January 2013 | OTSC used to prevent stent migration in the treatment of anastomotic leak
Toshniwal J et al. reported about the use of the OTSC System to anchor a fully covered self-expandable metal stent to prevent stent migration. The patient underwent distal esophagectomy with gastric pull-up. The stent was placed to a post-operative anastomotic leak in the esophagus. However, the stent partially migrated into the stomach. The stent was then repositioned onto the leak. The OTSC System was placed using the OTSC Twin Grasper to grasp the stent edge and suction. After application the OTSC clip fixed the stent to the esophageal wall. Follow-up showed successful closure of the anastomotic leak.

The authors conclude that the placement of the clip was easy, fast and prevented stent migration effectively. The fixation of stents is not a common indication for the OTSC System and there is only very limited experience.

Combination of the “bear claw” (over-the-scope clip system) and fully covered stent for the treatment of post-operative anastomotic leak
Full-text link: http://dx.doi.org/10.1055/s-0032-1310033

December 2012 | Closure of anastomotic leaks and chronic fistulas in the digestive tract: best results in earlier treatment cases
Dr. Selcuk Dijibeyzay and co-authors, Department of Gastroenterology, Istanbul University, Ankara, reported 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 median time between diagnosis of the defect and OTSC clip placement was 35 (20–80 days) days in the cases with successful placement and 70 days (38–94 days) days in the unsuccessful cases. The median defect size was 15 mm (5–20 mm). In 4 cases clip deployment was not undertaken, due to strong tissue fibrosis. No clip-related complications were encountered.

Endoscopic closure of gastrointestinal defects with an over-the-scope clip device. A case series and review of the literature

December 2012 | OTSC effective in closure of chronic esophago-jejunal anastomotic leaks after total gastrectomy
Prof. Dr. Gennaro Galizia and co-workers from the Second University of Naples, Italy recently described the application of OTSC clips in the treatment of postsurgical anastomotic failure after total gastrectomy. In a case series of 3, patients that developed anastomotic leaks after gastrectomy and Roux-en-Y jejunal transposition and esophago-jejunalostomy 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 not infrequent challenge in such patients.

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

December 2012 | The interesting case: ERCP-related jejunal perforation managed by OTSC clipping
In a recent issue of Gastrointestinal Endoscopy Dr. Buffoli and colleagues, Digestive Endoscopy and Gastroenterology Unit of the Hospital Institutes, Cremona, Italy, presented an interesting case report on OTSC clipping for jejunal perforation closure: An 85 y/o woman with bile obstruction due to pancreatic cancer presented with jaundice. The patient had Bilroth II anatomy from gastric resection due to a peptic ulcer 35 years in the past. Cholangiography showed a bile duct stricture. An endoscope-related perforation of the jejunum with a size of about 20 mm was visualized distal to the papilla. After placing a covered self-expanding stent through the biliary duct stricture 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 jejunal was successful. Retropertioneal fatty tissue was additionally pulled into the cap by suction and created a “retroperitoneal fat patch”. Abdominal CT revealed retropertitoneal air but no free liquids. The patient received parenteral nutrition and antibiotic treatment. The patient remained symptom-free and the jaundice disappeared. Control CT after 20 days demonstrated complete absorption of the air and the patient was discharged.

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

Endoscopic “retroperitoneal fatpatch” of a large ERCSP-related jejunal perforation by using a new over-the-scope clip device in Bilroth II anatomy (with video)

November 2012 | First publication of Japanese experience with OTSC
In the recent issue of the World Journal of Gastroenterology Dr. Hirohito Mori published first Japanese experiences with the OTSC System.

Two elderly patients who had suffered iatrogenic lesions in the rectum (one large rectal perforation with abscess forma- tion and one recto-vesical fistula). Both patients were not subject to a surgical intervention for poor general condition, and thus were successfully treated with one OTSC clip each. Both interventions resulted in a dramatic improvement of the patients’ status. It should be noted that both patients underwent direct endoscopic lavage before closure. This is noteworthy especially in the case with the abscess where no pararectal drainage was inserted.

The authors state: “The endoscopic closure of perforations and fistulae with OTSC is a simple and minimally invasive technique. Given the complete closure and healing of large fistula in our two cases, this approach may be less expensive and more advantageous than surgical closure.”

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

November 2012 | Efficacy of OTSC for the treatment of colorectal postsurgical leaks and fistulas: 86% overall success rate
Anastomotic leaks and fistulas are a severe complication in colorectal surgery. The incidence of clinically relevant leaks is in the range of 3–6% of cases.

Prof. Dr. Alberto Arrese 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 was 9.1 mm in diameter. One OTSC clip of either size 11 or 12 was sufficient in all defects. In one case two separate defects were treated in the same patient. In 8 cases the leak was a fresh, acute lesion, in 6 cases a chronic fistula. The overall success rate of durable defect closure in this prospective case series was 86%; for acute cases it was 87% and for chronic cases 83%. No OTSC-related complications were reported. Re-surgery was needed in 1 case, in a second failure case the patient refused re-surgery and was left untreated.

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

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

November 2012 | Performance of the OTSC System in the endoscopic closure of gastrointestinal fistulae – a meta-analysis
The recent issue of “Minimally Invasive Therapy & Allied Technologies” publishes a systematic review and meta-analysis on the challenging field of closing gastrointestinal fistulae by means of the OTSC System. The paper provides an extensive overview of relevant primary clinical research, case reports and conference abstracts published on this topic. The statistical evaluation of, in total, 19 examined articles revealed a high rate of procedural success (mean 84.6%; 95% confidence interval 66.6% to 93.8%) and durable clinical success (mean 69.0%; 95% confidence interval 51.8% to 92.2%) in OTSC-mediated closing of GI fistulae.

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

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

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

The study was limited to clinical publications and covered key applications of the OTSC System: hemostasis, closure of acute GI lesions (perforations) and chronic GI lesions (fistula). Only clinical reports with >4 patients were included into the survey, that was carried out by Dr.
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 revealed an ulcer with a 2-mm thick pulsating vessel. Injection therapy was difficult due to the fibrotic tissue. Thus OTSC placement was decided. To mobilize the target tissue into the cap, two edges of the ulcer were grasped by each of the two jaws of the OTSC Twin Grasper. After retraction of the grasper and additional suction the OTSC was applied and immediate hemostasis achieved.

The authors conclude that the OTSC was effective for hemostasis in this fibrotic ulcer which was very hard to treat with other endoscopic methods. They state that the placement of OTSC was quick and easy resulting in 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, Zabieński M, Mönkemüller K
Gastrointest Endosc. 2012 Oct;76(4):917-8

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

Barcelona, September 21st 2012: The 24th conference of the Society for Minimally Invasive Therapy (SMIT) was held in Barcelona, Spain, under the presidency of Dr. Enric Laporte. Prof. Dr. Alberto Arezzo and colleagues, 2nd Dept of General Surgery, University of Turin, Italy, presented latest data of 25 clinical cases with postsurgical anastomotic leaks or fistula after colorectal surgery.

In the general literature anastomotic leaks have an incidence of about 7-9% after laparoscopic or open colorectal surgery.

In the 25 cases prospectively collected in Turin, 21 were successfully treated with endoscopic OTSC clipping alone. This is a success rate of 84%. In 3 patients the fistula did not heal, and in 1 patient additional surgery was needed to close the defect.

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

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

Arezzo A, Verna M, Redavid R, Cravero F, Bonino MA, Mormo M

OTSC® update 11

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:

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

The authors conclude that although OTSC being “promising, further clinical experience will help to identify the optimal role and indication for OTSCs 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 hemorrhage: 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 established techniques.”

In the NOTES chapter they state that even though the number of NOTES related papers were on the decline the management of iatrogenic perforations of the gastrointestinal 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 interesting studies at UEGW 2011: Apart from two cited papers (v. Renteln et al. Endoscopy 2011; 43: 01A47, Hud 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, Endoscopy 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 features 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 suitable 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.

Gastrointest Endosc. 2012 May; 75 (5): 2012 933-7 [Epub 2012 March 23]

Ovesco takes the liberty to add 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 fibrotic tissue and difficult access environments.

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 below “June 2012 | OTSC® in emergency hemorrhage: 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.

OTSC® update 10

July 2012 | Experimental study from Norway confirms efficacy and safety of OTSC® in gastric closure for NOTES

Researchers at St. Olavs University Hospital, Trondheim, Norway report about a new experimental trial in the porcine animal model (n=15). After transgastric approach had been established and flexible pentonoscopy had been performed, gastrotomy closure with OTSC clips and T-bars was studied.

The safety of closure was tested with the methylene blue test after the procedure. The animals were kept for 2 weeks postoperatively and then re-operated for sample retrieval and histological examination. No postoperative complications were found and the methylene blue test did not reveal any leaks. Histology demonstrated full-thickness healing of all gastric lesions. Differences between both closure methods were not observed.

Efficacy and safety of transgastric closure in natural orifice transluminal endoscopic surgery using the OTSC system and T-bar sutures: a survival study in a porcine model

Suhail AH, Mårvik R, Halgunset J, Kryhus E
Surg Endoscopy. 2012 May 2 Epub ahead of print

July 2012 | First North American literature report on OTSC®

In a recent issue of the Canadian Journal of Gastroenterology, Dr. T.H. Koithan, 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 fistula. A case report describes the use of OTSC in a patient with a persistent gastrointestinal fistula after PEG feeding tube removal. 2 clips were placed to occlude the gastric orifice 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 demonstrate efficacy of the OTSC system in the closure of gastrointestinal fistula.

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

Kothan TH, Haber G, Sonpal N, Karanth N
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 Kraft, 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 and different locations. 69 OTSC clips had been placed in these patients. In 19 cases OTSC clipping was chosen due to acute failure of conventional other hemostatic 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.

http://www.sw-gastro.de/haupt/kongress.php

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 hemicolectomy

Arezzo A, Reddavid R, Verra M, Cravero F, Bonino MA, Morino M (S24, Thursday)

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 (S13, Thursday)


June 2012 | OTSC® in bariatric procedures: 30th GEWE workshop, Brussels, 18-20 June 2012

From June 18 to 20 the 30th GEWE – 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 gastro-jejunal 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 satisfying weight loss.

The OTSC® Clip in Revisional Endoscopy Against Weight Gain After Bariatric Gastric Bypass Surgery

Heylen AM, Jacobs A, Lybeer M, Probst RL

Obesity surgery 2011 Oct;21(10):1629-33

www.live-endoscopy.com

June 2012 | Successful gastric closure with OTSC® in porcine NOTES feasibility studies

Bernhardt et al. used the OTSC for gastric access closure in a recent pure NOTES sigmoid resection study in the porcine model. According to the study pure NOTES resection and anastomosis of the large bowel are feasible. The gastric access was successfully closed in all five animals using one OTSC clip and with the help of the OTSC Twin Grasper. Histology after 35 days showed the clip still in place and a healed gastric access site without adhesion or irregular scar formation.

Another recent pure NOTES porcine study by Donatsky et al. showed immediate closure of gastric access site in all ten pigs using the OTSC clip.

Pure NOTES sigmoid resection in an animal survival model


Endoscopy. 2012 Mar;44(3):205-9

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Pure NOTES sigmoid resection in an animal survival model


Endoscopy. 2012 Mar;44(3):205-9

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

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

Trattamento di duplice fistola anastomotica entero-cutanea dopo emicolectomia destra mediante Over The Scope Clip (OTSC)

Alberto Arezzo, Rosasella Reddavid, Mauro Verra, Francesca Cravero, Marco Augusto Bonino, Mario Morino

Casino Clinico proposto da Alberto Arezzo. Pubblicato il: 11/10/2012

Chirurgia Digestiva, Collettore e Mininvasiva; Dipartimento di Discipline Medico Chirurgiche; Università degli Studi di Torino

Click here to view the video:

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

At this year’s Congress of the German Society of Surgery in Berlin – 120th Congress of the Deutsche Gesellschaft für Chirurgie (DGCH), 24 - 27 April 2012 – Ovesco’s products were featured by Prof. Thomas Lehniert, Bremen and Prof. Ulrich T. Hopt, Freiburg during the session on „Management of post-surgery septical complications/anastomotic leakage“. Lehniert who reported on the upper GI tract also cited his good clinical experience with OTSC regarding severe bleedings of e.g. the duodenum. Hopt 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 behind the leak.

April 2012 | Pre-clinical research: Ovesco’s FTRD tested for resection of gastric submucosal tumors

Ovesco is conducting research on endoscopic full thickness resection techniques. Its FTRD-full thickness resection device is in late pre-clinical development for use in the colon. D. von Renteln and colleagues recently reported about the application of FTRD for resecting artificially created submucosal tumors in the porcine animal model (n=6);

The median procedure time was 15 min. Successful resection of the artificial submucosal lesion was achieved in 4/6 (67%) cases. Successful full thickness resection of the gastric wall was achieved in 3/6 (50%) cases. In all cases, the OTSC closed the resection site completely.

The current version of the device is designed for colonic application and not matched for harvesting thicker gastric tissue. However, the authors conclude that gastric resection is technically feasible with FTRD.

FTRD is not yet available for clinical use.

Endoscopic Full-Thickness Resection of Submucosal Gastric Tumors.Closure of Acute Perforations of the Gastrointestinal Tract

von Renteln D, Rösch T, Klaft T, Denzer UW, Elf-Maary S, Schachtschall G


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 XXXXIst 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 „Endoskopiheute“, the official journal of the DGE-BV.

Des 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 was the Dom case series of 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, Fährndich M

In a further paper, the same authors reported on the use of OTSC in a clinical case series with full-thickness colon resection (n=8). In 4 patients polypectomy revealed T1 colon cancer, in 3 patients an accidental carcinoid was found and in 1 patient local recurrence after several mucosectomies for colonic adenoma. In all these cases an 14-size OTSC system was deployed to close the full thickness of the wall after the lesion had been pulled into the OTSC application cap. Then a snare was used to cut the folded tissue just above the level of the clip. Complete lesion removal, confirmed by histology was achieved in all 8 cases. In 5 cases the level of resection was in the deep muscular layer and in 2 cases the entire wall layers were involved. The authors conclude that deep wall or even full thickness resection with wall closure by OTSC is safe and fast and can be seen as an alternative to surgical resection in specific clinical cases.

FV19 Ergebnisse der endoskopischen Vollwandresektion im Gastrointestinaltrakt mithilfe des OTSC-Systems

Fährndich M, Sandmann M, Heike M

The group of Prof. Hochberger from Hildesheim presented their results of a consecutive series of 40 OTSC interventions. In 65 % 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 were discharged without 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 the OTSC clinical model.

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 Erfangen 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 infected 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 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 mucosal 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-Sigmaresektion in einem Tier-Überlebensmodel


Further presentations dealt with the application of the OTSC system:

Over-clip bei Fisteln und Anastomoseninsuffizienz

Fährdich M, Dortmund

Ovesco-Clip bei iatrogenen Perforationen und zum Verschluss von Vollwandresektionen von Renteln D, Hamburg

Endoskopische Vollwandresektion von subepithelialen Magentumoren (EndoResectStudie)

Schlag C, von Delius S, Feussner H, Wilhelm D, Meinring A, München

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

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

Transgastrale Appendektomie

Kähler G, Mannheim

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

Stenfizierung mit Hilfe des OTSC-Systems zur Verhinderung der Stentmigration

Fährdich M, Sandmann M, Heike M, Dortmund

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


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


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, 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 gastroduodenal, 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 (detected by 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 89% (95% confidence interval, 75% – 96%). 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


March 2012 | OTSC® closure of esophageopericardial fistula

In the recent issue of the journal Endoscopy C Gubler and P Bauerfeind, Dept. of Gastroenterology and Hepatology, University Hospital, Zurich, Switzerland, report about the use of an OTSC clip for closing an esophago-pericardial fistula. A 56 year old female patient had received a lung transplant and was under triple immunosuppression. She developed a septic postoperative course with atrial fibrillation, septic shock and renal failure. CT revealed pneumopericardium, which was shown to be caused by an esophago-pericardial fistula through endoscopy. As an acute measure, a covered self-expanding metal stent was placed. After general improvement of the clinical condition of the patient the stent was removed and an OTSC clip of the type 11/3/a was placed. After 6 days the pericardial drain could be removed and closure of the fistula was confirmed by radiography. 4 weeks after the treatment that patient was on an oral diet with no further signs of pericardial effusion.

Successful closure of an esophago-pericardial fistula with an over-the-scope clip

C Gubler, P Bauerfeind | Endoscopy 2012; 44:E1-E2

March 2012 | OTSC® for treating anal fistula in proctology

The use of a new OTSC® clip, modified for proctology, has been described by R. Pross et al. in the journal Colorectal Disease. OTSC®, an established endoscopic clipping system, has been adapted to meet the requirements for application in the anal canal. The authors present the data of a successful pre-clinical trial in which the new OTSC® Proctology system was studied for closure of anal fistula in the porcine animal model.

Artificial anal fistula had been created in 10 cases. Closure with OTSC® Proctology was achieved in all cases. No complications were encountered. Compared to control fistula, left untreated in each animal, OTSC® clipping demonstrated superior results. 40% residual tracts and a more intense chronic inflammation were seen in the untreated control fistulas. After clip placement a higher density of collagen fibers indicated a better fistula scarring and healing.

The authors conclude that fistula closure using the OTSC® clip represents a promising sphincter-preserving minimally invasive procedure.

The Anal Fistula Claw: the OTSC-clip for anal fistula closure

Pross RL, Horald A, Jooa AK, Bussen D, Wehrmann M, Gottwald T, Schurr MD

Colorectal Dis. 2011 Nov 28 [Epub ahead of print].

OTSC® Proctology is a CE-marked medical device of Ovesco Endoscopy AG and is presented at the meeting of the German Society for Coloproctology in Munich, Germany (Deutscher Koloproktologen-Kongress; 15–17 March 2012 Hilton Munich Park | Am Tucherpark 7 | 80538 Munich OTSC® Proctology is not cleared by the FDA for clinical application in the United States.

OTSC® update 9

March 2012 | OTSC® is superior to other endoscopic clips in acute upper GI hemostasis in the experimental setting

The treatment of severe upper GI hemorrhage is one of the foremost indications of the OTSC® clip. Due to its size and compression force OTSC® is effectively used in peptic ulcer bleeding.

A recent prospective randomized trial, carried out by investigators from the USA, Japan and Korea has underlined the superior performance of OTSC®. The study was conducted by M Kato, J. Yung, MA Gromski, R Chuttani and K Matthes (Boston, Tokyo, Seoul) and was carried out in a standardized ex vivo animal tissue hemorrhage simulation (EASIE-R). Sprunting vessels were created using porcine stomach. The vessels were connected to a pressure transducer to measure the circulating blood substitute pressure in order to determine closure of the sprunting vessel. Two conventional endoscopic clips (QuickClip 2, Olympus, Resolution clip, Boston Scientific) and the OTSC® clip (Ovesco) were compared. 15 bleeding sites at randomized locations inside the stomach were treated with each of the clipping systems. Main outcome measurements were the time and the number of clips needed to achieve hemostasis, determined as a pressure increase in the circulation system. The mean number of clips needed was 1 +/- 0.3 for OTSC 2, 2 +/- 0.4 for Resolution and 2.5 +/- 0.4 for QuickClip 2. The lower number of clips needed in the OTSC® system was statistically significant (p<0.05) against both other devices. Mean procedure times to complete hemostasis were 49.2” +/- 1.8 s, 284.1” +/- 4.4 s and 336.8” +/- 4.7 s. OTSC® procedure time was significantly shorter than Resolution (p<0.05) and QuickClip 2 (p<0.001) procedure times. For changes in pressure significant differences between the 3 systems
were only found in the area of the fundus, where OTSC® had significantly higher pressure change than both other systems. The authors conclude that the differences observed between the 3 devices in terms of usability and efficacy were significant and OTSC was found superior to the other systems.

Prospective, randomized comparison of 3 different hemoclips for the treatment of acute upper GI hemorrhage in an established experimental setting


January 2012 | OTSC® has greater hemodynamic efficacy in stopping spurting bleeding in the EASIE model than other endoscopic clips

Dr. A Naegel, Dr. J. Maiss and colleagues from the 1st Department of Medicine at Erlangen University Hospital, Erlangen, Germany, published the results of an ex vivo trial on OTSC® in the treatment of upper GI hemorrhage in the January issue of Gastrointestinal Endoscopy. The setting of the trial was prospective for studying OTSC® and used a histologic control group of alternative endoscopic clips, studied earlier under identical model conditions. The Erlangen Active Simulator for Interventional Endoscopy (EASIE), used for the study, represents a well-established and standardized ex-vivo model for training and research. The EASIE model is equipped with an active and pressure-controlled bleeding simulator, operating a close to physiologic hemodynamic conditions. Two investigators took part in the trial, each treating 16 standard EASIE bleeding sites. Both investigators used either suction through the scope for positive pressure or the OTSC® applicator cap at the bleeding site or the OTSC® Anchor (n=8, each application condition). Systemic pressure in the EASIE circulation system was measured one minute before, during and one minute after clip application to objectify the effects of clipping on the vessel diameter. Result in result, OTSC® clipping led to significant increase of systemic pressure (indicating effective hemostasis) and vessel diameter decrease (p<0.001). The application technique had no significant effect on the main outcome variable. Historic comparison with conventional endoscopic clips, studied earlier, demonstrated a significantly higher hemodynamic efficacy of the OTSC® system.

January 2012 | Experimental trial on full-thickness perforation closure with OTSC®: defects 20 to 30 mm safely closed with one clip

The Boston research group around Dr. K. Matthes, Neurath MF, Maiss J. presented their data on the OTSC® prototype: the colonic wall was pulled and sucked up to 30 mm with one clip. Mean burst pressures were 117.9 +/- 40.1 mm Hg for 20-mm defects and 57.4 +/- 4.2 mm Hg for 30-mm defects. 35-mm lesions were not adequately closed with one clip. The authors see the limitations of their study in the ex-vivo conditions and the endoscopy simulator situation which may not reflect clinical conditions. For larger lesions than 20 mm in the stomach or 30 mm in the colon more than one clip is needed.

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

Dr. Mitthoe H. Strain and colleagues from the Dept. of Gastroenterology of Victor Babes University Hospital, Timisoara, Romania, reported about an unusual case of lower GI hemorrhage. A male 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 OVELSCO System


December 2011 | Closure of therapy-resistant enteric fistula with OTSC® clip and OTSC® anchor

PD Dr. J. Grossmann and colleagues, Evangelisches Krankenhaus, Moenchengladbach, Germany, report about a special case of OTSC® treatment in the recent issue of Deutsche Medizinische Wochenschrift.

A patient suffered from recurrent subphrenic abscesses following a complicated postoperative course after sigmoidectomy for chronic recurrent diverticulitis. Two previous attempts of abscess treatment by transectional drainage had failed. Radiographic studies revealed a fistula of the descending colon leading to the abscesses formation. An OTSC® clip was applied on the enteric fistula, retracted by means of the OTSC® anchor. This led to complete closure of the fistula within four days as demonstrated by radiographic studies and a repeated fistulography. Subsequently the transcaneous drainage was successfully removed within 14 days of OTSC® application without recurrence of abscess formation.

Endoskopischer Verschluss einer chronischen Fistel des Kolons unter Anwendung des „Over-the-scope“-Clips (OTSC®) [Article in German]


January 2012 | 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. Kirchmair et al., Dept of Surgery, Tuebingen University, Tuebingen, Germany, summarizes data of 37 original Medline-referenced publications. This includes 29 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.

OTSC®-Clipsystem – Klinische Anwendungen und Experimentelle Erfahrungen – Systematischer Review


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 due to other treatments, 1 from a laceration at the GE junction after balloon distillation 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 79%. 2 complications were reported, 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 an overview about the results of other OTSC case series reported in the literature. The overall success rate in these cases was 86%.


Edis Wéd, Germany; Detlev Menke; Elena Kruse; Jürgen Hochberger

Marc Barthel, 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 gastrocutaneous 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. Barthel 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 Mercky; Jean-François Demarquay; Rémy Dumas; Veronique Vitton; Jean-Charles Grimaud; Marc Barthel

(Paper accepted for publication in GIE.)

Daniel v. Renteln from the Hamburg (Germany) group of Thomas Rösch presented data from an animal study where they created 2-3 cm large lesions in the distal colon with an OTSC® prototype: the colonic wall was pulled and sucked into a large transparent cap, electric snare and special OTSC® clip preloaded. Full resection was successful in all 8 animals, in one case 2 additional clips had to be placed for complete closure, in one case clip release failed. Altogether the authors conclude that this device allows for reliable full-thickness resection and closure of the colonic wall in a single procedure as well as reliable wound healing of EFTR defects.

OP020 ENDOSCOPIC FULL-THICKNESS RESECTION AND DEFECT CLOSURE OF THE COLON WALL USING A CLIP AND CUT TECHNIQUE

Daniel von Renteln, Germany; Thomas Kratt. Thomas Rösch; Ulrike Denzer; Guido Schachshal

Full paper: GIE 2011 Nov; 74(5): 1108-14
A remarkable oral presentation was given by Anne Vijver and all but 2 perforations were controlled by endoscopic resection in 87% of cases. He emphasizes that all bleedings procedures with en-bloc resection rates of <95%, and R0 Martin Krak; Jana Maluskova; Eva Kieslichova; Martin Oliverius; Julius Spicač

The Munich (Germany) group around A. Meining reported of 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 cu-
rd with an OTSC® clip. 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 en-
counters with transgastric endoscopic surgery.

P1080 ENDOSCOPIC FULL THICKNESS RESECTION OF GASTRIC SUBEPITHELIAL MASSES – A STEP TOWARDS NOTES?
Christoph Schlag, Germany; Stefan von Delius; Hubertus Feussner; Dirk Wilhelm; Ananela Beitz; Roland M Schmidt; Alexander Meining

Donatsky et al. evaluated the feasibility of combining trans-
gastric (TG) pure NOTES peritoneoscopy and intraperitone-
el EUS (iEUS) with intraluminal EUS (iEUS) for peri-
meal evaluation, and the safety of EUS-guided access and OTSC® clip closure in a survival model with 10 pigs. All ani-
mals survived with histologically proven full-thickness closure again with signs of inflammation and micro-abscesses. They conclude that NOTES peritoneoscopy and iEUS 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 PERITO-
NEOSCOPY AND INTRAPEITONEAL EUS. A PORCINE SURVIVAL AND FEASIBILITY STUDY
Anders Melter Donatsky; Denmark; Louise Andersen; Ole Berthelsen; Cilbe; Barbara Holtecnicht; Peter Vilsmann; Saren Meisner; Lars Nannestad Jergensen; Jacob Rosenberg

Thomas Hud et al. reported of 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 ca-
s 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 NOTESASSISTEDMINILAPAROSCOPICTRANS-
GASTRIC CHOLECYSTECTOMY
Tomas Hudc, Czech Republic; Matej Kock; Marek Benes; Martin Krak; Jana Maluskova; Eva Kieslichova; Martin Oliverius; Julius Spicač

Pierre H. Deprez gave an oral presentation on 193 ES3 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-
ans including the use of the OTSC® system. A remarkable oral presentation was given by Anne Vijverman from the group of P. H. Deprez on the outcome of intraga-
teric 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 con-
cluded that their high rates of successful endoscopic ma-
nagement of iatrogenic perforations led to better outcomes in terms of length of hospital stay compared to surgery.

P0447 BETTER OUTCOME OF ENDOSCOPIC MA-
AGEMENT VS SURGERY FOR UPPER GASTROIN-
TESTINAL PERFORATION
Anne Vijverman, Belgium; Hubert Pissuvaux; Tanik Aouat-
tat; Jean-François Giot; Pierre H. Deprez

September 2011 | Viszeralmedizin 2011 in Leipzig, Germany, 15–17 September 2011 – Surgeons recommend the OTSC® System for the closure of anastomotic leaks and fistulas At the joint congress of the DGVS and the DAVG (German society of digestive & metabolic disease and German soci-
ety of general and visceral surgery) the OTSC® System was discussed by surgeons and gastroenterologists in the session Complications with interventions in the upper GI tract. Following lectures titled “Therapeutic concept for intrathora-
cic anastomotic insufficiency” and “Therapeutic concept for intrabdominal anastomotic insufficiency” session partici-
pants were sharing their clinical experience with the device. Both presenters are positive about the OTSC® System as an endoscopic device for the closure of anastomotic leaks and fistulas. One surgeon reported on his clinical experience where the OTSC® System was successfully used for the closure of two anastomotic leaks.

September 2011 | Endoscopic treatment of perforated peptic gastric ulcer: case report of two patients The surgical unit CLINTEC, Karolinska Institutet vid Karo-
lingska Universitetssjukhus Huddinge, Stockholm, Sweden, reports of a 42-year old woman with a 3x4-mm perforation in the antrum which was successfully treated with the OTSC® System. The patient was discharged after 4 days. At follow-
up, a month later, the patient presented fully recovered. The second patient, a 35-year old man, had a 23-mm perforation which could also be closed successfully using two OTSC® clips. The authors conclude that endoscopic closure with the OTSC® System offers an interesting alternative to conventi-
nal surgical treatment of peptic ulcer perforations.

At behandla perforerade peptiska ventrikels-med endoskop; fallrapport på två patienter
Fredrik Swahn, Lars Enochsson, Magnus Nilsson, Lars Lundell, Matthias Lühr, Urban Ameloe

Endoskopisk behandling av gastrocutanea fistula.

September 2011 | Closure rate of 90% in fistulas, anastomotic leaks and perforations treated with OTSC®: a 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 a series of 10 patients with penetrating defects within the digestive tract. Pathologies were fistulas (esophagotracheal, esophagopleural, gastrocutaneous and colocolic), perforations (after mucosectomy, after papilo-
tomy and PEG misplacement) and anastomotic leakages (after gastrostomy 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, Anastomomal Leaks and Perforations within the Gastrointestinal Tract

August 2011 | OTSC® clip among most promising technologies for closure of perforations in the digestive tract In the latest issue of the Spanish journal Gastroenterolo-
yga y Hepatología Dr. F. Junquera and colleagues, from the Servicio de Aparato Digestivo, Corporación Parc Taulí, Sabadell, Spain, describe the OTSC® system and its use in gastrointestinal tract perforations. The authors conclude that OTSC® is one of the most promising technolo-
gies for closure of perforations of the gastrointestinal tract because of its efficacy, safety and rapidity. Other indications include severe gastrointestinal bleeding, fistulae, anasto-
motic leaks, and bariatric surgery anastomosis remodelling.


August 2011 | OTSC® clamping for closure of gast-
rucutaneous fistula after surgery for peptic ulcer Dr. G. Koulkidas and colleagues from the University Gene-
ral Hospital of Alexandroupolis, Greece, describe a case of gastrocutaneous fistula after surgical treatment for a perfo-
rated gastric ulcer. By means of OTSC® clip placement the fistula was successfully closed. Therapeutic success was verified at the 2nd and 6th week after the application of the clip. The authors judge endoscopic application of the OTSC® device was safe and effective for the treatment of a gastrocutaneous fistula.


August 2011 | Endoscopic Full Thickness Re-
section with OTSC® as a spin-off from NOTES research for the therapeutic gastroenterologist
The research in natural orifice transluminal endoscopic sur-
gery (NOTES) has brought significant advances in flexible endoscopy in a recent overview in Minerva Gastroenterolo-
ica & Diabetologia RR Watson and CC Thompson analyse NOTES research and indicate candidate NOTES spin-off procedures. Among them is Endoscopic Full Thickness Re-
section of GI lesions with subsequent full thickness closure of the organ wall with an OTSC® clip by Ovesco Endoscopy. Preclinical research at Ovesco includes combined me-
chanisms for full thickness resection of polyps, adenoma or other suitable lesions, and a Technical Report on the prototype of a dedicated Full Thickness Resection Device (FTRD) has been recently published by MO Schur et al. in Minimally Invasive Therapy & Allied Technologies.

NOTES spin-off for the therapeutic gastroenterolo-

Endoluminal full-thickness resection of GI lesions: A new device and technique MO Schur, F Baur, ON Ho, G Antloch, T Kratt, T Gottwald Minimally Invasive Therapy. 2011;20:189-92
July 2011 | Removal of over the scope clips (OTSC) with an Nd:YAG Laser.

Fähndrich et al. from Dortmund recently reported of 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 oesophagomediastinal 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]

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 necrotizing pancreatitis to gastro-cutaneous fistulas and postoperative leaks). The follow-up time ranged from 6 to 68 weeks.

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


June 2011 | Clinical case studies on OTSC® presented at Hungarian gastroenterology congress

At the 53rd Annual Meeting of the Hungarian Society of Gastroenterology (4 – 7 June 2011 in Tihany) Dr. János Búngéi from the Boros-Abázi-Templen County Hospital, Miskolc, Hungary, reported about unusual clinical cases successfully treated with Ovesco’s OTSC® clip. The cases included the closure of an oesophageal fistula due to suture line failure after esophagogastrectomy and the management of gastric hemorrhage from a Dieulafoy ulcer.

June 2011 | Cost advantages for OTSC® treatment of gut fistula compared to surgical alternative

Referring to our news on the case report of April 2011 we are glad to let you know that the paper is now available as FREE ACCESS article under https://www.thieme-connect.de/ejournals/kooperation/62/13_06040671238Be8fg 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 therapecutic 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 gastro-intestinal fistulas using an over-the-scope-clip (OTSC) device: Case series from a tertiary referral center


May 2011 | Case report: closure of broncho-oesophageal fistula

In the April issue of the journal Gastrointestinal Endoscopy A Rebelo and colleagues, Ave Hospital, Guimaraes, Portugal, present a case report with closure of spontaneous esophageo-bronchial fistula in a lung cancer patient, after radio-chemotherapy. 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 orifice the OTSC® clip also worked as an anchoring 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-oesophageal fistula

Rebelo Ana, Mouinhinho-Ribeiro Pedro, Cotter José. Gastrointestinal Endoscopy 2011;73:4 833-4

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 gastro-intestinal 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 was 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 Kirschniak 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 preemptive 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


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

F. Iacopini, A. Scizzoraro and colleagues reported the emergency use of an OTSC® clip in a patient after col- lar stabling injury in suical intent at the 17th National Congress of the Italian Society for Digestive Disease (FISMAD), Torino, Italy, March 3-9, 2011. After self-inflicted stabling injury of the neck an elderly female patient with a history of severe depression was admitted to the S. Giuseppe Hospital, Albano Lazio, Rome, Italy. Endoscopy revealed a 12-mm cut of the left lateral wall of the hypopharynx. The lesion was endo- scopically closed by means of an OTSC® clip. 3 days af- ter the procedure normal contrast swallow with gastro- intestinal demonstratated normal liquid passage, a CT-scan showing no mediastinal emphysema or fluid collection. The patient had some discomfort with pharyngeal for- eign body feeling. After 5 weeks the clip detached and was swallowed by the patient without complications. The further course was uneventful.

March 2011 | OTSC® comparable to surgical suture for the closure of colonic perforations in a standardised porcine model

RP Voermans et al. report of an animal series of ex vivo colonic perforations that were treated with several methods, surgical suture being considered the gold standard.

Mean colotomy leak pressure (mm Hg) as primary outcome was comparable in surgical suture, flexible staplers, and OTSC®.

Comparison of endoscopic closure modalities for standardised colonic perforations in a porcine colon model


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 eventu- tally resected safely. The procedure was broadcasted by Germany’s largest public broadcasting company WDR. Co- logne. Audience ratings indicated almost 1 million viewers of the transmission.

February 2011 | EURO-NOTES working group report: safe closure with OTSC®

The 4th EURO-NOTES Meeting, Rome (September 2010) was also the venue for the official working groups of EURO-NOTES. The report of the working group meet- ing was recently published in the journal Endoscopy. With regard to closure of transmural access lesions in NOTES the report states that several studies menti- oned safe access and closure with new devices such as anchor systems or Ovesco’s large scale clip (OTSC®)

Natural-orifice transluminal endoscopic surgery (NOTES) in Europe: summary of the working group re- ports of the Euro-NOTES meeting 2010

February 2011 | Advance notice: OTSC® System prominently represented at 41st Congress of the DGE-BV, 17–19 March 2011 in Munich, Germany

The 41st Congress of the German Society for Endoscopy and Imaging Procedures (Deutsche Gesellschaft für Endoskopie und Bildgebende Verfahren, DGE-BV) is held at The Westin Grand München Anantelbellum under the presidency of Prof. Dr. Hubertus Feussner.

Ovesco is present at the industry exhibition, booth #205. Ovesco is also sponsoring several workshops for advanced endoscopists.

Thursday, 17 March 2011, Hands-on Training at the EASIE simulator, Workshop 11+2 Komplikationsmanagement: Perforationen und postoperative Leckagen

Workshop J1 and Workshop J2
NOTES-Tool-Box und neue Technologien – Dissektoren, neue Blutstillungs- und Verschlusssysteme, Nahmaschinen.

Furthermore, the OTSC® System is dealt with in a number of presentations:
Thursday, 17 March 2011 | Room Atlanta Session 08:30 – 10:00 am, Expertenvideos I 09:42 – 10:00 am

Neue Methode der endoskopischen Vollwandresektion mit Hilfe des OTSC® Systems nach endoskopischem Resektion eines low grade kolorektalen Frühkarzinoms M Sandmann, M Heike, M Fändrich, Dortmund
Session 02:00 – 03:30 pm Expertenvideos II 02:36 – 02:54 am

Successful complication management of a colon perforation after PEG implantation with the OTSC® system M Fändrich, M Sandmann, M Heike, Dortmund
Thursday, 17 March 2011 | Room Barcelona Session 02:00 – 03:30 pm Freie Vorträge I 02:24 – 02:36 pm

Der „Over the scope clip“ (OTS®) zum Verschluss von intestinalem Leckagen und zur Therapie der intestinalen Blutung J Albert, M Friederich-Rust, S Zeuzem, C Sarrazin, Frankfurt Friday, 18 March 2011 | Ballsaal, Session 02:00 – 03:30 pm

Neue endoluminale und transluminale Verfahren Transgastrale Appendektomie – erste Ergebnisse der Toga-Studie G Kähler, Mannheim

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

January 2011 | Successful treatment of duodenal fistula after gastrectomy with the OTSC® clip Dr. R. Bini 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 was 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.


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 Mangiavillano, 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 fistula orifice was first reduced by an OTSC® clip, and a minimal 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 Mangiavillano B, Pissi A, Viaggi P, Arena M, Opocher E, Mangano M, Santoro T, Masei E J Gastrointest Oncol 2010; 1: 122-4

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 colorectal 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.

In 4 of the 7 patients no surgery was required and OTSC® clipping was sufficient. In 1 additional case a laparotomy 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.


November 2010 | Successful use of the OTSC® Clip in Revisinal Endoscopy Against Weight Gain After Bariatric Gastric Bypass Surgery Ahead of print Obesity Surgery published an article by Alex Heylen et al., St.-Ursula Hospital, Kuringen, Belgium, who report about the closure of a rectovesical fistula in a patient after gastrectomy with the OTSC® System after gastric bypass is reliable and effective in treating weight gain due to a dilated pouch-outlet with favorable short- and midterm results.

The OTSC®-Clip in Revisonal Endoscopy Against Weight Gain After Bariatric Gastric Bypass Surgery Heylen AM, Jacobs A, Lybeer M, Proll RL Obesity Surgery 2010 Sept 3 (Epub ahead of print)

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 a post-traumatic esphagopharyngeal fistula and a chronic gastrectomus 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 fistulae of the GI tract. It can achieve leakproof, 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.”


October 2010 | Ovesco OTSC® clip: Reliable full-thickness organ closure in experimental transgastric cholecystectomy, mean time required for closure is only 7 min.
A recent experimental study by RP Voermans et al., Academic Medical Center, Amsterdam, The Netherlands, reports about transgastric cholecystectomy and organ closure with Ovesco’s OTSC clip. The study was carried out in the porcine animal model (n=16). A hybrid-NOTES technique was used, adding two 2-mm trocars and one umbilical laparoscope. The survival follow-up time was 10 days. Main outcome parameters included technical procedural success and organ closure, uncomplicated survival and histology-confirmed full-thickness closure of the gastric access site. Transgastric organ closure was successful in all cases in a mean time of 7 min (SD 3 min). Necropsy demonstrated absence of infectious complications. Histology revealed full-thickness healing in all cases (95 % CI: 81-100 %). The authors conclude: “Use of OTSC for gastrointestinal closure is feasible, reliable and results in histology-proven full-thickness closure in survival porcine experiments.”


October 2010 | September issue of Endoscopy: The treatment of esophageal perforations with the OTSC® clip – a valid alternative to stenting The September issue of the journal Endoscopy discusses the use of the OTSC clip for the closure of esophageal perforations.
In the editorial, Dr. P. Eisenshtra, Brussels, Belgium, states that the use of larger clips, such as the OTSC clip, could reduce the number of clips that must be placed and the dedicated forceps (remark: OTSC Twin Grasper®) may help to overcome the difficulties in approximating the two edges of the leak.

Esophageal leaks: extending our toolbox? Eisenshtra P | Endoscopy 2010; 42:753-4

An initial case series (n=2) on endoscopic closure of postoperative esophageal leaks with the OTSC clip is presented.
In his state-of-the-art lecture, Prof. Paul Fockens, Amsterdam, The Netherlands, presented the data of the recent completed multi-centric single-arm CLIPPER trial on the closure of acute perforations in the digestive tract. Which demonstrate that OTSC is an effective treatment 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. 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.

In 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. Jürgen Hochberger, MD, PhD, Hildesheim, Germany, and co-authors describe the state-of-the-art in technical aspects and equipment for Endoscopic Submucosal Dissection (ESD). Perforations of the esophageal, 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 Bärng KF
Endoskopie heute 2010; 23: 24–33

August 2010 | Feasibility of endoscopic full-thickness resection using the OTSC® system
In the June issue of the journal Gastrointestinal Endoscopy D. von Renteln, MD and colleagues report about an experimental feasibility trial on full-thickness resection of the colon. They compared different modalities of applying the Ovesco OTSC® clip in conjunction with full-thickness resection of the colonic wall, using the grasp-and-snare technique. Depending on application modalities burst pressure tightness of 76.6 mm Hg (range 35–120; SD, 31) was reached, demonstrating the possibility of secure wall closure after full-thickness resection (FTR).

The authors conclude that colonic FTR using the grasp-and-snare technique is feasible in an animal model.

Endoscopic full-thickness resection and defect closure in the colon
v. Renteln D, Schmidt A, Vassaliou MC, Rudolph HU, Caca K
Gastrointestinal Endoscopy 2010 Jun; 71(7): 1267-73

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=8). 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 Parodi, A Repici, A Pedroni, S Blanchi, M Conio
Gastrointestinal Endoscopy 2010 (in press)

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 chemoradiation therapy.

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 XXX National Congress of the Portuguese Society of Gastroenterology in Vilaamoura, June 8-12, 2010.

June 2010 | Tuebingen University reports experience in 60 consecutive patients treated with OTSC®
Bruchsal, Germany, June 11, 2010. At the XXII Congress of the Southwest German Society of Gastroenterology Thomas Katz, 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
• 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, Küper M, v. Feilitzsch M, Königsrainer A, Kirchniak A
There were two more reports on successful application of Ovesco’s OTSC® system:

Ulkus-Arrosionsschluß der A. gastroduodenalis – Vermeidung des Notfalleingriffs durch ein neuartiges Clipp-System – zwei Fallberichte
Kraft T, Stüker D, Brücher B, Heininger A, Miller S, Königsrainer A

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 endoscope. Gastric lesions of approx. 3 cm were simulated by RF marking. The OTSC® Anchor was used through one working channel and a monopolament snare through the other. The tisse anchor was advanced through the snare 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. In the other 2 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
v. Renteln D, Schmidt A, Vassaliou MC, Rudolph HU, Caca K
Endoscopy 2010 Jun;42(6):475-80
June 2010 | Clinical NOTES experience with OTSC® presented at German D-NOTES meeting in Mannheim, Germany

At the annual meeting of the German NOTES working group, D-NOTES, in Mannheim, Germany, June 3-5 2010, two research groups reported about their clinical experience with the OTSC® clip for gastric closure:

The chairman of the meeting, PD Dr. Georg Kühler, Mannheim University Hospital, is using the OTSC® clip for closure after transgastric appendectomy, Dr. Thomas Kratt, Tuebingen University Hospital for closure after transgastric diagnostic laparoscopy. Both centers have enrolled first patients into their respective studies. OTSC® was shown to be effective and safe in closing gastrointestinal after transgastric NOTES.

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 Kühler, 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 | Study demonstrates that Ovesco’s Traction Polypectomy Snare is 31% more efficient in tissue acquisition than conventional snares

Ovesco’s Traction Polypectomy Snare is a newly designed, serrated snare for endoscopic tissue acquisition procedures such as polypectomy, endoscopic mucosal resection (EMR) or similar techniques. Its specific design reduces slipping of the snare upon closure and loosing tissue intended for removal. At the same time the Traction Snare has excellent maneuverability and repositioning properties, making its handling simple and efficient.

A recent experimental trial by RL Proost and FE Baur, Stuttgart, Germany has shown that the Traction Snare removes 31% more tissue than a conventional snare. Comparing the weight of coctonic tissue removed with one snare deployment was 454 mg (SD 202) with the Traction Snare vs 347 mg (SD 165) with a conventional snare. This difference was statistically significant (p<0.017).

The authors conclude that the Traction Snare increases the effectiveness of snare resection by avoiding the accidental loss of entrapped tissue. In addition the achievable reduction of sample numbers during piecemeal resection may increase the precision of histo-pathological assessment. A new serrated snare for improved tissue capture during endoscopic snare resection

Proost RL, Baur FE | Minim Invas Therapy 2010; 19:100-4

May 2010 | DDW 2010 – OTSC® for endoscopic closure of acute perforations of the gas-trintestinal 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 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 patient of those 22 patients where the system could be administered suffered delayed leakage and had to be treated surgically. The trial is ongoing. Final results will be published as available.

May 2010 | Ovesco Endoscopy’s OTSC® system at DDW in New Orleans: clinical paper presenta-tions, hands-on workshop and industry exhibition

The OTSC® system is presented at the Digestive Disease Week, DDW 2010, New Orleans, May 1-5, 2010. Besides scientific paper presentations about clinical experience and data by different authors, the AGSE Hands-on Workshop „GI Emergencies: Sutures, Closures and Hernostasis“ by Juergen Hochberger, MD PhD, demonstrates the OTSC® system in practical use, supported by K Mathet, MD, G. Haber, MD and RI Rothstein.

April 2010 | New publication on the use of OTSC® in bariatric patients

Dr. Federico lacopini 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

Federicolacopini, Nicola Di Lorenzo, Fabrizio Allitoni, Marc Olivier Schun, Agostino Scozzaro World J Gastroenterol 2010 April 7; 16(13):1665-9

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, T-tags or endoscopic suture devices, OTSC® is evaluated „very good” under the categories „simplicity”, „security” and „effec-tiveness”, leading to the highest overall score of all systems.

Endoscopic closure of gastric access in perspective

Arezzo A, Morino M | Surgical Endoscopy 2010 24:2, 298-303

March 2010 | Ovesco supports lunch symposium on OTSC® clip and is sponsor of the 40th Congress of the German Society for Endo-scopy (DGE-BV) in Hanover, March 11–13, 2010

The 40th Congress of the German Society for Endoscopy (DGE-BV) is held in Hanover under the presidency of Prof. Dr. Jürgen Hochberger, Heddeshem. Ovesco supports the lunch symposium on clinical indi-cations and experiences with the OTSC® clip on Friday, March 12, 2010, 13:00-14:00 h, Saal 1A

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 ballon, the abdo-men was explored and staging was performed in a patient suffering from an infrequent type of a 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.

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 after 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


February 2010 | Researchers report secure closure of duodenal perforations using the OTSC® clip in a randomized controlled experimen-tal trial

In the recent issue of the journal Gastrointestinal Endoscopy, Dr. Daniel von Renteln and colleagues report about a series of 24 animals (domestic pig) in which duodenal perforations had been intentionally created. All cases were randomized to undergo either surgical repair by hand sewing or endo-scopic closure by means of the OTSC® clip.

At necropsy, all OTSC® and surgical closures demonstrated complete sealing of duodenotomy sites. Mean time for OTSC® closure was 5 minutes (range, 3-8 min; SD 2).

Leak testing under pressure demonstrated a mean burst pressure of 166 mm Hg (range 80-260, SD 85) for OTSC® closures and 143 mm Hg (range 30-300, SD 83) for surgical sutures.

This shows that OTSC® closure of duodenal full thickness wall lesions can result in higher pressure resistance than hand suturing, although the difference was not significant. There were no complications related to the OTSC® clip reported.

Endoscopic closure of duodenal perforations by using an over-the-scope clip: a randomized, controlled por-cine study


February 2010 | Résumé to the 12th Düsseldorf International Endoscopy Symposium, 5–6 Feb-ruary 2010

This year’s 12th Internationales Endoskopie Symposium again enjoyed an impressive acceptance by a national and international audience as well as an excellent faculty of some of the finest experts in the field.

Prof. Dr. Stefan Seewald from Zürich in his oral presen-tation ("Neue Produkte zur endoskopischen Therapie von Perforationen und Fisteln/New devices for endoscopic treatment of perforations and fistulas") very much focussed on the OTSC® system. It was basically cited to be the answer
OTSC® update 12 | research & clinical trials

to many problems in GI endoscopy. This was followed by a lively discussion on challenging indications for the system like esophageal-tracheal fistulas.

Ovesco's booth again was able to attract a huge crowd. The feedback on the OTSC® system plus the accessories including the latest product “traction snare” was overwhelming.

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, Soonchunhyang 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 Hae Lee, Yoon Seon Park, Ju Young Cho Endoscopic Submucosal Dissection (ESD), pp 16-52.

Jin Publishing Co. Ltd. Seoul, Korea, 2009


Prof. Dr. Juergen Hochberger, Hildesheim, Germany, showed the use of the Ovesco OTSC® system at the 33rd Annual New York Course.

In an experimental laboratory demo, transmitted live from Lenox Hill Hospital, he closed a 8–10-mm full thickness esophageal perforation successfully by means of one OTSC® clip.

November 2009 | Ovesco exhibits at Gastro 2009, UEGW/WCOG, the jointly organised landmark meeting of UEGF, WGO, OMED 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 GASTRIC BAND PENETRATION is the title of a poster presentation of F. Lapicconi 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 enteric material persisted for 2 weeks. Both fistulas were successfully closed with OTSC®s (one in combination with a full-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 fistulas or leaks.

In an oral presentation D. v. Renteln et al. report data of a RANDOMIZED CONTROLLED TRIAL COMPARING ENDO-SCOPIC CLIP TECHNIQUES FOR NOTES GASTRO- MY CLOSURE. In 20 pigs an 18-mm gastrostomy was performed after either conventional endoclip or the Ovesco OTSC® clip. No leaks were observed after OTSC® closure 3 minutes and 1 major leak after endoclip closure. The time required for the gastroscopy closure procedure was 8.5 ±9.1 minutes with OTSC® and 31.5±24.2 minutes with endoclips. After necropsy 2 animals in the endoclip group showed signs of peritonitis. 1 animal in that group had to be sacrificed before finishing the study due to severe peritonitis. The authors conclude that standard endoclips have an increased risk of failure in the closure of NOTES gastromy.

Randomized controlled trial comparing endoscopic clips and over-the-scope clips for closure of natural orifice transluminal endoscopic surgery gastromy

D von Renteln, MC Vassiliou, RI Rothstein
Dept. of Gastroenterology and Hepatology; Dept. of Surgery Dartmouth-Hitchcock Medical Center, Lebanon, NH, USA

November 2009 | Experimental study confirms pressurization strength of gastric closure with OTSC® compared to the gold standard of hand-suturing

R. Voermans et al. published comparative data on gastric closure after NOTES in the ex vivo experimental model. Gastric closure with the OTSC® clip was compared to gastric closure by hand-suturing, determined as the gold standard. Surgical suturing demonstrated pressure tightness of the closure up to a mean leak pressure of 206 mm Hg (SD 59), (n = 15 samples), OTSC® closure demonstrated tightness up to a mean pressure of 233 mm Hg (SD 47), (11 samples). This was non-inferior to the gold standard (p = 0.003).

The authors conclude that closure of gastric incisions meeting predetermined pressure resistance criteria was attainable and easy with the OTSC® system.

Novel over-the-scope-clip system for gastroscopy closure in natural orifice transluminal endoscopic surgery (NOTES): an ex vivo comparison study

RP Voermans, MI van Berge Henegouwen, WA Bemelman, P Fockens
Department of Gastroenterology and Hepatology, Academic Medical Center, Amsterdam, The Netherlands
Department of Surgery, Academic Medical Center, Amsterdam, The Netherlands

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

At this year’s EndoClubNord at the Congress Center Ham-burg Ovesco’s OTSC® (over the scope clip) 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 transtumoral endoscopically 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 intraperitoneally 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.


At the 21st Conference of the Society for Medical Innovation & Technology (SMIT) Ovesco’s OTSC® clip is presented in various scientific sessions.

Dr. Agostino Scozzarro 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 Arazzo, Torino, Italy, within a hands-on workshop on basic techniques in NOTES. He also shows recent data on trans-gastric cholecystectomy and secure 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 postsurgical healing problems in bowel anasto-mosis. 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.

September 2009 | Reports about OTSC® clip as a closure device at EURO-NOTES workshop, Barcelona, Spain

Leading scientists present their results at the EURO-NOTES workshop, 24–26 Sept. 2009, Barcelona, Spain.

Prof. Dr. P. Fockens, Amsterdam, The Netherlands, explains the technique of OTSC® application for NOTES gastric closure and its successful use in the experimental model.

Dr. D. von Renteln and colleagues, Ludwigswig, Germany, present a randomized controlled trial comparing endoscopic clipping techniques for gastroscopy closure with favourable results of the OTSC® clip.

Dr. R. Voermans et al., Amsterdam, The Netherlands, present an ex vivo comparison of current colotomy closure modalities, including OTSC®.

Successful clinical cases with OTSC® for the closure of gastric fistula after gastric banding are shown by Dr. F. Laciopoli et al., Rome, Italy.
Future prospects in complication management are a major topic of this meeting (43. 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. Dr. M. Raithel.

Further, Prof. Dr. J. Hochberger emphasizes the significance of the OTSC® in view of NOTES.

**June 2009 | HU Rudolf is awarded a prize for his study on endoscopic closure of duodenal perforations applying OTSC® clips and the OTSC® Twin Grasper® at the XXth Congress of the South-West German Society of Gastroenterology**

A working group of researchers of the Medizinische Klinik I in Ludwigshurg and the University of Heidelberg, Medical Faculty Mannheim was honoured with a poster award for their presentation of results of an experimental randomised animal study on endoscopic closure of duodenal perforations.

**Endoskopischer Verschluss von Duodenalperforationen: Eine randomisierte tierexperimentelle Studie**

HU Rudolf, D von Renteln, A Schmidt, M Gieselmann, T Gutmann, K Caca
Klinikum Ludwigshurg, Medizinische Klinik I
Universität Heidelberg, Medizinische Fakultät Mannheim

**June 2009 | Dr. Thomas Kratt wins award for his presentation of case reports on endoluminal OTSC® treatment of Boerhaave syndrome**

At the XXth 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

**Suffiziente endoskopische Therapie bei Boerhaave-Syndrom**

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

**June 2009 | Experimental study proves effectiveness of the new clip version. OTSC® gc for gastric closure in NOTES; EAES congress in Prague, 17–20 June 2009**

The OTSC® gc is a derivative of the established OTSC® clip. It is specifically designed for the needs of gastric closure and has longer teeth to support gastric wall capture even more strongly than the OTSC® clip.

In his oral presentation at the EAES congress in Prague in a session on Sutureless Tissue Approximation, Prof. Dr. Alberto Arezzo from Torino, Italy, reports on successful gastric closure with the new OTSC® gc special clip:

**Transgastric cholecystectomy and secure endoscopic closure of transgastric approaches in a surviving porcine model.**

Hollow organ closure devices and techniques for NOTES.