as no development and two endoscopist’s decision to resect the lesion was obtained in 9/20 cases (45 %). 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 pre-treated or difficult lesions, such as non-sonating adenomas, EFTR could be an interesting treatment option.

Endoscopic full-thickness resection of duodenal lesions—a retrospective analysis of 20 FTRD cases.


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 therapy.

Manta R et al., Digestive Endoscopy Unit, S.Agostino-Estense Hospital, Modena, Italy, published a study comparing antimicrobial therapy at the time of the intervention with antimicrobial therapy prior to the intervention. Briefly, all high-risk patients and/or those with high-risk bleeding lesions were considered for the OTSC approach. Patients on antiplatelet therapy and those with relevant comorbidities (heart, kidney, and hepatic impairment) were considered at high-risk. Endoscopic full-thickness resection scars treated with FTRD, all were histologically confirmed. Among the 7 resection scars treated with FTRD, all were histologically negative for neoplasia. Among the 9 non-bleeding lesions, seven were histologically diagnosed as T1/G1/sm1, one as T1G1/sm2, and one as T1G1/sm3; this patient underwent a surgical resection. Mean size of the resected lesions was 26 mm, ranging from 10 to 42 mm. In major resections or in cases of endoscopic resection scars, no other effective endoscopic methods currently are available to treat these lesions and scars of R1 resections.


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 95.6 % for bleeding, 96.6 % 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 acute bleeding, perforation, dehiscence, and anastomotic dehiscence. An extensive 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 % (n = 388) for fistula, 66 % (n = 97) for anastomotic dehiscence, and 95 % for other conditions, respectively. The authors noted 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 % (26/1517 cases), the incidence rate of severe complications that required surgery was 0.59 % (9/1517 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.

Kobara H, Mor H, Nishiyaama N, Fujihara S, Okano K, Suzuki Y, Masaki T.

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 ulcers

In a multicentric cohort of 100 consecutive patients with mean age 72 y, 51 % severe cardiovascular comorbidity, and 73 % on antplatelet or/and anticoagulation therapy presenting with non-vascular upper GI bleeding from ulcers with median size of 3 cm, OTSC therapy led to 94 % primary hemostasis and 86 % long-term clinical success. Non-vascular upper gastrointestinal bleeding (NVUGIB) is a common clinical problem with high rates of morbidity and a mortality rate between 5-10 %. An aging patient population with a high prevalence of cardiovascular comorbidity has led to an increase in NVUGIB in patients older than age 70 years. A high comorbidity rate has also been identified as an independent risk factor for complications and mortality after NVUGIB.

Wedi E et al., Department of Gastroenterology und GI Oncology, University Medical Center Goettingen, Germany presented prospectively collected multicentric data from 02/2009 to 09/2015 from all patients who underwent emergency endoscopy for high-risk NVUGIB in two academic centers and were treated with OTSC as first-line (n=81) or second-line (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 antiplatelet or/and anticoagulation therapy, other comorbidities in the patient cohort included kidney disease (n=20), former or recent malignancy (n=23), respiratory disease (n=16), liver disease (n=6) and diabetes mellitus (n=26). The median size of the treated ulcers was 3 cm (range 0.5-10 cm), 85 % of ulcers 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 with 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 %. The authors concluded that in this cohort the OTSC System was demonstrated to be a safe and effective device for 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 bougienage and no complications
• FTDR® system: the use of rectal neuroendocrine tumors is feasible, safe and effective and allows for definite diagnosis and treatment in the same session
• OTSC®: large systematic review (2462 patients) shows 77-98 % 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 an endoscope and forms a stable cushion within seconds, which provides additional working space. The 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 an original intervention study on patients with a benign oesophageal stenosis and with clinical symptoms of dysphagia treated with the BougieCap at three endoscopy units in Germany and UK. 50 patients (mf 25/25) underwent the procedure, mean age was 67.1 years (±16.8), Etiology of strictures was postcicatricial (n=23), radiation induced (n=12), caustic ingestion (n=4), post ESD (n=2), EsE (n=1) or unknown (n=1). Successful dilation 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 gastroscopy in 2 cases. In two cases with a narrow stricture and no usage of guide wire failed as a result of high resistance at the site of structure causing breaking of the endoscope in the pharynx. Symptoms of dysphagia (as assessed per Dysphagia Handicap Index score) decreased significantly after bougienage in short-term follow-up (14 days post-interventional). No severe complications were reported. Adverse events were loss of Bolus 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 avoid endoscopic treatment even more precisely to the stricture. Symptoms of dysphagia are improved in short-term follow-up. Additional wire guidance is reasonable.

FTDR System

An multicenter UK experience: EFTR highly successful in the treatment of colonic strictures not previously amenable to endoscopy

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 Rockland study (0 % vs. 53 %, p < 0.01). Also in intermediate-risk (RS = 4 – 7) patients rebleeding was reduced (0 % vs. 24 %, p = 0.08).

Ovesco Research Update 30 | Research & clinical trials

2 | 2019-03-15
I. Rahman et al., Department of Gastroenterology University Hospital Southampton, UK, presented data from the UK FTRD registry. Registry data from 04/2015 – 01/2018 comprised 52 cases of FTRD application in 8 centers. Patients had a median age of 72 years (39-93). The target lesion could be reached with the FTRD mounted on top of the endoscope in 99.1% (95/96) patients, and technical problems (98.9%) could not be reached due to sigmoid diverticulosis. Median total procedure time was 45 minutes (10-150). Median FTRD insertion time was 5 minutes (1-100). Median specimen size was 22 mm (10-30). Technical success was achieved in 99% (96/97) of cases. Resection margins were achieved in 93% (91/98). 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 Ludwigshafen, Germany, reported on a 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 98.2% (523/532). Technical success was achieved in 99.7% (529/532). 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 393 of 494 patients for which data on resection margins was reported. Technical problems were mostly related to the resection snare, which occurred in 34 cases. In most of these cases a successful resection however was achieved by use of a conventional resection snare following EFTR application with the FTRD. Complications included minor bleeding and post-polypodyctomy syndrome in 14 (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 proved to have high technical efficacy in the colorectum. 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, University Hospital Hamburg, Germany, presented data evaluating the use of EFTR for rectal neuroendocrine tumors in all cases. However, in 7 cases (28%) a NET could no longer be proven. Adverse events occurred in 5 cases (12.5%) 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 was performed with a conventional snare). Follow-up data was available for 32/40 patients. Mean follow-up time was 7.4 years (range 1-15 years). Technical 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 therapy (R0 resection) at once. 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 UEGW to provide a platform for live encounter and interaction among aspiring endoscopists and renowned experts in the field.

In the ESGE Learning Area, three 90-minute Hands-On Trainings with the OTSC System were offered. All Hands-On Trainings were fully booked.

Besides, a talk on the OTSC System was held in the ESGEENA Lunch Session (A. Caputo: “Advantages of the OTSC System in the treatment of UGIB”) and the exhibition of Ovesco products attracted lively interest.

Large systematic review shows 77.96% clinical success of OTSC in various indications without the need for further intervention

A. Wannhoff et al., Department of Gastroenterology and Hepatology, University of Rochester, United States, reported on a systematic review with the OTSC System. The study evaluated a large body of literature to determine the overall efficacy and safety of OTSC. 81 case series/retrospective/retrospective reviews (31 Korean patients) with a total of 2285 patients and 157 case reports (Group B with a total of 177 patients) were included.

In Group A, technical success of OTSC placement was 95.3%, with a clinical success of 77.2%. Indications for OTSC placement were fistula closure (30.6%), bleeding (28.9%), perforation closure (16.3%), leaks (15.1%), EFTR (8.4%) and stent fixation (0.7%). Complete luminal obstruction (n=1) was the only reported adverse event across all studies. 24/81 papers reported the need for further surgery despite OTSC placement (506/73 patients, 13.4%). 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/retrospective reviews (30 Korean patients) was 99% and clinical success was 96.0%. 7/177 (4%) of 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-sparring endoscopic tool in today’s GI practice with 77.96% of patients 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 therapeutic efficacy of OTSC for the treatment of high-risk peptic ulcer bleeding (HUB). Between 4/2014 and 03/2018, 100 patients with peptic ulcer bleeding (Forest Ia/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 secondary treatment after failure of an initial endoscopic treatment in 34 patients. OTSC clipping led to successful primary hemostasis in 94.1%. Recurrent bleeding occurred in n=9 for primary OTSC (15.3%) and in n=7 patients with secondary OTSC (21.9%) (p=0.812). No treatment beside the single OTSC clip was necessary in 75.8% (n=50) in the primary-OTSC arm and in 73.5% (n=52) 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 negative helicobacter test (p=0.045). The patients with OTSC failure received more blood transfusions (p=0.002). Potential risk factors for failure treatment 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 Dorfarkassestraße 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 alone Lee IK et al., Department of Internal Medicine, Hanyang University College of Medicine, Seoul, Korea, performed a prospective multicentre multicenter study at seven centers in Korea in order to examine the therapeutic success rate of endoscopic treatment of gastrointestinal perforations, fistulas and anastomotic leakages using the OTSC System in Korean patients.

A total of 19 patients were included, with gastrointestinal leakages from gastrojejunostomy sites (n=3), esophago-jejunostomy sites (n=3), esophago-gastrostomy sites (n=4), esophago-colonostomy sites (n=1), jejunoj-jejunostomy sites (n=1), esophageal endoscopy in 21 thickness resection site closures (n=2), Boehrave’s syndrome (n=1), esophage-bro-chronical fistulas (n=2), gastro-coli-fistulas (n=1), and colo-pseudocyst fistulas (n=1). The size of the leakage ranged from 5 to 30 mm (median diameter 10 mm). The median procedure time was found for 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.


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, Zürich 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, 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=6), 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 gastroscopy with
guidewire was used. In two cases a standard gastroscopy 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 ± 0.8 before dilation to 2.0 ± 0.7 after dilation (Mann–Whitney rank sum test p < 0.0001). No major complications occurred. In two cases, a BougieCap was lost in the stomach; no clinical discomfort of complications resulted.

The authors stated that endoscopic treatment of benign esophageal strictures with the BougieCap allows direct visual control of the dilation process and of beginning mucosal lacerations. Thus, in contrast to the conventional blind method, overtublization and re-traumatization are reduced and the dilation 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 stenosis, usage of a pediatric gastroscopy).

The BougieCap: a new method for endoscopic treatment of esophageal strictures:

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

*UENG Week, Vienna, Austria, October 20-24, 2018.

November 2018 | Conference Report DGVS / DGAQ

The 73th annual conference of the German Society of Gastroenterology, and Digestive and Metabolic Diseases (DGVS) and Gastroenterology Section (DGAV) took place together with the 12th autumn conference of the German Society of General Surgery and Visceral Surgery (DGAV) on September 12-15, 2018 in Munich, Germany.

Ovesco products were presented in talks, posters, research, innovation and video forums and hands-on training sessions. Dr. med. Edris 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

Meta-analysis of all to date published data (777 patients) regarding FTRD application in the colorectum shows 78% R0 resection rate and < 1% surgery because of complications. A Vahedi et al. presented a pooled analysis of all published data (full texts and conference contributions) evaluating FTRD application in the colorectum. 21 studies comprising overall 777 patients were included. The target lesion was reached in 746 (95%) cases. Resection was technically successful in 684 (88%) cases. Main reason for technical failure was problems with the snare in 35 cases, in 29 of these cases resection succeeded with subsequently introduced conventional snare. Histological examination confirmed full-thickness resection in 326 of 401 (81.3%) cases and R0 resection in 383 of 494 (78%) cases. Reserve information was not available for the remaining cases. Complications occurred in overall 8%, thereof 13 post-polypectomy-syndrome (1.7%), 16 minor haemorrhage (2%), 2 major haemorrhage (0.3%), 12 perforations (2%, partially due to wrong order of operating 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.

Effektivität und Sicherheit des Voll-Thickness Resection Device (FTRD) im Kolorektum: 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.

T 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 lesion had a median size of 16 ± 4.7 mm and were located in the colon (n=11, involving different colon segments [n=2], left flexure [n=1], and right flexure [n=3]). The technical success rate was 100%. The procedural time was 72 ± 40 min. R0 resection was achieved in 85 % of cases (11/13). Histological examination of the specimen yielded the following results: adenoma with low-grade intrapapillary neoplasia (n=6), adenoma with high-grade intra-sphelial neoplasia (n=4), fibrotic area without dysplasia (n=2), adenocarcinoma (n=2). No complications occurred. In one patient, a relapse lesion was found at the site of the colorectal carcinoma. The R0 resection rate could be achieved 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 R0 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).


colon FTRD is suitable for therapy of early colorectal carcinoma

5 Hemmer et al. presented the experiences of the Clinical Center in Neuperlach, Munich, with the FTRD System. Between 01/2015 and 04/2018 indication for eFTR was present in 30 patients. In 11 patients malignant histology was previously known (8 adenocarcinomas, thereof 2 verified by biopsy, 2 pre-treated with resulting R0/R1 situation, 3 NETs). The remaining 19 patients showed residual or recurring adenoma, non-lifting sign or difficult localisation. Technical success was achieved in 25 of 30 patients (83.3%). In 5 patients, the procedure had to be discontinued due to insufficient mobilisation of the lesion into the cap (n=4) or due to failure of the snare (n=1). 4 of the 5 technically unsuccessful procedures took place in the first 12 patients. The R0 resection rate in technically successful procedures was 92 % (23/25). Resected lesions were 27 ± 6.4 mm in size. 12 of the 25 resected specimen proved to be R0 resection and could be resected in R0. Oncological surgery was necessary in 3 patients. Thus, colonic FTRD was the curative treatment in 84 % (21/25) of patients. Complications occurred in 3 cases: post-polypectomy-syndrome (n=1), clip failure (n=1), and perforation (n=1). All complications could be managed conservatively. Endoscopic full-thickness resection was performed during follow-up after 3 months (SSA without dysplasia). In conclusion, the authors stated that the future primary application field of the FTRD could be small pretherapeutically verified carcinomas, because eFTR yields a safe R0 resection option and enables definitive evaluation of sm-invasion for histologically based therapy stratification.

Endoskopische full thickness resection (eFTR): Effektivität der eFTR für komplexe kolorektale Läsionen, insbesondere als Therapieoption (Evaluation of the risk of post-interventional complications following FTR application at the appendiceal origin. All patients of the Clinic of General and Digestive Surgery, University Hospital Ulm undergoing endoscopic full-thickness resection at the appendiceal area using the FTRD between 2014 and 2018 were analysed retrospectively. The available follow-up data was analysed in regard of the development of appendicitis. Patients that had undergone an appendectomy prior to FTR application were not included in the study. Overall 38 patients (65.8% female, median age at FTR application 68 years (47-85)) met the inclusion criteria. FTR application was successful in all cases. During follow-up (average of 21 weeks, range 0-126 weeks) 9 patients (23.7%) developed acute appendicitis. In 5 patients the appendicitis occurred within 10 days after FTR 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 FTR application at the appendiceal origin developed acute appendicitis. The complication may occur early after FTR application or with greater latency. Patients should be informed about the risk of appendicitis development before FTR application at the appendiceal origin.

Untersuchung des Appendizitis-Risikos nach endoskopischer Vollwandresektion von Adenomen im Bereich der Appendix mit dem FTRD System (Evaluation of the risk of appendicitis following FTR application at the appendiceal origin. All patients undergoing endoscopic full-thickness resection of colorectal adenomas close to the appendix using the FTRD System).


gastric FTRD

RESET 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 resection of full-thickness gastric (SETs) of the stomach. Gastric SETs are rare, mostly benign and usually coincidently 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 the study. gFTRD 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, 66.5 % (19/29) in full-thickness. In 31 % of cases peri-interventional minor bleeding occurred, which
could be directly treated endoscopically. In the follow-up examination after 3 months, clips were already dislocated 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 combination approaches using injection and hemoclipping, cutting of gastric SETs. Sufficient risk stratification (in case of GIST/NET) is possible. Besides, sufficient therapy by R0 resection is achieved in most cases.

Endoskopische Vollwandresektion subepithelialer Tumoren (gFTRD): Sekundäre OTSC Therapie – Eine prospektive Pilotstudie (RESET Study) (Endoscopic full thickness resection of subepithelial tumours of the stomach with the gFTRD-system – A prospective pilot study (RESET study)).

Meier B, Schmitt A, Meining A, Caca K, Ludwigshafen, Freiburg, Ulm.

OTSC® System – presented studies confirm superiority of the OTSC in acute gastrointestinal haemorrhage

Marburg: OTSC highly effective for the treatment of acute ulcer bleeding

A Walther presented retrospective data gathered in the University Hospital of Giessen and Marburg evaluating different therapeutic modes of therapy for non-variceal upper gastrointestinal bleeding (NV-UGIB). Between 2010/2016 and 1/2018, 131 patients (median age 68 years, 77 male) with NV-UGIB were treated. In 68 patients, the bleeding required intervention at the time of examination. Cause of hemorrhage was a peptic ulcer in 47 cases (69.1 %; 31 duodenum, 13 stomach, 1 carina, 2 anastomosis), a Mallory-Weiss syndrome in 7 cases (10.3 %), tumor bleeding in 6 cases (8.8 %), angiovascula in 5 cases (7.4 %), and other causes in 3 cases (4.4 %). Primary endoscopic therapy consisted of a combination approach consisting of injection and hemoclipping, both patients received a second rebleeding which in turn was treated using an OTSC Clip. The authors concluded that therapy of acute ulcer bleeding with the OTSC proves to be highly efficient as primary and secondary therapy. They enhanced acute ulcer bleeding with the OTSC proves to be highly effective as primary and secondary therapy. They enhanced

Analysis of the STING treatment cases: haemorrhage treatment versus standard therapy not only cost-effective, but also cutting

A Külmer et al. presented results of a study based on data gathered during a prospective randomized study (STING), exploring whether OTSC treatment is more cost-effective than conventional clips due to the higher success rate, despite of the higher price per clip. Two parameters for cost effectiveness were calculated: (1) ICER (Incremental Cost Effectiveness Ratio): defines additional expenses for additional clinical results, measuring Δcosts of both alternatives divided by scinical effect. (2) ACER (Average Cost Effectiveness Ratio): costs arising from a specific clinical result. The clinical status that had to be achieved was similar to the primary outcome of the STING study: successful hemostasis without any recurrent bleeding. The parameters for the total procedure, including costs for accommodation etc. were calculated as well as the costs for the endoscopic treatment only. The overall costs of standard treatment approaches were 13,025.95 €, versus 12,776.19 € for OTSC treatment: costs for the endoscopic procedure alone were 2,100.03 € (standard therapy) versus 1,960.17 € (OTSC-therapy). The ICER regarding the overall treatment was -589,01 € and -329,86 € for the endoscopic treatment. The ACER for the overall costs was 30,721.58 € for standard therapy and 15,066.26 € for OTSC therapy. ACER for the endoscopic procedure showed 4,952.90 € and 2,311.52 € for standard and OTSC therapy respectively. OTSC therapy of recurrent ulcer bleeding was rated cost-effective and cost-cutting when compared to standard approaches. OTSC- versus Standard-Therapy der Rezidiv- Ulkusblutung: eine Kostenfektivitätsanalyse (OTSC versus standard treatment of recurrent ulcer bleeding: an analysis of cost effectiveness).


Cross-sector routine data from social health insurance confirms safety and efficacy of colonic OTSC

D Horenkamp-Sonntag et al., German Technicians’ Health Insurance, Hamburg, presented a study based on cross-sector routine data gathered by social health insurance (n > 10 million insured persons) 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 5460s3). Using further codes from for peptic ulcer bleeding, 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 of the initial procedure, 12 patients (3.4 %) received abdominal surgery within 10 days after OTSC procedure, 41 patients (11.9 %) within 100 days of the procedure. Surgery after more than 30 days after OTSC application was mostly due to treatment of the underlying disease (carcinoma, diverticulitis etc.). Overall 9 patients (2.6 %) deceased within 100 days after the intervention. The authors concluded that, in the actual care setting, OTSC is mostly used for the primary control of hemorrhage when conventional treatment fails. They presented data supports first findings indicating that OTSC application in the colon is safe and helps to prevent surgery due to iatrogenic complications.

Sind OTS-CliPs am Kolon kollupt effektiv und sicher? Evidenz-Generierung von endoskopischen Innovations mit GKV-Routinedaten (Are OTS-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 oncological 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 esophageal stents and OTSCs. A total of 21 patients received a combination therapy using standard endoscopic perforation and 17 with PAI. 12/17 PAI patients had received a preoperative radiochemotherapy (5 CROSS, 11CF, 1 FLT+RTC, 2 FLT, 1 RTC, 1 GASTRIPEC, 1 unknown). Overall 8 patients received a fully-covered esophagus stent as primary therapy whereas 13 patients 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 (76.2 %) patients, the necessity of local resection 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 heterogenic and showed complex disease courses. The concept of combination therapy using EndoVac, esophageal stent, OTSC and endoscopic debridement seems to be promising. Further large scale studies are necessary to reliably describe the efficacy of this approach.

Was ist die richtige Strategie? (Multimodal endoscopic treatment of esophageal perforation and – post-surgical anastomotic insufficiency following oncological resection. Which is the correct strategy?)


remOVE – registry study on clip removal and first multicenter case series evaluating the BougieCap

remOVE System – endoscopic removal of OTSC and FTRD clips is effective and safe

M Bauder and colleagues presented multicentric prospective registry data regarding application of the remOVE System. Data on 119 patients from 63 centers were submitted. Main indications for clip removal were: (1) clips in colon, rectum or local resection margins, (2) associated complications (27/119), and ineffective clip placement (16/119). Cutting of the clip through both bowels was successful in 69.1 % of cases, esophageal retrieval of both clip fragments was possible in 62.8 %. Recovering the clips through the clips pouch might be necessary in 15.3 % of cases. The remOVE System was necessary in 23 cases. Average procedure time was 62 min, whereby a correlation to the thickness of the nitinol scaffold of the clip was seen (statistically significant between OTSC 11 and FTRD). Complications occurred in 3.4 % (4/119). These were in all cases minor bleedings, which could be managed endoscopically. The authors concluded that removal of OTSC and FTRD clips
New demilune ESD-device (Coag Dissector) allows for rapid, effective and safe endoscopic submucosal dissection

Endoscopic submucosal dissection (ESD) has been established as an effective treatment option for early gastrointestinal cancer. To date, various devices for ESD are available. H. Neumann and colleagues presented a prospective preclinical study evaluating the efficacy and learning curve of a new demilune device for ESD, which potentially allows for fast submucosal cutting above the muscular layer due to its special design. In addition, the device can be opened like scissors therefore also acting for hemostasis. The study was performed in two steps. First, ex vivo porcine models were utilized in an advanced endoscopic simulator or interventional endoscopy. After the initial learning curve, the study was repeated in living pigs under general anesthesia. For both study arms, artificial lesions, each 25 x 25 mm in size, were created in the fundus, corpus and antrum of the stomach. ESD was performed after marking of the lesions with the ESD instrument, followed by lifting of the mucosa with submucosal injection of colored saline. Afterwards, circular incision of the lesions was performed with the new ESD device. For resection, the submucosa was cut with a distal clear cap and cut with the new demilune device. Resection specimen were retrieved to evaluate if all marks were included (R0). Average size of removed lesions was 30 mm. En-bloc resection rate was 100% and R0 resection rate was 95%. Mean total procedure time was 25 minutes and not dependent on the location or if the resection was performed in ex vivo models or in vivo. No perforations occurred during the study despite the rapid dissection speed through the submucosa. Satisfaction of the endoscopist and the supporting nurse staff was high throughout all cases. The authors concluded that the new demilune device for ESD is safe and efficient and allows for rapid dissection of the submucosa due to its inherent design.

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


For questions and further information: Ovesco Endoscopy AG
Scientific Information Service
Dorlackenstraße 26
D-72074 Tübingen
science@ovesco.com
Application of the OTSC resulted in immediate hemostasis in all 75 patients (100% primary success rate). In 28 patients (34.7%) a rebleeding episode was noted. In the group of first-line OTSC treatment the rebleeding rate was 28.3% (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 surgical or surgical treatment because of final failure of endoscopic therapy 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 gastrointestinal bleeding in patients under antithrombotic therapy.


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

87.9% R0-resection of non-lifting and submucosal colonic lesions with FTRD

Aeppli P et al., Gastroenterology and Hepatology Unit, Luzern, Switzerland, and Division of Gastroenterology/Hepatology, Kantonsspital St. Gallen, St. Gallen, Switzerland, reported on the clinical experience of the two tertiary referral centers with FTRD procedures. 33 consecutive patients with colonic neoplasms (21 colon, 12 rectum) were scheduled for FTRD using the FTRD device between 05/2015 and 11/2016. Indications were residual adenoma without non-lifting sign after previous polypectomy (n=18), non-lifting adenoma without previous polypectomy (n=4), staging following resection of a malignant poly (n=4), adenoma at appendiceal orifice (n=2), primary EFTR of polyps suspected to be malignant (n=2), primary EFTR of polyps suspected to be malignant (n=2), adenoma involving a diverticulum (n=1), non-lifting adenoma recurrence after EFTR (n=1), and incomplete resection of neuroendocrine tumor G1 (n=1).

31 resections were successfully performed. In one case the target lesion had to be retracted because of sigmoid stenosis due to diverticulosis, the other failure was due to snare malfunction. Resection was en bloc and histologically complete (R0) in 87.9% (29/33) of patients. The mean diameter of resected specimens was 21 mm. The mean time of procedure was 39 min (range 18-43 mm). Three post-procedure bleedings and one perforation were seen.

The authors concluded that the FTRD System offers an additional endoscopic approach in the management of non-lifting colorectal lesions and helps to avoid surgical interventions.

Endoscopic full thickness resection (EFR) of colorectal neoplasms with the Full Thickness Resection Device (FTRD): Clinical experience from two tertiary referral centers in Switzerland


October 2018 | OTSC® safe and effective for treatment of leak at the tip of the “J” ileal pouch

66.8% of patients with leaking from the “J” of the tip of an ileo-anal pouch anastomosis were spared surgery by use of the OTSC

The tip of the “J” ileal pouch is the vulnerable location for leak after restorative proctocolectomy, which has normally been treated with surgery.

Lian L and Shen B, Interventional IBD Center, Digestive Diseases Institute, Cleveland, Cleveland, OH, USA, described the first case of endoscopic treatment of the leak at the tip of the “J” with OTSC in 2014. Since then, OTSC therapy has become the first-line approach for this lesion in the Cleveland Clinic.

Recently, Kochhar GS and Shen B, same affiliation, published a cohort study comprising 12 consecutive patients with a leak at the tip of the “J” from the Center’s prospectively maintained Pouch Registry. In all patients, OTSC was used for leak closure.

All 12 patients had a single deployment of OTSC during endoscopy. No excessive bleeding or perforation was observed. Eight patients (66.6%) achieved complete closure of the leak documented by endoscopy confirmed with guidewire and/or contrasted pouchogram, with 6 requiring a single endoscopic session and 2 undergoing a repeat session. Four patients (33.3%) had a persistent leak and required surgical intervention, of whom 1 developed abscess in the pre-sphinage region 14 days after the endoscopic procedure and underwent pull revision surgery.

The authors concluded that leaking from the tip of the “J” in patients with ileo-anal pouch anastomosis can be effectively and safely treated with the over-the-scope clipping system.

Endoscopic treatment of leak at the tip of the “J” ileal pouch.


Endoscopy International Open 2017; 05: E64-E66.

September 2018 | Clinical experience with the remoVE System, a bipolar cutting device for OTSC® removal

Bauder M et al., Department of Gastroenterology and Oncology, Ludwigshurg Hospital, Ludwigsburg, Germany, presented a clinical 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, such as 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 bipolar grasping device. The bipolar grasping can be advanced through a 2.8 mm endoscope working channel. Its tip consists of three electrodes that are brought in contact with the thinnest parts of the nitinol clip. Application of DC impulses causes the grasping device to be closed and expelled. 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.

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 97.6% (41/42) of all cases. Significant differences were observed between the two groups (p=0.007), complications 1.8% (1/42), and median procedure time 8 minutes (range 1-36 min).

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® in 86.3%.

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 Shoor S et al., Baranetic 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. The leak/fistula was defined by the leak from a staple line, and had a size from 3 to 20 mm. Time between leak 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, 83 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 (36.9%) required one or more clips and 5 patients (9.6%) required two 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 from 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 Gastroectomy: A Systematic Review.


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

August 2018 | Multicenter experience comparing simple suction and OTSC® Twin Grasper®

Kobara H 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 leak/fistulae and 76 leaks/fistulae in 59 patients. The overall rates of 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 simple suction (SS-group) and 42 cases using OTSC Twin Grasper group.

Secondary evaluation was performed to clarify the predictors 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-groups were compared, 32 (45.0%) and 39 (93.0%) 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. Individualized selection of the suction method based on particular clinical conditions may contribute to the improvement of OTSC success.

Comparison of gastrointestinal defect closure with an over-the-scope clip system in a multicenter experience: An analysis of a successful suction method.
July 2018 | Closure of acute GI defects with OTSC® successful in more than 75% of patients of an unselected cohort
Rathel M and colleagues, Department of Medicine II, University Hospital Freiburg, presented data from three tertiary referral centers with 24-hour emergency endoscopy (Erfangen, Wuerzburg, Fuerth) on patients receiving OTSC therapy for acute gastrointestinal wall defects.

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 interdisciplin ary consensus. Their clinical data and intervention characteristics were evaluated in an intention to treat analysis during a 24-month period assessing closure rates, 30-day mortality, hospitalization and comorbidity.

In total, 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 perforations and leaks was achieved in 26 patients (76.5%). 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 18 days, p = 0.03). In the group with OTSC failure, 6 of 8 patients (75%) required immediate surgery. In the group with successful OTSC closure, comorbidity 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 comorbidity, while one death in the OTSC failure group was related to a refractory perforation. Favorable 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.

July 2018 | Single center experience: OTSC® especially valuable in treating defects of the upper gastrointestinal tract
Mizrahi I and colleagues, Digestive Disease Institute, Cleveland Clinic Florida, Weston, FL, USA, reported their institutional experience with OTSC for patients with GI defects.

Gastrointestinal tract defects are associated with high patient morbidity and pose a clinical and technical challenge for surgeons and gastroenterologists. Defects such as anastomotic leak and fistulae are reported in up to 13% of patients following upper GI tract surgery for weight loss. Even higher rates are reported after colorectal surgery for malignant and inflammatory indications. The conventional treatment of the defects mentioned above is surgery, often including stoma creation or percutaneous drainage with the obvious related morbidity. For the study, prospective data from all patients treated with OTSC in the institution were analyzed. Primary outcome was the clinical success of the OTSC for the individual indications.

During the study period, 51 patients (28 females, mean age 54.9 ± 19.4 years) were treated with OTSC, 21 patients had defects in the lower GI tract (LGI) and 30 patients in the upper GI tract (UGI). The most common indication for OTSC was anastomotic leak (n=24; UGI = 12, LGI =12), followed by chronic fistula (n=17; UGI = 8, LGI = 9), acute perforation (n=4), acute bleeding (n=4) and stent anchoring (n=2). OTSC was the primary therapy in all patients with bleeding and stent anchoring, in all other patients alternative endoscopic or Surgical attempts had been made prior to OTSC placement.

Technical success was achieved in 98% of all patients. Clinical success rates for UGI perforation, bleeding, and stent anchoring indications were 75, 75, and 50%, respectively. Clinical success rate for the treatment of anastomotic leaks was 59% (UGI 66 vs LGI 33%). A lower success rate was noted for chronic fistula (UGI 62 vs LGI 0%). The authors conclude that the OTSC is a reasonable minimally invasive option for managing patients with various GI defects before a more invasive operative approach is attempted. It appears that the OTSC is especially valuable in the treatment of acute defects of the upper gastrointestinal tract. The Clinical Utility of Over-the-Scope Clip for the Treatment of Gastrointestinal Defects

July 2018 | Large single center experience presented: Establishment of the OTSC® clip in daily endoscopic routine
Honegger C and colleagues, Division of Gastroenterology and Hepatology, University Hospital Zürich, Zürich, Switzerland, presented data on 262 OTSC placements in a total of 233 interventions. Since 2009, the placement of OTSC has been established at the University Hospital Zürich for the entire spectrum of indications. OTSC has become a device of daily practice. A retrospective study now presents data of all patients treated with the OTSC device at the institution, focussing 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 84.6% (26/31); iatrogenic bleeding 100% (absolute difference, 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 days follow-up, the 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 86.1% (62/72); prophylaxis for perforation 100% (24/24); anastomotic leakage 33.3% (6/18); fistulae 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 safe and feasible in clinical routine, with high immediate success rates with sustained clinical success at 30-day follow-up.

Establishment of Over-The-Scope-Clips (OTSC) in daily endoscopic routine.

June 2018 | 100% long-term success with OTSC® in acute GI defects, 73% in chronic defects
Gianfranco G. et al., Interventional Endoscopy Unit, Hospital Privé des Peupliers, Paris, France, presented a retrospective study from a prospectively-maintained database evaluating lines and long-term success rates of OTSC deployment in acute and chronic gastrointestinal pathologies.

Between 01/2012 and 12/2015 a total of 51 OTSCs were delivered in 45 patients (35 female, average age 56 years, range 24-90) due to GI defects resulting from a diagnostic or interventional endoscopic procedure (acute setting group; n=15) or due to fistula following abdominal surgery (chronic setting group; n=30). All procedures were carried out in a private endoscopic service.

Technical success was always achieved in the acute setting group with an excellent clip adherence and a clinical success rate of 100% (15/15, median follow-up 9 months, range 1-24 months).

Considering the chronic setting group (OTSC treatment after an average period of 146.6 days (range 5-880 days) after surgery), technical success was achieved in 50% of patients (15/30). Long-term clinical success in patients with succeeded primary fistula closure by OTSC was 73.3% (11/15; mean follow-up 23 months, range 1-34 months). Two minor complications occurred. A total of three patients died due to causes not directly related to clip deployment.

The authors concluded that OTSC deployment is an effective and minimally-invasive procedure for GI defects in acute settings. It avoids emergency surgical repair and it allows, in most cases, completion of the primary endoscopic procedure. OTSC should be incorporated as an essential technique of today’s modern endoscopic armamentarium in the management of GI defects in acute settings. OTSCs were less effective in cases of chronic defects.

Closing of gastrointestinal defects with Vespri clip: long-term results and clinical implications.
Between 2015 and 2017, full-thickness excision of rectal wall with the FTDR System was performed in 12 patients (5 female, median age 73 years (29–81)] with suspected amyloidosis. Sigmoidoscopy was performed under light sedation in all patients. Biopsies were taken from the upper third of the rectum – 18 cm ab ano. FTDR application and full-thickness resection was successful in all cases. Maximal procedural time was 20 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 FTDR application for diagnosis of gastrointestinal amyloidosis is a safe and very effective method and mitigates the diagnostic challenges that amyloidosis can pose.

Neoplasms, which were not accessible for EMR, in over 90% resected with the FTDR System A. von Helden and colleagues, Community Hospital Bonn, presented a case series on endoscopic full-thickness resection (EMR) with the FTDR System in colorectal neoplasms with difficult localisation or extensive fibrosis. In 27 patients minor adenomas were found, which were not accessible for endoscopic mucosal resection (EMR) due to localisation (5 x appendix, 1 x diverticulum) or extensive fibrosis in consequence of prior attempts of endoscopic resection or chronic inflammatory bowel disease. 74% of the reported lesions were located in the right colon, 15% in the left colon, and 11% in the rectum. All interventions were performed with the FTDR System on standard colonoscope with peri-interventional antibiotics (2g Ceftriaxon) and under analgo-sedation. Technical success was achieved in 25/27 patients (92.5%). The lesion could not be reached with FTDR cap in two cases due to distal stenosis. The size of the resected specimen was median 27 mm (12- 33 mm). Histopathological examination showed 2 carcinomas (8%, 1 x cutaneous, 1 x eplectonic origin due to high-risk histological findings), 6 high-grade intra-epithelial neoplasms (24 %), 11 low-grade intra-epithelial neoplasms (44%) and 6 serrated adenomas (24%). R0-resection rate was 76% (19/25). Two perforations occurred (8%), one was treated by emergency surgery. In one case a perforation of the appendix at the appendiceal basis occurred and was developed after two days and required ileocoeal resection. Relevant haemorrhage was not observed. 30-days mortality rate was 0%.

In summary this study confirms that application of the FTDR System for endoscopic resection of neoplasms with difficult localisation and extensive fibrosis possible. Technical problems arise from stenosis distal to the target lesion. The authors warn against using the device in cases with native appendix.

Endoskopische Wandresektion mit dem FTDR System: Effektivität der Methode bei 25 Patienten mit kolorektalen Neoplasien, die einer Mukosaresektion nicht zugänglich waren. Von Heiden A, Sido B, Hildenbrand R, Damoulis F, Bonn. FTDR System Diagnosis of amyloidosis with FTDR full-thickness rectal biopsy sampling A. Braun and H. Dawson, Gastroenterology and Endoscopy, SRO Langenfeld, Switzerland and Institute of Pathology, University of Bern, Switzerland, presented their findings on amyloidosis diagnosis with the FTDR System. This is the first description of FTDR 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 must be confirmed by biopsy and histological examination, and the specimen must contain submucosal vessels and muscularis propria. This is currently no reliably minimal invasive sampling technique. The study investigated feasibility, performance and safety of endoscopic full-thickness resection with the FTDR System in the rectum for gastrointestinal amyloidosis diagnosis.

May 2018 | Single-center study confirms safety and efficacy of the FTDR® in the colorectum Valti and colleagues, Division of Gastroenterology and Hepatology, Zurich University Hospital, Switzerland, reported on their data on the colonic FTDR® 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-lifting adenomas, combined procedure of EMR and EFTR in large polyps (EFTR for 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 adverse event rate was 7%. One patient (2%) developed appendicitis after resection at the appendix base and another (2%) had interventional antibiotics (2g Ceftriaxon) and sedation. Technical success was achieved in 25/27 patients (92.5%). The lesion could not be reached with FTDR cap in two cases due to distal stenosis. Technical success was achieved in 25/27 patients (92.5%). The lesion could not be reached with FTDR cap in two cases due to distal stenosis. The size of the resected specimen was median 27 mm (12- 33 mm). Histopathological examination showed 2 carcinomas (8%, 1 x cutaneous, 1 x eplectonic origin due to high-risk histological findings), 6 high-grade intra-epithelial neoplasms (24 %), 11 low-grade intra-epithelial neoplasms (44%) and 6 serrated adenomas (24%). R0-resection rate was 76% (19/25). Two perforations occurred (8%), one was treated by emergency surgery. In one case a perforation of the appendix at the appendiceal basis occurred and was developed after two days and required ileocoeal resection. Relevant haemorrhage was not observed. 30-days mortality rate was 0%.

In summary this study confirms that application of the FTDR System for endoscopic resection of neoplasms with difficult localisation and extensive fibrosis possible. Technical problems arise from stenosis distal to the target lesion. The authors warn against using the device in cases with native appendix.

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 must be confirmed by biopsy and histological examination and samples must contain submucosal vessels and muscularis propria. There is currently no reliably minimal invasive sampling technique. The study investigated feasibility, performance and safety of endoscopic full-thickness resection with the FTRD System 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 (29-81)) with suspected amyloidosis. Sigmoidoscopy was performed under light sedation in all patients. Biopsies were taken from the upper third of the rectum – 18 cm abo. FTRD application and full-thickness resection were successful in all cases. Maximal procedure time was 20 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 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 FTRD (Full-Thickness Resection Device).


April 2018 | 100 % hemostasis with OTSC® reported for first-line emergency treatment of acute hemorrhage

The 48th Conference of the German Society for Endoscopy and Imaging Procedures (Deutsche Gesellschaft für Endoskopie und Bildgebende Verfahren, DGE-BV) took place on March 15-17, 2018 in Munich, Germany. Dr. A. Braun, 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. All patients had shown acute hemoglobin decrease and severe bleeding signs such as hematemesis, melaena, hematochezia. Bleeding was located in the upper GI tract in 34 cases (14 Forrest Ia, 15 Forrest Ib, and 5 Forrest IIa) and in the lower GI tract in 14 cases (4 Forrest Ia, 7 Forrest Ib and 3 Forrest IIIa). Patients with upper GI bleeding received peri-interventional PPI medication (50mg i.v. bolus + 200 mg i.v. / 24 h). For placement of the OTSC in some cases an endoscopic forceps was used to grasp tissue. No further local therapies were applied. All OTSC applications were performed by one single endoscopist. OTSC application and primary hemostasis were successful in all cases, median procedure time was 20 minutes. No relapse hemorrhage occurred. 26 patients (15 F, 9 F, 9 I) received follow-up endoscopy on 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 author concludes that OTSC application for emergency endoscopic treatment of acute hemorrhage is safe and very effective. Primary hemostasis is achieved in a large fraction of patients, which makes reduction of the mortality rate of acute gastrointestinal hemorrhage possible. OTSC application is related to short procedural time.

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


March 2018 | One step application of OTSC® for salvage hemostasis and simultaneous perforation closure

El Douhaly Y et al., Department of Internal Medicine, Staten Island University Hospital - Northwell Health System, Staten Island, New York, USA, reported on a case of acute bleeding from a gastroduodenal artery pseudoaneurysm and simultaneous perforation, which was treated by deployment of a single OTSC-Clip. The 61-year-old male patient with history of duodenal ulcer and angiographic embolization of a gastroduodenal artery pseudoaneurysm 6 months before presented to the emergency room for bright red blood per rectum with signs of upper GI bleed. In esophagogastroduodenoscopy two vessels were identified at the base of an ischemic ulcer correlating with an angiographic pseudoaneurysm. The time elected to inject epinephrine and apply electrocautery which resulted in an arterial pulsatile bleed and a perforation. The field of vision was extremely compromised in addition to the difficult location. Mounting of a cap on the gastroscope to improve stability of the scope and applying point pressure to decrease bleeding, as well as vigorous water irrigation permitted the identification of the exact bleeding site. Then, an OTSC was deployed in a single attempt which resulted in immediate adequate hemostasis and closure of the perforation. The authors emphasize that deployment of the OTSC requires pin-point precision to achieve satisfactory hemostasis. They rate the use of the over-the-scope clip 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.

Over-the-scope clip to the rescue of a bleeding gastroduodenal artery pseudoaneurysm.


OTSC® Update 27

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

J Brandler and colleagues, Department of Internal Medicine, Mayo Clinic, Rochester, Minnesota, USA, performed a study on 67 patients with gastrointestinal bleeding from 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 /or a deep penetrating, excavated fibrilar 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, hemoclips, coagulation). Between 12/2011 and 02/2015, data from 67 patients with high risk non- variceal gastrointestinal bleeding, of which 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 rebleeding at 30 days after OTSC placement. No difference was found in the proportion of patients with rebleeding who received primary or rescue therapy (hazard ratio 0.89; 95 % CI: 0.084 – 4.860; P= 0.6653). Only 9 rebleeding events were linked clearly to OTSCs and required intervention, indicating an OTSC success rate of 81.3 %.

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

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

Mangiafico S et al., Azienda Ospedaliero, University of Modena, Italy, presented at the 25th UEG week (October 28 – November 1, 2017, Barcelona) data on 9 Italian tertiary referral centers offering a large series of patients with non-variceal upper and lower gastrointestinal bleeding lesions in whom OTSC was used as first-line endoscopic treatment. 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. 106/201 patients were treated with the a version of the OTSC system while in 95/201 patients the 1 clip was preferred. Indications for OTSC treatment included duodenal ulcer pseudoaneurysm (n=28) and Forrest 1 b (n=35), gastric ulcer Forrest 1a (n=19) and Forrest 1b (n=29), Mallory Weiss (n=19), Dieulafoy’s lesion (n=9), post gastric- ESD bleeding (n=14), post EMR bleeding (n=15), post ESD bleeding (n=12), traumatic rectal ulcer (n=2), chronic enteritis (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 a radiological 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 through 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

Chen SM and Lau JW, 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
In this indication for now. They state that further comparative studies will show the clinical value and the longterm outcome in such lesions.

Colonscopic full-thickness resection using an over-the-scope device: a prospective multicentre study in various indications


OTSC® Update 26

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, 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 4.8g/dl. Endoscopy revealed bleeding from a 2 cm chronic bulbar ulcer. She was treated by angiographic embolization to her right gastroepiploic artery (GEA). Three days later, she again experienced massive bleeding. A pulsatile vessel at the ulcer base was discovered and treatment with an OTSC clip induced. The cap was adjusted to encompass the vessel, and a suture 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 on a history of recurrent bleeding from a chronic gastric ulcer. Additional screening tests confirmed the presence of a large perforation of the main gastric vein. The patient was urgently referred to the treatment of deep vein thrombosis complicated by pulmonary embolism. Endoscopy revealed bleeding from a chronic ulcer at the antrum incisura of the stomach. The first attempt to stop the bleeding with heaterprobe and hemoclips 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.

Over-the-scope clip treatment of refractory peptic ulcer bleeding


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

R Maia et al., Northwestern Co Grand Hospital, Milan, Nuovo S. Agostino Hospital, Modena, Nuovo Regina Margherita Hospital, Rome, Baggiovara Hospital Modena and Federico II University of Naples, Naples, all Italy, published a large case series on patients with post-surgical gastrointestinal leaks managed with endoscopy as initial approach.

A total of 76 patients underwent endoscopic treatment for a leak either in the upper (47 cases) or lower (29 cases) gastrointestinal tract. The first attempt for leak closure was the application of one or more OTSC clips. Fibre glue was used as an adjunctive treatment to close the gap between two OTSCs where needed. A covered self-expanding metal-stent (SEMS) was applied when the closure was considered incomplete at endoscopy. When dehiscence characteristics were not fitting for OTSC positioning, a SEMS was directly used. Endosponge was the first line therapy, when an abscess cavity was present beyond the anastomotic leak.

Leak closure was successful in 39 patients with upper GI- leaks (83 %) and 22 patients with lower GI leaks (75.9 %), accounting for an overall 80.3 % success rate. Leak closure failed in 15 (19.7 %) patients, and the surgical approach was successful in all 14 patients who underwent re-intervention, whilst one patient died due to sepsis at day 7 post-op.

The authors conclude that endoscopic approach is successful and safe in the majority of patients with anastomotic gastrointestinal leaks. Therefore, endoscopic treatment should be attempted before resorting to more invasive, costly and risky re-interventions.

Endoscopic management of patients with post-surgical leaks involving the gastrointestinal tract: A large case series.


OTSC® Update 25

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

HJ Richter-Schrang and colleagues, Center of Interdisciplinary Gastrointestinal Endoscopy and Department of General and Visceral Surgery, University of Freiburg, Germany, presented 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 and lower 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 GIB lesions fulfilled the inclusion criteria. One patient had 3 OTSC applications, and five other patients had 2 OTSCs on different lesions.

First-line OTSC treatment was performed in 61 cases and second line OTSC treatment in 42 cases. The mean hospital stay was 19.8 days (range 1-79). Primary hemostasis was achieved in 88 % of cases (88/100). Clinical success (no in-hospital rebleeding) was achieved in 78 % of cases (78/100). Primary failure was significantly lower when OTSCs were applied as FLET compared to SLET (4.9 % vs 23 %, P=0.0008). Patients with Rockall scores ≥ 7 had a significantly higher in-hospital mortality compared to those with scores < 7 (35 % vs 10 %, P=0.034). No significant differences were observed in patients with surgical vs 0 or 7 in rebleeding and rebleeding related 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 therapeutics spectrum and reduces surgery rate

A formal meeting 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 Champion Award at the meeting. The FTRD System is used at the hospital.
November 2016 | Large single-center experience with 101 OTSC® applications in patients with severe hemorrhage, perforations and fistulae: 89 % overall primary clinical success

Wedi E and colleagues, Strasbourg University Hospitals, Strasbourg, France and St. Bernard Academic Teaching Hospital, Hildesheim, Germany, and Iacoh School of Medicine at Mount Sinai, New York, United States, and 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 02/2009 to 10/2012, 84 patients were treated with 101 OTSC® clips. Among these, 84 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 (14.5 %) had control of secondary bleeding after endoscopic mucosal resection or endoscopic submucosal dissection (ESD) and 3 patients (3.6 %) had an intervention on a chronic fistula. In 78/84 patients (92.8 %), primary treatment with the OTSC was technically successful. Clinical primary success was achieved in 75/84 patients (89.3 %) who had severe hemorrhage, perforation and fistulae. One patient (1.3 %) suffered a post-polypectomy syndrome after resection of an adenoma at the appendiceal orifice, this complication could be managed conservatively. No other complications occurred. In 5 patients, correct oncological follow-up resection was undertaken due to the T-stage (T3xT1sm3, T2xT2). During 3 months follow-up, which could be carried out in 26 patients, a relapse adenoma was found in one patient and treated with a second EFTR.

The authors concluded that EFTR with the FTRD System broadens the therapeutic spectrum of lesions in the lower gastrointestinal tract and helps to avoid surgery in selected patients.

Endoskopische Vollwandresektion (EFTR) – endoscopic full-thickness resection) mit dem FTRD-System (Full-Thickness-Resection-Device): Dölauser Daten


September 2016 | Complete endoscopic resection of early colorectal cancer with FTRD®: case study of a high-risk anticoagulated patient

A case report on the use of the FTRD System for R0-resection of early colorectal cancer was published by P. Lagoussis et al., Polyclinic San Donato, San Donato Milanese, Italy.

Colonooscopy was performed due to hematochezia in a 78-year-old man with a history of coronary artery disease and recent pulmonary embolism, therefore under anticoagulant therapy. A 3-cm non-pancreatecolized colorectal polyp was observed and resected by en-bloc endoscopic mucosal resection. Histology revealed an adenocarcinoma (pT1 G2 Sm3) with a positive resection margin (0.7 mm) and deep submucosal invasion (1.4 mm). Total body computed tomography and rectal endoscopic ultrasound showed no lymph node or metastatic disease. Because of the patient’s comorbidities and anticoagulant treatment, endoscopic resection with the FTRD System was considered the appropriate therapeutic option to achieve R0-resection.

After antibiotic prophylaxis with an intravenous cephalosporin and the 19 dose of low-molecular-weight heparin being administered 12 hours before, the procedure was carried out. The lateral margins of the scanned resection site were marked with argon plasma coagulation (APC). The FTRD was mounted on the tip of an operative gastrointestinaloscope. Through a tissue anchor, the whole scanned lesion was pulled into the cap and the clip was deployed. The pseudopolyp thereby created was resected using the preloaded snare and a standard electrocautery setting. The procedure took about 8 minutes and there were no complications. Low-molecular-weight heparin was reintroduced 24 hours thereafter and the patient was discharged.

Histological examination of the full-thickness specimen 15 mm in size revealed no remnant dysplasia. This outcome was confirmed in the biopsy samples taken from the rectal scar 3 months later. Endoscopic ultrasound and CT further confirmed the absence of lymphatic or metastatic disease, therefore a chemotherapy was relinquished. In summary, full-thickness resection with the FTRD System was therefore a safe treatment for early colorectal cancer in this high risk patient, where standard surgery would carry considerable risks and require aggressive strategies.

Over-the-scope clip-assisted endoscopic full-thickness resection after incomplete resection of rectal adenoma

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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 09/2013 and 09/2014. Ulcer floor closure was achieved either by conventional clips (in 12 patients) or over-the-scope clips (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±12.57 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±1.1 mm for 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 Mochizuki K, Koga M, Kohno M, Fujihara S, Matsumiya N, Matsumaga T, Yashida T, Masaki T (2015) World J Gastroenterol 2015; 21 (17): 5281-5286 ISSN 1007-9327 (print) ISSN 2219-2840 (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 with an endoscope passed through a natural orifice, which allows to decrease the number of trocars placed through the abdominal wall or eliminating them completely. However, obtaining reliable closure of access points at the completion of a NOTES procedure is currently the most significant limitation and one of the main factors that will determine the future of NOTES in clinical use. Magdeburg R and Kaehler G, Department of Surgery, Medical Faculty Mannheim, University of Heidelberg, Germany, conducted a retrospective study prospectively collecting data of patients who underwent transgastric flexible endoscopic NOTES with final gastric access closure by OTSC clip application.

Between 04/2010 and 03/2014, a total of 43 patients (mean age 34 years) underwent a combination of an endoscopic procedure and mesh closure after a transgastric NOTES procedure. Indications have been acute appendicitis (n=36), prophylactic bilateral salpingo-oophorectomy (n=6), and uterus myomatosis (n=1). In all 43 cases, the endoscopic access to the abdominal cavity succeeded without any difficulty. After performing the operation, closure of the access by OTSC application was also possible in all cases. Overall, three adverse events occurred: in two patients (4.7 %) clinical signs of acute gastrointestinal bleeding appeared, gastroscopically there was no demand for action in one case and in the other one bleeding could be stopped by hemoclip application. The third patient (2.3 %) suffered insufficiency of the gastric closure with local peritonitis; this patient received laparoscopic suturing and the abdominal cavity was cleaned with liquid solution. With antibiotic therapy, no further problems occurred.

In summary, this retrospective study showed in more than 40 consecutive patients that OTSC application is safe and effective for closure of gastroscopy after NOTES procedures, however, further investigation in clinical settings is absolutely necessary to establish clear indications and guidelines for the use of transgastric NOTES. Natural orifice transluminal endoscopic surgery in humans: feasibility and safety of transgastric closure using the OTSC system Menniger R, Feuerbach M, Kaehler G (2015) Surg Endosc DOI 10.1007/s00464-015-4163-4, Epub March 24, 2015

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

R. Mennigen, 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 anastomotic 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 anastomotic fistulae were selected.

Between 10/2012 and 06/2014, five male and five 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 31–109 days). Median total follow-up time was 230.5 days (range 156–523 days). There were three failures (30 %), including two cryptoglandular and one Crohn’s disease-associated fistula. In all three cases, the OTSC was used for fistula retraction 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 after the 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 transsphincteric and suprasphincteric fistulae.


June 2016 | OTSC® vs. cSEMS for intestinal leakage: clipping 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. Farnik, 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 eloxy, 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 (68 %) were treated by cSEMS and 34 (31 %) by OTSC.

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 41.1±25 days (p<0.001), median leakage size was 10 mm (range 1-50 mm) vs. 5 mm (range 1-30 mm), and complications were observed in 68 % vs. 8.8 % (p<0.001), respectively.

Clinical success for primary interventional treatment was observed in 29/27 (40 %) vs. 24/34 (70 %, p = 0.006), and clinical success at the end of follow-up was 46/72 (64 %) vs. 29/34 (85 %) for patients treated by cSEMS vs. OTSC; p = 0.04.

In conclusion, cSEMS and OTSC are rather complementary techniques rather than to be mutually exclusive. The authors suggest, that, due to its low complication profile and high effectiveness 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 existing contamination accompanying the leak, cSEMS placement might be preferred.


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

Guo J and colleagues, Shengdong Hospital of China Medical University, Shenyang, China, reported on their experience of defect closure with OTSC after gastric full-thickness resection (EFTR) of gastric subepithelial tumors. Between October 2013 and March 2014, 23 patients underwent EFTR of a gastric subepithelial tumor ≤2 cm originating from the muscularis propria by intentional transection of the gastric wall. Defect closure was achieved by tissue approximation with an OTSC clip. Endoscopic closure 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). There were no intraoperative or postoperative 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 gastric subepithelial tumor resection.

April 2016 | Technical success rates and long-term clinical outcomes of fistula closure with OTSC®
Dr. R. Law and Dr. L.M. Wong Kee Song, Division of Gastroenterology and Hepatology, Mayo Clinic, Rochester, MN, USA together with 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, who were treated 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), colo-rectum (10) and esophagus (3). Previous percutaneous endoscopy gastrostomy/ejunostomy and prior bariatric procedure were the cause of these fistulas in 10 cases respectively. Patients with endoluminal gastric tumors (treated with the gc closure) OTSC clip for gastric indications and 1 (traumatic) clips for all other indications. A guidewire, tissue graspers and tract ablative therapies (i.e., argon plasma coagulation or cytology brush) were used where deemed beneficial by the physicians.

Initial technical success rate, measured by lack of contrast extravasation after OTSC placement, was 80% (42/47). At a median of 39 days (range: 26-86 days), however, fistulas recurred in 19 patients (46 %). The OTSC was still present adjacent to these fistulas in 16 cases (84 %) at repeat intervention. The authors cite current literature reporting similar technical success rates to their own findings, but note that reported long-term success varies widely, from 74 % in a systematic meta-analysis by Weiland et al., to three studies reporting success rates of 38, 50 and 67 % respectively.

Since nearly 2/3 of fistula recurrence in their study was discovered over 4 weeks after initial technical success, the authors conclude that longer term follow-up is necessary to properly assess success rates. They call for future studies to determine the long-term outcomes of fistula disease. Different aspects of fistula care are most likely to respond well to OTSC closure and which assistant therapies might facilitate long-term treatment success.


March 2016 | OTSC® helps to avoid emergency laparotomy, according to review on endoscopic treatment of iatrogenic gastrointestinal perforations
The “Deutsches Ärzteblatt” (German journal of physicians) reports on a review conducted by Schmidt and colleagues assessing endoscopic treatment of iatrogenic gastrointestinal perforations. Emergency laparotomy after iatrogenic gastrointestinal perforation can often be avoided by application of modern endoscopic occlusion techniques. The review presents different strategies for management of iatrogenic perforations. These include supportive therapies such as broad-spectrum antibiotic treatment or decompression of high intrabdominal pressure. For endoscopic closure of the perforations different techniques are displayed, namely standard and OTSC-clips and, for perforations on the duodenal side, covered staples. Standard over-the-scope (TTS)- clips are used for small colonic perforations and slit-shaped gastric perforations < 10 mm. However, these clips normally only grasp mucosa and submucosa, closure of larger lesions especially in perforating stomach and colon cannot be accomplished by standard clips.

Over-the-scope clips (OTSC) on the contrary also grasp deeper layers of the gastrointestinal wall. This enables closure of 20-30 mm lesions. Besides, deployment of the OTSC is a time saving one-step action in contrast to the sequential occlusion with standard clips. Mainly retrospective clinical studies can be found assessing the use of OTSC-clips for iatrogenic gastrointestinal perforations. These studies examined between 3 and 48 patients. Patients with a follow-up of one week to 3 months. Technical success rates reported were between 50 and 100%. Clinical success rates vary because of heterogeneous size and localisation of the perforations and time of diagnosis. The prospective, multicentric CLIPPER - study comprises 36 patients with iatrogenic gastrointestinal perforations < 30 mm. Technical and clinical success rates reached 92 and 89 %, respectively. A systematic review conducted by Weiland et al. in 2013 reports on a technical success rate of 80-100 % and a clinical success rate of 60-100 %. Authors of recently published retrospective multicentre studies with 106 and 48 patients recount similar results. Based on the named results the occlusion with OTSC-clips in stomach and colon found entry into the recommendations of the current position paper of the European Society of Gastrointestinal Endoscopy (ESGE).


March 2016 | Use of OTSC® system 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 Fähndrich 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 tumors. The retrospective, observational, open-label, single-arm, consecutive case series 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 from R1 situations after conventional endoscopic polypectomy with low risk for colorectal cancer of the colon, one from a tumor 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.

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 8cc or 14/6) or FTRD clips.

The application of the clip was successful in 16/17 cases, only in one case the clip did not deploy correctly. In the other case, the endoscopic successful resection was accomplished in all remaining patients (16/16, 100%). On final pathology, a full-thickness section was achieved in 69 % (11/16) and a deep muscle margin of resected specimen (DMMR) was accomplished in the remaining 31 % (5/16). Also a Complete resection (R0) was achieved in all patients.

The authors discuss that the OTSC System is safe and feasible for EFTR and eDMR 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 endoscopists may do).


February 2016 | 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
Maekawa S, Nomura R, Murase T, Ann Y and Harada M from the Department of Gastroenterological Medicine, Japan Labour Health and Welfare Organization Nigata Rosai Hospital, 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 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 per patient were used.

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 8.3 % two 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. Beside the safety of fistulas, perforations 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 therapy with through-the-scope clips only. 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
Endoscopedia, the official blog of “GIE: Gastrointestinal Endoscopy” recently published a video on OTSC use by Dr. James 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 ulcer bleedings with refractory bleeding after failed angiographic embolization and endoscopic treatment respectively. 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, Chu PWY, Teoh YB and Lau JYW from the Department of Surgery, Institute of Digestive Disease, The 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 from included nine patients (4 men, 5 women) with a median age of 72.5 years (range 39 - 91 years).
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 18 conventional clips were applied to the nine ulcers. 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 77.6% (19/25), 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 endoscope 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 Kohthari, T Kohthari and V Kaul of the Center for Advanced Therapeutic Endoscopy, Division of Gastroenterology and Hepatology at the University of Rochester/Strong Memorial Hospital, Rochester, presented the results of a 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 coronary artery disease, chronic renal insufficiency and Laennec’s cirrhosis before he was admitted for a Staphylococcus infection leading to an endoscopic variceal bleed. The patient underwent coagulation therapy, a tagged red blood cell scan, angiography, coil embolization, repeat mesenteric angiography and repeat (push) enteroscopy. 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. Instant and complete hemostasis was achieved with the size of the 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 measures only” and he passed away several days later. The authors stated 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 endoscopic management of high-risk patients in a variety of challenging clinical settings, especially in case of poor candidates for surgery. They further stated that endoscopic perforation management with the OTSC clip may avoid the cost and morbidity 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. The Over-The-Scope-Clip Device: An Indispensable Tool in Interventional Endoscopy: A Case Series. Kohthari S, Granato CM, Sharma S, Kohthari T, Fagan N, Adamoretz W, Wang G, Ullah A, Kaul V. Program No. 2183. AAGLA 2013 Abstracts. Honolulu, HI: American College of Gastroenterology.

January 2016 | Novel remOVC DC ClipCutter for endoscopic removal of OTSC’s: a retrospective case series

Dr. Schmidt and colleagues from the Department of Gastroenterology and Oncology, Klinikum Ludwigshafen, Germany, report about a novel method of removing OTSC using a bipolar DC impulse cutting device. The retrospective study includes 11 consecutive patients who underwent endoscopic OTSC removal between December 2012 and November 2013. The clips were located all along the digestive tract, in the esophagus, gastric antrum, pylorus, pyloric-jejunal anastomosis, descending duodenum, sigmoid colon and rectum. By that time, the DC ClipCutter was applied under compassionate use conditions, given the lack of suitable alternative methods. Mean time between 31 and 469 days (mean clip time in situ: 138 days) before extraction. The DC ClipCutter is an endoscopic, bipolar instrument device connected to an electrical generator (DC Impulse) producing direct current impulses which are applied at two opposite sides of the clip. The maximum strength of 140 A selectively heats up the nitinol and separates it thermally. The mean procedure time for clip removal in this case series was 47 minutes (range 35 - 75 minutes), given the specific circumstances of compassionate ruse with a pre-series system. Cutting of the clip was successful in 100% of cases (11/11). All clip fragments were successfully removed in 10/11 patients (91%). In one patient a single clip fragment could not be removed due to deep ingrowth into the duodenal wall. The fragment was left in place and had not caused any complications in follow-up visits three months later. During clip cutting, no local or systemic complications were observed. Minor bleeding occurred in two patients after clip removal and was treated with epinephrine injection. One patient had a superficial mucosal tear with minor bleeding which promptly stopped. Furthermore, bleeding could be managed by application of two standard clips. OTSCs have been demonstrated to be effective tools for endoscopic treatment of gastrointestinal perforation, leakages and fistulas and are also used for full-thickness resection. They usually dislocate during extraction and are expelled after a few months. Although OTSCs are made of biocompatible material and suitable as implants, active removal can be indicated in special situations. The remOVC technique is described as safe and effective with a high overall success of 91%. In conclusion, Dr. Schmidt et al. expect the remOVC System to be a valuable tool for OTSC removal for emergency situations, e.g. inadvertent misplacement of the clip as well as for elective OTSC removal, where clip extraction is indicated.

Endoscopic removal of over-the-scope clips using a novel cutting device: a retrospective case series


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


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

Dr. A. Schmidt, Dr. A. Riecken, Dr. M. Damm, Dr. O. Cayfried, Dr. M. Bauder and Dr. K. Caca, Department of Gastroenterology and Oncology, Ludwigshafen Hospital, Germany, reported the results of a case series of OTSC clip removal with a specifically developed cutting device (future remOVC® remOVC® TOOL in Interventional Endoscopy: A Case Series. The authors note that over-the-scope clips (OTSC) have proven their efficacy in an ever-growing variety of indications. Still, there is a lack of follow-up studies on the outcome of the clip once it is deployed in the gastrointestinal tract. Clinical experience shows that clips usually fall off after several weeks or months, depending on the amount 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 of all fragments. 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 cutting device for OTSC removal 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” status. In a follow-up set at 3 months, this fraction had not caused any complications. Indications for clip removal included intermittent epigastric/abdominal pain, the need for a repeat biopsy at the resection site and patients’ wishful.

The cutting device consists of a grasping connected to a generator. Two electrodes in the grasping tips direct a current impulse, which heats up the clip and thermally cuts the material. The current has a maximum strength of 140 amper and maximum duration of 100 milliseconds. After successful cutting, the device stops automatically, 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. If the clipping was not successful, the OTSC site was inspected for sharp fragments, the OTSC site was inspected for sharp fragments, the OTSC site was inspected for sharp fragments, the OTSC site was inspected for sharp fragments, the OTSC site was inspected for sharp fragments, the OTSC site was inspected for sharp fragments, the OTSC site was inspected for sharp fragments, the OTSC site was inspected for sharp fragments, the OTSC site was inspected for sharp fragments, the OTSC site was inspected for sharp fragments, the OTSC site was inspected for sharp fragments, the OTSC site was inspected for sharp fragments, the OTSC site was inspected for sharp fragments, the OTSC site was inspected for sharp fragments, the OTSC site was inspected for sharp fragments, the OTSC site was inspected for sharp fragments, the OTSC site was inspected for sharp fragments, the OTSC site was inspected for sharp fragments, the OTSC site was inspected for sharp fragments, the OTSC site was inspected for sharp fragments, the OTSC site was inspected for sharp fragments, the OTSC site was inspected for sharp fragments, the OTSC site was inspected for sharp fragments, the OTSC site was inspected for sharp fragments, the OTSC site was inspected for sharp fragments, the OTSC site was inspected for sharp fragments, the OTSC site was inspected for sharp fragments, the OTSC site was inspected for sharp fragments, the OTSC site was inspected for sharp fragments, the OTSC site was inspected for sharp fragments, the OTSC site was inspected for sharp fragments.
prevented closure due to excessive coagulation in the muscularis propria or excessive tissue resection with FTRD 

The authors note that a device for cutting the clip for later removal as well as other instruments based on the OTSC concept show promising results in ex vivo experiments.

The paper concludes that OTSC is an asset in interventionendoscopy, especially in case of complex endoluminal resections. According to the literature, 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 recurrent bleeding, e.g. in anti-coagulated patients or treatment of acute Forrest Ia bleed hemorrhage.

As a chronic fistula can be a long-term 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 perforations since these may require sufficient external drainage.

Klinische Erfahrungen mit dem Over-the-Scope Clip (OTSC) 


June 2015 | Prophylactic OTSC® application for prevention of complications after colorectal ESD 

A Meining, University Hospital Ulm, together with M. Bakajov, Technical University Munich, as well as H. Feusser and D. Hartl, 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 lye ingestion. Because of coarse, scarred mucosa at the fistula opening in the submucosa-esophagus region, it was impossible to place the clip permanently and securely anchor an endoscopic clip.

Overstenting 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 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 inflamed lesions. For endoscopic therapy, one patient with a criptoglandular fistula was treated using FTRD. During initial intervention, successful closure was achieved in 70 percent of patients. Permanently successful closure was achieved in 47 percent of cases. Average duration of hospital stay was 4 days (1–12).

The group recommends incision of the mucosa before application of the OTSC clip in case of coarse and chronically inflamed lesions. For endoscopic therapy, one patient with a criptoglandular fistula was treated using FTRD. During initial intervention, successful closure was achieved in 70 percent of patients. Permanently successful closure was achieved in 47 percent of cases. Average duration of hospital stay was 4 days (1–12).

Rationale Handeln nach Perforation: Clippen, Stenten oder Sponge? A. Meining, Ulm.

“Live Demonstration on Stage” on correcting OTSC clip placement.

During the live demonstration using a porcine stomach model, K. Caca, Ludwigsburg hospital, showed possible mistakes in placing OTSC clips and offered suggestions for preventing or correcting these errors. He also demonstrated OTSC removal with the remOVE system.

OTSC Clip/Clip-Fehlplatzierung.

K. Caca, Ludwigsburg; R. Landschoof, Düsseldorf.

FTRD (Full-Thickness Resection Device)

FTRD for endoscopic full-thickness resection in case of NET.

P. Klare, B. Neu, M. Bajbouj, R.M. Schmid and S. von Delius, TU Munich, together with R. Burlefinger, Maria Theresia Hospital, Munich, and K. Specht, TU Munich, presented a case of treatment of a 50-year-old male with a neuroendocrine tumor (NET). During a screening procedure, the asymptomatic patient had a rectal polyp removed with a snare. Histological examination identified a NET with a proliferation rate of G1 and G2. A video was presented by M. Bauer, M. Allescher, Garmisch-Partenkirchen hospital, presenting the use of FTRD for full-thickness resection on a porcine gastric model in a special 3D demonstration.


OTSC Proctology

OTSC Proctology deemed effective for closure of therapy-resistant complicated anal fistulae. R. Menningen, University Hospital Münster, presented his center’s experience in using OTSC Proctology. Technical success rate for fistula closure with OTSC Proctology was 95 percent in 100 patients (5 male, 95 female) with a median age of 41 years (26 to 69). All patients had been treated unsuccessfully before (e.g. mucosa flap, Anal Fistula Plug), and some had undergone several unsuccessful procedures. 4 patients suffered from crypto-glandular fistulae, and in 6 patients fistulae were complicated by Crohn’s disease. In 70 percent of patients permanently successful closure and healing was achieved. In 3 patients fistulae recurred (2 crypto glandular, one patient with Crohn’s disease), and the clip dislodged spontaneously after over three weeks. In 3 patients the clip was surgically removed after unsuccessful resutting and healing was achieved in 70 percent of patients permanently successful closure and healing was achieved. In 3 patients fistulae recurred (2 crypto glandular, one patient with Crohn’s disease), and the clip dislodged spontaneously after over three weeks. In 3 patients the clip was surgically removed after unsuccessful resutting and healing was achieved.
cryptoglandular, one patient with Crohn’s disease), and the clip dislodged spontaneously after over three weeks. In 3 patients the clip was surgically removed after successful healing of the fistula. Dr. Menningen deemed the OTSC Proctology system a safe and effective treatment option, even for recurrent complicated anal fistulae.

Verschlusreiben komplizierter therapieresistenter Analfisteln mit dem OTSC Proctology System

Menningen R, Laukötter M, Vowinkel T, Senninger N, Rijken E

Münster. (45. DGE-BV-Kongress)

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. Mel Wilcox, Dr. Chad Burski and Dr. Klaus Mönkemüller of the Bas I. Hirschowitz 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 during endoscopy.

The study was conducted at a large tertiary care hospital, comprising 12 patients (8 male, 4 female), mean age of 59 (range: 29–86) with ongoing upper gastrointestinal bleeding despite two or three previous sessions of endoscopic therapy. Patients had a mean ASA score of 3 (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), Dieulafoy lesion (2), anastomotic ulceration (1) and Mallory–Weiss tear (1). Hemostasis was achieved in all patients, but reblooding occurred in two patients 1 day and 7 days after OTSC placement. There were no complications associated with OTSC application.

The OTSC System was loaded onto a standard gastroscopic scope and introduced into the upper gastrointestinal tract under standard direct visualization. The bleeding lesion was located and the endoscopic hemostasis 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 engulphed inside the transparent clip before the clip was released. In two patients with post-bulbar ulcers, a wire or a wire looped inside a feeding tube was advanced into the distal duodenum and the scope advanced alongside the wire. This measure helped to prevent small-bowel luminal occlusion, which has previously been reported as a major adverse event. The authors conclude that the OTSC System provides tissue apposition far superior to traditional clipping and can sue apposition far superior to traditional clipping and can

March 2015 | German Congress of Coloproctology: further clinical data on OTSC® Proctology

Munich, March 12–14, 2015:

The annual congress of the German Society for Gastroenterology and Proctology 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 using OTSC technology.

In their abstract (Coloproctology 2015; 1:76) they summarize the data of 22 patients, treated between March and August 2014. The majority had trans-sphincteric fistulas (n=10), followed by inter-sphincteric, rectal, recto-vaginal and pouch fistula (one case each). 13 patients had prior fistula surgery and 8 patients suffered from IBD. Post-surgical follow-up was 3–9 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 optimize the clinical result.

Das OTSC-Verfahren und seine (Miss-)Erfolge im klinischen Alltag


41. Deutsch Koloproktologen-Kongress

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, together with Dr. Baron, Division of Gastroenterology & Hepatology, Mayo Clinic Rochester, Rochester, Minnesota, explored the efficacy of OTSC for securing self-expanding metal stents (SEMS) in patients undergoing treatment with SEMS. Indications for SEMS included post-operative leaks in 4 patients (2 esophagogastrosopic anastomotic leaks, 2 fistulae after bariatric surgery), 1 perforation, 3 benign esophageal strictures (2 peptic, 1 anastomotic), and 5 malignant esophageal strictures. The patients (8 male, 4 female) had a median age of 67 years with a range from 40 to 89 years. Before anchoring the stent with OTSC, three patients had a new SEMS deployed, in the other ten cases the migrated stent was merely repositioned. A standard upper endoscopy was advanced to the stomach and then the stent was applied, attempting to position tissue and stent in such a way that upon deployment half of the OTSC would grasp the stent and the other half the esophageal wall. Clip placement was successful in all cases with a median procedure time of 3.5 minutes (range of 2 to 5.5 minutes). Cutting and OTSC/SEMS removal was 6 minutes on average. Migration occurred in two patients, both with benign esophageal strictures at a mean of 32 days compared with a mean of 3.5 days for prior migrations without OTSC use. In 4 of 5 patients with malignant disease, the SEMS remained in place indefinitely. Successful healing occurred in 11 of 13 patients (85%) with a median stent dwell time of 57 days (2–228 days range). Of three patients with refractory benign esophageal strictures, two had complete stent disengagement. The authors discuss several uses of esophageal stents, noting that fully covered SEMS have high migration rates, which call for external or internal fixation. They note that in spite of worse stent fixation times from 2.6 to 12.5 months with short-term usage of a suturing device, the use of OTSC is much more time efficient at a median of 3.5 minutes.

Additionally, OTSC placement does not require the use of an overtube or double-channel upper endoscope and prevents additional costs of 700 to 800 USD for suturing. The authors state that all patients in this study had previously experienced stent migration, the reduction of stent migration from 100 % to 15 % through OTSC use seems promising. The authors note that prospective data is needed to define an optimal approach for OTSC use in SEMS placement.

Dr. Mudumbai, Dr. Velazquez-Avila of the Bas I. Hirschowitz Endoscopic Center of Excellence, Division of Gastroenterology and Hepatology, University of Alabama at Birmingham, United States cooperated with Dr. Baig and Dr. Gluck.

Department of Medicine, University of Erlangen, Nürnberg, Germany as well as Dr. Neumann, affiliated with both institutions, in a single-center, retrospective cohort study of SEMS anchoring with OTSC and subsequent removal of clip and stent with an inject-and- dissect technique. The study covered a total of 12 patients (8 male, 4 female) at a median age of 57 years (range: 42–72 years). Indications included different nonstricturing benign or malignant esophageal diseases (transesophageal fistula, postoperative leaks, and esophageal perforation).

Application and initial anchoring of the OTSC clip was successful in all cases, in one small clip migration 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 currently at up to 40 % in esophageal stent placement by using OTSC as an anchoring device. The inject-and- dissect technique used for removal was successful in all cases in which the underlying condition had been resolved, 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 lead to stent migration. The authors also mention two 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 SEMS as an easy and safe method for treatment of esophageal stent migration rates and call for further studies to assess and refine the technique.

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

February 2014 | Endoscopic migration of fully covered esophageal stents with an over-the-scope clip device (with videos).


Epub 2014 Jan 25

A novel technique of self-expanding metal stents using the over-the-scope clip and a technique for subsequent removal


Epub 2014 Dec;46(12):1106-9

210

Epub 2014 Sep 30

Dr. Irani et al. videos: To watch videos of the procedures
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 Ohashi 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-Bawardy 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. Koke, T. Kudo, T. Shigesawa et al., Department 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 acute pancreatitis including an abscess in the left abdominal cavity and immense peripancreatic fluid collection. Concerning this patient, a middle-aged man in his 40s was suspected for disruption on the tail of the main pancreatic duct was suspected and confirmed after 90 days and treated with an ENPD tube and a pancreatic stent, which proved ineffective. After conservative management options had been exhausted, surgical therapy was considered, but postponed due to unavailability of E.C. cell and MRSA in ascites culture. Finally, an OTSC clip was used on day 148 to endoscopically seal the fistula. A follow-up indicated 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 percutaneous drainage. Several follow-ups showed the success of the procedure with improvement of the abscess, clip in situ and healed perforation with 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 69-year-old female with necrotizing pancreatitis, who had had 3 previous transgastric necrosectomies. When she was hospitalized 3 weeks after her last necrosectomy, there was reflux of fecal material from the duodenum to the stomach as a sigmoidal structure, likely caused by pancreatic necrosis and pancreatic secretions directly into the colon through fistulae. Two fistulae were located and closed from a colonic approach using OTSC clips. Closure was confirmed fluoroscopically and endoscopically. After 7 months, the patient was 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 recurrence. Several months after the endoscopic procedure, the pseudocyst alone cannot ensure colonic fistula closure, the OTSC System is an interesting treatment option since it is less invasive than surgery.

January 2015 | ASGE: Over-The-Scop© 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 for primary or rescue therapy. The overall clinical success for the closure of perforations and leaks ranged between 90 percent and 73 percent; however, successful closure of fistulae was achieved in less than half of the patients. The type of defect (i.e. perforation or leak) is the best predictor of successful long-term closure. The study results appear in GIE: Gastrointestinal Endoscopy, the monthly peer-reviewed scientific journal of the American Society for Gastrointestinal Endoscopy (ASGE)."

For Immediate Release:
Media Contact: Anne Owenssey abrownsey@asge.org
American Society for Gastrointestinal Endoscopy
www.asge.org | www.screen4coloncancer.org

An OVER-THE-SCOPE CLIPPING DEVICE FOR ENDOSCOPIC MANAGEMENT OF GASTROINTESTINAL DEFECTS IS SAFE AND EFFECTIVE
DOWGERS, III — October 23, 2014 — 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 for primary or rescue therapy. The overall clinical success for the closure of perforations and leaks ranged between 90 percent and 73 percent; however, successful closure of fistulae was achieved in less than half of the patients. The type of defect (i.e. perforation or leak) is the best predictor of successful long-term closure. The study appears in GIE: Gastrointestinal Endoscopy, the monthly peer-reviewed scientific journal of the American Society for Gastrointestinal Endoscopy (ASGE). “An international multicenter study reports that over-the-scope clip 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 for primary or rescue therapy. The overall clinical success for the closure of perforations and leaks ranged between 90 percent and 73 percent; however, successful closure of fistulae was achieved in less than half of the patients. The type of defect (i.e. perforation or leak) is the best predictor of successful long-term closure. The study appears in GIE: Gastrointestinal Endoscopy, the monthly peer-reviewed scientific journal of the American Society for Gastrointestinal Endoscopy (ASGE).”

ENDO Research Update 30 | Research & clinical trials

Ovesco Research Update 30 | Research & clinical trials | Version 30 | 2019-03-15
November 2014 Clinical presentations confirm efficacy of OTSC® clipping at German Congress of Visceral Medicine in Leipzig

Clinical presentations at German Congress on Visceral Medicine confirmed 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, DGGV, was held under the presidency of Prof. Dr. med. Peter R. Galle. A significant number of presentations provided clinical data on OTSC clipping and confirmed clinical efficacy and safety in the primary indications of the product, hemostasis, closure of acute lesions/perforations and chronic lesions/fistulae (source: www.viszeralmedizin.com).

Conference report

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Reports on Ovesco OTSC

OTSC proves to be preferable treatment option for several indications.

Glitsch A, Schreiber A, Boldt J, Kellé R, and Mayerle J, Greifswald, reported about a cohort of 46 patients treated with OTCS clips. The indications include postoperative anastomotic insufficiency (n=13), bleeding (n=7), perforations (n=15), pancreatic fistula 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 were achieved for all but one indication. In the case of postoperative anastomotic insufficiencies 3 out of 13 insufficiencies could not be closed successfully (76.93 % success rate). These patients had to undergo further laparoscopic treatment. In all other cases, no complications were observed and thus further treatment was not 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 complex surgical techniques in case of failure.

Retrospektive Auswertung der OTSC Anwendung an der Universitätsmedizin Greifswald


Braun A, Friedel J, and Kröhnke A, Greifswald, presented data about a total of 16 patients (median age=75.5 years; R 61–82 years; m=9, f=7) over three years with acute bleeding, who were treated with OTSC application during emergency endoscopy. 7 procedures were performed in the upper and 8 in the lower gastrointestinal tract. Patients with upper gastrointestinal bleeding were given a highly dosed proton pump inhibitor (80mg i.v. Bolus, 30 mg i.v. 24h). Hemorrhages were classified as follows: Forrest la (n=7), Forrest lb (n=7), and Forrest IIa (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 Flu, 1 Fib, 1 Fila) 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-Scop Clip (OTSC)

Braun A, Kirchhahn A

Interdisciplinary treatment regime for thoracic anastomosis insufficiencies.

Pautner M, May A, Lorenz D, and Eil C, Offenbach, introduced the complication management regime for thoracic anastomosis insufficiencies (AI) at HSK Wiesbaden hospital. From 07/2000 to 12/2013, they counted 622 cases of resections in the esophagus, 557 of which included transhiatal esophageal resections with intrathoracic anastomosis of a gastric sleeve. 49 of these 557 patients (8.8 %) suffered from confirmed AI.

Of these cases, 13 (26.5 %) were treated conservatively with a temporarily placed and gasless 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 transmural vacuum therapy. 12 patients (26.5 %) had to undergo repeat esophagectomy, 7 of which had a second place 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 sleeve shows good blood circulation and the AI is small, either a clip or a TL is placed. Routine check endoscopy after 36–48h is performed with stents; routine check after 24 h and placement of TTL to protect stent from bile. If pleural empyema occurs, a repeat thoracotomy is performed, including decoridicating and sewing-over of the AI as well as stent placement; stent is fixed with an absorbable suture. The authors report that this interdisciplinary treatment regime for thoracic anastomosis insufficiency (n=13), bleeding (n=7), perforations (n=15), pancreatic fistula 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 were achieved for all but one indication. In the case of postoperative anastomotic insufficiencies 3 out of 13 insufficiencies could not be closed successfully (76.93 % success rate). These patients had to undergo further laparoscopic treatment. In all other cases, no complications were observed and thus further treatment was not 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 complex surgical techniques in case of failure.

Report on OTSC Proctology

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

Probst R presented the experiences of a prospective pilot study at St. Anna hospital, Stuttgart, and ed 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 trans sphincteric and 6 suprasphincteric anorectal fistulae. Average procedure time for clipping of fistulae was 32 minutes (R 17 to 66 minutes). There were no severe or critical complications. In 6 patients fistulae were treated 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 due to distal fistula extension. The other 17 fistulae were treated with a macro OTSC clip. 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 efficacy and 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 existing treatment methods. In addition, it seems to eliminate the risk of postoperative incontinence, and does not impede further treatment options. Additionally, patient satisfaction is high and the instrument is easy to use.

OTSC ohne Endoskop: Anorektaler Fistelverschluss mit OTSC-Proctology

The second case was a 36-year-old female with a history of diverticulosis, presenting with passage of feculent material from her vaginal canal and recurrent urininary tract infections. CT scan revealed a fistula between sigmoid colon and vagina, but locating it endoscopically was difficult. The OTSC clip was deployed, resulting in good tissue apposition. The patient was symptom-free for several weeks. When symptoms recurred, surgery revealed an abscess communicating with the colovaginal fistula, which prevented healing.

The third case was a 41-year-old female with colonic interposition after ileostomy and PEG tube placement. After the tube was removed, gastrosomal 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 cap 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 an enterocutaneous fistula for four months, leading to malnourishment. Prior attempts to close the fistula with fibrin glue had failed. The OTSC clip was placed onto the fistula opening under continuous suction and success fully deployed. Follow-up after 12 months showed complete closure.

The over-the-scope clip system – a novel technique for gastrocutaneous fistula closure: the first North American experience


Over-the-Scope-Clip (OTSC) application as rescue therapy for postoperative enterocutaneous fistula closure

Meister T, Kuhlgatt J, Floer M
Acta Chir Belg. 2014 Jan-Feb;114(1):87-9

August 2014 | Management of postoperative anastomotic defects: OTSC® System as preferred treatment option

Two case reports recently published by Dr. Tontini and colleagues, Dept. of Medicine I, University of Erlangen-Nuernberg, Germany, and by Dr. Chen and colleagues, Dept. of Gastroenterology, Riverside, University of California, USA illustrate the complete closure of large anastomotic leaks with the OTSC System when other techniques have failed or deemed unsuitable. A 69-year-old man had an Ivor-Lewis esophagostomy due to esophageal carcinoma. After the development of chest pain 6 days later a CT scan revealed an anastomotic dehiscence. During an EGD a minor stent was placed but a persistent defect was 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 enteroscopic 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, tachycardia and low hemoglobin level 3 weeks after a Billroth I gastrointestinal anastomosis. EGD showed an oozing bleeding and as well a defect at the anastomosis. In this case the dehiscence extended over half the circumference of the anastomosis. Since other techniques seemed inappropriate due to large leak, massive bleeding and difficult target position it 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


Over-the-scope clip for closure of persistent post- esophagostomy gastric conduit fistula

Chen AI, Lim BS, Ma JS, Chay CT Gastrointest Endosc. 2014 Apr;79(4):546

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 dehiscence (n=5), anastomotic leak (n=4), perforation after mucosal resection (n=3), prophylactic closure of mucosal defect after EMR (n=1), postpolypectomy bleeding (n=2), postendoscopic perforation (n=2), tracheoesophageal fistula (n=1) and leakage from a percutaneous jejunostomy site (n=1). Instruments or modalities used to grasp the tissue were dedicated devices (OTSC Twin Grasper and OTSC Anchor) in 16 and nondedicated devices (rat tooth/illigator forceps or suction alone) in 15. Median follow-up time was 2.9 months; mean defect size 10 mm (5-22 mm). A complete closure and healing was noted in 75% of all cases. Furthermore, a trend towards higher success rate was noted in defects 10 mm compared to defects >10 mm. No patient 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 through the scope 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


OTSC Update 17

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, Hospital Universitario de la 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 in a 58-year-old patient. The 3-stage treatment of dilatation, subsequent percutaneous gastrostomy and closure with an OTSC clip implicated a substantial improvement of food supply and quality of life.


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 H. Gómez, MetalClínic agrobiotechnology, Corp., Deltebre, Catalonia, Spain, Dept. 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 curvature. Due to the large size and difficult position of the lesion, conventional through-the-scope clips were not used, but an OTSC clip was successfully deployed.

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.

Novel treatment of a gastrlic Dieulafoy lesion with an over-the-scope clip


Endoscopic closure of gastric perforation using over-the-scope clip: a surgery-sparing approach


Closure of an Ischemic Duodenal Fistula with an Over-The-Scope Clip


June 2014 | Prophylactic closure of large mucosal defects after colorectal ESD significantly reduces the inflammatory reaction and abdominal symptoms of patients with neoplasms

Fujihara 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) was indicated for patients with excessive coagulation in the muscularis propria or larger resection size. The closure group reduced the peritoneal 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 case was indicated for patients with excessive coagulation because the endoscopic treatment was ineffective. Without increasing 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


May 2014 | Sleeve gastrectomy leaks: Closure with the OTSC® System

Sleeve gastrectomy 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 colleague, 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 64-year old woman, a fistula (n=2), endoscopically adjustable gastric band to a sleeve gastrectomy was performed.

To prevent leakage from the resection line, Seaguard®, a staple line reinforcement product was used in both cases. After initial recovery both patients presented with abdominal pain and fever (8th/30th postoperative day) and a CT scan confirmed leaks at the gastroesophageal junction. Intravenous antibiotics and nutritional support were instituted and fluid collections drained percutaneously and laparoscopically. In the case of the 58-year old woman conservative management was continued for 6 weeks, but the leak persisted. Therefore, it was decided to use the OTSC System. By applying an OTSC clip complete closure was achieved in both patients. After 6 and 8 months respectively, there was no evidence of further leaks 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 an easy and simple endoscopic 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):606-8 101

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 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 gastrointestinal bleeding (n=6), gastroduodenal ulcer (n=5) and/or esophageal ulcer (n=3), resection of submucosal tumor (n=2), stent fixation (n=1), and anastomotic leak after esophagectomy (n=1). The overall per case 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 impede an adequate apposition of the device.

The authors also report that 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 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 (in the case of a Dieulafoy’s lesion) with the main underlying mechanism being compressing the surrounding tissue around the vessel. They continue “…The OTSC device may become a better device to treat bleeding ulcers located in difficult positions because of its balloon shaped transperitoneal 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 approximation of tissue to facilitate subsequent closure. Interestingly, they do not have the device closed to 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 devices still remaining in situ even in this case, the “wire technique” as described by Mönkemüller et al., and the use of an Nd-Yag laser, as described by Fährndrich et al. earlier. Comment Ovesco: we are aware of this issue and are currently finalizing the development of an own, easy to use device.

Multipurpose use of the ‘bear claw’ (over-the-scope clip system) to treat endoluminal gastrointestinal disorders


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. Approximately 1500 people attended the event, with a significant number of both oral presentations and posters having 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 alongside the conference (Chairs: Hochberger J., Mais J., 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.

• Neue Clips für Blutung und Verschlussverfahren

Caca K, Ludwigsburg, Germany

K, Caca gave a talk on “New tools for the treatment of GI-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: “the OTSC device achieves hemostasis more quickly than alternative devices and is more effective particularly regarding acute, difficult and heavy bleedings.” For the treatment of perforation OTSC was the standard choice. Also, he showed first experiences with the new DC Clip Cutter device as an important tool for removing the OTSC which will be launched later this year.

Update Endoskopie – meine Toppapers

Haffen D, Rimplingen, Austria.

M. Häßler updated the plenary session on important recent 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 efficient 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


Use of Over-The-Scope Clip for treatment of refractory upper gastrointestinal bleeding: a case series

Chen SM, Chu PW, Teoh AY, Lau JY Gastrointest Endosc. 2014 May;80(5):E71-5


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Clip-Karussell

Groth S, Hamburg, Germany

S. Groth elaborated on the endoscopist’s option once it became clear that OTSC is from the rest of all products stating that OTSC is possibly the only device which can be used in this particular lesion.

Comment Ovesco: the comparator of OTSC is surgery!)
The authors conclude that OTSC is the preferred primary therapy of smaller post-interventional leakages. It might also be used in combination where cSEMS treatment was incomplete. They conclude that the longer treatment period with cSEMS and the higher complication rate might be due to sicker patients, but also due to the relevant dislocation rate of cSEMS, which they observed. The authors conclude that OTSC is a novel and promising therapeutic option for the treatment of anorectal fistula which is procedurally simple and time efficient. The risk profile is favourable, without relevant risk of fecal incontinence.

R. Probst and co-authors, Stuttgart and Mannheim, Germany, presented data from a prospective multicentric trial including 20 patients treated with OTSC Proctology for anal fistula. 18 of 20 patients (90 %) reached the treatment success defined as clinical healing of the anal fistula and absence of recurrence at 6-month postoperative period. The authors conclude that OTSC Proctology is a new minimally invasive device for the treatment of anorectal fistula which is procedurally simple and time efficient. The risk profile is favourable, without relevant risk of fecal incontinence.

Verschluss an Rezidivfisteln mit dem OTSC Proctology System
R. Menningen, M. Laukoetter, N. Senninger, E. Rijken
Klinik für Allgemein- und Viszeralchirurgie, University Medical Center Mainz
For more detailed information on the studies see reports in a pdf file on: www.ovesco.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 Salord et al., Dept. of Digestive Disease, University Hospital of Barcelona, Spain and by Dr. Gianfranco Donatelli and colleagues, Endoscopy Unit, Hôpital Privé des Peupliers, Paris, France demonstrate the successful use of the OTSC System in case of iatrogenic duodenal perforation.

The authors (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 and further surgical interventions were avoided. The two patients with cholangitis underwent therapeutic endoscopic retrograde cholangiography (ERC) afterwards without any complications. Oral food intake was restarted 2-6 days, respectively.

Endoscopic closure of duodenal perforation with an over-the-scope clip during endoscopic ultrasound
March 2014 | OTSC® @FISMAD, Naples, Italy: 77 % success in anastomotic leak treatment At the 2014 FISMAD (Federazione Italiana Chirurgia Digestiva) meeting held in 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 colocolical leaks. The mean 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 fistulae. In 3 cases OTSC was used to complete earlier vacuum sponge therapy. The overall success rate was 77% (20/26), 90 % in acute (9/9) and 58% (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 inefrent complication in colorectal surgery. Incidence rates in the literature range from 1 to 39 %. Clinically relevant leaks are commonly seen in 3-4 % of the cases. OTSC closed colocolical post-surgical leaks and fistulae is a safe technique with a high success rate.

Efficacia della clip OTSC per il trattamento dei deiscenze e fistole chirurgiche del colon retto

Efficacy of the Over-The-Scope Clip (OTSC) for treatment of colocolical post-surgical leaks and fistulas

Bonino MA, Verna A, Salvai A, Bullano A, Rapetti L, Azzero 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 iatrogenic 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 stated by Ovesco也能 see in 3

Guided cholangiopancreatoscopy

Sabori S, Gornais 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 ERCP to be safely performed after acute duodenal perforation.

Two patients were treated with the OTSC clip within 12 hours. Although the other two 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 successful. After complete closure was achieved, 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 Boherave’s syndrome).

Endoskopischer Verschluss von distalen Ösophagus-Perforationen mit einem Over-The-Scope Clip (OTSC)

Braun A, Hogt UF, Richter-Schrag HJ

Endo heute 2013; 131

Management of Boherave’s syndrome with an over-the-scope clip

Bona D, Aiolfi A, Rausa E, Bonavina L


Snapper fishbone esophageal perforation closed with an over-the-scope clip

Ferreira 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 Singhaj et al. have searched and analysed the literature using the key words "endoscopy" and "over-the-scope clip" 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 current literature are 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 dilatation of the gastro-jejunostomy.

The authors conclude that OTSC is easy to use with good results, thus decreasing the 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 studies by Weiland et al.:

Performance of the OTSC System in the endoscopic closure of iatrogenic gastrointestinal perforations: a systematic review


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


Epub 2012 Jun 14

February 2014 | New case series on use of OTSC® for treatment of refractory upper GI bleeding

Apart from using the OSTC System in acute and chronic perforations (i.e. perforations, anastomotic leakage, fistulae) 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 gastroduodenal 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 bleeding from ulcerative 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 78.2 % (complete 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, the other patient’s rebleeding was not possible due to stiff, fibrotic lesion edges. The overall clinical success rate (complete closure by using only OTSC clip) 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). No patient reported any complications after OTSC application. 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 complications after endoscopic submucosal dissection

Chen SM, Chiu PW, Tsoh AT, Lau KY

Endoscopy. 2014 Feb 6. [Epub ahead of print]

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. Noriko 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, concluding that the OTSC System is a highly useful technology that can be utilized for these indications. Their case series consisted of 23 consecutive patients treated between November 2011 and September 2012 (mean age 77 years) included the following indications for OTSC placement: stopping GI bleeding (n=9), closing perforation (n=10), closing chronic fistula (n=4) and prevention of post endoscopic submucosal dissection (ESD) duodenal ulceric 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=3). 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 was 91.3 % (21/23). In 7 of the complications of the OTSC clip was not possible due to stiff, fibrotic lesion edges. The overall clinical success rate (complete closure by using only OTSC clip) 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). No patient reported any complications after OTSC application. In conclusion, the OTSC is an interesting and novel device that enhances the armamentarium of therapeutic gastroenterologists.
January 2014 | OTSC® in mucosal flap closure after peroral endoscopic myotomy (POEM)
Maintaining the integrity of the mucosal flap and the reliable closure of the proximal entry during peroral endoscopic myotomy (POEM) is paramount in preventing leakage of esophageal contents into the mediastinal space. In a recently published case series (n=2) Payal Saxena, MD and colleagues, Dept. of Medicine and Div. of Gastroenterology and Hepatology, Johns Hopkins Medical Institutions, Baltimore, Maryland, USA describe their positive experience with the application of the OTSC System for reliable and easy flap closure after POEM. Both patients presented with dysphagia and regurgitation and were diagnosed with achalasia. It was decided to proceed with POEM. After myotomy of the inner circular muscle bundles it was noted that the mucosal incision had elongated from 2 cm to 4 cm in one case. Whereas the distal part of the mucosal entry was successfully closed with conventional hemostatic clips (Resolution Clip, Boston Scientific) in both cases, closure of the proximal half was not possible even with different clips. As the clips were noted to slip to one side of the mucosal incision, there was a risk of displacing clips into the submucosal tunnel. Hence, all partially attached clips were removed with biopsy forceps. Finally, a rigid scope was used to pull the mucosal incision with the OTSC clip and the OTSC Twin Grasper in both cases. Contrast swallow of the esophagus the following day revealed no leaks in either patient. The authors state that the OTSC clip provides more durable closure when compared to conventional clips and full closure is achievable due to greater compressive force. Considering that failure of closure risks serious adverse events, like mediastinitis and sepsis, these features of the OTSC clip appear even more attractive.


January 2014 | Avoiding Surgery: Minimally invasive endoscopic management of an iatrogenic colon perforation
Iatrogenic lesions of GI organs are a significant complication of diagnostic or interventionan endoscopic procedures. Dr. Pilar Diez-Redondo and colleagues, Dept. of Gastroenterology, Hospital Universitario, Río Hortega, Valladolid, Spain present a case report on OTSC clipping for colon perforation closure: For assessment of iron deficiency an 82-year-old woman was referred to the endoscopic unit. A gastroscopy confirmed a hialt hernia. Colonoscopy revealed no abnormalities. 18 cm proximal to the anus an iatrogenic perforation with a size of 12 mm occurred. To close the perforation endoscopically an 11a OTSC clip was chosen. The target tissue and a piece of omentum were pulled into the applicator cap by suction and the clip released successfully, approaching the edges of the lesion. A residual recess was closed with two conventional, endoscopic clips. The patient was discharged 10 days after the intervention. A 7-month follow-up confirmed the correct placement of the OTSC. Iatrogenic colon perforations can cause severe complications and often require surgery, as the major drawback of an endoscopic approach with conventional clips is the limited ability of these clips to achieve sufficient adhesion of the mucosa and submucosa to ensure tight sealing of the perforation. With the advent of the larger and more power- ful OTSC clips, surgery can be avoided and perforation can be closed in a minimally invasive way. For that reason the authors suggest that the OTSC System should be available to all endoscopy units as a bail- out device.

A novel system for endoscopic closure of iatrogenic colorectal perforations using the Otsc® clip and omental patch

January 2014 | Closure of gastric fistulas after bariatric surgery with the OTSC® System – two case studies
Juxtapositional gastric fistulas after bariatric surgery are a potentially dangerous situation as they can lead to severe complications, such as peritonitis and abscess formation. Two case reports recently published by Dr. Victoria Gómez and colleagues, Dept. of Gastroenterology and Hepatology, Mayo Clinic, Jacksonville, USA, and Dr. Harry Shehab et al., Dept. of Gastroenterology, Dar Alfloood 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 postoperative 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 failed, an attempt to seal the leak was made with an 11 and 14 mm esophageal stent was applied. A second stent had to be deployed to bridge the prior stent. Since there was no improvement of the fistula, 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 approach with drainage and insertion of a feeding jejunostomy. 5 months after the first surgery an EGD revealed a well-epithelialized fistula with a wide lumen. It was decided to close the fistula by OTSC clipping. To remove the edges 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 desirable, a minimally invasive, endoscopic approach with the OTSC System is an attractive treatment option. In comparison to conventional clips that are only suitable for small fistulas, OTSC clips can also attach to the submucosal and muscular layer, the OTSC clip offers a deeper grasp of the tissue and a sturdier closure.

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

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

December 2013 | First report on successful management of delayed presentation of Boerhaave’s syndrome
A current growing endoscopic application for delayed presentations of Boerhaave’s syndrome with evidence of mediastinal contamination. However, Dr. Eamon Ramhamadany and colleagues, Dept of General Surgery, University Hospital Coventry and Warwickshire, UK, present the successful case of a 69-year-old man in a 69-year-old man by means of the OTSC System, sparing the patient surgery and possible associated complications. The man 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 contrast swallow 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 discharged on a nasogastric tube. Intravenous antibiotics and bilateral chest drains led to a resolving mediastinitis. 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 and 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

December 2013 | Management of postoperative gastrointestinal leakages and fistulas with the OTSC® System: long-term success rate of 79 %
This publication by Dr. Shehab and Weenigen and colleagues, 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 endoscopic clipping as opposed to conventional endoclip. Their case series of 14 consecutive patients (May 2011–November 2012) included patients with anastomotic leakage (n=6) e.g. after gastroectomy, perforation after fundoplication (n=3) and post-operative fistulas (n=7, colocolanueous, enterocutanueous, gastrochilic, rectorectanueous, rectocutanueous, gastrointestinal). 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 %, 3/14 patients (21 %) required further treatment during follow-up. Reasons for OTSC failure were massive fibrosis of the fistula orifice (n=3), and the delay in treatment in Crohn’s disease. However, unsuccessful OTSC treatment did not impair subsequent surgical therapies. Complete and clinically durable closure of the 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 fistulas.

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

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 a large amount of tissue, leading to a more efficient hemostasis. Dr. R. Manta and colleagues, Gastroenterology and Endoscopy Unit, New S. Agostino Hospital, Modena, Italy draw this conclusion on the basis of a retrospective analysis of a large single-centre cohort study of 30 patients with 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. The 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 26 of 30 cases (87%). Rebleeding in two cases was successfully treated with injection of saline and adrenaline. Endoscopic follow-up was 6-9 days after and after 4-weeks, month revealed correct placement of the OTSC clip and no procedure-related 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.

Over-the-scope 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, Department of Gastroenterology and Hepatology, 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 esophageojugal Roux-en-Y anastomosis. On the fifth postoperative day she developed a septic condition caused by a fistulous orifice just above the intact anastomosis. 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 as compared to conventional endoscopic clips.

Total gastrectomy in an elderly patient complicated by esophageal fistula: rescue by the over-the-scope clip

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

Dr. B. Mangiavillano and colleagues, Gastrointestinal Endoscopy, Azienda Ospedaliera San Paolo Universitario, Hospital University of Milan, Italy, present a case study of a 69-year-old woman with an episode of melena. EGD showed a Dieulafoy’s bleeding lesion in the proximal third of the posterior wall of the stomach. The lesion was treated with 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 hemorrhagic shock. The now 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 gastric lesion resistant to conventional endoscopic treatment

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

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

The two case reports published in the journal Digestive Endoscopy by Dr. Hirohito Mori and his colleagues, Department 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 reflux, a diagnostic jejuno-duodenal anastomosis was created. The risk of 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 close the lesion 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 closing 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 Munino, Wolfson Unit for Endoscopy, St Mark’s Hospital, Harrow, 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 clinical remission without further episodes.

The second case report published in the World Journal of Gastrointestinal Endoscopy by Prof. Klaus Mönkemüller and colleagues, Division of Gastroenterology and Hepatology, Basil Hirschowitz Endoscopic Center of Excellence, University of Alabama, Birmingham, USA, describes the effective endoscopic closure of a large gastroesophageal fistula with the OTSC System in an extremely malnourished patient with complex post-surgical upper GI anatomy. The 47 y/o man presented with chronic diarrhea and severe weight loss of 32 kg in a 1-year period. He had a history of chronic pancreatitis, alcoholism and bile reflux gastrojejunostomy due to a perforated peptic ulcer. Endoscopy showed a clean based ulceration at the anastomosis and a second orifice that represented the fistula. Connecting stomach and colon, the 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 an OTSC clip led to a complete closure of the gastric 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 chronic peptic and post-surgical GI fistulas.” 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 GI fistula endoscopists.”

First report of endoscopic closure of a gastric fistula using an over-the-scope clip system (with video)

Gastrointest Endosc. 2012 Apr;75(4):893; discussion 894

Endoscopic closure of gastric fistula using the over-the-scope clip system

August 2013 | The interesting case: OTSC® closure of esophagogastroduodenal 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 esophagogastroduodenal fistula.

An 83 y/o woman presented with a symptomatic fistula arising from an anterior esophageal diverticulum with recurrent pulmonary infections. 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 12/6T 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 obtained and verified by barium esophagogram 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 6 weeks after the procedure. Final follow-up at 3 months revealed no recurrence or postpandural cough.


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 allowing surgery in 64.7 % of cases. In 6 cases surgical closure was done. The authors conclude: “OTSC application yields a high rate of endoscopic perforation closure in patients with macroscopic gastrointestinal perforation, even in an emergency setting, 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.”


OTSC® Update 14
July 2013 | OTSC® System in transgastric appendectomy
Kaeher et al. report the results of their first 15 patients in a prospective trial on “Transgastric appendectomy” which now already recruited 30 patients who are currently under follow-up.

From April 2010 the Mannheim group offered to their patients a transgastric appendectomy. Patients with generalised peritonitis and/or local contraindications were not recruited. Out of 111 eligible candidates 15 agreed to undergo the proposed NOTES procedure. 14 out of 15 were actually operated through NOTES, whereas 1 patient was switched to laparoscopic procedure due to severe inflammation and adhesions. In each case the gastrotomy was closed by a single OTSC System using Twin Grasper and 12/6T clip. All closures were tight primarily and uneventful throughout the follow-up.

This is the first series of transgastric appendectomy using the OTSC System (and the second series overall). All 30 patients who have been recruited altogether will be reported in a separate publication.


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 even less efficacious 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 or after failed 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 (Kratz 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 taking an anastomotic leak with the OTSC System, there was still a leak due to displacement of the clip. The clip had to be removed to place another OTSC clip into the leak. At first clip rinsing was accomplished by injecting saline solution below the OTSC. A snare was positioned around the clip, slowly closed and retracted. The clip dialoged and was retrieved carefully without injury by catching it with a clip. It was closed completely and the endoscope was the anaesthetic leak wa therefor closed successfully with a new OTSC.


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 Endoscopy: the FTRD. A 62 year old patient showed 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. Initially the FTRD closure clip was mounted 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 released to seal the invaginated 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.

Venue: Klinikum Augsburg, Augsburg, Germany

May 2013 | Iatrogenic digestive tract perforations: OTSC® closure as preferred method
Dr. C. Gubler and Prof. P. Baurlefer, 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 that occurred 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 30 mm diameter, observed during endoscopy should be treated with endo- scopic OTSC clip closure.


OTSC® 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 patients earlier on) 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 electrocoagulation 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 and 500 ml methylen blue solution resulted in成功的 closure of the OTSC clip. 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-manoveur.

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 Nd:YAG laser cutting to intentionally remove the stent. In all 24 patients the procedure was technically successful. In 1 patient an undesired stent migration before intentional retrieval 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 significantly prevented stent migration in the cases studied.

**Verwendung des Ovesco-Cliips zur Verhinderung der Migration bei vollgecoerten selbststexpandierenden Stents**

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

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

Hagel A, Nägel A, Raihnel S, Diebel H, Neurath M, and Raihnel M, Erfangen, showed data on the management of GI perforations with OTSC clips. They studied 18 patients with 15 perforated appendicitis, 1 with perforated diverticulitis, 1 with various perforations 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 hospital stay 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 mediastinitis. The authors draw the conclusion that OTSC treatment can significantly reduce morbidity and mortality in GI perforations.

**OTSC-Anwenung bei manifest Perforation, 30-Tages-Mortalität, Hospitalisationsdauer und Out-come nach endoskopisch erfolgreicher und nicht erfolgreicher Perforationsverschluss**

A. Hagel, A. Nägel, S. Raihnel, H. Diebel, M. Neurath, and M. Raihnel, Erlangen

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

Nichts H, Hammelmann F, and Asperger W, Halle, summarized their initial experience with OTSC in endoscopic closure of the GI organ wall in 10 consecutive cases. In 8 cases with transmural rectal lesion and transient anastomotic leak (n=2), rectal ESD perforation (n=1), gastric ESD perforation (n=2), esophageal perforation 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 OTS is short.

**Erfahrungsbericht der ersten 10 Anwendungen des endoskopischen OTSC-Cliipsystems**

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

OTSC for closure of distal esophageal perforation

Braun A, Richter-Schrag H, Hopt U, Fischer A, Freiburg, showed data on OTSC in the treatment of distal esophageal perforation after vomiting (Boerhaave, n=1) and iatrogenic injury (n=1). 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 hours after the lesion. Both patients received data from thorax drainage and antibiotic therapy. No patient developed sepsis. Starting oral intake was without problems. 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-Schrag, U. Hopt, A. Fischer, Freiburg

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

Thomsen T, Berthold B, Khabanchain M, and Trabandt I, Neubrandenburg, presented data of a case series (n=11). Indications included upper and lower GI bleeding, PEG-fistula closure, rectal-pelvic fistula closure, sigmoid anastomosis leak, bleeding from diverticulum (Hartmann situation) arterial bleeding from colon anastomosis. 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 procedure), 1 rebleeding and 1 remaining perforation were 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. Khabanchain, and I. Trabandt, Neubrandenburg

OTSC for stopping gastroduodenal artery bleeding in duodenal ulcer

Kratz T, Stüker D, Kirschmayr A, Heininger A, Wietek B, Königsrainer A, Tübingen, showed a case series (n=7) in which OTSC was applied in upper GI emergency cases to stop bleeding. In 6 cases the bleeding was caused by GI aneurysms and in one case by a duodenal ulcer. 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 surgical emergency hemostasis 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 were 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 arterial 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 bei malignen Aortenduodenalen Ulkus-Arrosionsblutungen: alleinige endoskopische Therapie oder „bridge-to-surgery“**


Report on Ovesco FTRD (pre-commercial device)

Kratz T, Stüker D, Gräfker F, Schnek M, Adam P, and Königsrainer 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; in 2 cases technical and operator 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 gave a detailed case history of an elderly patient with recurrent adenoma (high grade dysplasia, partially adenocarcino- ma) of the rectum. The patient had full thickness resection with FTRD under single shot antibiotic 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.
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Klinische Evaluation eines neuen endoskopischen GI-Trakt-Vollwandresektionsystems: das OTSC-basierte “full thickness resection device” (FTRD)

T. Kratt, D. Stüker, F. Fräpiger, M. Schneider, P. Adam, and A. Königspurg, Tübingen

FTRD is not yet commercially available.

March 2013 | Dr. Thomas Kratt, University of Tübingen, Germany, wins award for clinical research with Ovesco’s FTRD®

Dr. Thomas Kratt, Interdisciplinary Endoscopy, University Hospital, Tübingen, 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 retraction with the primary purpose of enhanced histological examination of the whole full-thickness specimen. The target lesions were in the upper GI tract, melanoma metastasis (n=5), 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, colonoscopy 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.

www.dge-bv.de/german/home.php

March 2013 | Prospective trial on OTSC® Proctology in anal fistula treatment presents 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 (PD. Dr. R. Proßt, Dr. W. Ehni, Stuttgart Proctology Institute, Stuttgart, Germany), pioneers in the application of Ovesco’s OTSC Proctology system, recently described their preferred technique for anal fistula closure with the device. The procedure consists of 3 steps: local removal of the anoderm around the fistula opening, cutting of a clip hinge is performed and OTSC clip placement was 35 (20–65) days in the cases with successful placement and 70 days (38–94) days in the unsuccessful cases. The median follow up time in this cohort was 77 days (30–330) days. Indication break-down included hemostasis (n=7), closure of chronic fistula (n=28), closure of iatrogenic perforations (n=5), closure of post-sphincterotomy anal sepsis (n=3) and miscellaneous (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. Anaesthetic 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 non-variceal bleeding. 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 stent is reported by Hadi 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 could be in 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


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

Techna J et al. report about the use of the OTSC System to anchor a fully covered self-expandable metal stent to prevent stent migration. The patient underwent distal esophagectomy with gastric pull-up. The stent was placed to a post-operative anastomotic leak in the esophagus. 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. The authors conclude that the placement of the clip was easy, fast and prevented stent migration effectively. The fixation of stents is not a common indication for the OTSC System and there is only very limited experience.

Combination of the “bear claw” (over-the-scope-clip system) and fully covered stent for the treatment of post-operative anastomotic leak


December 2012 | Closure of anastomotic leaks and chromic fistulas in the digestive tract: best results in earlier treatment cases

Dr. Selcuk Dignebez and co-authors, Department of Gastroenterology of Türkiye İhlas Hospital, Ankara, report about their case series of 9 patients (age 22–65 years). Anastomotic leakage from GI surgical anastomosis was treated at our institution in 5, fistula in 3 and acute perforation in 1 patient. Type "a" fistulas were mostly 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 of further treatment. The median time between diagnosis of the defect and OTSC placement was 35 (20–65) days in the cases with successful placement and 70 days (38–94) 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

December 2012 | OTSC® effective in closure of chronic esophago-jejunal 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, 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 non-inferior 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 case report 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 85-year-old-woman with bowel 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 through the biliary duct structure it was decided to close the perforation of the bowel with an OTSC clip. The patient was considered to inappropriate for laparoscopic surgery and morbidity.

Closure of the jejunum was successful. Retropertioneal fatty tissue was additionally pulled into the cap by suction and created a “retropertoneal fat patch”. Abdominal CT revealed retroperitoneal air but no free liquid. 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.

ERCP 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 OTSC may be considered as a possible treatment.

Endoscopic “retropertoneal fatpaxy” of a large ERCP-related jejunal perforation by using a new over-the-scope clip device in Billroth II anatomy (with video)


November 2012 | First publication of Japanese experience with OTSC®

In the recent issue of the World Journal of Gastroenterology Dr. Hirohito Mori 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 abscess where no pararectal drainage was inserted. 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 treatment."

Rectal perforations and fistulae secondary to a gynaecore enema: Closure by over-the-scope clip


November 2012 | Efficacy of OTSC® for the treatment of colorectal postsurgical leaks and fistulas: 86 % overall success rate

Anastomotic leaks and fistulas are a severe complication in colorectal surgery. The incidence of clinically relevant leaks is in the range of 3-6 % of cases.

Prof. Dr. Alberto Arezzo and colleagues, Dept of Digestive, Colorectal and Minimal Invasive Surgery, University of Turin, Italy report about a prospective case series covering 14 consecutive patients, treated between April 2008 and September 2011. Criteria for treatment with OTSC were a wall opening of 4-15 mm with no extraluminal abscess and absence of stenosis. The mean defect size was treated 9.1 mm in diameter. One OTSC clip of either size 11 or 12 was sufficient in all defects. In one case two separate defects were treated in the same patient. In 8 cases the leak was a fresh, acute lesion, in 6 cases a chronic fistula.

The overall success rate of durable defect closure in this prospective case series was 86 %; for acute cases it was 87 % and for chronic cases 83 %. No OTSC-related complications were reported. Re-surgery was needed in 1 case, in a second failure case the patient refused re-surgery and was left untreated.

The authors conclude that endoscopic closure of colorectal postsurgical leaks are a safe technique with a high success rate, including rectovaginal and colocutaneous fistula.

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


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, in total, 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


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 study was limited to 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, novonine CRO, a specialized contract research organization for the medical device industry including OTSC®.

The success rates defined as permanent achievement of the therapeutic goal for hemostasis in severe GI bleeding, perforation closure (including acute anastomotic suture 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 feasible.


October 2012 | Hemostasis in large gastric ulcer with the OTSC® System

In an emergency EGD removal of clots and fresh blood revealed an ulcer with a 2-mm thick pulsating vessel. Injection therapy 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 grasped 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 achieved.

The authors conclude that 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 potentially life-saving hemostasis.

Use of the “bear claw” (over-the-scope clip) to achieve hemostasis of a large gastric ulcer with bleeding visible vessel


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

In the 24th conference of the Society for Minimally Invasive Therapy (SMIT) held in Barcelona, Spain, the president of Dr. Ertic 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

Vombrock et al. report a successful 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.

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