Hemostasis

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

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

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

Mönkemüller K, Toshniwal J, Zabielski M, Vormbrock K, Neumann H


August 2013 | OTSC successful after repeat failure of conventional techniques ...

Dr. Michael Peters and colleagues, Jewish Hospital, Department of Medicine II – Gastroenterology and Diabetology, Berlin, Germany report on the use of the OTSC System to stop a persistent bleeding from a duodenal ulcer.

Three weeks after the initiation of a double platelet aggre-
gitation inhibitor therapy due to NSTEMI a female patient was readmitted to hospital with melena and hematemesis. Endoscopy revealed a duodenal ulcer (Forest Ia) with arterial bleeding that was treated with saline and adrenaline injection and application of conventional hemoclips. After an overnight stay at the ICU control endoscopy displayed a rebleeding that was again stopped with injection of epinephrine, further hemoclips, and additional injection of fibrin. The patient opted strongly for the treatment with the OTSC System instead of undergoing the proposed surgical inter-
vention. During the OTSC procedure the hemoclips were found loose again, leading to an active rebleeding of the ulcer (now Forrest Ib). Since it was not possible to clip the whole ulcer the OTSC was applied to the laterally located vessel which stopped the bleeding immediately. Follow-up endoscopies showed a successfully placed OTSC and no signs of further bleeding.

Over-the-scope clip used to control bleeding from a duodenal ulcer


July 2013 | Recommendation of OTSC System in complex GI bleeding

In an overview article the authors are referring to the cur-
rent 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 succeeding with the OTSC is the strength of the jaws of a clip and the amount of tissue captured. They state that this is ob-
viously fulfilled by the design of the OTSC System which al-
lows for the capture of a large amount of tissue and is more secure than other clips in the experimental setting. Thus the OTSC System is being recommended and used in complex GI bleeding. According to Leung & Lau a single clip suffices for most circumstances and therefore the procedure is shorter when compared to multiple applications of hemoclips.

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

New endoscopic hemostasis methods

Leung K,E L, Lau JY


February 2013 | Retrospective multicentric re-
view of early OTSC patients in the US: overall clinical success rate of 71%

Dr. Todd H. Baron and colleagues, Division of Gastroenter-
ology & Hepatology, Mayo Clinic, Rochester MN, USA report about their experience with 45 OTSC clip placements from March 2011 to January 2012. Median follow-
up time in this mixed 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-esophagectomy anastomotic leakage (n=3) and miscellaneous (n=2). Before OTSC placement 49% of the patients had undergone other therapies for their condition that failed.

The overall clinical success rate was 71%. Hemostasis was achieved in 100% of cases. Ana-
stomotic 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 (with videos)

Baron TH, Song LM, Ross A, Tokar JL, Ihan S, Kozarek RA

Gastrointest Endosc. 2012 Jul;76(1):202-8 85

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

Vormbrock et al. report a successful treatment of gastric ulcer bleeding with the OTSC System.

In an emergency EGD removal of clots and fresh blood re-
vealed 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, the 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 the OTSC was effective for he-
mostasis in this fibrotic ulcer which was very hard to treat with other endoscopic methods. They state that the place-
ment of OTSC was quick and easy and 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

Vormbrock K, Zabielski M, Mönkemüller K

Gastrointest Endosc. 2012 Oct;76(4):917-8 100

August 2012 | OTSC® featured for gastrointestinal bled-
ing and NOTES in UEGW 2011 Report

In the UEGW 2011 Report: putting endoscopy into perspec-
tive, Papankolaukou and Rösch feature the OTSC® System for gastrointestinal bleedin and NOTES:

OTSC® update 15 EXTRA | research & clinical trials | sorted by indication 1

UEGW 2011 report: putting endoscopy into perspective

Papankolaukou IS, Rösch T


The authors conclude that although OTSC® is “promising, further clinical experience will help to identify the optimal role and indication for OTSC® in gastrointestinal bleeding”. Ovesco would like to add that recently Dr. T. Kratt (Endo-
scopy Unit, Dept. Gen. Surgery, University of Tübingen) has respectively evaluated 50 consecutive patients with complicated GI hemorrhages with encouraging results (see Ovesco news above June 2012 | OTSC® in emergency hemostasis: new data demonstrate superior results).

At the same time a multicenter prospective, randomised, controlled trial is about to start to identify patients and lesions that are most suitable for the OTSC® device, comparing its efficacy and safety relative to those of estab-
lished techniques.

In the NOTES chapter they state that even though the number of NOTES regarded papers were on the decline the „management of iatrogenic perforations of the gastro-
intestinal tract is a basic aspect that influences safety and outcomes not only in NOTES but also endoscopic resection... The recently developed OTSC® was presented in some inter-
esting studies at UEGW 2011...” (v. Renteln et al. Endoscopy 2011; 43: 01A47; Hucl et al. Endoscopy 2011; 43: 01A48) that deal with animal models and prove safety and efficacy of OTSC®, the authors are referring to “an interesting German prospective study ... on snare-resection of gastric subepithelial masses (<3 cm) in 16 patients (Schlag et al. Endoscopy 2011; 43: 01A329).

Although endoscopic resection was possible in 12/16 cases perforation occurred in four patients, which was successfully treated with an OTSC® clip. The technique per se can be regarded as a step towards transgastric endoscopic surgery, and the possibility of secure closure with the OTSC® has a pivotal role providing safety of the procedure...”.

Remark from Ovesco: G. Kähler (Dept. of Surgery, Endo-
scopy Unit, University Hospital Mannheim) during the 2012 meeting of the German Congress for Coloproctology in Munich reported preliminary data of 25 transgastric appendectomies where gastric closure was successfully performed with the OTSC® System in 100% of cases. It is planned to stop patient recruitment after 30 patients.

July 2012 | ASGE Technology Committee fea-
tures OTSC® System as “most suitable as a hemostatic tool for selected bleeding lesions”

In the latest report on Emerging technologies the ASGE Technology Committee featured the OTSC® System as the new device for mechanical closure and called it “most suit-
able as a hemostatic tool for selected bleeding lesions”. Even though published data on efficacy and safety were limited the cited results were supporting the committee’s opinion.

Emerging technologies for endoscopic hemostasis


Ovesco takes the liberty to make a few additional comments: “the technical limitations ... regarding access (e.g. posterior duodenal wall and gastric lesser curvature) and grasping of certain lesions (e.g. deep, indurated ulcers)” are acknowledged, even though they also apply to the alternative treatment options. Ovesco developed the OTSC® Anchor especially to facilitate the OTSC® application under these circumstances. Clinical experience from all over the world supports the advantages of the OTSC® Anchor in both fib-
rotic and tissue difficult access situations.
Recently Dr. T. Kratt (Endoscopy Unit, Dept. Gen. Surgery, University of Tübingen) has evaluated 60 consecutive patients with complicated GI hemorrhages with encouraging results (see Ovesco news above “June 2012 | OTSC® in emergency hemostasis: new data demonstrate superior results”). At the same time a multicenter prospective, randomised, controlled trial is about to start to “identify patients and lesions that are most suitable for the OTSC® device, in addition to randomized trials comparing its efficacy and safety relative to those of established techniques”.

Ovesco also has performed a cost-analysis study proving OTSC® being superior to both conventional endoscopy and surgery.

June 2012 | OTSC® in emergency hemostasis: new data demonstrate superior results.

Freiburg, Germany, June 15, 2012 – Congress of the South-West German Society for Gastroenterology. Dr. Thomas Kratt, Department of Visceral and Transplant Surgery of Eberhard Karls University, Tuebingen, Germany, presented latest data on the use of OTSC® in the emergency treatment of GI hemorrhage. He reported on a consecutive series of 60 patients with severe GI bleeding based on different pathologies, mainly peptic ulcer in different locations. 69 OTSC® clips had been placed in these patients. In 19 cases OTSC® clipping was chosen due to acute failure of conventional or haemostatic techniques to stop the bleeding or relapse of the bleeding after such conventional treatment. The overall success rate was 65 of 69 or 94.2%. No severe complications related to the OTSC® procedure were noted and 2 minor complications (mucosal injury), requiring no further treatment.

May 2012 | Conference report: OTSC® System recommended for the treatment of anastomotic leak and bleeding (Congress of German Society of Surgery, DGGH, in Berlin)

At this year’s Congress of the German Society of Surgery in Berlin – 129th Congress of the Deutsche Gesellschaft für Chirurgie (DGCH), 24 - 27 April 2012 – Ovesco’s products were featured by Prof. Thomas Lehntert, Bremen and Prof. Ulrich T. Hopf, Freiburg, during the session on “Management of post-surgery septic complications/anastomotic leakage”. Lehntert who reported on the upper GI tract also cited his good clinical experience with OTSC® regarding severe bleedings of e.g. the duodenum. Hopf pointed out that with the OTSC® being very effective in the closure of post-surgical defects in the lower GI tract, one must always consider proper drainage of a potential abscess before the leak.

April 2012 | Conference report: OTSC® at German Society for Endoscopy (DGE-BV) – latest clinical data

The German Society for Endoscopy and Imaging Techniques (DGE-BV) held its 42nd Annual Conference in Munich, Germany, from March 22 to 24. Ovesco’s OTSC® clip was the topic of a number of presentations in the scientific programme, as listed below. Part of these presentations were recently published in “Endoskopie heute”, the official journal of the DGE-BV.

The group of Prof. Hochberger from Hildesheim presented their results of a consecutive series of 40 OTSC® interventions. In 85% of cases the primary therapeutic goal was reached. Dr. Wedi reported on 23 cases of upper GI bleeding which had been refractory to other therapy before being treated with OTSC® clipping. 19 patients were successfully treated. 2 patients died in spite of attempted surgical hemostasis and 2 other patients for reasons not related to the endoscopic intervention. He also showed data of 3 perforations with a closure rate of 100%. 2 complications were reported: 1 new sigmoid perforation that was seen after successful closure of an EMR-related perforation in the hepatic flexure and one implanting of an endoscopic instrument with an OTSC® clip.

FV24 Der Over-The-Scope Clip (OTSC® – Erste klinische Erfahrung bei der Behandlung von schweren Blutungen, Perforationen und Fisteln an 40 Patienten Wedi E, Menke D, Hochberger J

January 2012 | Unusual case of foreign body-related lower GI bleeding managed with OTSC®

Dr. Miheoa H. Strain and colleagues from the Dept. of Gastroenterology of Victor Babes University Hospital, Timisoara, Romania, report about an unusual case of lower GI hemorrhage. A 58 year patient was diagnosed with a toothpick impaction at the recto-sigmoid junction. Normally swallowed toothpicks are entrapped in the upper digestive tract. In the reported case endoscopic removal was possible and hemostasis was achieved by means of OTSC® clipping.

Successful Endoscopic Treatment of an Unusual Cause of Lower Gastrointestinal Bleeding Using the OVESCO System


November 2011 | In retrospect: OTSC® notably mentioned at UEGW, October 22–26, 2011, Stockholm, Sweden

The OTSC® clip was the topic of numerous scientific presentations at UEGW 2011. The primary areas of application of Ovesco’s Over-the-scope clipping technology include the treatment of severe upper GI hemorrhage, the closure of acute perforations and the closure of chronic lesions of the wall, e.g. fistula. Clinicians from various centers presented their data on the use of OTSC®.

E. Wedi et al., Hildesheim, Germany, presented a mixed case series of 24 patients treated between February 2009 and March 2011. 15 patients suffered from upper GI bleeding, refractory to other treatments, 1 from a laceration at the GE junction after balloon dilatation for achalasia, 1 from injury of the duodenum after laparo-scopic cholecystectomy and 5 from iatrogenic post-interventional perforations and 1 from a persistent PEG fistula. The overall success rate in this mixed series was 79%. 2 complications were related, 1 perforation of a sigmoid diverticulum by device passage and 1 unintended clipping on the shaft of an instrument with subsequent removal. The authors also presented a overview about the results of other OTSC® case series reported in the literature. The overall success rate in these cases was 86%


Edita Wedi, Germany; Detlev Menke; Elena Kuse; Jürgen Hochberger

Pierre H. Deprez gave an oral presentation on 193 ESD procedures with en-bloc resection rates of ~95%, and R0 resection in 87% of cases. He emphasizes that all bleedings and all but 2 perforations were controlled by endoscopic means including the use of the OTSC® System.

OP026 LOW COMPLICATION RATE FOR ESD: REPORT ON 193 PROCEDURES IN THE ESOPHAGUS, STOMACH AND DUODENUM

Pierre H. Deprez, Belgium; Hubert Pissaveaux

September 2011 | Closure rate of 90% in fistulas, anastomotic leaks and perforations treated with OTSC®: new case series published

A new case series, reported by Dres Sandmann, Heike and Faehndrich, Klinikum Dortmund Mitte, Germany, was published in the German Zeitschrift fuer Gastroenterologie. The authors present 10 patients with penetrating defects within the digestive tract. Pathologies were fistulas (esophagotracheal, esophagopleural, gastrocutaneous and colorectal), perforations (after mucosectomy, after papilotomy and PEG misplacement) and anastomotic leakages (after gastrootomy and gastrectomy). They report a closure success rate of 90% (9 out of 10 patients).

Application of the OTSC® System for the Closure of Fistulas, Anastomotic Leaks and Perforations within the Gastrointestinal Tract


July 2011 | Benefit of a clipping device in use in intestinal bleeding and intestinal leakage

Recently JG Albert et al. published the results of their experience with the OTSC® System for the treatment of intestinal bleeding and closure of GI leaks in a series of 19 consecutive patients (12 leaks, 7 hemorrhages). All bleeding cases had unsuccessfully undergone conventional endoscopic treatment and were therefore included. The primary success rate then was 100% with 37 patients requiring further treatment afterwards. The overall success rate regarding leaks was 66% (ranging from closure of stomach perforation due to necrotising pancreatitis to gastro-cutaneous fistulas and postoperative leakage). The follow-up time ranged from 5 to 69 weeks.

Benefit of a clipping device in use in intestinal bleeding and intestinal leakage


March 2011 | The Over-The-Scope Clip (OTSC®) for the treatment of gastrointestinal bleeding, perforations, and fistulas

In the latest issue of Surgical Endoscopy Andreas Kirschnak et al. report of a series of 50 patients that had been treated with the OTSC® System for hemostasis (n = 27) in the colon and the upper GI tract, closure of esophageal, gastric, and colonic perforations (n = 11) as well as closure of fistulas (n = 8) and for reparative marking (n = 4). The primary treatment was reported successful in all cases. In more detail, there were two secondary bleedings that required endoscopic re-intervention, and the permanent closure of fistulas could not be achieved in all cases. The authors conclude that the OTSC® System is effective and safe for complicated bleeding and closure of fresh perforations of the gastrointestinal tract.

The Over-The-Scope Clip (OTSC®) for the treatment of gastrointestinal bleeding, perforations, and fistulas


June 2010 | Tuebingen University reports experience in 60 consecutive patients treated with OTSC®

Bruché, Germany, June 11, 2010. At the 21st Congress of the Southwest German Society of Gastroenterology Thomas Kradt, MD, Surgical Endoscopy, Tuebingen University Hospital, Germany, reported about a case series of 60 patients treated with OTSC® for various indications. 37 patients were treated for stopping gastrointestinal hemorrhage, 11 for closure of perforation, 8 for closure of fistulas and 4 for the marking of lesions. In all 60 cases technical success, defined as ability to place the OTSC® at the desired location, was achieved. In the 37 cases of GI bleeding 2 relapse bleedings were seen. In all 11 cases of GI perforation therapeutic success, defined as absence of faecruence or leakage was achieved. In the 8 fistulas patients 3 recurrences were found.

The authors conclude that based on their experience OTSC® is best applied in the following indications:

OTSC® update 15 EXTRA | research & clinical trials | sorted by indication
Emergency:
• Severe peptic ulcer bleeding
• Iatrogenic perforations
• Spontaneous perforations
• Hemorrhoidal post-surgical hemorrhage

Elective:
• Anastomotic failure
• Fistula
• Anastomotic correction

NOTES
Das Over-The-Scope Clip System (OTSC®): Erfahrungen in der klinischen Anwendung bei 60 Patienten
Kraft T, Stücker D, Küper M, v. Felitzsch M, Körninger A, Kirschniak A
There were two more reports on successful application of Ovesco’s OTSC® System. Ulkus-Arrosionblutung der A. gastroduodenalis – Vermeidung des Notfalleingriffs durch ein neuartiges Clip-System – zwei Fallberichte
Kraft T, Stücker D, Brücher B, Heininger A, Miller S, Körninger A


Closure of acute lesions

September 2013 | OTSC in post-surgical complications: retrospective case review confirms high clinical efficacy
Dr. Alisa Coker and colleagues, Dept. of Surgery, University of California San Diego, USA, report on their experience with the OTSC System in a retrospective review of all cases treated between August 2011 and March 2012. All 10 patients had clinically significant gastrointestinal post-surgical complications. Indications included: gastric leaks after sleeve gastrectomy (n=4), post-operative colonic leak following extended hemicolectomy and palliative debulking (n=1), gastro-gastric fistulas following Roux-en-Y gastric bypass (n=2), esophageal perforation (n=3).

Three of the four patients with gastric leaks had undergone previous unsuccessful attempts at endoscopic repair (stenting, fibrin glue application, traditional clipping, endoscopic OTSC clip). The overall clinical success rate was 73%. Re-surgery was needed in the two cases of gastro-gastric fistulas. In the colonic leak patient the clip placement procedure was aborted due to a fixed tortuous sigmoid colon as a result of the metastatic disease and adhesions, limiting endoscope passage. For the subgroup of seven patients treated for leaks and perforations a success rate of 87.5% with complete resolution was achieved. The mean follow-up period was 83 days. No complications occurred.

The authors conclude that the OTSC System is simple to use, safe and effective with a great potential for success in a broad number of applications. For the treatment of gastroduodenal lesions after sleeve gastrectomy the OTSC System is their first-line treatment.

Initia! Experience with an Innovative Endoscopic Clipping System
Coker AM, Jacobsen GR, Acosta G, Talamar MA, Savides TJ, Horgan S
Surg Technol Int., 2012 Dec 1. [Epub ahead of print]

September 2013 | Preventive closure of duodenal ulcer with the OTSC System after endoscopic submucosal dissection to obviate delayed perforation
The two case reports published in the Journal Digestive Endoscopy by Dr. Hirohito Mori and colleagues, Dept. of Gastroenterology and Neurology, Faculty of Medicine, Kagawa University, Japan illustrate the complete closure of secondary duodenal ulcers after endoscopic submucosal dissection (ESD) with the OTSC System without any complications.

Two elderly patients were diagnosed with early duodenal cancer. ESD was carried out, successfully removing the lesions en bloc. In one case the muscle layer was slightly injured but not perforated. Because of the exposure to bile and pancreatic juices the risk of post-ESD delayed perforation is much higher in the duodenum than in other parts of the gastrointestinal tract. As conventional clips are less suitable due to small size and insufficient gripping 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

July 2013 | OTSC effective in emergency closure of iatrogenic GI perforations instead of abdominal surgery
Dr. Hagel and colleagues, Dept. of Gastroenterology, University of Erlangen-Nuremberg, Germany reported about a consecutive series of 17 cases with perforations of the digestive tract, treated with OTSC clipping. All cases were considered as being candidates for abdominal surgery for closing the perforation. In 11 cases perforation closure with OTSC was immediately successful, thus avoiding surgery in 64.7%. In 6 cases surgical closure was done. The area size of perforation in the successful cases was 21.1 ± 9.1 sqmm; in the unsuccessful group the area size was 30.7 ± 14.9 sqmm. Unsuccessful cases had on average a larger size, necrotic margins and required more OTSC clips during closure attempts (2.3 ± 0.5, p=0.018).

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

Over-the-Scope Clip Application Yields a High Rate of Closure in Gastrointestinal Perforations and May Reduce Emergency Surgery

July 2013 | OTSC System in transgastric appendicectomy
Kaelher et al. report the results of their first 15 patients in a prospective trial on “Transgastric appendicectomy” which now already recruited 30 patients who are currently under follow-up. From April 2010 the Mannheim group offered to their patients a transgastric appendicectomy. Patients with generalised peritonitis and/or local contraindications were not recruited. Out of 111 eligible candidates 15 agreed to undergo the pro-posed 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 gastrointestinal tract was closed by a single OTSC System using Twin Grasper and 12/46 clip. All closures were tight primarily and uneventful throughout the follow-up.

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

Transgastric appendicectomy
Kaelher G, Schoenborg MB, Kienle P, Post S, Magdeburg R
Blt J Surg; 2013: 100; 911–915

May 2013 | Iatrogenic digestive tract perforations: OTSC closure as preferred method
Dr. C. Gubler and Prof. P. Bauerfeind, Dept of Gastroenterology, Zürich 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 endoscopic OTSC clip closure.

Endoscopic closure of iatrogenic gastrointestinal tract perforations with the over-the-scope clip
Gubler C, Bauerfeind P

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 electrocautery and a needle knife in seven dogs. Closure was performed with one OTSC clip each. The closure was performed in 18.5 ± 0.4 minutes (team without prior experience). The following leak pressure test with maximum air insufflation and 500 ml methylene blue solution resulted in one minor leak (laparoscopic control) without clinical consequences though. The authors conclude that the OTSC System is safe and appropriate for the closure of acute perforations in the stomach despite the wel! known difficulties with the J-maneuver.

Feasibility study of secure closure of gastric fundus perforation using over-the-scope clips (OTSC) in a dog model
Zhang XL, Qu JH, Sun G, Tang P, Yang YS
J Gastroenterol Hepatol. 2012 Jul;27(7):1200-4

March 2013 | EndoResect study – Endoscopic full-thickness resection of gastrointestinal subepithelial tumors
Meining et al. report of 20 patients with gastric subepithelial tumors (SET) up to 3 cm in diameter. Patients were prospectively enrolled and 14 of them treated by endoscopic resection using the OTSC Anchor and a monolifton snare. In cases where perforation occurred the defect was closed with Twin Grasper and OTSC System. The authors conclude
that this method seems to be faster and easier than other endoscopic techniques such as ESD or submucosal tun- neling. Perforations could be adequately managed by the OTSC System (100% closure). Thus, endoscopic resection without laparoscopic control seems possible in selected pa- tients with purely intraluminal tumors. The authors discuss the malignant potential of SETs, especially GISTs which could not be reliably determined by either endoscopic or endo- sonographic surveillance. According to guidelines GISTs larger than 2 cm should be resected. However, since also smaller tumors have malignant potential complete resection of all suspected lesions seems advisable according to the authors. They argue that GISTs rarely develop lymph node metastases, and thus local resection with large negative margins and without lymph node resection are considered curative approaches.

Comment by Ovesz: since only tumors without connection to the muscularis propria layer have a 80–100% resection rate in literature, it might be feasible to perform full-wall resection-in-SETS and similar tumors. Ovesz is currently completing the development of a new Full Thickness Resec- tion Device (FTRD) for the lower GI tract to start with.

EndoResect study – Endoscopic full-thickness resec- tion of gastric subepithelial tumors

February 2013 | Retrospective multicentric re- view of early OTSC patients in the US: overall clinical success rate of 71%
Dr. Todd H. Baron and colleagues. Division of Gastroentero- logy & Hepatology, Mayo Clinic, Rochester MN. USA report about their experience with 45 patients and 48 OTSC clip placements from March 2011 to January 2012. Median follow-up time in this mixed cohort was 77 days (30–330 days). Indication break-down included hemostasis (n=7), closure of chronic fistula (n=28), closure of iatrogenic perforations (n=5), closure of post-esophagectomy anastomotic leakage (n=3) and miscellaneous (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. Ana- stomotic 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 (with videos)

January 2013 | Combined use of OTSC System and stent to close large EMR-related perfora- tions
Treatment of large EMR-caused perforations with a combined use of OTSC and stenting is reported by Hadj Amor et al. One patient with a 20-mm esophageal perforation was tre- ated with an OTSC, several other clips and an endoloop. A fully covered stent was placed on top to bypass the perfor- ation. 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

Full-text link: dx.doi.org/10.1055/s-0032-1309861

January 2013 | OTSC used to prevent stent migration in the treatment of anastomotic leak
Toshniwal J et al report about the use of the OTSC System to anchor a fully covered self-expanding metal stent to pre- vent stent migration. The patient underwent distal esophag- ectomy 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 Grapper 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
Full-text link: http://dx.doi.org/10.1055/s-0032-1310033 94

December 2012 | Closure of anastomotic leaks and chronic fistulas in the digestive tract: best results in earlier treatment cases
Dr. Selcuk Döşmez and co-authors, Department of Gastroenterology of Türkiye İhtisas Hospital, Ankara, report about their case series of 9 patients (age 22–65 years). Anastomotic leakage from GI surgical anastomosis was present in 5, fistula in 3 and acute perforation in 1 patient. Type “a” clips were placed in all cases. In 4 cases clip deployment was not undertaken, due to strong tissue fibrosis. In the other 5 patients the clip was successfully deployed and closed the defect without the need of further treatment. The me- dian time between diagnosis of the defect and OTSC clip placement was 35 (20–80 days) days in the cases with successful placement and 70 days (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

November 2012 | First publication of Japanese experience with OTSC®
In the recent issue of the World Journal of Gastroenterology Dr. Hirohito Mori published their 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 condi- tion, 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 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 fistulas 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 invasive and more advantageous than surgical closure.”

Recal perforations and fistulae secondary to a glycine- rin enema: Closure by over-the-scope clip

August 2012 | Efficacy of OTSC® for the treat- ment of colorectal postsurgical leaks and fist- ulas: 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 Arnezzo 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 <15 mm with no extraluminal abscess and absence of stenosis. The mean defect size treated was 9.1 mm in diameter. One OTSC® clip of either size 11 or 12 was sufficient in all de- fects. 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 complica- tions 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 colocolutaneous fistula.

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

August 2012 | The interesting case: ERCP- related jejunal perforation managed by OTSC® clipping
In the issue 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 per- foration closure. An 85 y/o women with bile obstruction due to pancreatic cancer presented with jaundice. The patient had Billroth II anatomy from gastric resection due to a peptic ulcer 36 years in the past. Cholangiography showed a bile duct stricture. An endo- scope-related perforation of the jejunum with a size about 20 mm was visualized distal of the papilla. After placing a covered self-expanding stent through the biliary duct struc- ture it was decided to close the perforation of the bowel with an OTSC® clip. The patient was considered inoperable due to age and comorbidities.

Closure of the jejunum was successful. Retroperitoneal fatty tissue was additionally pulled into the cap by suction and created a “retroperitoneal fat patch”. Abdominal CT revealed retroperitoneal air but no free liquids. The patient received parenteral nutrition and antibiotic treatment. The patient re- mained symptom-free and the jaundice disappeared. Con- trol 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 de- scribed in the clinical literature. The authors conclude that for the endoscopic closure of large ERCP-related perfora- tions OTSC® may be considered as a possible treatment.
Endoscopic “retroperitoneal fatpexy” of a large ERCP-related jejunal perforation by using a new over-the-scope clip device in Billroth II anatomy (with video)

August 2012 | OTSC® featured for gastrointestinal bleeding and NOTES in UEGW 2011 Report
In the UEGW 2011 Report: putting endoscopy into perspective, Papanikolaou and Rösch feature the OTSC® System for gastrointestinal bleeding and NOTES:

UCWG 2011 report: putting endoscopy into perspective
Papanikolaou I, Rösch T
Endoscopy 2012; 44:512-526. [Epub 2012 Apr 24]

The authors conclude that although OTSC® is “promising, further clinical experience will help to identify the optimal role and indication for OTSC® in gastrointestinal bleeding”. Ovesco would like to add that recently Dr. T. Kratt (Endoscopy Unit, Dept. Gen. Surgery, University of Tübingen) has prospectively evaluated 60 consecutive patients with complicated GI hemorrhages with encouraging results (see Ovesco news below “June 2012 | OTSC® in emergency hemostasis: new data demonstrate superior results”).

At the same time, a multi-center prospective, randomised, controlled trial is about to start to identify patients and lesions that are most suitable for the OTSC® device, comparing its efficacy and safety relative to those of established techniques.

In the NOTES chapter they state that even though the number of NOTES noted papers regarding were on the decline the number of reports regarding enterosurgical perforations of the gastrointestinal tract was a basic aspect that influences safety and outcomes not only in NOTES but also endoscopic resection…

The recently developed OTSC® was presented in some interesting studies at UEGW 2011”. Apart from two cited papers (v. Renteln et al. Endoscopy 2011; 43: 01A44, Hül et al, Endoscopy 2011; 43: 01A46) that deal with animal models and prove safety and efficacy of OTSC®, the authors are referring to “an interesting German prospective study… on snare-resection of gastric subepithelial masses (<3 cm) in 16 patients (Schlag et al. Endoscopy 2011; 43: 01A329). Although endoscopic resection was possible in 12/16 cases, perforation occurred in four patients, which was successfully treated with an OTSC® clip. The technique per se can be regarded as a step towards transgastric endoscopic surgery, and the possibility of secure closure with the OTSC® has a pivotal role providing safety of the procedure…”. Remark from Ovesco: G. Kährer (Dept. of Surgery, Endoscopy unit, University Hospital Mannheim) during the 2012 meeting of the German Congress for Cytology in Munich reported preliminary data of 25 transgastric appendectomy cases where gastric closure was successfully performed with the OTSC® System in 100% of cases. It is planned to stop patient recruitment after 30 patients.

June 2012 | OTSC®@EAES 2012: new data in the treatment of post-surgical leaks and fistulas
From June 20-23 the 20th International Congress of the European Association of Endoscopic Surgery took place in Brussels, Belgium.

New clinical data on Ovesco’s OTSC® clip were presented by Prof. Dr. Alberto Arezzo and colleagues from Turin, Italy. They described results from a consecutive patient series with post-surgical leaks and fistula, closed with OTSC® clipping, 16 patients were treated at the Department of Surgery at Molinette Hospital in Turin. The rate of permanently successful closure was 86%.

Effective Over-The-Scope Clip for double enterocutaneous anastomotic fistula treatment after right hemicolecotomy Arezzo A, Verra M, Cavena F, Bonino MA, Morino M
In a second talk, Prof. Dr. Arezzo presented a case study on OTSC® closure of a double enterocutaneous fistula after colonic resection.

Endoscopic treatment of colorectal post-surgical leaks and fistulas using an Over-The-Scope Clip (OTSC®)
Arezzo A, Verra M, Reddavid R, Cravero F, Bonino MA, Morino M

April 2012 | Efficacy of endoscopic closure of acute perforations of the gastrointestinal tract

Voermans at al. – Department of Gastroenterology and Hepatology, Academic Medical Center, University of Amsterdam, the Netherlands – report of the first international prospective study on efficacy and safety of the OTSC® System for acute iatrogenic perforations in the GI tract.

36 patients were recruited over a time period of 1.5 years and started almost three years ago. 5 esophageal, 6 gastric, 12 duodenal, and 13 colonic perforations were included and endoscopic repair was performed by using the Over-the-Scope Clip according to a standardized operating procedure. Primary end point was successful closure, which was determined as endoscopic successful closure without leakage (detection of water-soluble contrast x-ray analysis) and absence of adverse events within 30 days after the procedure.

Immediate closure was endoscopically successful in 33 patients (92%). One patient developed an esophageal perforation while the cap was introduced, and in 2 patients the perforations did not close; these 3 patients were successfully treated with surgery. None of the patients had leakage of soluble contrast on the basis of contrast x-ray. One patient with a closed colonic perforation deteriorated clinically within 6 hours after the procedure. Despite surgery the patient died within 36 hours. The remaining 32 patients had successful endoluminal closures; the overall success rate was 96% (95% confidence interval, 75% – 98%). The mean endoscopic closure time was 5 minutes 44 seconds ± 4 minutes 15 seconds. The authors conclude that the OTSC® System is effective for the endoluminal closure of acute iatrogenic perforations. It allows patients to avoid surgery, and 89% of patients had successful closures without adverse events.

Efficacy of Endoscopic Closure of Acute Perforations of the Gastrointestinal Tract


April 2012 | Conference report: OTSC® at German Society for Endoscopy (DGE-BV) – latest clinical data

The German Society for Endoscopy and Imaging Techniques (DGE-BV) held its 42nd Annual Conference in Munich, Germany, from March 22-24.

Ovesco’s OTSC® clip was the topic of a number of presentations in the scientific programme, as listed below. Part of these presentations were recently published on “Endoskopie heute”, the official journal of the DGE-BV.

Dres Faehndrich and Sandmann from Dortmund presented their 2-year experience using OTSC® in various indications. Their case series included 31 patients with GI fistula, acute perforations or post-surgical suture dehiscence. The therapeutic goal of closure was achieved in 83%, 100% and 75%, respectively. They also report about successful removal of clips with the Nd:YAG laser. A special application of OTSC® in the Dortmund case series was endoscopic gathering of the hiatus in patients with reflux disease.

FV17 Neue Einsatzmöglichkeiten des OTSC-Systems im Gastrointestinaltrak – Ergebnisse und Verläufe nach 2 Jahren Erfahrungsbericht
Sandmann M, Heike M, Fährndrich M
The group of Prof. Hochberger from Hildesheim presented their results of a consecutive series of 40 OTSC® interventions. In 85% of cases the primary therapeutic goal was reached. Dr. Wedi reported on 23 cases of upper GI bleeding which had been refractory to other therapy before being treated with OTSC® clipping. 19 patients were successfully treated, 2 patients died in spite of attempted surgical hemostasis and 2 other patients for reasons not related to the endoscopic intervention. He also showed data of 3 perforations with a closure rate of 100%, Also 2 complications were reported, 1 new sigmoid perforation that was seen after successful closure of an EMR-related perforation in the hepatic flexure and 1 unsuccessful endoscopic embolisation with an endoscopic instrument with an OTSC® clip.

FV24 Der Over-The-Scope-Clip (OTSC) – Erste klinische Erfahrung bei der Behandlung von schweren Blutungen, Perforationen und Fisteln an 40 Patienten
Wedi E, Menke D, Hochberger J
The group around Prof. Raithel from Erlangen summarized their experience of 17 cases of OTSC® perforation closures in a retrospective evaluation. Dr. Hagle reported an overall success rate of 64.7%. He distinguished between cases with vital and with necrotic or inflamed tissue margins. In cases without non-vital wound margins the number of clips was greater that in cases with non-altered wound margins (1.8 ± 0.5 clips per case).

P22 Over-the-scope-clip – Applikation ermöglicht eine hohe Verschlussrate bei verschiedenen Arten von gastrointestinalen Perforationen
In a pre-clinical study Dr Bernhard and co-workers, Rostock, assessed OTSC® for gastric closure after pure NOTES sigmoid resection using a combined transgastric and transrectal approach in 5 animals. Closure of the gastric cavity with the OTSC® clip was successful in all cases. All clips were still present at the end of the follow-up period (5 weeks). The mean operative time was 3 h 20 min (2.5 – 4.5 hrs).

P22 Pure-NOTES-Signaresektion in einem Tier-Überlebensmodell
Further presentations dealt with the application of the OTSC® System:
Perforationen am GI-Trakt: Wann endoskopische Therapie, wie lange warten, wann Chirurgie? Poht J, Wiesbaden vs. Fuchs KH, Frankfurt/Main
Moreover, several posters showed results of OTSC®-System applications:
Over-the-scope-Clip-Applikation ermöglicht eine hohe Verschlussrate bei verschiedenen Arten von gastrointestinalen Perforationen
Hocheffektive konservative Therapie einer beginnenden Sezepsis infolge Magenperforation nach PEG-Anlage durch endoskopischen Over-the-scope Clip (OTSC®)-Perforationsverschluss und frühzeitige Tigecyclin Linezolidapplikation

December 2011 | Systematic literature review: OTSC® is a safe and uncomplicated alternative to surgery in perforation closure
The recent issue of “Endoskopie heute”, the official journal of the German Society for Endoscopy (DGE-BV), publishes a systematic literature review on Ovesco’s OTSC® clip. The paper, presented by Dr. A. Kirshnak et al., Dept. of Surgery, Tuebingen University, Tuebingen, Germany, summarizes data of 37 original Medline-referenced publications. This includes 20 clinical and 8 experimental publications.

In summary the authors state that the current literature supports the use of OTSC® for the closure of spontaneous and iatrogenic perforations in the digestive tract up to 20 mm in size
The OTSC® clip was the topic of numerous scientific presentations at UEGW 2011. The primary areas of application of Ovesco’s over-the-scope clipping technology include the treatment of severe upper GI hemorrhage, the closure of acute perforations and the closure of chronic lesions of the wall, e.g. fistula.

Clinicians from various centers presented their data on the use of OTSC®:

A remarkable oral presentation was given by Anne Vrijerman from the group of P. H. Deprez on the outcome of iatrogenic perforations of the GI tract. They had reviewed a total of 40,243 procedures (over 6 years) including EUS, ERCP and EMR/ESD where altogether 44 perforations occurred, 8/44 perforations (1 esophagus, 7 duodenum) were handled with the OTSC® System. Amongst others, the authors concluded that their high rates of successful endoscopic management of iatrogenic perforations led to better outcomes in terms of length of hospital stay compared to surgery.

The primary treatment was reported successful in all cases. In 4 of the 7 patients no surgery was required and OTSC® clipping was sufficient. In 1 additional case a laparoscopy was performed to release free air from the abdomen but closure of the perforation had been achieved.

In conclusion, the author’s judge is the OTSC® is a very valuable method for closing GI perforations.

Ovesco is also sponsoring several workshops for advanced endoscopists:

- Thursday, 17 March 2011, Hands-on Training at the EASIE simulator, Workshop 1+2
  - Kompilationsmanagement: Perforationen und post-operative Leckagen
  - Workshop J1 and Workshop J2

- NOTES-Tool-Box und neue Technologien – Dissektoren, neue Blutstillungs- und Verschlussysteme, Nähmaschinen.

- Furthermore, the OTSC® System is dealt with in a number of presentations:
  - Thursday, 17 March 2011 | Room Atlanta Session 08:00 – 10:00 am, Expertenvideos II 08:00 – 09:42 – 10:00 am
  - Neue Methode der endoskopischen Vollwandresektion mit Hilfe des OTSC Systems nach endoskopischer Ril Resektion eines low grade kolorektalen Frühkarzinoms
  - M Sandmann, M Heike, M Fähndrich, Dortmund

For further information on the congress see: www.dgbv.de (pdf)

December 2010 | „Sparing the surgeon“: OTSC® for gastrointestinal perforation

The Gastroenterology Department of the University of Zurich, Switzerland (Dr. L. Seebach, Prof. Dr. P. Bauerfeind, Dr. C. Gubler) reports about 7 patients treated with OTSC® for gastrointestinal perforation.

- Causes for the intervention were colonic perforation (n=3), gastric perforation (n=1) and anastomotic leakage after surgery (n=3). All patients were considered candidates for surgery and OTSC® clipping was used as an alternative to surgery. In all but 1 patient closure was demonstrated.

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For further information on the congress see: www.dgbv.de (pdf)
An initial case series (n=2) on endoscopic closure of post-operative esophageal leaks with the OTSC® clip is presented by Dr. J. Pohl et al., Wiesbaden, Germany. The authors conclude that OTSC® clipping is an effective endoscopic treatment of intrathoracic esophageal leaks and might be considered as a valid alternative to stent if a case series of selected cases. Endoscopic closure of postoperative esophageal leaks with a novel over-the-scope clip system

Pohl J, Borgulya M, Lorenz D, Eib C
Endoscopy 2010;42:757–9

August 2010 | State-of-the-art report by J Hochberger et al. on techniques for ESD refers to OTSC® clip

The leading German speaking endoscopy journal “Endoskopie heute”, Official Journal of the German Society for Endoscopy (DGE-BV), reports about the OTSC® clip. Juergen Hochberger, MD, PhD, Hildesheim, Germany, and coauthors describe the state-of-the-art in technical aspects and equipment for Endoscopic Submucosal Dissection (ESD). Perforations of the esophagus, gastric or colonic wall are not rare in ESD and happen in 6 – 8 percent of the cases, according to clinical experience. For the immediate closure of perforations the OTSC® clip is a promising solution, the authors state.

Technische Aspekte bei der endoskopischen Submukosa-Dissektion (ESD)

Hochberger J, Dammer S, Menke D, Kruse E, Köhler P, Büsing KF
Endoskopie heute 2010; 23: 24–33

July 2010 | Successful management of GI perforations with the Ovesco OTSC® clip

A multicentric study performed at 2 Italian endoscopy centers (General Hospital, San Remo, and Humanitas Hospital, Milan) has investigated the use of the OTSC® clip for closure in 10 patients. Indications for digestive organ wall closure included acute perforations, fistula and anastomotic leakage. The location of the leak was gastric (n=2), duodenal (n=2) and colonic (n=6). The leak diameter ranged from 7 to 20 mm. After closure with the OTSC® clip, patients received follow-up endoscopy 3 months after the intervention. The technical success was 8 out of 10 cases. None of the cases with initial technical success required additional treatment.

The authors of the study conclude that the OTSC® System is a useful device for the management of larger GI leaks in a variety of clinical indications.

Endoscopic management of GI perforations with a new over-the-scope clip device

A Parod, A Repici, A Pedroni, S Blanchi, M Conio

June 2010 | Tuebingen University reports experience in 60 consecutive patients treated with OTSC®

Bruchsal, Germany, June 11, 2010. At the 21st Congress of the Southwest German Society of Gastroenterology Thomas Kratt, MD, Surgical Endoscopy, Tuebingen University Hospital, Germany, reported about a case series of 60 patients treated with OTSC® for various indications. 37 patients were treated for stopping gastrointestinal hemorrhage, 11 for closure of perforation, 8 for closure of fistulae and 4 for the marking of lesions. In all 60 cases technical success, defined as ability to place the OTSC® at the desired location, was achieved. In the 37 cases of GI bleeding 2 relapse perforations were seen. In all 11 cases of GI perforation therapeutic success, defined as absence of failure/recurrence was achieved. In the 8 fistula patients 3 recurrences were found.

The authors conclude that based on their experience OTSC® is best applied in the following indications:

- Emergency:
  - Severe peptic ulcer bleeding
  - Iatrogenic perforations
  - (Spontaneous perforations)
  - Hemorrhoidal post-surgical hemorrhage

- Elective:
  - Anastomotic failure
  - Fistula
  - Anastomotic correction

NOTES

Das Over-The-Scope Clip System (OTSC®): Erfahrungen in der klinischen Anwendung bei 60 Patienten

Kraft T, Stüker D, Köper M, v. Feilitzsch M, Königsauner, A
There were two more reports on successful application of Ovesco’s OTSC® System:

Ulkus-Arrosionsblutung der A. gastroduodenalis – Vermeidung des Notfalleingriffs durch ein neuartiges Clip-System – zwei Fallberichte

Kraft T, Stüker D, Brücher B, Heininger A, Miller S, Königsauner A

Aus dem Labor in die Klinik: Die transgastrisch-flexible NOTES-Laparoskopie


May 2010 | Central Endoscopy Department (Zentrale Interdisziplinäre Endoskopie) of Mannheim University Hospital starts clinical trial on transgastric NOTES appendectomy

The Central Endoscopy Department at Mannheim University Hospital, Germany (Director: Georg Kähler, MD, PhD) has started enrolling patients into an investigator initiated trial on transgastric NOTES appendectomy. Ovesco’s OTSC® clip is used for closure of the gastric access site after completion of the procedure.

The Central Endoscopy Department in Mannheim is among the leading international institutions in interventional endoscopy and NOTES research and is hosting the 2010 D-NOTES meeting, June 3–5, Mannheim, Germany.

May 2010 | DDW 2010 – OTSC® for endoscopic closure of acute perforations of the gastrointestinal tract using the Over-The-Scope Clip: A prospective multicenter human trial (CLIPPER-trial)

In his presentation “Endoscopic closure of acute perforations of the gastrointestinal tract using the Over-The-Scope Clip: A prospective multicenter human trial (CLIPPER-trial)” at DDW 2010, New Orleans, May 4, Dr. Rogier Voermans, Dept. of Gastroenterology and Hepatology, Academic Medical Center, University of Amsterdam, Netherlands, gave an update on intermediate results of this prospective multicenter cohort study conducted at 10 tertiary-care medical centers in Europe. The aim of the trial is to evaluate safety and reliability of the endoscopic closure of acute perforations of the human gastrointestinal tract (esophagus, stomach, duodenum, colon) using Ovesco’s OTSC® System.

The primary endpoint was successful closure, defined as macroscopic adequate closure and no leakage on water soluble contrast X-ray within 24 hours without additional interventions. He reported on 24 of 36 planned consecutive patients in the participating centers. Primary closure could be achieved in 22 of 24 patients. One patient suffered other complications before the clip could be applied, and one patient failed adequate placement of the clip. Only one of those 22 patients would be administered further delayed leakage and had to be treated surgically. The trial is ongoing. Final results will be published as available.

April 2010 | OTSC® System referenced as best gastric closure system in latest review paper

A new review paper by Alberto Arezzo and Mario Morino, Torino, Italy, published in Surgical Endoscopy references Ovesco’s OTSC® System as safe and efficacious for gastric closure in NOTES.

Compared to other available closure technologies, such as other clips, Flaps or endoscopic suture devices, OTSC® is evaluated “very good” under the categories “simplicity”, “security” and “effectiveness”, leading to the highest overall score of all systems.

Endoscopic closure of gastric access in perspective NOTES: an update on techniques and technologies


March 2010 | Tuebingen University starts clinical NOTES trial on diagnostic laparoscopy.

Successful closure of gastric NOTES access

The first patient was recruited in the Transgastric NOTES Laparoscopy Trial. Through an incision in the anterior gastric wall which was dilated with a 15-mm balloon, the abdomen was explored and staging was performed in a patient suffering from an intractable type of lymphoma.

The closure was performed with an OTSC® clip 12-6 gc. The gastrotomy was immediately gas tight. Postoperative follow-up was without any complications.

January 2010 | Korean endoscopists make reference to the OTSC® clip as a device in ESD for gastric cancer

Prof. Won Young Cho et al. from the Dept. of Gastroenterology (Director: Prof. Ju Young Cho) at the College of Medicine, Sooncheonhyang University, Korea, refer to the OTSC® clip as an endoscopic device for treating post-interventional bleeding or organ wall lesions in the chapter on Endoscopic Submucosal Dissection (ESD) of the recently published book “Endoscopic Treatment of Gastric Cancer”.

Prof. Won Young Cho and his colleagues are leading users of Ovesco’s OTSC® in South Korea.

Endoscopic Treatment of Gastric Cancer

Won Young Cho, Tae Hee Lee, Yoon Seon Park, Ju Young Cho
Endoscopic Submucosal Dissection (ESD), pp 16-52;
Jin Publishing Co. Ltd, Seoul, Korea, 2009

November 2009 | Ovesco presents at the EndoClubNord, 6–7 November 2009 in Hamburg, Germany

At this year’s EndoClubNord at the Congress Center Hamburg Ovesco’s OTSC® system has been presented in a live demo: Prof. Dr. Thomas Rösch (Dept. and Clinic for Interdisciplinary Endoscopy, University Hospital Eppendorf, Hamburg) endoscopically removed a submucosal tumor in the anterior wall of the stomach.

In a rendez-vous procedure he was supported by a team of surgeons of the Dept. of Surgery (also UKE) via a single port access. The respective area of the stomach was marked and dissected full wall, first by ESD then by transmural endoscopic cutting of the muscular layer. The stomach was closed through the flexible endoscope with two OTSC® gc clips, was re-inflated thereafter and proved to be tight. The surgical team then closed the outer of the stomach intrasubmucosally with an endo-TEA® stapler. Ovesco is currently testing full thickness resections of the GI tract with the approved OTSC® System. Smaller lesions already have been closed through the endoscope alone. Yet, the company is currently developing an “all-in-one” system which will allow for safe resection and closure in one procedure. The device is planned for approval and launch later next year.

The new systems will enable healthcare professionals of both specialties to more aggressively diagnose and yet less invasively treat e.g. submucosal tumors of uncertain dignity.
June 2009 | Dr. Thomas Kratt wins award for his presentation of case reports on endoluminal OTSC® treatment of Boerhaave syndrome

At the 20th Congress of the South-West German Society of Gastroenterology in Stuttgart, a poster of a working group from the University Hospital Tuebingen presenting a case report on endoluminal OTSC® clip therapy with Ovesco’s OTSC® clip in Boerhaave syndrome is awarded a poster prize Sufficient en do skopische Therapie bei Boerhaave-Syndrom

T Kratt, D Stüker, B Brücher, A Heininger, S Miller, A Königsrainer
Klinik für Allgemeine, Viszer al- und Transplantations-Chirurgie; Klinik für Anästhesie; Klinik für Radiologie University Hospital Tuebingen

Closure of chronic lesions

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

Dr. Alisa Coker and colleagues, Dept. of Surgery, University of California San Diego, USA, report on their experience with the OTSC System in a retrospective review of all cases treated between August 2011 and March 2012.

All 10 patients had clinically significant gastrointestinal post-surgical complications. Indications included: gastric leaks after sleeve gastrectomy (n=4), post-operative colonic leak following extended hemiocolicectomy and palliative debulking (n=1), gastro-gastric fistulas following Roux-en-Y gastric bypass (n=2), esophageal perforation (n=3).

Three of the four patients with gastric leaks had undergone previous unsuccessful attempts at endoscopic repair (stenting, fibrin glue application, traditional clipping, endoscopic suturing). The overall clinical success rate was 70%. Re-surgery was needed in the two cases of gastro-gastric fistulas. In the colonic leak patient the clip placement procedure was aborted due to a fixed tortuous sigmoid colon as a result of the metastatic disease and adhesions, limiting endoscopic passage.

For the subgroup of seven patients treated for leaks and perforations a success rate of 87.5% with complete resolution was achieved. The mean follow-up period was 83 days. No complications occurred.

The authors conclude that the OTSC System is simple to use, safe and effective with a great potential for success in a broad number of applications. For the treatment of gastrectomy leaks following sleeve gastrectomy the OTSC System is their first-line treatment.

Initial Experience with an Innovative Endoscopic Clipping System

Coker AM, Jacobson GR, Acosta G, Talamini MA, Savides TJ, Horgan S
Surg Technol Int., 2012 Dec 1; [Epub ahead of print] 111

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

Dr. Alberto Murino, Wolfson Unit for Endoscopy, St Mark’s Hospital, London, UK, and his colleagues report on a successfully treated gastrointestinal fistula using the OTSC System. A migrated PEG tube caused a gastrointestinal 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 transverse colon in a 41 y/o male with cerebral palsy. The successfully treated gastrocolic fistula was a case of OTSC clipping was used to approximate the edges of the fistula. The application of the OTSC led to a complete closure of the gastrointestinal fistula which was confirmed by an endoscopy.

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

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


Endoscopic closure of gastro-intestinal fistula using the over-the-scope clip system

Mönkemüller K, Peter S, Akurt B, Ramesh J, Popa D, Wilcox C

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

An 83 y/o woman presented with a symptomatic fistula arising from an 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 12/8 OTSC clip was placed under endoscopic control and with the aid of the OTSC Anchor for better manipulation and targeting of the fistula orifice. Immediate technical success was achieved and verified by 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 unchanged as seen in CAT scan 45 days after the procedure. Final follow-up at 3 months revealed no recurrence or postprandial cough.

Esophagogastrostomal fistula closure using a novel endoscopic over-the-scope clip

Zolotarevsky E, Kwon Y, Bains M, Schattner M

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

Dr. Todd H. Baron and colleagues, Division of Gastroenterology & Hepatology, Mayo Clinic, Rochester MN, USA report about their experience with 45 patients and 48 OTSC clip placements from March 2011 to January 2012. Median follow-up time in this mixed cohort was 77 days (30-330 days). Indication break-down included hemostasis (n=7), closure of chronic fistula (n=28), closure of iatrogenic perforations (n=5), closure of post-oesophagectomy anastomotic leakage (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. Anastomotic leakage and fistula was closed in 65%. Also one case of OTSC clip removal by means of APC-cutting of a clip hinge is described.

The authors conclude that the OTSC clip appears clinically effective and is a welcome addition to the therapeutic armamentarium in the closure of leaks, fistula, perforations and non-vanishing bleeding.

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

Baron TH, Song LM, Ross A, Tikar JL, Irani S, Kozarek RA
Gastrointest Endosc. 2012 Jul;76(1):202-8 85

December 2012 | OTSC effective in closure of chronic esophago-jejunal anastomotic leaks after total gastrectomy

Prof. Dr. Germaro 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-jejunoscopy were endoscopically treated with OTSC clipping. The case series was published in the Journal of Gastrointestinal Surgery. In all patients clip closure of the leak was technically simple, clinically effective and did not result in complications. The authors conclude that the OTSC System may represent a new option in the management of postoperative esophago-jejunal leaks. The incidence of anastomotic leaks ranges from 4 to 27% after total gastrectomy and is a not infrequent challenge in such patients.

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


November 2012 | First publication of Japanese experience with OTSC®

In the recent issue of the World Journal of Gastroenterology Dr. Hidroshi 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 paracolonic drainage was inserted.

The authors state: “The endoscopic closure of perforations and fistulae with OTSC is a simple and minimally invasive

8 OTSC® update 15 EXTRA | research & clinical trials | sorted by indication
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 case reports and conference abstracts published on this topic. 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 post-surgical fistulae are a safe technique with a high success rate, including rectovaginal and colocolonic fistula.

July 2012 | First North American literature report on OTSC®

In a recent issue of the Canadian Journal of Gastroenterology, Dr. T.H. Kothari, Dr. G. Haber and colleagues from the Dept. of Gastroenterology at Lenox Hill Hospital, New York City, reported about their initial experience using Ovesco’s OTSC® clip.

They report about the application of OTSC® in the treatment of gastrointestinal fistulae. A case report describes the use of OTSC® in a patient with a persistent gastrointestinal fistula after PED feeding tube removal. 2 clips were placed to occlude the gastric office of the fistula tract. The closure was immediately successful and the patient was discharged home. At 3-month gastrointestinal follow-up the fistula had completely healed. The 2 clips were found spontaneously detached from the tissue and were removed from the gastric cavity with an endoscopic net retriever. The authors conclude that the results from the literature and their own experience demonstrates efficacy of the OTSC® System in the closure of gastrointestinal fistula.

May 2012 | Treatment of double anastomotic fistula by OTSC® published online by the Italian Society of Digestive Endoscopy

On their website, the Italian Society of Digestive Endoscopy publish an interesting clinical case report of Dr. Alberto Arazzo from the University of Torino, Italy, of a double anastomotic fistula to the skin after right hemicolectomy, both treated by OTSC®.

Trattamento di duplice fistola anastomotica enterocutanea dopo emicolectomia destra mediante Over The Scope Clip (OTSC) Alberto Arazzo, Rossella Reddivad, Mauro Vera, Francesca Cravero, Marco Augusto Bonino, Mario Morino M

May 2012 | Conference report: OTSC® at German Society for Endoscopy (DGE-BV) – latest clinical data

The German Society for Endoscopy and Imaging Techniques (DGE-BV) held its 42nd Annual Conference in Munich, Germany, from March 22-24. Ovesco’s OTSC® clip was the topic of a number of presentations in the scientific programme, as listed below. Part of these presentations were recently published on “Endosкопie heute”, the official journal of the DGE-BV.

Dres Faehndrich and Sandmann from Dortmund presented their 2-year experience using OTSC® in various indications. Their case series included 31 patients with GI fistula, acute perforations or post-surgical suture dehiscence. The therapeutic goal of closure was achieved in 83%, 100% and 75%, respectively. They also report about successful removal of clips with the Nd:YAG laser. A special application of OTSC® in the Dortmund case series was endoscopic gathering of the hiatus in patients with reflux disease.

FV17 Neue Einsatzmöglichkeiten des OTSC-Systems bei Gastrointestinalstränken – Ergebnisse und Verläufe nach 2 Jahren praktischer Anwendung Sandmann M, Heike M, Fähndrich M

The group of Prof. Hochberger from Hildesheim presented their results of a consecutive series of 40 OTSC® interventions. In 85% of cases the primary therapeutic goal was reached. Dr. Wedi reported on 23 cases of upper GI bleeding which had been refractory to other therapy before being treated with OTSC® clipping. 19 patients were successfully treated, 2 patients died in spite of attempted surgical hemostasis and 2 other patients for reasons not related to the endoscopic intervention. He also showed data of 3 perforations with a closure rate of 100%. Also 2 complications were reported, 1 new sigmoid perforation that was seen after successful closure of an EMR-related perforation in the hepatic flexure and one impingement of an endoscopic instrument with an OTSC® clip.

FV24 Der Over-The-Scope-Clip (OTSC) – Erste klinische Erfahrung bei der Behandlung von schweren Blutungen, Perforationen und Fisteln an 40 Patienten Wedi E, Menke D, Hochberger J

The group around Prof. Rathel from Erlangen summarized their experience of 17 cases of OTSC® perforation closures in a retrospective evaluation. Dr. Hagel reported an overall success rate of 64.7%. He distinguished between cases with vital and with non-vital or inflamed tissue margins. In cases with non-vital wound margins the number of clips was greater than in cases with non-altered wound margins (1.1 - 0.3 vs 2.3 -0.5 clips per case).

P22 Pure-NOTES-Sigmaresektion in einem Tier-Überlebensmodell


Further presentations dealt with the application of the OTSC® System:

Perforationen am GI-Trakt: Wann endoskopische Therapie, wie lange warten, wann Chirurgie?
Pohl J, Wiesbaden vs. Fuchs KH, Frankfurt/Main
Over-the-scope Clip Application ermöglicht eine hohe Verschlussrate bei verschiedenen Arten von gastrointestinalem perforieren. Hocheffektive konservative Therapie einer beginnenden Sepsis infolge Magenperforation nach PEG-Anlage durch endoskopischen Over-the-scope Clip (OTSC) - Perforationsverschluss und frühzeitige Tigecyclin-Lineozidapplikation

March 2012 | OTSC® closure of esophageal-pericardial fistula

Clinicians from various centers presented their data on the use of OTSC®:

- E. Wedi et al., Hildesheim, Germany, presented a mixed case series of 24 patients treated between February 2009 and March 2011. 15 patients suffered from upper GI bleeding, refractory to a laceration at the GE junction after balloon dilation for achalasia. 1 from injury of the duodenum after laparoscopic cholecystectomy and 5 from iatrogenic post-interventional perforations and 1 from a persistent PEG fistula. The overall success rate in this mixed series was 78%. 2 complications were related, 1 perforation of a sigmoid diverticulum by device passage and 1 unintended closure of an instrument with subsequent removal. The authors also presented an overview about the results of other OTSC case series reported in the literature. The overall success rate in these cases was 86%.

- P0003 A NEW VALUABLE TOOL FOR THE ENDOSCOPIST: THE OVER-THE-SCOPE CLIP (OTSC) – CLINICAL EXPERIENCE IN THE TREATMENT OF GASTROINTESTINAL LEAKS. BLEEDINGS AND FISTULAS IN 24 PATIENTS: Edwa Wedi, Germany; Detlev Menke; Elena Kroese; Jörgen Hochberger

Marc Barthet, Marseille, France, and his group presented preliminary data of a prospective study on the endoscopic treatment of postoperative GI fistulas with the OTSC® System. In 19 patients (23-76 years) they treated 11 gastrointestinal fistulas after sleeve resection (bariatric surgery) with a success rate of 91%. The overall success rate was 74% with 42% primary, and 32% secondary efficacy. Barthet pointed out explicitly that an initial failure should not deter the endoscopist. He concluded that the OTSC® System represents a satisfactory alternative, in first and second intention, in the treatment of postoperative GI fistulas.

P0012 ENDOSCOPIC MANAGEMENT OF DIGESTIVE FISTULA WITH OTSC® CLIPS: A PROSPECTIVE STUDY Monica Surace, Italy; Pascale Mercely; Jean-François Demarquay; Rémy Dumas; Veronique Vitton; Jean-Charles Grimaut; Marc Barthet

Paper published in GIE: Endoscopic management of GI fistulae with the over-the-scope clip system (with video)


Daniel v. Renteln from the Hamburg (Germany) group reported their experience with the OTSC® clip closure in a survival model with 10 pigs. All animals survived with histologically proven full-thickness closure again with signs of inflammation and micro-abcesses. They conclude that OTSC® and i-ESUs are feasible and render sufficient peritoneal evaluation, given that the OTSC® System ensures a full thickness closure of the stomach.

November 2011 | Retrospect: OTSC® notably mentioned at UEGW, October 22–26, 2011, Stockholm, Sweden

The OTSC® clip was the topic of numerous scientific presentations at UEGW 2011. The primary areas of application of Ovesco’s over-the-scope clipping technology include the treatment of perforations over the scope for upper GI hemorrhage, the closure of acute perforations and the closure of chronic lesions of the wall, e.g. fistula.

- Thomas Hucl et al. presented data from a porcine survival model where they compared feasibility and safety of gastric and colonic NOTES closure using the OTSC® System (10 animals each). Closure was successful in all 20 animals with mean application time of 8 min (stomach) and 5 min (colon). Histology revealed transmural healing in all animals. Due to signs of mucosal inflammation in some animals further investigation is recommended according to the authors (although they are probably just normal in this setting, acc. to Ovesco).

P0204 OVER-THE-SCOPE-CLIP CLOSURE OF GASTRIC AND COLONIC ACC ES SITES IN NATURAL ORIFICE TRANSLUMINAL ENDOSCOPIC SURGERY E. Wedi et al., Hildesheim, Germany, presented a mixed case series of 24 patients treated between February 2009 and March 2011. 15 patients suffered from upper GI bleeding, refractory to a laceration at the GE junction after balloon dilation for achalasia. 1 from injury of the duodenum after laparoscopic cholecystectomy and 5 from iatrogenic post-interventional perforations and 1 from a persistent PEG fistula. The overall success rate in this mixed series was 78%. 2 complications were related, 1 perforation of a sigmoid diverticulum by device passage and 1 unintended closure of an instrument with subsequent removal. The authors also presented an overview about the results of other OTSC case series reported in the literature. The overall success rate in these cases was 86%.

P0003 A NEW VALUABLE TOOL FOR THE ENDOSCOPIST: THE OVER-THE-SCOPE CLIP (OTSC) – CLINICAL EXPERIENCE IN THE TREATMENT OF GASTROINTESTINAL LEAKS. BLEEDINGS AND FISTULAS IN 24 PATIENTS: Edwa Wedi, Germany; Detlev Menke; Elena Kroese; Jörgen Hochberger

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P0204 OVER-THE-SCOPE-CLIP CLOSURE OF GASTRIC AND COLONIC ACC ES SITES IN NATURAL ORIFICE TRANSLUMINAL ENDOSCOPIC SURGERY

Tomas Hucel, Czech Republic; Marek Benes; Matej Kocik; Martin Kral; Jana Malusova; Eva Kieslichova; Martin Olverius; Julius Spicak

The Munich (Germany) group around A. Meining reported on 16 prospective patients with gastric subepithelial masses (>3 cm). Solely endoscopic resection was possible in 12/16 patients. Gastric perforation occurred and was cu-

P1080 ENDOSCOPIC FULL THICKNESS RESECTION OF GASTRIC SUBEPITHELIAL MASSES – A STEP TOWARDS NOTES?

Christoph Schlag, Germany; Stefan van Deuren; Hubertus Feusmann; Dirk Wilhelm; Analea Beitz; Roland M Schmid; Alexander Meining

Donatsky et al. evaluated the feasibility of combining transgastric (TG) pure NOTES peritoneoscopy and intraperitoneal EUS (ip-EUS) with intraluminal EUS (il-EUS) for peritoneal evaluation, and the safety of EUS-guided access and OTSC® clip closure in a survival model with 10 pigs. All animals survived with histologically proven full-thickness closure again with signs of inflammation and micro-abcesses. They conclude that OTSC® and i-ESUs are feasible and render sufficient peritoneal evaluation, given that the OTSC® System ensures a full thickness closure of the stomach.

P1044 TRANSGASTRIC PURE NOTES WITH PERITONEOSCOPY AND INTRAPERITONEAL EUS. A PORCINE SURVIVAL AND FEASIBILITY STUDY

Anders Möller Donatsky, Denmark; Luise Andersen; Ole Lerborg Nielsen; Barbara Holkmehnt; Peter Vilmann; Søren Meisner; Lars Namstedt Jørgensen; Jacob Rosenberg

Thomas Hucl et al. reported on NOTES-assisted transgastric cholecystectomy in a porcine survival model with 10 pigs. The intervention was successfully performed in all cases (mean overall time 85 min). OTSC® closure was successful in all cas-es as well (mean time 9 min, range 4-12 min). All animals survived without complication. The authors concluded that hybrid cholecystectomy was feasible and safe with the OTSC® System for gastric closure being safe and efficient.

P1180 NOTESASSISTED MINILAPAROSCOPIC TRANS-GASTRIC CHOLECYSTECTOMY

Tomas Hucel, Czech Republic; Matej Kocik; Marek Benes; Martin Kral; Jana Malusova; Eva Kieslichova; Martin Olverius; Julius Spicak

Pierre H. Deprez gave an oral presentation on 193 ESD procedures with en-bloc resection rates of <95%, and R0 resection in 87% of cases. He emphasizes that all bleedings and all but 2 perforations were controlled by endoscopic me-

P0206 LOW COMPLICATION RATE FOR ESD: REPORT ON 193 PROCEDURES IN THE ESOPHAGUS, STOMACH AND DUODENUM

Pierre H. Deprez, Belgium; Hubert Plesssevaux

A remarkable oral presentation was given by Anne Vlyser-man from the group of P. H. Deprez on the outcome of iatrogenic perforations of the GI tract. They had reviewed a total of 40,243 procedures (over 6 years) including EUS, ERCP and EMR/ESD where altogether 44 perforations occurred. The Munich (Germany) group around A. Meining reported on 16 prospective patients with gastric subepithelial masses (>3 cm). Solely endoscopic resection was possible in 12/16 patients. Gastric perforation occurred and was cu-

P0204 OVER-THE-SCOPE-CLIP CLOSURE OF GASTRIC AND COLONIC ACC ES SITES IN NATURAL ORIFICE TRANSLUMINAL ENDOSCOPIC SURGERY
In their recent report about a series of 12 consecutive patients with post-surgical or traumatic fistulas of the gastrointestinal tract treated by OTSC® clipping, R. Manta et al., Modena, Italy, carried out a cost comparison. They found OTSC® therapy considerably cheaper than alternative surgical intervention (USD 1,050 vs USD 3,800 in this particular hospital setting). Besides the cost advantage also the therapeutic results are reported as favourable: “No complications occurred, and the leaks were all healed at follow-up 1–3 months later. In 9 of the 11 patients, the leak was sealed within 4 days by a single application.”

The authors conclude that OTSC® clipping is an effective and technically simple technique for the closure of wall defects.

Endoscopic treatment of gastrointestinal fistulas using an over-the-scope clip (OTSC®) device: Case series from a tertiary referral center

May 2011 | Case report: closure of broncho-esophageal fistula
In the April issue of the journal Gastrointestinal Endoscopy A Rebelo and colleagues, Ave Avo Hospital, Guimarães, Portugal, present a case report with closure of spontaneous esophagobronchial fistula in a lung cancer patient, after radiochemotherapy. Closure of the fistula was feasible by means of OTSC® clip application and additional placement of a self-expandable covered stent. Besides partial occlusion of the fistula the OTSC® clip also worked as an anchor-ing mechanism for the stent to avoid migration. Until one month after there were no signs of fistula re-opening. The patient died of the underlying pulmonary tumor.
Complex endoscopic resolution of a large broncho-esophageal fistula
Rebelo Ana, Moutinho-Ribeiro Pedro, Cotter José
Gastrointestinal Endoscopy 2011;73:4 833-4 36

April 2011 | Post-surgical gastrointestinal fistulas treated with OTSC®
In the March issue of the journal Endoscopy R. Manta et al. report about a case series of 12 consecutive patients treated with OTSC® for closure of post-surgical gastrointestinal fistula in a tertiary referral center (S. Agostino Estense Hospital, Modena, Italy). Fistula closure with OTSC® clipping was successful in 11 out of 12 cases. Healing rates were confirmed by radiographic control or endoscopy. No device-related complication occurred.
The authors conclude that OTSC® clipping is an effective and technically simple technique for the closure of wall defects.
Endoscopic treatment of gastrointestinal fistulas using an over-the-scope clip (OTSC®) device: Case series from a tertiary referral center

March 2011 | The Over-the-scope clip (OTSC®) for the treatment of gastrointestinal bleeding, perforations, and fistulas
In the latest issue of Surgical Endoscopy Andreas Kirchmair et al. report of a series of 50 patients that had been treated with the OTSC® System for hemostasis (n = 27) in the colon and the upper GI tract, closure of esophageal, gastric, and colonic perforations (n = 11) as well as closure of fistulas (n = 8) and for preoperative marking (n = 4).
The primary treatment was reported successful in all cases. In more detail, there were two secondary bleedings that required endoscopic re-intervention, and the permanent closure of fistulas could not be achieved in all cases.

The authors conclude that the OTSC® System is effective and safe for complicated bleeding and closure of fresh perforations of the gastrointestinal tract.

The Over-The-Scope Clip (OTSC®) for the treatment of gastrointestinal bleeding, perforations, and fistulas
Kirchmair A, Subotova N, Zieker D, Königsrair A, Kratt T

January 2011 | Successful treatment of duodenal fistula after gastrectomy with the OTSC® clip
Dr. R. Biri and colleagues, SG Bosco Hospital, Torino, Italy, report about the successful closure of a duodenal fistula with Ovesco’s OTSC® clip. The fistula arose in an elderly patient who was treated with emergency gastrectomy for severe peptic ulcer bleeding. The postoperative fistula associated to sepsis, malnutrition and hydro-electrolyte disorders and did not respond to surgical and medical treatment attempts. The fistula was then closed endoscopically by means of an OTSC® clip.

Endoscopic Treatment of Postgastrectomy Duodenal Fistula With an Over-The-Scope Clip

January 2011 | Closure of rectovesical fistula by means of OTSC® and cyano-acrylate reported
Anastomotic fistula after colorectal surgery is not infrequent and can happen in up to 10% of cases. Also rectovesical fistula can result and is cause of significant morbidity and discomfort. Temporary diverting ileostomy for 2–3 months is a common surgical treatment.
Dr. Benedetto Mwangiavillano, Dept. of Gastrointestinal Endoscopy, University of Milan, Italy and colleagues report about the closure of a rectovesical fistula in a patient after laparoscopic sigmoid resection for adenocarcinoma of the sigmoid. A two-step approach was used in which the 6-mm OTSC® clip, and a small residual opening was subsequently closed with cyano-acrylate injection in a second procedure. The patient was followed for approx. 10 weeks when CT showed the fistula completely closed. The authors conclude that OTSC® clipping with possible additional cyano-acrylate can be effective in the treatment of anastomotic leakage and fistula and should be considered in such cases before the patient is referred to surgery.
Endoscopic sealing of a rectovesical fistula with a combination of an over the scope clip and cyano-acrylate injection

November 2010 | New clinical report about successful chronic fistula closure with OTSC® clips
In the October issue of the journal Gastrointestinal Endoscopy, Dr. Daniel von Renteln et al., Dept. of Interdisciplinary Endoscopy, University of Hamburg-Eppendorf, Germany, report about the successful closure of post-traumatic esophageal-pulmonary fistula and a chronic gastroduodenal fistula.
Closure was not successful in 2 other cases, due to substantial scarring at the fistula site. The mean procedure time was 54 minutes (range 24-93 minutes), there were no procedure-related complications.
The authors conclude: “The OTSC® seems to be a feasible device to close chronic fistula of the GI tract. It can achieve leak-proof, full-thickness closure of transmural defects. Nevertheless, in circumstances of severe fibrosis and scarring, complete incorporation of the defect into the applicator cap and successful OTSC® application might not be possible.”
Endoscopic closure of GI fistulae by using an over-the-scope clip
von Renteln D, Denzer UW, Schachsschal G, Anders M, Grath S, Rösch T
Gastrointest Endosc. 2010 Dec;72(6):1289-96
[Epub 2010 Oct 16] 39

September 2010 | OTSC® for closure of recto-vesical fistula after radical prostatectomy
There is growing positive clinical experience worldwide with the use of Ovesco’s OTSC® clip in the treatment of chronic fistula. Dr. M. Cavina and coauthors, Reggio Emilia, Italy, report about the successful treatment of a chronic recto-vesical fistula in a male patient, subsequent to prostatectomy. The size of the chronic fistula was 4 mm and it was effectively occluded by means of a single OTSC® 12/6a clip. The case was reported in the Italian Journal of Digestive Endoscopy.
Utilizzo della clip Ovesco nel trattamento di una fistola retto-vesicale
Maurizio Cavina, Romano Sassatelli, Francesco Assozzini, Lorenzo Camellini, Francoce Decembrino, Veronica Iori, Giuliana Sereni, Cristiana Toli, Giuliano Bedogni Servizio di Gastroenterologia ed Endoscopia Digestiva, Arcispedale Santa Maria Nuova di Reggio Emilia Giorn Ital End Dig 2010;33:147-8

June 2010 | Successful OTSC® closure of esophago-bronchial fistula reported at national gastroenterology congress in Portugal
Dr. P. Moutinho-Ribeiro and colleagues, Centro Hospitalar do Alto Ave – Guimarães, Portugal, report about the successful closure of a 15-mm esophago-bronchial fistula in an esophageal cancer patient following chemotherapy-radiotherapy. By using the OTSC® Anchor to pull the fistula orifice to the tip of the OTSC® cap and application of an OTSC® clip, the fistula was successfully closed. Supplementary stent placement was done to secure the result. The case was presented at 30th National Congress of the Portuguese Society of Gastroenterology in VilaMoura, June 9-12, 2010.

June 2010 | Tuebingen University reports experience in 60 consecutive patients treated with OTSC®
Bruchsal, Germany, June 11, 2010. At the 21st Congress of the Southwest German Society of Gastroenterology Thomas Kratt, MD, Surgical Endoscopy, Tuebingen University Hospital, Germany, reported about a case series of 60 patients treated with OTSC® for various indications. 37 patients were treated for stopping gastrointestinal hemorrhage, 11 for closure of perforation, 8 for closure of fistula and 4 for the marking of lesions. In all 60 cases technical success, defined as ability to place the OTSC® at the desired location, was achieved. In the 37 cases of GI bleeding 2 relapse bleedings were seen. In all 11 cases of GI perforation therapeutic success, defined as absence of failure/recurrence was achieved. In the 8 fistula patients 3 recurrences were found. The authors conclude that based on their experience OTSC® is best applied in the following indications:

Emergency: • Severe peptic ulcer bleeding • Iatrogenic perforations (spontaneous perforations) • Hemorrhoidal post-surgical hemorrhage
Elective: • Anastomotic failure • Fistula • Anastomotic correction

Notes

The Over-The-Scope-Clip System (OTSC®): Erfahrung in der klinischen Anwendung bei 60 Patienten
Kraft T, Stieler D, Küper M, v. Felitsch M, Königsmair A, Kirschmick A

April 2010 | New publication on the use of OTSC® in bariatric patients
Dr. Federico Iacopini published a case report on the use of OTSC® to treat complications of gastric banding in the World Journal of Gastroenterology. Ovesco’s OTSC® clip was used to close full thickness stomach erosions resulting from long-term gastric band implantation. Two patients were successfully treated.

Over-the-scope clip closure of two chronic fistulas after gastric band penetration
Federico Iacopini, Nicola Di Lorenzo, Fabrizio Altorito, Marc Olivier Schurr, Agostino Scozzaro World J Gastroenterol 2010 April 7; 16(13):1865-9

March 2010 | Italian gastroenterologists report successful closure of tracheo-esophageal fistula using Ovesco’s OTSC® clips
In the recent issue of the journal Endoscopy, Dr. M. Traina and colleagues, Palermo, Italy, report about the closure of a chronic tracheo-esophageal fistula emerging in a patient after long-term ventilation.
The fistula was located 20 cm from the mouth. After closure with an OTSC® clip the clinical condition of the patient improved and healing of the fistula was seen at follow-up endoscopy, 2 and 4 weeks later. No complications were reported.

New endoscopic over-the-scope clip system for closure of a chronic tracheo-esophageal fistula
M Traina, G Curcio, I Tarantino, S Soresi, L Barresi, P Vitulo, B Gindeli | IsMett, UPMC, Palermo, Italy
Endoscopy 2010; 42:E1-E2 [UCTN]

January 2010 | Korean endoscopists make reference to the OTSC® clip as a device in ESD for gastric cancer
Prof. Won Young Cho et al. from the Dept. of Gastroenterology (Director: Prof. Ju Young Cho) at the College of Medicine, Soochonhongyang University, Korea, refer to the OTSC® clip as an endoscopic device for treating post-interventional bleeding or organ wall lesions in the chapter on Endoscopic Submucosal Dissection (ESD) of the recently published book “Endoscopic Treatment of Gastric Cancer”. Prof. Won Young Cho and his colleagues are leading users of Ovesco’s OTSC® in South Korea.

Endoscopic Treatment of Gastric Cancer

November 2009 | Ovesco exhibits at Gastro 2009, UEGWIWCOC, the jointly organised landmark meeting of UEGF, WGO, OMEDE and BSG, London, November 21–25, 2009
Moreover, OTSC® is focussed in a poster and in an oral presentation: OVER-THE-SCOPE-CLIP (OTSC®) CLOSURE OF TWO CHRONIC FISTULAS AFTER GASTRO INTESTINAL BAND PENETRATION is the title of a poster presentation of F. Iacopini et al. A 44-year-old woman presented with a band erosion and penetration through two large tears at the posterior wall of the gastric fundus. A sub-phrenic abscess was demonstrated by computed tomography (CT-scan). Surgery was performed but external drainage of enteral material persisted for 2 weeks. Both fistulas were successfully closed with OTSC®s (one in combination with a fully-covered esophageal SEMS) and remained successfully closed. Both OTSC®s were spontaneously lost after 4 weeks. The authors conclude that if prospective large comparative studies with fully-covered stents and OTSC® will confirm this initial observation, the OTSC® may be the least invasive, easiest and safest endoscopic method to close chronic small fistulae or leaks.

At the 21st Conference of the Society for Medical Innovation & Technology (SMIT) Ovesco’s OTSC® clip is presented in various scientific sessions.
Dr. Agostino Scozzaro and colleagues, Rome, Italy, report about the successful closure of chronic fistula related to adjustable gastric band erosion, using OTSC® clipping.
The use of OTSC® in Natural Orifice Transluminal Endoscopic Surgery (NOTES) is presented by Prof. Dr. Alberto Aruzzo, Torino, Italy, within a hands-on workshop on basic techniques in NOTES. He also shows recent data on trans-gastric cholecystectomy and successful endoscopic closure of the stomach with the OTSC® clip in a surviving porcine model.
Further, he reports about the use of OTSC® for the treatment of post-surgical healing problems in bowel anasto-moisis. He recommends OTSC® clipping for suitable cases in his overview presentation on closure of fistula and chronic pelvic abscess after colorectal surgery.
A summarizing overview about global clinical experiences with the OTSC® clip is given by Prof. Dr. Marc O. Schurr, Member of the Executive Board of Ovesco Endoscopy AG.

Various of the above and other indications: bleeding, fistulas, perforations

June 2013 | Report on successful removal of an OTSC Clip
Prof. Mönkemüller and colleagues presented a clip removal case in a letter to the editor of Gastrointestinal Endoscopy.
Ten days after treating an anastomotic leak with the OTSC System, there was still a leak due to misplacement of the clip. The clip had to be removed to place another OTSC onto the leak. At first clip rising was accomplished by injecting saline solution below the OTSC. A snare was positioned around the clip, slowly closed and retracted. The clip dislodged and was retrieved carefully without injury by catching it with the snare and keeping it close to the distal end of the endoscope. The anastomotic leak was thereafter closed successfully with a new OTSC.

Endoscopic removal of an over-the-scope clip (“bear claw”)

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 sub-mucosal tumor of about 9 mm diameter. Biopsy revealed a neuroendocrine tumor. Prof. Dr Thomas Rösch (University Hospital Hamburg-Eppendorf) used the FTRD to resect the lesion. The FTRD consists of an elongated OTSC cap premounted with a specially designed, derivative OTSC clip and the cap incorporates a resection snare.
Prof. Rösch grasped the lesion with a grasping forceps and pulled the target tissue into the cap in a full thickness fashion. After mobilizing the tissue into the cap, the clip was released to seal the invaginated tissue before resection.
Right afterwards the snare was closed and the tissue was secured 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.

Venue: Klinikum Augsburg, Augsburg, Germany

The FTRD device is not yet commercially available.

April 2013 | Conference report | OTSC at German Endoscopy Conference (DGE-BV 2013 in Munich)
OTSC was well-covered in the scientific programme of this year’s German Endoscopy Conference in Munich.
Clinical presentations confirm efficacy of OTSC clipping in a range of indications
Munich, March 14–16, 2013. The 43rd German Endoscopy Congress, DGE-BV, was held under the presidency of Prof. Dr. Christoph F. Dietrich.
A significant number of presentations had clinical data of OTSC clipping as their topic and confirmed clinical efficacy and safety in the primary indications of the product, hemostasis, closure of acute lesions/ perforations and closure of chronic lesions. (source: www.dge-bv.de)
Large single center OTSC cohort with hemostatic and organ wall closure indications
Wedi E, Menke D, and Hochberger J, Strasbourg (France) reported about a cohort of 84 patients with OTSC clipping for GI bleeding, fistula and GI wall insufficiency. 101 OTSC clips had been used in this cohort, or 1.2 clips per patient.
Indications included mainly severe upper GI peptic ulcer hemorrhage (n=38) and preventive clipping to avoid re- bleeding (n=12) or secondary perforation (n=18) after large area ESD. The clinical success rate in peptic ulcer bleeding was 79%, most patients had already been treated unsuccessfully with other hemostatic techniques before OTSC clipping or had been candidates for surgical hemostasis.
2 complications were encountered: 1 inadvertent clipping of an instrument with OTSC and fixation of the instrument to the tissue and one perforation of the sigmoid with the OTSC cap. The authors state that OTSC application is an effective procedure to deal with endoscopic situations that otherwise would require a surgical approach.
Der Einsatz des OTSC-Makroclips bei 84 Patienten mit schwerer Gl-Bleeding, Fisteln und Insuffizienzen – ein Rekapitulierung
E. Wedi, D. Menke, and J. Hochberger, Strasbourg (France) reported about a cohort of 84 patients with OTSC clipping for GI bleeding, fistula and GI wall insufficiency. 101 OTSC clips had been used in this cohort, or 1.2 clips per patient. Indications included mainly severe upper GI peptic ulcer hemorrhage (n=38) and preventive clipping to avoid re-bleeding (n=12) or secondary perforation (n=18) after large area ESD. The clinical success rate in peptic ulcer bleeding was 79%, most patients had already been treated unsuccessfully with other hemostatic techniques before OTSC clipping or had been candidates for surgical hemostasis.
2 complications were encountered: 1 inadvertent clipping of an instrument with OTSC and fixation of the instrument to the tissue and one perforation of the sigmoid with the OTSC cap. The authors state that OTSC application is an effective procedure to deal with endoscopic situations that otherwise would require a surgical approach.

Das OTSC-Clip-System: Klinische Erfahrungen zur Therapie der schweren GI-Blutung bei 85 Patienten
T. Kratt, D. Stüker, F. Gräpler, M. Kıpker, D. Wichmann, A. Königsrainer, Tübingen
OTSC to prevent migration of covered self-expanding stents
Fährndrich M, Pohl T, Rolfs S, Sandmann M, and Heike M, Dortmund, presented their technique of using OTSC to avoid migration of covered, self-expanding stents. Stent migration has an incidence of up to 30% and represents a significant clinical challenge. To prevent stent migration the authors used OTSC to fix the stent permanently to the neighboring GI wall. In 24 cases with benign indication for stent placement OTSC fixation was carried out in the following indications: 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 removal was observed. In another case the stent had to be removed after a few days due to intolerance by the patient in a location close to the upper esophageal sphincter. The authors conclude that OTSC clipping was found to be a safe and practical technique and has prevented stent migration in all the cases studied.

Verwendung des Ovesco-Clips zur Verhinderung der Migration bei vollgecoverten selbststapelnden Stents
M. Fährndrich, T. Pohl, S. Rolfs, 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, Raithel S, Diebel H, Neurath M, and Raithel M, Erlangen, showed data on the management of GI perforations with OTSC clips. They studied 19 patients with apparent perforation of a digestive organ wall in various anatomical locations. In 13 patients the perforation could be closed with OTSC (‘O’+) to avoid emergency surgery. In 6 patients OTSC closure was technically unsuccessful and emergency surgery was needed (‘O’–). In the O+ group the duration of hospitalisation was 10.7 ± 10 days, no mortality. 2 patients in this group had co-morbidities, unrelated to clip closure, leading to a prolonged hospital stay; excluding these 2 patients, hospitalisation was 5.8 ± 2.2 days. In the O– group hospital stay was 12.1 ± 7.7 days, one patient with esophageal perforation died (oesophageal perforation surgery was indicated in each case). The authors conclude that OTSC treatment can significantly reduce morbidity and mortality in GI perforations.

OTSC-Anwendung bei manifesten GI-Perforationen: 30-Tages-Mortalität, Hospitalisationsdauer und Outcome nach endoskopisch erfolgreichem und nichterfolgreichen Perforationsverschlüssen
A. Hagel, A. Nägel, S. Raithel, H. Diebel, M. Neurath, and M. Raithel, Erlangen
Monocentric case experience with OTSC in a broad range of wall closure indication: safe transmural closure
Nietzsch H, Hammelmann F, and Asperger W, Halle, summarized their initial experience with OTSC in endoscopic closure of the GI organ wall in 10 consecutive applications. Indications included: postsurgical rectal 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 surgery suture line leak. All cases were successful. The authors conclude: OTSC enables a safe transmural closure of spontaneous and iatrogenic perforations. In a majority of cases target tissue handling is possible with suction only and does not require additional instruments. In well-trained endoscopy centers the learning curve for OTSC is short.

Erfahrungsbericht der ersten 10 Anwendungen des endoskopischen OTSC-Clipsystems
H. Natitsch, 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 hrs after the lesion. Both patients received bilateral thorax drainage and antibiotic therapy. No patient developed sepsis. Starting oral intake was without problems. Control esophagostomy 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 der distalen Oosphagussperren 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 chronic lesions
Thomsen T, Berthold B, Khiabanchian M, and Treubrand I, Neuenburgland, 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 diverticulitis (Hartmann situation), arteri- al bleeding from colon anastomosis. The overall clinical suc- cess 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 Neuenburgland
T. Thomesen, B. Berthold, M. Khiabanchian, and I. Treubrand, Neuenburgland
OTSC for stopping gastroduodenal artery bleeding in duodenal ulcer
Krafft T, Stüker D, Kirschnick A, Heininger A, Wietek B, Königsrainer A, Tübingen, showed a case series (n=7) in which OTSC was applied in upper GI emergency hemostasis to stop bleeding from the gastroduodenal artery. Gastroduode- nal artery bleeding is besides aortoduodenal fistula conside- red the most severe bleeding complication in the digestive tract, associated with high morbidity and mortality. Two of 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 endo- scopic treatment. In all 7 patients the acute bleeding from an ulcer at the posterior duodenal wall was successfully controlled with OTSC, in 4 cases fibrin glue was additionally applied. After the initial 72 hrs, 3 patients suffered from re-bleeding, which was then controlled surgically. No mortality was encountered in this case series. The authors draw the conclusion that OTSC is effective in emergency manage- ment 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 surge- ry” and allowed stabilizing the patient before the operation.

OTSC-basierte Notfall-Hämostase der lebensbedrohlichen A. gastroduodenalis Ulkus-Arrosionsblutung: alleinige endoskopische Therapie oder „bridge-to-surgery“
Report on Ovesco FTRD (pre-commercial device)
Krafft T, Stüker D, Gräpler F, Schneek M, Adam P, and Königsrainer A, Tübingen, presented data of their first 8 ca- ses 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 resection 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 (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 follow day. As histology demonstrated complete remo-
al of the lesion, no further therapy was done. Follow-
up was uncomplicated. After 14 weeks control endoscopy revealed that the clip had detached from the tissue, normal scar formation was seen at the resection site and no signs of residual lesion or new recurrence were found.

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

T. Kratt, D. Stüker, F. Größler, M. Schneb, P. Adam, and A. Königsrainer, Tübingen

FTRD is not yet commercially available.

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

Dr. Thomas Kratt, Interdisciplinary Endoscopy, University Hospital, Tuebingen, Germany, received an award for this presentation of clinical research in the field of full-thickness resection at the 53rd 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 de-
vice 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 re-
section with the primary purpose of enhanced histological ex-
amination of an in toto full thickness specimen. The target lesions were in the upper GI tract, melanoma metastasis (n=3), GIST (n=1) or in the lower GI tract (adenoma or early colorectal cancer, low risk histology; n=4).

The presentation of Dr. Kratt gave a detailed case history of an elderly patient with recurrent adenoma (high grade dysplasia, partially adenocarcinoma) of the rectum. The patient had full thickness resection with FTRD under single-shot antibiotic and was discharged the follow 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. www.dge-bv.de/de/german/home.php

February 2013 | Retrospective multicentric re-
view of early OTSC patients in the US: overall clinical success rate of 71%

Dr. Todd H. Baron and colleagues of Gastroenterology & Hepatology, Mayo Clinic, Rochester MN, USA report about their experience with 45 patients and 48 OTSC clip placements from March 2011 to January 2012. Median fol-
low-up time in this mixed 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=3), closure of post-endarterectomy anastomotic leakage (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. Ana-
 stomotic leakage and fistula was closed in 65%. Also one case of OTSC clip removal by means of APC-cutting of a clip hinge was 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 (with videos)


October 2012 | The success rates for hemosta-
sis 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, hemostosis, closure of acute GI lesions (perforations) and chronic GI lesions (fistula). Only clinical reports with >4 patients were included into the survey, that was carried out by Dr. Timo Weiland, novineon CRD, a specialized contract research organization for the medical device industry (www.novineon.com).

The success rates defined as permanent achievement of the therapeutic goal for hemostasis in severe GI bleeding, perforation closure (including acute anastomotic suture line failure) and chronic fistula closure are 88%, 79% and 73%, respectively. The OTSC System compares to the effective-
ness of a surgical intervention in the respective indications or offers a new therapeutic option in situations where surgery is not feasible.


(English)


(German)

April 2012 | Conference report: OTSC® at German Society for Endoscopy (DGE-BV) – latest clinical
data

The German Society for Endoscopy and Imaging Techniques (DGE-BV) held its 42nd Annual Conference in Munich, Germany, from March 22-24.

Ovesco’s OTSC® clip was the topic of a number of presen-
tations in the scientific programme, as listed below. Part of these presentations were recently published on “Endoskopie heute”, the official journal of the DGE-BV.

Dres Faehndrich and Sandmann from Dortmund presented their 2-year experience using OTSC® in various indications. Their case series included 31 patients with GI fistula, acute perforations or post-surgical suture dehiscence. The therapeu-
tic goal of closure was achieved in 83%, 100% and 75%, respectively. They also report about successful removal of clips with the Nd:YAG laser. A special application of OTSC® in the Dortmund case series was endoscopic gathering of the hiatus in patients with reflux disease.

FV17 Neue Einsatzmöglichkeiten des OTSC-Systems im Gastrointestinaltrakt – Ergebnisse und Verläufe nach 2 Jahren praktischer Anwendung

Sandmann M, Heike M, Fähndrich M.

The group of Prof. Hochberger from Hildesheim presented their results of a consecutive series of 40 OTSC interventions. In 85% of cases the primary therapeutic goal was reached.

Dr. Wedi reported on 23 cases of upper GI bleeding which had been refractory to other therapy before being treated with OTSC® clipping. 19 patients were success-
fully treated, 2 patients died in spite of attempted surgical hemostasis and 2 other patients for reasons not related to the endoscopic intervention. He also showed data of 3 perforations with a closure rate of 100%. Also 2 compli-
cations were reported, 1 new sigmoid perforation that was seen after successful closure of an EMR-related perforation in the hepatic flexure and one impingement of an endoscopic instrument with an OTSC® clip.

FV24 Der Over-The-Scope-Clip (OTSC) – Erste klinische Erfahrung bei der Behandlung von schweren Blu-
tungen, Perforationen und Fisteln an 40 Patienten

Wedi E, Menke O, Hochberger J

The group around Prof. Rathel from Erlangen summarized their experience of 17 cases of OTSC® perforation closures in a retrospective evaluation. Dr. Hagel reported an overall success rate of 64.7%. He distinguished between cases with vital and with necrotic or inflamed tissue margins. In cases with non-vital wound margins the number of clips was greater that in cases with non-altered wound margins (1.1±0.3 vs 2.3±0.5 dets each case).

P22 Over-the-scope clip – Applikation ermöglicht eine hohe Verschlussrate bei verschiedenen Arten von gastrointestinale Perforationen


In a pre-clinical study Dr Bernhard and co-workers, Rostock, assessed OTSC® for gastric closure after pure NOTES sigm-or resection using a combined transgastric and transrec-
tal approach in 5 animals. Closure of the gastric cavity with the OTSC® clip was successful in all cases. All clips were still present at the end of the follow-up period (5 weeks). The mean operative time was 3 h 20 min (2.5 – 4.5 hrs).

P22 Pure-NOTES-Sigmaresektion in einem Tier-Über-
lebensmodell


Further presentations dealt with the application of the OTSC® System:

Perforationen am GI-Trakt: Wann endoskopische
Therapie, wie lange warten, wann Chirurgie?

Pohl J, Wiesbaden vs. Fuchs KH, Frankfurt/Main

Moreover, several posters showed results of OTSC-
System applications:

Over-the-scope Clip-Applikation ermöglicht eine hohe Verschlussrate bei verschiedenen Arten von gastrointestinale Perforationen


Hocheffektive konservative Therapie einer beginnenden Sepsis infolge Magenperforation nach PEG-Anlage durch endoskopischen Over-the-scope Clip (OTSC)-
Perforationsverschluss und frühzeitige Tigecyclin-
Linseodipplikation


November 2011 | In retrospect: OTSC® notably mentioned at UEGW, October 22–26, 2011, Stockholm, Sweden

The OTSC® clip was the topic of numerous scientific pre-
sentations at UEGW 2011. The primary areas of application of Ovesco’s over-the-scope clipping technology include the treatment of severe upper GI hemorrhage, the closure of acute perforations and the closure of chronic lesions of the wall, e.g. fistula. Clinicians from various centers presented their data on the use of OTSC®.
The Munich (Germany) group around A. Meining reported on 16 prospective patients with gastric subepithelial masses (<3 cm). Solely endoscopic resection was possible in 12/16 cases. In 4/12 patients gastric perforation occurred and was cured with an OTSC® clip successfully. The authors conclude that endoscopic snare resection of gastric subepithelial masses (<3 cm) seems to be a safe and minimal invasive procedure. If perforation occurs, it can be adequately managed by placing the OTSC® clip. These results can be regarded as a further encouraging step towards transgastric endoscopic surgery. Fähndrich et al. recently reported their experience with a Nd:YAG-Laser for the removal of the OTSC® clip in 3 cases: (i) after closure of an oesophageal fistula, (ii) after closure of a perforation of the distal common bile duct in the roof of the papilla and (iii) after clip misplacement in a case of a wide oesophago-gastric fistula resulting in a severe oesophageal stenosis. Clinically relevant thermal lesions were not observed after the procedure. If clinically necessary, the OTSC® System® can be safely removed by the Nd:YAG Laser in centres for interventional endoscopy according to them.

OTSC® update 15 EXTRA | research & clinical trials | sorted by indication


Fähndrich et al. from Dortmund recently reported on their experience with a Nd:YAG Laser for the removal of the OTSC® clip in 3 cases: (i) after closure of an oesophageal fistula, (ii) after closure of a perforation of the distal common bile duct in the roof of the papilla and (iii) after clip misplacement in a case of a wide oesophago-gastric fistula resulting in a severe oesophageal stenosis. Clinically relevant thermal lesions were not observed after the procedure. If clinically necessary, the OTSC® System® can be safely removed by the Nd:YAG Laser in centres for interventional endoscopy according to them.

Removal of over the scope clips (OTSC®) with an Nd:YAG Laser.
Fähndrich M, Sandmann M, Heike M.
Z Gastroenterol. 2011 May;49(5):579-83. [Epub 2011 May 9]

March 2011 | The Over-The-Scope Clip (OTSC®) for the treatment of gastro-intestinal bleeding, perforations, and fistulas

The latest issue of Surgical Endoscopy Andreas Kirschnia et al. report on a series of 50 patients that had been treated with the OTSC® System for hemorrhasia (n = 27) in the colon and the upper GI tract, closure of esophageal, gastric, and colonic perforations (n = 11) as well as closure of fistulas (n = 8) and for preoperative marking (n = 4).

The primary treatment was reported successful in all cases. In more detail, there were two secondary bleedings that required endoscopic re-intervention, and the permanent closure of fistula could not be achieved in all cases. The authors conclude that the OTSC® System® is effective and safe for complicated bleeding and closure of fresh perforations of the gastrointestinal tract.

The Over-The-Scope Clip (OTSC®) for the treatment of gastrointestinal bleeding, perforations, and fistulas
Kirschnia A, Subotiva N, Zieker D, Königsrainer A, Krell T

March 2011 | First pharyngeal placement of OTSC reported at FISMAD conference, Torino, Italy

F. Iacopini, A. Scozzarro and colleagues reported the emergency use of an OTSC® clip in a patient after collar stabbing injury in suicidal intent at the 17th National Congress of the Italian Society for Digestive Disease (FISMAD), Torino, Italy, March 3-9, 2011.

After self-inflicted stabbing injury of the neck an elderly female patient with a history of severe depression was admitted to the S. Giuseppe Hospital, Albano Laziale, Rome, Italy. Endoscopy revealed a 12-mm cut of the left lateral wall of the hypopharynx. The lesion was endoscopically closed by means of an OTSC® clip. 3 days after the procedure normal contrast swallow with gastrografin demonstrated normal liquid passage, a CT-scan showing no mediastinal emphysema or fluid collection. The patient had some discomfort with pharyngeal foreign body feeling. After 5 weeks the clip detached and was swallowed by the patient without complications. The further course was uneventful.

March 2011 | OTSC® System successfully administered in full wall resection for early colon cancer

Dr. Martin Fähndrich and Dr. Marcel Sandmann of the Department of Gastroenterology, Klinikum Dortmund, Germany for the fourth time successfully used the OTSC® System in a full wall resection for early colon cancer. The tumor was secured within the resection cap of the system, the clip then released, and the target tissue eventually resected safely. The procedure was broadcasted by Germany’s largest public broadcasting company WDR, Cologne. Audience ratings indicated almost 1 million viewers of the transmission.

June 2010 | Tuebingen University reports experience in 60 consecutive patients treated with OTSC®

Bruchsal, Germany, June 11, 2010. At the 21st Congress of the Southwest German Society of Gastroenterology Thomas Kritt, MD, Surgical Endoscopy, Tuebingen University Hospital, Germany, reported about a case series of 60 patients treated with OTSC® for various indications. 37 patients were treated for stopping gastrointestinal hemorrhage, 11 for closure of perforation, 8 for closure of fistulae and 4 for the marking of lesions. In all 60 cases technical success, defined as ability to place the OTSC® at the desired location, was achieved. In the 37 cases of GI bleeding 2 relapse bleedings were seen. In all 11 cases of GI perforation therapeutic success, defined as absence of failure/recurrence was achieved. In the 8 fistula patients 3 recurrences were found. The authors conclude that based on their experience OTSC® is best applied in the following indications:

Emergency:
• Severe peptic ulcer bleeding
• Intragastric perforations (spontaneous perforations)
• Hemorrhoidal post-surgical hemorrhage

Elective:
• Anastomotic failure
• Fistula
• Anastomotic correction

NOTES
Das Over-The-Scope Clip System (OTSC®): Erfahrungen in der klinischen Anwendung bei 60 Patienten
Kraft T, Stüker D, Kühr M, Feilitzsch M, Königsrainer A, Kirschknia A.

There were two more reports on successful application of Ovesco’s OTSC® System: Ulkus-Resorptionsblutung der A. gastroduodenalis – Vermeidung des Notfalleingriffs durch ein neuartigesClip-System – zwei Fallberichte
Krafl T, Stüker D, Brücher B, Heininger A, Miller S, Königsrainer A.

Aus dem Labor in die Klinik: Die transgastrisch-flexible NOTES-Laparoskopie

June 2010 | Ovesco’s OTSC® Anchor for supporting gastric mucosal resection

Daniel von Renteln, MD, and co-authors report about the use of the OTSC® Anchor in EMR. They carried out an experimental study in 10 domestic pigs using a dual channel endoscopic gastric lesions of approx. 3 cm were simulated by RF marking. The OTSC® Anchor was used through one working channel and a monofilament snare through the other. The snare anchor was advanced through the scope and anchored in the submucosal layer. After lifting the lesion, the snare was closed and the mucosal resection completed. The mean time to perform gastric EMR was 32.4 min. The mean surface area of the resected specimen was 9.36 sq cm. Complete en-bloc resection of the large specimen was achieved in one maneuver in 9 cases, it required two maneuvers in one case. One gastric wall perforation occurred. The authors conclude that grasp-and-snare EMR is feasible with the OTSC® Anchor.
Endoscopic mucosal resection using a grasp-and-snare technique

September 2009 | Ovesco’s OTSC® System applied in live demos at 43rd Erlangen Symposium for Practical Gastroenterology and Hepatology, Erlangen, University, 18–19 Sept 2009
Future prospects in complication management are a major topic of this meeting. (Erlanger Tagung für Praktische Gastroenterologie und Hepatologie). Ovesco’s OTSC® System is applied in live demos transmitted from the Department of Gastroenterology and favourably pointed out by Prof. M. Raitel. Further, Prof. Dr. J. Hochberger emphasizes the significance of the OTSC® in view of NOTES.

Bariatric
June 2012 | OTSC® in bariatric procedures: 30th GEEW workshop, Brussels, 18-20 June 2012
From June 18 to 20 the 30th GEEW – Gastroenterology and Endotherapy European Workshop – took place in Brussels, Belgium, under the directorship of Prof. Dr. Jacques Devière and colleagues.
The use of Ovesco’s OTSC® clip was presented in a live procedure for the treatment of weight regain after Roux-en-Y gastric bypass.
The procedure was performed by Prof. Dr. J. Devière, Brussels, supported by Prof. Dr. G. Costamagna, Rome. The gastrojejunal pouch anastomosis that had enlarged over time, leading to weight-regain, was reduced in size by means of the placement of 2 OTSC® clips. A variation of the original technique described by Dr. A. Heylen was applied. The procedure took about 15 min. Prof. Dr. Devière also mentioned that he is currently running a study on 20 patients and that he treated 3 patients so far with satisfactory weight loss.

The OTSC Clip in Revisitional Endoscopy Against Weight Gain After Bariatric Gastric Bypass Surgery
Heylen AM, Jacobs A, Lybeer M, Proßt RL
Obesity surgery 2011 Oct;21(10):1629-33
[Epub 2010 Sept 3]

April 2010 | New publication on the use of OTSC® in bariatric patients
Dr. Federico Iacopini published a case report on the use of OTSC® to treat complications of gastric banding in the World Journal of Gastroenterology. Ovesco’s OTSC® clip was used to close full thickness stomach erosions resulting from long-term gastric band implantation. Two patients were successfully treated.

Over-the-scope clip closure of two chronic fistulas after gastric band penetration
Federico Iacopini, Nicola Di Lorenzo, Fabrizio Altorio, Marc Oliver Schurr, Agostino Scozzaro
World J Gastroenterol 2010 April 7; 16(13):1685-9

Anorectal fistula closure
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 Colonoproctology (DGK). In his paper he refers to OTSC Proctology as a new therapeutic alternative.

Neue Techniken bei der Therapie der Anal fistel
Herold A. | Chirurgische Allgemeine (2013); 14: 99–102

March 2013 | Prospective trial on OTSC Proctology in anal fistula treatment presents first data
March 6, 2013. The annual conference of the German Society for Colonoproctology (DGK) was held in Munich, March 6 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 and the German Anorectal Center (EDZ) (Dr. A. Joos, Prof. Dr. A. Herold, PD Dr. D. Bussem, Mannheim).
The trial presented an interim analysis on the first 15 patients. Inclusion criteria are supra-, extra- or high-transsphincteric anal fistula, including first recurrence but excluding patients with IBD.
Mean follow-up was 6.9 months (1–15 months) after OTSC placement. 8 patients had already completed follow-up (6 months), 7 patients were still followed. In patients who had already completed the trial, mean follow-up was 10.8 months (6–15 months).
In these patients the healing rate, defined as post-surgical closure of the fistula, absence of drainage from the fistula and absence of recurrence after 6 months was 88%.
In his presentation PD Dr. R. Proßt, Stuttgart, coordinator of the trial, summarized that data were encouraging but completion of the trial had to be awaited. The trial is expected to close in 2013.

www.mcn-nuernberg.de/DGK2013/programm_98032013.php

February 2013 | OTSC Proctology – description of operative technique in MITAT
PD Dr. R. Proßt and 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 inner orifice of the fistula, debridement of the fistula tract and clip closure of the fistula.
They also present an indicative case study of a 54-year old female patient suffering from a high transsphincteric anal fistula and recurrence after unsuccessful prior surgery. After transanal clip release from the OTSC Proctology applicator, the internal fistula opening was adequately closed by the clip. Eight months after clip closure the fistula had permanently healed. The authors conclude fistula closure using the OTSC Proctology system represents a promising sphincter-preserving minimally invasive procedure.

The OTSC Proctology clip system for anorectal fistula closure: the „Anal Fistula Claw“: Case report
Proßt RL, Ehni W
[Epub 2012 Jun 4]

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