

Hemostasis

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

Dr. Vijay Jayaraman and colleagues, Cedars Sinai Medical Center, Los Angeles, recently presented a retrospective study on their experience with the OTSC System in the treatment of GI bleeding, fistula and perforation. Their case series consisted of 24 consecutive patients treated between January 2011 and April 2012 (mean age 70 years) included the following indications for OTSC placement (28 clips): postsurgical enterocutaneous fistula (n=10), spontaneous perforation (n=1), anastomotic leak (n=4), perforation after mucosal resection (n=3), prophylactic closure of mucosal defect after EMR (n=1), postpolypectomy bleeding (n=2), postendoscopic perforation (n=2), tracheoesophageal fistula (n=1) and leakage from a percutaneous jejunostomy site (n=1).

Instruments or modalities used to grasp the tissue were dedicated devices (OTSC Twin Grasper and OTSC Anchor) in 16 and nondedicated devices (rat tooth/alligator forceps or suction alone) in 15. Median follow-up time was 2.9 months; mean defect size 10 mm (range 5–2 mm). The overall success rate was 61%. In their experience the success rate of closure of an acute defect is higher compared to chronic fistula. 9 out of 24 lesions were chronic (> 1 month) in this series which might explain the lower overall success rate in comparison to the literature (72–100%).

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

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

Clinical Application and Outcomes of Over the Scope Clip Device: Initial US Experience in Humans

Jayaraman V, Hammerle C, Lo SK, Jamil L, Gupta K
Diagn Ther Endosc. 2013;2013:381873
doi: 10.1155/2013/381873

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April 2014 | Multipurpose use of the OTSC System to treat endoluminal gastrointestinal disorders

Recently Mönkemüller et al. from Birmingham, AL, USA report the analysis of an observational retrospective case series of 16 patients (median age 65.8 years) with mixed indications for the treatment with the OTSC System. The overall success rate of 75% is well in line with other reports and with the meta-analyses of Weiland et al. with a 71% success rate in fistulas and anastomotic leaks, 79% in acute perforations, and 88% in acute GI hemorrhages. The range of indications included gastrointestinal bleeding (n=6), gastrocutaneous fistulas (n=3), esophago-tracheal and/or esophagopleural fistulae (n=3), resection of submucosal tumor (n=2), stent fixation (n=1), and anastomotic leak after esophagectomy (n=1). The overall per case success rate was 70% (14 of 20 applications). Mean follow-up was 10 months (range 1–10). There were no complications (0%) related to endoscopy, sedation or application of the clipping device.

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

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

In essence the authors draw a very positive conclusion stating "that the OTSC device is ideally suited to treat soft tissue leaks or fistulizing lesions and high-risk bleeding lesions such as ulcers in the posterior duodenum or Dieulafoy's lesions" with the main underlying mechanism being compressing the surrounding tissue around the vessel. They continue "...The OTSC device may become a better device to treat bleeding ulcers located in difficult positions because of its barrel-shaped transparent cap design which allows it to suction the bleeding lesion. It is well known that these bleeding ulcers and lesions are of a higher risk and also more difficult to treat because of their awkward location and/or position...". This statement is followed by an elaborate discussion of the shortcomings of alternative devices. It is important to underline also that the authors support "...multiple OTSC applications in a single session..." as sometimes being useful and allowing approximation of tissue to facilitate subsequent closure. "Interestingly, the device does not tear tissue, as it snaps it together. So far, there have been no reports of GI wall tearing...".

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

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

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

Mönkemüller K, Peter S, Toshniwal J, Popa D, Zabielski M, Stahl RD, Ramesh J, Wilcox CM
Dig Endosc. 2014 May;26(3):350-7
doi: 10.1111/den.12145 | Epub 2013 Jul 16

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April 2014 | Conference report | 44th DGE-BV Congress, Hamburg

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

Again a significant number of both oral presentations and posters have been featured at this year's event. In summary they all reported their mostly positive experiences with the OTSC System in all main indications. In addition our products were featured in several hands-on courses alongside the conference (Chairs: Hochberger J., Maiss J., Kraus F.). Ovesco presented their new products, the DC Clip Cutter and the FTRD device which are both due to be launched later this year. The reaction of the medical world was more than promising.

• Neue Clips für Blutung und Verschlusstechniken

Caca K, Ludwigsburg, Germany

K. Caca gave a talk on "New tools for the treatment of GI-hemorrhage and perforation". Even though also mentioning other devices he mainly elaborated on the OTSC System. In his summary of clinical cases his take home message was: "the OTSC device achieves hemostasis more quickly than all other devices and is more effective particularly regarding acute, difficult and heavy bleedings." For the treatment of perforation OTSC was the standard choice. Also, he showed first experiences with the all new DC Clip Cutter device as an important tool for removing the OTSC which will be launched later this year.

• Update Endoskopie – meine Toppapers

Häfner M, Vienna, Austria

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

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

Manta R, Galloro G, Mangiavillano B, Conigliaro R,

Pasquale L, Arezzo A, Masci E, Bassotti G, Frazzoni M

Surg Endosc. 2013 Sep;27(9):3162-4
doi: 10.1007/s00464-013-2871-1 [Epub 2013 Feb 23]

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

Chan SM, Chiu PW, Teoh AY, Lau JY

Endoscopy. 2014 May;46(5):428-31
doi: 10.1055/s-0034-1364932 [Epub 2014 Feb 6]

• Clip-Karussell.

Groth S, Hamburg, Germany

S. Groth elaborated on the endoscopist's option once it comes to use clips. Interesting enough he exempted the OTSC from the rest of all products stating that OTSC is playing in a different league.

Comment by Ovesco: the comparator of OTSC is surgery!

• Techniken zum Perforationsverschluss

Fritscher-Ravens A, Kiel

A. Fritscher-Ravens underlined in her talk on techniques of perforation closure the importance and advantages of the use of the Twin Grasper. Other than that she referred to OTSC as standard treatment.

Altogether five posters were dealing with OTSC:

• Over-the-Scope Clip System (OTSC) – One Therapy for Safety Closure

Leonhardt K, Ohse A, Bauer B, Repp M, Altenburg, Germany report their 3.5-year experience with our system regarding the three major indications: hemorrhage, acute perforation, and chronic fistula/anastomotic leakage where they achieved a 85.7%, 84.6%, and 60% success rate. 33 patients were included in this retrospective analysis.

Average age was 69 years (41–92 ys). Three patients received two clips at once. Across the GI tract the number of patients was equally distributed, except for Jejunum and Ileum with only one patient each. The authors conclude that OTSC is a useful and effective tool for the endoscopist sparing the surgeon in many cases.

• The OTSC System in the treatment of a perforation of the colon complicated by adhesion of small bowel

H. Albrecht et al., Erlangen, Germany presented a case report. During diagnostic colonoscopy they experienced an acute perforation which was as usual closed with an OTSC clip. After a few days the patient developed acute symptoms with free sub-diaphragmatic air which led to a sigmoidal resection and overstitch of the small bowel. The authors point out the possible risks of the use of OTSC.

Comment by Ovesco: the authors used suction only for getting colonic tissue into the cap. Already during this process small bowel was trapped in the cap and could clearly be seen between the teeth of the closed clip. The IFU of the product recommend the use of the Twin Grasper for fresh perforations. Suction may be used after the edges of a fresh perforation have clearly been identified and pulled into the cap.

Einsatz des Over-the-Scope Clips (OTSC) zur Behandlung einer Colon-Perforation verursachte eine Dünndarmfixation mit nachfolgender chirurgischer Resektion

Albrecht H, Nägel A, Hagel A, Rösler W, Förtsch T, Neurath MF, Raitchel M

• Comparison of the OTSC and cSEMS in the treatment of gastrointestinal leakages: results of retrospective multicenter analysis

H. Farnik et al. reported in a very important paper of the interventional therapy of postoperative (73, 69%), postinterventional leakages (24, 23%), and 9 (8%) spontaneous perforations. Primary closure was done with an cSEMS in 72 patients (69%), and with OTSC in 31 pts. (29%). Average duration of the treatment needed 45.6 days with cSEMS versus only 19.8 days in patients of the OTSC group. Treatment was complicated in 66.7% of cSEMS patients, and only in 5.9% in the OTSC group. 1.12 interventions (1.00-1.23) were needed with OTSC, 2.44 (2.12 – 2.76) in the cSEMS group. The diameter of the defect was larger in the cSEMS group (12.6 mm, 10.9–15.2) than in the OTSC group (7.1, 4.4-9.7).

	OTSC	cSEMS	P
Age (mean, years)	60.82	63.3	n.s.
Gender (m/f)	22/12	53/19	
Diameter of leakage (mean mm, 95% ci)	7.1 (4.4-9.7)	12.6 (10.9-15.2)	
Duration of defect (days)	10.97	7.96	n.s.
Local infection (n, %)	15(44%)	51(71%)	
Number of interventions (mean, 95% ci)	1.12 (1.00-1.23)	2.44 (2.12-2.76)	
Technical success (n,%)	33 (97.1%)	71 (98.6%)	n.s.
Duration of treatment	24.8	38.9	
Dislocation rate (n,%)	1 (3%)	17 (24%)	

The authors conclude in their discussion that OTSC is the preferred primary therapy of smaller post-interventional leakages. It might also be used in combination where cSEMS treatment was incomplete. They conclude that the longer treatment period with cSEMS and the higher complication rate might be due to sicker patients, but also due to the relevant dislocation rate of cSEMS.

Vergleich zwischen OTS Klipp und cSEMS zur Indikationsstellung bei der Behandlung gastro-intestinaler Leckagen: Ergebnisse einer retrospektiven, multizentrischen Analyse

Famik H¹, Driller M¹, Kratt T², Schmidt C³, Fähndrich M⁴, Friedrich-Rust M¹, Filmann N¹, Königsrainer A², Stallmach A³, Heike M⁴, Zeuzem S¹, Albert J¹

¹Frankfurt am Main, ²Tübingen, ³Jena, ⁴Dortmund, Germany

• Endoscopic treatment of acute bleedings with an Over-The-Scope Clip (OTSC)

A. Braun et al. investigated the role of OTSC in the treatment of acute GI hemorrhage in an emergency. Between 2011 and 2013 they treated 16 patients (median 75.5 y/o (61-92), m=9, f=7) with OTSC for upper and lower-GI bleeding (8 each). Patients with upper-GI bleeding received high PPI-medication simultaneously. 7 patients were classified F Ia, 7 F Ib, and 2 F IIa. All patients presented with an acute decrease of hemoglobin, with hematemesis, melena, and hematochezia. The clip was applied by using a standard forceps. Technical success was achieved in all 16 patients (100%) with immediate primary hemostasis. None of the interventions took longer than 20 minutes. Only 6 patients underwent follow-up endoscopy between day 1 and 7 after clip application. All control endoscopies were uneventful and showed clinical success. 9 patients did not need any further endoscopy. None of the patients needed any further therapy for bleeding. All patients started normal oral intake from day 2.

The authors conclude that OTSC is safe and effective for the treatment of hemorrhage which reduces mortality, with short intervention times.

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

Braun A, Richter-Schrag HJ, Fischer A, Freiburg, Germany

• Clinical experience in the treatment of perforations, leakages, and fistulas in the GI tract with the Over-the-scope clip (OTSC)

J. Stücker et al. report their retrospective results in the standard indications of OTSC.

21 patients (Median 69 years (30–87), m=11, f=10) were treated for leakages and fistulas (n=11, 52%) due to anastomotic leaks. 5 patients had complications due to diagnostic or therapeutic endoscopy. 2 patients had fistulas due to necrotizing pancreatitis. 2 patients suffered from a persistent PEG fistula. Technical success was reported in 20/21 cases (95%). All 5 endoscopic complications could successfully be treated with OTSC. 7/11 anastomotic leaks could successfully be treated as well. One patient with duodenal leak due to acute necrotizing pancreatitis and a patient with perforated antrum died due to sepsis. The treatment of persistent PEG fistula was clinically not successful in this series.

The authors conclude that altogether the treatment of perforations, leakages, and fistulas with OTSC is very

promising, and point out that this is especially true for the management of complications during endoscopy and surgical complications like anastomotic leakage.

Klinische Erfahrungen bei der Behandlung von Perforationen, Leckagen und Fistelungen im Gastrointestinaltrakt mit dem Over the scope Clip (OTSC®)

Stücker J, Probst A, Bittinger M, Scheubel R, Ebigo A, Messmann H, Gölder S, Augsburg, Germany

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

Apart from using the OTSC System in acute and chronic perforations (i.e. perforations, anastomotic leakage, fistulae) the authors of the renowned Institute of Digestive Disease, Department of Surgery, Chinese University of Hong Kong are reporting of patients in whom OTSC was used for endoscopic control of refractory or major upper gastrointestinal bleeding from lesions in the gastroduodenal tract between 1 July and 31 December 2012. Nine patients were included (median age 72.5 years, range 39–91) with bleeding gastric ulcers (n=2), bleeding duodenal ulcers (n=5), bleeding gastrointestinal stromal tumor in the stomach (n=1), and bleeding from ulcerative carcinoma of the pancreas (n=1). The median size of the ulcers was 2.5 cm (range 1–4). Six of the nine patients had undergone previous endoscopic hemostasis. Technical success (defined as hemostasis achieved at index endoscopy) was achieved in all patients and the clinical effectiveness was 77.8% (defined as technical success with no rebleeding). All procedures were carried out by two experienced endoscopists. Those two patients that experienced rebleeding suffered from complex duodenal ulcer. One of them had been treated with radiotherapy for residual disease after resection of common bile duct cholangiocarcinoma. After several additional EGDs, transarterial embolization, and one surgical intervention which all failed to stop the bleeding, the patient died eventually. The second patient bled from the inferior pancreaticoduodenal artery and needed arterial embolization as well.

The authors discuss a meta-analysis of 1156 patients in 15 randomized trials where endoclips were shown to be superior to injection alone, and as effective as heater probe treatment. The overall rate of rebleeding in those conventionally treated patients ranged between 7.1% and 9.5% though.

Since rebleeding correlates with the adverse outcome of this indication they speculate that control of bleeding would have a positive impact on patient outcome. Even though the study was carried out in patients with complex duodenal ulcer and underlying malignancies the technical success rate of OTSC was 100%. They also point out that usually in cases like these the application of conventional clips is difficult, the repeated application of heater probe being associated with a higher risk of perforation. Whereas the application of OTSC allows for larger amounts of tissue and constitutes a quite durable treatment (OTSC in situ after a median of 28 days in this study). The authors conclude that the use of OTSC is a safe and effective method of endoscopic hemostasis for major bleeding from miscellaneous upper gastrointestinal causes and should be considered in refractory bleeding after conventional endoscopic hemostasis, before surgery or angiographic embolization.

Comment by Ovesco: a prospective controlled randomized multicenter trial with 64 patients with recurrent upper GI bleeding is recruiting in Germany (Endoscopic Treatment of Recurrent Upper GI Bleeding: OTSC [Over the Scope Clip] Versus Standard Therapy (STING). ClinicalTrials.gov Identifier: NCT01836900)

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

Chan SM, Chiu PW, Teoh AY, Lau JY

Endoscopy. 2014 Feb 6. [Epub ahead of print] 162

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

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

Their case series consisted of 23 consecutive patients treated between November 2011 and September 2012 (mean age 77 years) included the following indications for OTSC placement: stopping GI bleeding (n=9), closing perforation (n=10), closing chronic fistula (n=4) and prevention of post endoscopic submucosal dissection (ESD) duodenal artificial ulcer perforation (n=1). One patient had a perforation that formed a fistula. Lesions were located in the esophagus (n=1), the stomach (n=10), the duodenum (n=5), the sigmoid colon (n=3) and in the rectum (n=4). In 8 patients other therapies preceded OTSC application (e.g. conventional hemostatic clips, local injections, hemostatic coagulation forceps). Median follow-up time was 67 days. The primary technical success rate was 91.3% (21/23). In two cases application of the OTSC clip was not possible due to stiff, fibrotic lesion edges. The overall clinical success rate (complete closure by using only OTSC clips) was 82.6%. Major contributing factors for OTSC failure were a large lesion size (greater than 20 mm) and a delayed diagnosis (more than 1 week). No patient reported any complications associated with OTSC placement. In conclusion, the OTSC is an interesting and novel device that enhances the armamentarium of therapeutic gastroenterologists.

Efficacy and safety of over-the-scope clip: including complications after endoscopic submucosal dissection

Nishiyama N, Mori H, Kobara H, Rafiq K, Fujihara S, Kobayashi M, Oryu M, Masaki T

World J Gastroenterol. 2013 May 14;19(18):2752-60

doi: 10.3748/wjg.v19.i18.2752

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November 2013 | OTSC in endoscopic treatment of acute GI bleeding after failure of conventional techniques: primary hemostasis of 97%

The OTSC System can overcome the limitations of conventional clips in the treatment of patients with acute GI bleeding by providing compression of large amounts of tissue, leading to a more efficient hemostasis. Dr. R. Manta and colleagues, Gastroenterology and Endoscopy Unit, New S. Agostino Hospital, Modena, Italy draw this conclusion on the basis of a retrospective analysis of a consecutive case series of 30 patients with severe acute GI bleeding treated with the OTSC System after failure of conventional techniques.

Data were collected from six high-volume endoscopy units in a period between December 2011 and September 2012. All 30 patients suffered from bleeding lesions unresponsive to saline/adrenaline injection and through-the-scope clipping located in the upper and lower GI tract in 23 and 7 cases, respectively. Bleeding lesions included duodenal ulcer (n=12), gastric ulcer (n=6), Mallory-Weiss (n=2), Dieulafoy (n=2) and surgical anastomosis (n=1) in the upper GI tract and endoscopic mucosal resection (n=5), endoscopic submucosal dissection (n=1) and colonic diverticulum (n=1) in the lower GI tract.

Primary hemostasis with OTSC was achieved in 29 of 30 cases (97%). Rebleeding in two cases was successfully treated with injection of saline and adrenaline. Endoscopic follow-up after 2–4 days and after 1 month revealed correct placement of the OTSC clip and no procedure-related complications. Thus, the OTSC is an effective and safe device for treatment of acute GI bleeding and represents a useful adjunct to the therapeutic armamentarium in endoscopic emergencies.

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

Manta R, Galloro G, Mangiavillano B, Conigliaro R, Pasquale L, Arezzo A, Masci E, Bassotti G, Frazzoni M

Surg Endosc. 2013 Sep;27(9):3162-4
doi: 10.1007/s00464-013-2871-1

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

Dr. B. Mangiavillano and colleagues, Gastrointestinal Endoscopy, Azienda Ospedaliera San Paolo University, Hospital-University of Milan, Italy, present a case study of a 69-year old woman with an episode of melena. EGD showed a Dieulafoy's bleeding lesion in the proximal third of the posterior wall of the stomach. The lesion was treated with an epinephrine injection and application of two conventional working-channel delivered metallic clips and the patient was discharged two days later. After three days the patient again presented with melena. Blood transfusions were necessary. An EGD was performed, showing no sign of an actively bleeding ulcer. The patient was admitted to hospital and suffered from another episode of melena with hemorrhagic shock. The now actively bleeding Dieulafoy's lesion was then treated with an OTSC clip, stopping the hemorrhage completely and persistently. Endoscopic follow-up after 30 days displayed correct placement to the OTSC and no signs of further bleeding.

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

Mangiavillano B, Arena M, Morandi E, Viaggi P, Masci E
Endoscopy. 2012;44 Suppl 2 UCTN:E387
doi: 10.1055/s-0032-1310141

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

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

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

Mönkemüller K, Toshiwaki J, Zabielski M, Vormbrock K, Neumann H
Endoscopy. 2012;44 Suppl 2 UCTN:E412-3.
doi: 10.1055/s-0032-1325737 [Epub 2012 Nov 20]

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August 2013 | OTSC successful after repeat failure of conventional techniques

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

Three weeks after the initiation of a double platelet aggregation inhibitor therapy due to NSTEMI a female patient was readmitted to hospital with melena and hematemesis. Endoscopy revealed a duodenal ulcer (Forrest Ia) with arterial bleeding that was treated with saline and adrenaline injection and application of conventional hemoclips. After an overnight stay at the ICU control endoscopy displayed a rebleeding that was again stopped with injection of epinephrine, further hemoclips, and additional injection of fibrin. The patient opted strongly for the treatment with the OTSC

System instead of undergoing the proposed surgical intervention. During the OTSC procedure the hemoclips were found loose again, leading to an active rebleeding of the ulcer (now Forrest Ib). Since it was not possible to clip the whole ulcer the OTSC was applied to the laterally located vessel which stopped the bleeding immediately. Follow-up endoscopies showed a successfully placed OTSC and no signs of further bleeding.

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

Peters M, Meyer P, Martin J, Poerschke A, Rupp S, Kirschstein KH
Endoscopy. 2012;44 Suppl 2 UCTN:E36-7
doi: 10.1055/s-0031-1291515 [Epub 2012 Mar 6]

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July 2013 | Recommendation of OTSC System in complex GI bleeding

In an overview article the authors are referring to the current guideline therapies available and new developments. They report that other new three-dimensional clips seem to be even less efficacious than normal hemoclips. Thus, the authors conclude that obviously one of the key elements to successful hemostasis is the strength of the jaws of a clip and the amount of tissue captured. They state that this is obviously fulfilled by the design of the OTSC System which allows for the capture of a large amount of tissue and is more secure than other clips in the experimental setting. Thus the OTSC System is being recommended and used in complex GI bleeding. According to Leung & Lau a single clip suffices for most circumstances and therefore the procedure is shorter when compared to multiple applications of hemoclips.

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

New endoscopic hemostasis methods

Leung Ki EL, Lau JY
Clin Endosc. 2012 Sep;45(3):224-9
doi: 10.5946/ce.2012.45.3.224 [Epub 2012 Aug 22]

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

Dr. Todd H. Baron and colleagues, Division of Gastroenterology & Hepatology, Mayo Clinic, Rochester MN, USA report about their experience with 45 patients and 48 OTSC clip placements from March 2011 to January 2012. Median follow-up time in this mixed cohort was 77 days (30–330 days). Indication breakdown included hemostasis (n=7), closure of chronic fistula (n=28), closure of iatrogenic perforations (n=5), closure of post-esophagectomy anastomotic leakage (n=3) and miscellaneous (n=2). Before OTSC placement 49% of the patients had undergone other therapies for their condition that had failed. The overall clinical success rate was 71%. Hemostasis was achieved in 100% of cases. Anastomotic leakage and fistula was closed in 65%. Also one case of OTSC clip removal by means of APC-cutting of a clip hinge is described. The authors conclude that the OTSC clip appears clinically effective and is a welcome addition to the therapeutic armamentarium in the closure of leaks, fistula, perforations and non-variceal bleeding.

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

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

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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, Zabielski M, Mönkemüller K
Gastrointest Endosc. 2012 Oct;76(4):917-8

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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 bleedin and NOTES:

UEGW 2011 report: putting endoscopy into perspective

Papanikolaou IS, Rösch T
Endoscopy 2012; 44:512-526. [Epub 2012 Apr 24]

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The authors conclude that although OTSC® is „promising, further clinical experience will help to identify the optimal role and indication for OTSC®s 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 above „June 2012 | OTSC® in emergency hemostasis: new data demonstrate superior results“).

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

In the NOTES chapter they state that even though the number of NOTES regarded papers were on the decline the „management of iatrogenic perforations of the 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, Hucl et al, Endoscopy 2011; 43: 01A48) that deal with animal models and prove safety and efficacy of OTSC®, the authors are referring to „an interesting German prospective study ... on snare-resection of gastric subepithelial masses (<3 cm) in 16 patients (Schlag et al. Endoscopy 2011; 43: 01A329).

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

Remark from Ovesco: G. Kähler (Dept. of Surgery, 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.

Emerging technologies for endoscopic hemostasis

ASGE Technology Committee, Wong Kee Song LM,

Banerjee S, Barth BA, Bhat Y, Desilets D, Gottlieb KT, Maple JT, Pfau PR, Pleskow DK, Siddiqui UD, Tokar JL, Wang A, Rodriguez SA
Gastrointest Endosc 2012 May; 75 (5): 2012 933-7 [Epub 2012 March 23] 73

Ovesco takes the liberty to make a few additional comments:

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

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

Freiburg, Germany, June 15, 2012 – Congress of the Southwest German Society for Gastroenterology. Dr. Thomas Kratt, Department of Visceral and Transplant Surgery of Eberhard Karls University, Tuebingen, Germany, presented latest data on the use of OTSC® in the emergency treatment of GI hemorrhage. He reported on a consecutive series of 60 patients with severe GI bleeding based on different pathologies, mainly peptic ulcer in different locations. 69 OTSC® clips had been placed in these patients.

In 19 cases OTSC® clipping was chosen due to acute failure of conventional 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.

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 – 129th Congress of the Deutsche Gesellschaft für Chirurgie (DGCH), 24 - 27 April 2012 – Ovesco's products were featured by Prof. Thomas Lehnert, Bremen and Prof. Ulrich T. Hopt, Freiburg, during the session on „Management of post-surgery septic complications / anastomotic leakage“.

Lehnert 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 postsurgical defects in the lower GI tract, one must always consider proper drainage of a potential abscess behind the leak.

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

The German Society for Endoscopy and Imaging Techniques (DGE-BV) held its 42nd Annual Conference in Munich, Germany, from March 22 to 24. Ovesco's OTSC® clip was the topic of a number of presentations in the scientific programme, as listed below.

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

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

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

Dr. Mihnea H. Strain and colleagues from the Dept. of Gastroenterology of Victor Babes University Hospital, Timisoara, Romania, report about an unusual case of lower GI hemorrhage. A 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 OVESCO System

Mihnea H. Strain, Dorina M. Chisevesu, Sorin Potopea.
Journal of Gastrointestinal Liver Disease 2011; 20(1):85-7 42

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

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

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

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

P0003 A NEW VALUABLE TOOL FOR THE ENDOSCOPIST: THE OVER-THE-SCOPE CLIP (OTSC) – CLINICAL EXPERIENCE IN THE TREATMENT OF GASTROINTESTINAL LEAKS, BLEEDINGS AND FISTULAS IN 24 PATIENTS

Edris Wedi, Germany; Detlev Menke; Elena Kruse; Jürgen Hochberger

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

System.

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

Pierre H. Deprez, Belgium; Hubert Piessevaux

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

A new case series, reported by Dres Sandmann, Heike and Faehndrich, Klinikum Dortmund Mitte, Germany, was published in the German *Zeitschrift fuer Gastroenterologie*. The authors present a series of 10 patients with penetrating defects within the digestive tract. Pathologies were fistulas (esophago-tracheal, esophago-pulmonary, gastrocutaneous and colovesical), perforations (after mucosectomy, after papillotomy and PEG misplacement) and anastomotic leakages (after gastrotomy 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, Anastomosal Leakages and Perforations within the Gastrointestinal Tract

Sandmann M, Heike M, Faehndrich M. 54
Z Gastroenterol. 2011 Aug;49(8):981-5 [Epub 2011 Aug 2]

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 3/7 patients requiring further treatment afterwards. The overall success rate regarding leaks was 66% (ranging from closure of stomach perforation due to necrotising pancreatitis to gastrocutaneous 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

Albert JG, Friedrich-Rust M, Woeste G, Strey C, Bechstein WO, Zeuzem S, Sarrazin C.
Gastrointest Endosc. 2011 Aug;74(2):389-97 [Epub 2011 May 25] 45

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 preoperative marking (n = 4).

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

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

Kirschniak A, Subotova N, Zieker D, Königsrainer A, Kratt T
Surg Endosc. 2011 Sep;25(9):2901-5 [Epub 2011 Mar 18] 59

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

Bruchsal, Germany, June 11, 2010. At the 21st Congress of the Southwest German Society of Gastroenterology Thomas Kratt, MD, Surgical Endoscopy, Tuebingen University Hospital, Germany, reported about a case series of 60 patients treated with OTSC® for various indications. 37 patients were treated for stopping gastrointestinal hemorrhage, 11 for closure of perforation, 8 for closure of fistulae and 4 for the marking of lesions. In all 60 cases

technical success, defined as ability to place the OTSC® at the desired location, was achieved. In the 37 cases of GI bleeding 2 relapse 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

Kratt T, Stüker D, Küper M, v. Feilitzsch M, Königsrainer A, Kirschniak A

There were two more reports on successful application of Ovesco's OTSC® System:

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

Kratt T, Stüker D, Brücher B, Heininger A, Miller S, Königsrainer A

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

Kratt T, Kramer M, v. Feilitzsch M, Strese C, Küper M, Schenk M, Greiner T, Lange J, Kirschniak A, Minkley L, Schröppel K, v. Weyhern CH, Königsrainer A

Closure of acute lesions

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

Dr. Vijay Jayaraman and colleagues, Cedars Sinai Medical Center, Los Angeles, recently presented a retrospective study on their experience with the OTSC System in the treatment of GI bleeding, fistula and perforation. Their case series consisted of 24 consecutive patients treated between January 2011 and April 2012 (mean age 70 years) included the following indications for OTSC placement (28 clips): postsurgical enterocutaneous fistula (n=10), spontaneous perforation (n=1), anastomotic leak (n=4), perforation after mucosal resection (n=3), prophylactic closure of mucosal defect after EMR (n=1), postpolypectomy bleeding (n=2), postendoscopic perforation (n=2), tracheoesophageal fistula (n=1) and leakage from a percutaneous jejunostomy site (n=1). Instruments or modalities used to grasp the tissue were dedicated devices (OTSC Twin Grasper and OTSC Anchor) in 16 and nondedicated devices (rat tooth/alligator forceps or suction alone) in 15. Median follow-up time was 2.9 months; mean defect size 10 mm (range 5–2 mm). The overall success rate was 61%. In their experience the success rate of closure of an acute defect is higher compared to chronic fistula. 9 out of 24 lesions were chronic (> 1 month) in this series which might explain the lower overall success rate in comparison to the literature (72–100%).

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

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

Clinical Application and Outcomes of Over the Scope Clip Device: Initial US Experience in Humans

Jayaraman V, Hammerle C, Lo SK, Jamil L, Gupta K

Diagn Ther Endosc. 2013;2013:381873
doi: 10.1155/2013/381873

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June 2014 | Three case reports on surgery-sparing uses of the OTSC clip in multiple indications

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

The first case report describes the use of the OTSC System in the management of a Dieulafoy lesion. A 74-year old man suffered from a recurrent, obscure, life-threatening gastro-intestinal bleeding. EGD revealed a non-bleeding Dieulafoy lesion at the lesser gastric curvature. Due to the large size and difficult position of the lesion, conventional through-the-scope clips were not used, but an OTSC clip was success-fully deployed.

In another case report a 61-year old woman presented for EGD for evaluation of dysphagia. Four arteriovenous malformations were found in the duodenum, which were cauterized. On withdrawing the endoscope, a 2-cm gastric perforation was identified on the lesser curvature. Using the suction technique an OTSC clip was applied to close the defect.

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

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

Gómez V, Kyanam Kabir Baig KR, Lukens FJ, Woodward T
Endoscopy. 2013;45 Suppl 2 UCTN:E71.

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

Singhal S, Atluri S, Changela K, Gupta SS, Krishnaiah M, Anand S
Gastrointest Endosc. 2014 Jan;79(1):23.

150

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

Albert JG
Video Journal and Encyclopedia of GI Endoscopy. 2013 June, pages 219–20

155

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

Fujihara et al., Department of Gastroenterology and Neurology, Faculty of Medicine, Kagawa University, Kagawa, Japan, assessed the efficacy and safety of a prophylactic closure for large mucosal defects after colorectal ESD.

From April 2010 to December 2012, 68 patients with colorectal tumors were treated with ESD. The prophylactic closure using a conventional clip and the over-the-scope clip (OTSC) system was indicated for patients with excessive coagulation in the muscularis propria or larger resection size. The closure group reduced the peritoneal inflammatory reaction and abdominal symptoms without increasing complications. The closure group also had a significantly lower WBC count (post operative day 1), CRP (post operative day 4) and abdominal pain after colorectal ESD compared to the non-closure group. Perforation occurred in 1 case, and postoperative bleeding in 2 cases, with only 1 bleeding case needing an emergency

endoscopy in the non-closure group. One perforation case needed emergency surgery because the endoscopic treatment was ineffective. Without increasing adverse effects, the prophylactic closure efficiently reduced the inflammatory reaction and abdominal symptoms of colorectal ESD in patients with large superficial colorectal neoplasms.

The efficacy and safety of prophylactic closure for a large mucosal defect after colorectal endoscopic submucosal dissection

Fujihara S, Mori H, Kobara H, Nishiyama N, Kobayashi M, Rafiq K, Masaki T

Oncol Rep. 2013 Jul;30(1):85–90 |

doi: 10.3892/or.2013.2466 [Epub 2013 May 14] 129

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

Sleeve gastrectomy is increasing in popularity for the treatment of morbid obesity. The most serious and dreaded complication of this procedure is an anastomotic leak typically at the gastroesophageal junction.

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

To prevent leakage from the resection line, Seamguard®, a staple line reinforcement product was used in both cases. After initial recovery both patients presented with abdominal pain and fever (8th/30th postoperative day) and a CT scan confirmed leaks at the gastroesophageal junction. Intravenous antibiotics and nutritional support were instituted and fluid collections drained percutaneously and laparoscopically. In the case of the 58-year old woman conservative management was continued for 6 weeks, but the leak persisted. Therefore it was decided to use the OTSC System. By applying an OTSC clip complete closure was achieved in both patients. After 6 and 8 months respectively, there was no evidence of further leaks and inflammatory markers remained normal. As spontaneous closure of a gastric staple line fistula is rare, many patients require further complex surgery for definitive closure. The OTSC System has the potential to significantly simplify the management of leaks after sleeve gastrectomy by offering a simple endoscopic solution.

The use of over the scope clip (OTSC) device for sleeve gastrectomy leak

Aly A, Lim HK

J Gastrointest Surg. 2013 Mar;17(3):606–8

doi: 10.1007/s11605-012-2062-8

April 2014 | Multipurpose use of the OTSC System to treat endoluminal gastrointestinal disorders

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

The range of indications included gastrointestinal bleeding (n=6), gastrocutaneous fistulas (n=3), esophago-tracheal and/or esophagopleural fistulae (n=3), resection of submucosal tumor (n=2), stent fixation (n=1), and anastomotic leak after esophagectomy (n=1). The overall per case success rate was 70% (14 of 20 applications). Mean follow-up was 10 months (range 1–10). There were no complications (0%) related to endoscopy, sedation or application of the clipping device.

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

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

In essence the authors draw a very positive conclusion stating "that the OTSC device is ideally suited to treat soft tissue leaks or fistulizing lesions and high-risk bleeding lesions such as ulcers in the posterior duodenum or Dieulafoy's lesions" with the main underlying mechanism being compressing the surrounding tissue around the vessel. They continue "...The OTSC device may become a better device to treat bleeding ulcers located in difficult positions because of its barrel-shaped transparent cap design which allows it to suction the bleeding lesion. It is well known that these bleeding ulcers and lesions are of a higher risk and also more difficult to treat because of their awkward location and/or position...". This statement is followed by an elaborate discussion of the shortcomings of alternative devices. It is important to underline also that the authors support "... multiple OTSC applications in a single session..." as sometimes being useful and allowing approximation of tissue to facilitate subsequent closure. "Interestingly, the device does not tear tissue, as it snaps it together. So far, there have been no reports of GI wall tearing..."

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

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

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

Mönkemüller K, Peter S, Toshniwal J, Popa D, Zabielski M, Stahl RD, Ramesh J, Wilcox CM
Dig Endosc. 2014 May;26(3):350-7
doi: 10.1111/den.12145 | Epub 2013 Jul 16 133

April 2014 | The OTSC System: a surgery-sparing device for the management of iatrogenic duodenal perforation during endoscopic ultrasound

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

Endoscopic closure of duodenal perforation with an over-the-scope clip during endoscopic ultrasound-guided cholangiopancreatography

Salord S, Gornals JB, Maisterra S, Pons C, Busquets J, Fabregat J
Rev Esp Enferm Dig. 2012 Sep;104(9):489-90 98

Closure with an over-the-scope clip allows therapeutic ERCP to be safely performed after acute duodenal perforation during diagnostic endoscopic ultrasound

Donatelli G, Vergeau BM, Dritsas S, Dumont JL, Tuszynski T, Meduri B
Endoscopy. 2013 Nov;45 Suppl 2 UCTN:E392-3

doi: 10.1055/s-0033-1344872

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April 2014 | Conference report | 44th DGE-BV Congress, Hamburg

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

Again a significant number of both oral presentations and posters have been featured at this year's event. In summary they all reported their mostly positive experiences with the OTSC System in all main indications. In addition our products were featured in several hands-on courses alongside the conference (Chairs: Hochberger J., Maiss J., Kraus F.). Ovesco presented their new products, the DC Clip Cutter and the FTRD device which are both due to be launched later this year. The reaction of the medical world was more than promising.

• **Neue Clips für Blutung und Verschlusstechniken**

Caca K, Ludwigsburg, Germany

K. Caca gave a talk on "New tools for the treatment of GI-hemorrhage and perforation". Even though also mentioning other devices he mainly elaborated on the OTSC System. In his summary of clinical cases he take home message was: "the OTSC device achieves hemostasis more quickly than all other devices and is more effective particularly regarding acute, difficult and heavy bleedings." For the treatment of perforation OTSC was the standard choice. Also, he showed first experiences with the all new DC Clip Cutter device as an important tool for removing the OTSC which will be launched later this year.

• **Update Endoskopie – meine Toppapers**

Häfner M, Vienna, Austria

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

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

Manta R, Galloro G, Mangiavillano B, Conigliaro R, Pasquale L, Arezzo A, Masci E, Bassotti G, Frazzoni M
Surg Endosc. 2013 Sep;27(9):3162-4 114
doi: 10.1007/s00464-013-2871-1 [Epub 2013 Feb 23]

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

Chan SM, Chiu PW, Teoh AY, Lau JY
Endoscopy. 2014 May;46(5):428-31
doi: 10.1055/s-0034-1364932 [Epub 2014 Feb 6] 162

• **Clip-Karussell.**

Groth S, Hamburg, Germany

S. Groth elaborated on the endoscopist's option once it comes to use clips. Interesting enough he exempted the OTSC from the rest of all products stating that OTSC is playing in a different league.

(Comment by Ovesco: **the comparator of OTSC is surgery!**)

• **Techniken zum Perforationsverschluss**

Fritscher-Ravens A, Kiel

A. Fritscher-Ravens underlined in her talk on techniques of perforation closure the importance and advantages of the use of the Twin Grasper. Other than that she referred to OTSC as standard treatment.

Altogether five posters were dealing with OTSC:

• **Over-the-Scope Clip System (OTSC) – One Therapy for Safety Closure**

Leonhardt K, Ohse A, Bauer B, Repp M, Altenburg, Germany report their 3.5-year experience with our system regarding the three major indications: hemorrhage, acute perforation, and chronic fistula/anastomotic leakage where they achieved a 85.7%, 84.6%, and 60% success rate.

33 patients were included in this retrospective analysis. Average age was 69 years (41–92 ys). Three patients received two clips at once. Across the GI tract the number of patients was equally distributed, except for Jejunum and Ileum with only one patient each. The authors conclude that OTSC is a useful and effective tool for the

endoscopist sparing the surgeon in many cases.

• **The OTSC System in the treatment of a perforation of the colon complicated by adhesion of small bowel**

H. Albrecht et al., Erlangen, Germany presented a case report. During diagnostic colonoscopy they experienced an acute perforation which was as usual closed with an OTSC clip. After a few days the patient developed acute symptoms with free sub-diaphragmatic air which led to a sigmoidal resection and overstretch of the small bowel. The authors point out the possible risks of the use of OTSC.

Comment by Ovesco: the authors used suction only for getting colonic tissue into the cap. Already during this process small bowel was trapped in the cap and could clearly be seen between the teeth of the closed clip. The IFU of the product recommend the use of the Twin Grasper for fresh perforations. Suction may be used after the edges of a fresh perforation have clearly been identified and pulled into the cap.

Einsatz des Over-the-Scope Clips (OTSC) zur Behandlung einer Colon-Perforation verursachte eine Dünndarmfixation mit nachfolgender chirurgischer Resektion

Albrecht H, Nägel A, Hagel A, Rösler W, Förtsch T, Neurath MF, Raitheil M

• **Comparison of the OTSC and cSEMS in the treatment of gastrointestinal leakages: results of retrospective multicenter analysis**

H. Famik et al. reported in a very important paper of the interventional therapy of postoperative (73, 69%), postinterventional leakages (24, 23%), and 9 (8%) spontaneous perforations. Primary closure was done with an cSEMS in 72 patients. (69%), and with OTSC in 31 pts. (29%). Average duration of the treatment needed 45.6 days with cSEMS versus only 19.8 days in patients of the OTSC group. Treatment was complicated in 66.7% of cSEMS patients, and only in 5.9% in the OTSC group. 1.12 interventions (1.00-1.23) were needed with OTSC, 2.44 (2.12 – 2.76) in the cSEMS group. The diameter of the defect was larger in the cSEMS group (12.6 mm, 10.9-15.2) than in the OTSC group (7.1, 4.4-9.7).

	OTSC	cSEMS	P
Age (mean, years)	60.82	63.3	n.s.
Gender (m/f)	22/12	53/19	
Diameter of leakage (mean mm, 95% ci)	7.1 (4.4-9.7)	12.6 (10.9-15.2)	
Duration of defect (days)	10.97	7.96	n.s.
Local infection (n, %)	15(44%)	51(71%)	
Number of interventions (mean, 95% ci)	1.12 (1.00-1.23)	2.44 (2.12-2.76)	
Technical success (n, %)	33 (97.1%)	71 (98.6%)	n.s.
Duration of treatment	24.8	38.9	
Dislocation rate (n, %)	1 (3%)	17 (24%)	

The authors conclude in their discussion that OTSC is the preferred primary therapy of smaller post-interventional leakages. It might also be used in combination where cSEMS treatment was incomplete. They conclude that the longer treatment period with cSEMS and the higher complication rate might be due to sicker patients, but also due to the relevant dislocation rate of cSEMS.

Vergleich zwischen OTS-Klipp und cSEMS zur Indikationsstellung bei der Behandlung gastrointestinaler Leckagen: Ergebnisse einer retrospektiven, multizentrischen Analyse

Famik H¹, Driller M¹, Kratt T², Schmidt C³, Fährdrich M⁴, Friedrich-Rust M¹, Filmann N¹, Königsrainer A², Stallmach A³, Heike M⁴, Zeuzem S¹, Albert J¹

¹Frankfurt am Main, ²Tübingen, ³Jena, ⁴Dortmund, Germany

• **Endoscopic treatment of acute bleedings with an Over-The-Scope Clip (OTSC)**

A. Braun et al. investigated the role of OTSC in the treatment of acute GI hemorrhage in an emergency. Between 2011 and 2013 they treated 16 patients (median 75.5 y/o (61-92), m=9, f=7) with OTSC for upper and lower-GI bleeding (8 each). Patients with upper-GI bleeding

received high PPI-medication simultaneously. 7 patients were classified F Ia, 7 F Ib, and 2 F IIa. All patients presented with an acute decrease of hemoglobin, with hematemesis, melena, and hematochezia. The clip was applied by using a standard forceps. Technical success was achieved in all 16 patients (100%) with immediate primary hemostasis. None of the interventions took longer than 20 minutes. Only 6 patients underwent follow-up endoscopy between day 1 and 7 after clip application. All control endoscopies were uneventful and showed clinical success. 9 patients did not need any further endoscopy. None of the patients needed any further therapy for bleeding. All patients started normal oral intake from day 2.

The authors conclude that OTSC is safe and effective for the treatment of hemorrhage which reduces mortality, with short intervention times.

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

Braun A, Richter-Schrag HJ, Fischer A, Freiburg, Germany

• Clinical experience in the treatment of perforations, leakages, and fistulas in the GI tract with the Over-the-scope clip (OTSC)

J. Stücker et al. report their retrospective results in the standard indications of OTSC.

21 patients (Median 69 years (30–87), m=11, f=10) were treated for leakages and fistulas (n=11, 52%) due to anastomotic leaks. 5 patients had complications due to diagnostic or therapeutic endoscopy. 2 patients had fistulas due to necrotizing pancreatitis. 2 patients suffered from a persistent PEG fistula. Technical success was reported in 20/21 cases (95%). All 5 endoscopic complications could successfully be treated with OTSC. 7/11 anastomotic leaks could successfully be treated as well. One patient with duodenal leak due to acute necrotizing pancreatitis and a patient with perforated antrum died due to sepsis. The treatment of persistent PEG fistula was clinically not successful in this series.

The authors conclude that altogether the treatment of perforations, leakages, and fistulas with OTSC is very promising, and point out that this is especially true for the management of complications during endoscopy and surgical complications like anastomotic leakage.

Klinische Erfahrungen bei der Behandlung von Perforationen, Leckagen und Fistelungen im Gastrointestinaltrakt mit dem Over the scope Clip (OTSC®)

Stücker J, Probst A, Bittinger M, Scheubel R, Ebigo A, Messmann H, Gölder S, Augsburg, Germany

March 2014 | OTSC@FISMAD, Naples, Italy: 77% success in anastomotic leak treatment

At the 20th National Congress of Digestive Diseases, Napoli, Italy, March 19-22, MA Bonino and colleagues, Department of Surgery, Turin University reported about a consecutive series of 26 patients treated with OTSC for postsurgical colorectal leaks.

The mean defect size was 8.7 mm. In 10 cases there were acute and in 16 cases chronic leaks (fistula). 4 cases were complicated by recto-vaginal, 3 by recto-vesical and 7 by colo-cutaneous fistula. In 3 cases OTSC was used to complete earlier vacuum sponge therapy. The overall success rate was 77% (20/26), 90% in acute (9/19) and 69% (11/16) in chronic cases. There were no OTSC-related complications, additional surgery was needed in 2 cases.

Anastomotic leakage is a serious and non infrequent complication in colorectal surgery. Incidence rates in the literature range from 1 to 39%. Clinically relevant leaks are commonly seen in 3-6% of the cases. OTSC closure of colorectal post-surgical leaks and fistula is a safe technique with a high success rate.

Efficacia della clip OTSC per il trattamento di difese e fistole chirurgiche del colon-retto

Efficacy of the Over-The-Scope Clip (OTSC) for treatment of colorectal postsurgical leaks and fistulas

Bonino MA, Verra M, Salvai A, Bullano A, Rapetti L, Arezzo A, Morino M

March 2014 | Management of esophageal perforation with the OTSC System – four new case studies by different authors report favourable results

Spontaneous or iatrogenic esophageal perforation is a life-threatening condition that can lead to severe mediastinitis, sepsis and multiple organ failure.

Endoscopic management has contributed to the decrease of morbidity and mortality associated with surgical repair.

Four different case reports lately published by Dr. Alexander Braun et al., Div. of General Surgery, University of Freiburg, Germany, Dr. Davide Bona et al., Div. of General Surgery, University of Milan, Italy and Dr. Alexandre Ferreira, Dept. of Gastroenterology and Hepatology, Hospital de Santa Maria, Lisbon, Portugal illustrate the successful closure of esophageal perforations with the OTSC System. Two patients presented with Boerhaave's syndrome, one patient had an iatrogenic perforation and one patient suffered from a perforation caused by a fishbone. In all four cases a minimally invasive approach with the OTSC System was chosen.

Two patients were treated with the OTSC clip within 12 hours. Although the two other patients were admitted to hospital not until after 48 h after an episode of vomiting, late management of the esophageal perforation with the OTSC System was successful. After complete closure of the defect, all patients were kept on antibiotic therapy and were discharged in stable condition after 10 days (patient with iatrogenic perforation), 21 days (patient with perforation caused by a fishbone) and 20 or 28 days respectively (patients with Boerhaave's syndrome). 3-month follow-up revealed a free esophageal passage and correct placement of the OTSC clip. The OTSC clip is a new, safe and effective treatment alternative for the management of esophageal perforation. Due to the endoscopic approach and shorter hospital stay, the procedure is more cost effective than conventional surgical procedures.

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

Braun A, Hopt UT, Richter-Schrag HJ

Endo heute 2013; doi:10.1055/s-0033-1334004 131

Management of Boerhaave's syndrome with an over-the-scope clip

Bona D, Aiolfi A, Rausa E, Bonavina L 141

Eur J Cardiothorac Surg. 2013 Jul 18 [Epub ahead of print]

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

Ferreira AO, Lopes J, Velosa J

BMJ Case Rep. 2013 Oct 25;2013 144

pii: bcr2013201614 doi: 10.1136/bcr-2013-201614

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

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

Their case series consisted of 23 consecutive patients treated between November 2011 and September 2012 (mean age 77 years) included the following indications for OTSC placement: stopping GI bleeding (n=9), closing perforation (n=10), closing chronic fistula (n=4) and prevention of post endoscopic submucosal dissection (ESD) duodenal artificial ulcer perforation (n=1). One patient had a perforation that formed a fistula. Lesions were located in the esophagus (n=1), the stomach (n=10), the duodenum (n=5), the sigmoid colon (n=3) and in the rectum (n=4). In 8 patients other therapies preceded OTSC application (e.g. conventional hemostatic clips, local injections, hemostatic coagulation forceps). Median follow-up time was 67 days. The primary technical success rate was 91.3% (21/23). In two cases application

of the OTSC clip was not possible due to stiff, fibrotic lesion edges. The overall clinical success rate (complete closure by using only OTSC clips) was 82.6%. Major contributing factors for OTSC failure were a large lesion size (greater than 20 mm) and a delayed diagnosis (more than 1 week). No patient reported any complications associated with OTSC placement. In conclusion, the OTSC is an interesting and novel device that enhances the armamentarium of therapeutic gastroenterologists.

Efficacy and safety of over-the-scope clip: including complications after endoscopic submucosal dissection

Nishiyama N, Mori H, Kobara H, Rafiq K, Fujihara S, Kobayashi M, Oryu M, Masaki T

World J Gastroenterol. 2013 May 14;19(18):2752-60

doi: 10.3748/wjg.v19.i18.2752 126

January 2014 | OTSC in mucosal flap closure after peroral endoscopic myotomy (POEM)

Maintaining the integrity of the mucosal flap and the reliable closure of mucosal entry during peroral endoscopic myotomy (POEM) is paramount in preventing leakage of esophageal contents into the mediastinal space. In a recently published case series (n=2) Payal Saxena, MD and colleagues, Dept. of Medicine and Div. of Gastroenterology and Hepatology, Johns Hopkins Medical Institutions, Baltimore, Maryland, USA describe their positive experience with the application of the OTSC System for reliable and easy flap closure after POEM.

Both patients presented with dysphagia and regurgitation and were diagnosed with achalasia. It was decided to proceed with POEM. After myotomy of the inner circular muscle bundles it was noted that the mucosal incision had elongated from 2 cm to 4 cm in one case. Whereas the distal part of the mucosal entry was successfully closed with conventional hemostatic clips (Resolution Clip, Boston Scientific) in both cases, closure of the proximal half was not possible even with different clips. As the clips were noted to slip to one side of the mucosal incision, there was a risk of displacing clips into the submucosal tunnel. Hence, all partially attached clips were removed with a biopsy forceps. Finally, complete closure of the mucosal incision was performed with the OTSC clip and the OTSC Twin Grasper in both cases. Contrast swallow of the esophagus the following day revealed no leaks in either patient.

The authors state that the OTSC clip provides more durable closure than standard hemostatic clips and full-thickness closure is achievable due to greater compressive force. Considering that failure of closure risks serious adverse events, like mediastinitis and sepsis, these features of the OTSC clip appear even more attractive.

An alternative method for mucosal flap closure during peroral endoscopic myotomy using an over-the-scope clipping device

Saxena P, Chavez YH, Kord Valeshabad A, Kalloo AN, Khashab MA

Endoscopy. 2013 Jul;45(7):579-81

doi: 10.1055/s-0032-1326398 122

January 2014 | Avoiding Surgery: Minimally invasive endoscopic management of an iatrogenic colon perforation

Iatrogenic lesions of GI organs are a significant complication of diagnostic or interventional endoscopic procedures. Dr. Pilar Díez-Redondo and colleagues, Dept. of Gastroenterology, Hospital Universitario, Río Hortega, Valladolid, Spain present a case report on OTSC clipping for colon perforation closure: For assessment of iron deficiency a 82-year old woman was referred to the endoscopic unit. A gastroscopy confirmed a hiatal hernia. Colonoscopy revealed no abnormalities. 18 cm proximal to the anus an iatrogenic perforation with a size of 12 mm occurred. To close the perforation endoscopically an 11/a OTSC clip was chosen. The target tissue and a piece of omentum were pulled into the applicator cap by suction and the clip released successfully, approximating the edges of the lesion. A small residual recess was closed with two conventional, endoscopic clips. The patient was discharged 10 days after the intervention. A 7-month follow-up confirmed the correct placement of the OTSC.

Iatrogenic colon perforations can cause severe

complications and often require surgery, as the major drawback of an endoscopic approach with conventional clips is the limited ability of these clips to achieve sufficient apposition of the mucosa and submucosa to ensure tight sealing of the perforation. With the advent of the larger and more powerful OTSC clips, surgery can be avoided and perforations managed in a minimally invasive, endoscopic way. For that reason the authors suggest that the OTSC System should be available to all endoscopy units as a bail-out device.

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

Diez-Redondo P, Blanco JI, Lorenzo-Pelayo S, De-la-Serna-Higuera C, Gil-Simón P, Alcaide-Suárez N, Pérez-Miranda M
Rev Esp Enferm Dig. 2012 Oct-Nov;104(10):550-2 103

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

Current guidance has advocated surgery for delayed presentations of Boerhaave's syndrome with evidence of mediastinal contamination. However, Dr. Eamon Ramhamadany and colleagues, Dept. of General Surgery, University Hospital Coventry and Warwickshire, UK, present the successful management of Boerhaave's syndrome in a 69-year-old man by means of the OTSC System, sparing the patient surgery and possible associated complications. The man presented to hospital with an episode of forceful vomiting. A chest radiograph was performed revealing a pleural effusion. After several days without improvement a CT chest showed an oesophageal perforation with mediastinitis. Because of the size of the defect and the delay in presentation, it was decided not to perform surgery, but to apply the OTSC clip for endoscopic repair. A contrast swallow confirmed the correct placement of the clip and the successful closure of the leak. After a total parenteral nutrition for 3 days, the patient was fed via a naso-jejunal tube. Intravenous antibiotics and bilateral chest drains led to a resolving mediastinitis. The whole procedure resulted in a favourable outcome without the need for surgery.

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

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

Ramhamadany E, Mohamed S, Jaunoo S, Baker T, Mannath J, Harding J, Menon V
J. surg. case rep. (2013) 2013 (5): rjt020.
doi: 10.1093/jscr/rjt020 120

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

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

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

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

For the subgroup of seven patients treated for leaks and

perforations a success rate of 87.5% with complete resolution was achieved. The mean follow-up period was 83 days. No complications occurred.

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

Initial Experience with an Innovative Endoscopic Clipping System

Coker AM, Jacobsen GR, Acosta G, Talamini MA, Savides TJ, Horgan S
Surg Technol Int. 2012 Dec;22:39-43 [Epub ahead of print] 111

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

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

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

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

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

Mori H, Shintaro F, Kobara H, Nishiyama N, Rafiq K, Kobayashi M, Nakatsu T, Michi N, Suzuki Y, Masaki T
Dig Endosc. 2013 Jul;25(4):459-61
doi: 10.1111/j.1443-1661.2012.01363.x.
[Epub 2012 Aug 7] 89

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

Dr. Hagel and colleagues, Dept. of Gastroenterology, University of Erlangen-Nuremberg, Germany reported about a consecutive series of 17 cases with perforations of the digestive tract, treated with OTSC clipping. All cases were considered as being candidates for abdominal surgery for closing the perforation. In 11 cases perforation closure with OTSC was immediately successful, thus avoiding surgery in 64.7%. In 6 cases surgical closure was done. The area size of perforation in the successful cases was 21.1 ± 9.1 sqmm; in the unsuccessful group the area size was 97.6 ± 149 sqmm. Unsuccessful cases had on average a larger size, necrotic margins and required more OTSC clips during closure attempts (2.3 ± 0.5, p=0.018).

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

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

Hagel AF, Naegel A, Lindner AS, Kessler H, Matzel K, Dauth W, Neurath MF, Raithe M
J Gastrointest Surg. 2012 Nov;16(11):2132-8
[Epub 2012 Aug 18] 88

July 2013 | OTSC System in transgastric appendectomy

Kaehler et al. report the results of their first 15 patients in a prospective trial on „Transgastric appendectomy“, which now already recruited 30 patients who are currently under follow-up.

From April 2010 the Mannheim group offered to their patients a transgastric appendectomy. Patients with generalised peritonitis and/or local contraindications were not recruited. Out of 111 eligible candidates 15 agreed to undergo the proposed NOTES procedure.

14 out of 15 were actually operated through NOTES, whereas 1 patient was switched to laparoscopic procedure due to severe inflammation and adhesions. In each case the gastrotomy was closed by a single OTSC System using Twin Grasper and 12/6/t clip. All closures were tight primarily and uneventful throughout the follow-up.

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

Transgastric appendectomy

Kaehler G, Schoenberg MB, Kienle P, Post S, Magdeburg R
Brit J Surg. 2013; 100: 911-915 130

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

Dr. C. Gubler and Prof. P. Bauerfeind, Dept of Gastroenterology, Zurich University Hospital, Switzerland, report about the use of the OTSC clip for endoscopic closure of iatrogenic organ perforations. In a consecutive patient series (n=14) they investigated technically successful closure of perforations that occurred as a result of an endoscopic intervention. All patients were followed clinically for 24 hrs. Endoscopic closure was achieved in 13 of the 14 cases (92.8%). In 3 patients abdominal pain led to evaluation of the closure site by laparoscopy as a precaution. All 3 OTSC closure sites were found intact and no segmental resection of the bowel was needed. One OTSC gastric closure patient had gastric resection after histology revealed gastric adenocarcinoma after endoscopic mucosal resection. The authors conclude that GI perforations up to 30 mm diameter, observed during endoscopy should be treated with endoscopic OTSC clip closure.

Endoscopic closure of iatrogenic gastrointestinal tract perforations with the over-the-scope clip

Gubler C, Bauerfeind P
Digestion. 2012;85(4):302-7
doi: 10.1159/000336509. Epub 2012 May 17 81

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

In this first trial from China (after compassionate use cases in patients earlier on) the authors investigated the feasibility of the OTSC System for the closure of gastric perforations in the fundus. This location is of special interest since the handling of a flexible scope in the retroflex position is sometimes quite challenging. The investigation was done in a dog model. The perforation was performed with electrocautery and a needle knife in seven dogs. Closure was performed with one OTSC clip each. The closure was performed in 18.5 +/- 6.4 minutes (team without prior experience). The following leak pressure test with maximum air insufflation and 500 ml methylen blue solution resulted in one minor leak (laparoscopic control) without clinical consequences though. The authors conclude that the OTSC System is safe and appropriate for the closure of acute perforations in the stomach despite the well known difficulties with the J-manoeuvre.

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

Zhang XL, Qu JH, Sun G, Tang P, Yang YS
J Gastroenterol Hepatol. 2012 Jul;27(7):1200-4 86

March 2013 | EndoResect study – Endoscopic full-thickness resection of gastric subepithelial tumors

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

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

EndoResect study – Endoscopic full-thickness resection of gastric subepithelial tumors

Schlag C, Wilhelm D, von Delius S, Feussner H, Meining A
Endoscopy. 2013 Jan;45(1):4-11. Epub 2012 Dec 19

110

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

Dr. Todd H. Baron and colleagues, Division of Gastroenterology & Hepatology, Mayo Clinic, Rochester MN, USA report about their experience with 45 patients and 48 OTSC clip placements from March 2011 to January 2012. Median follow-up time in this mixed cohort was 77 days (30–330 days). Indication break-down included hemostasis (n=7), closure of chronic fistula (n=28), closure of iatrogenic perforations (n=5), closure of post-esophagectomy anastomotic leakage (n=3) and miscellaneous (n=2). Before OTSC placement 49% of the patients had undergone other therapies for their condition that had failed. The overall clinical success rate was 71%. Hemostasis was achieved in 100% of cases. Anastomotic leakage and fistula was closed in 65%. Also one case of OTSC clip removal by means of APC-cutting of a clip hinge is described. The authors conclude that the OTSC clip appears clinically effective and is a welcome addition to the therapeutic armamentarium in the closure of leaks, fistula, perforations and non-variceal bleeding.

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

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

85

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

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

One patient with a 20-mm esophageal perforation was treated with an OTSC, several other clips and an endoloop. A fully covered stent was placed on top to bypass the perforation. The large duodenal perforation in the other patient was initially unsuccessfully treated with a fully covered stent and several clips to avoid migration. After removal of the stent an OTSC and two other clips

were used to close the perforation completely. The perforation was bridged by another fully covered stent that was placed over the closed perforation without fixation. In both patients the stents were removed after several weeks and both sites showed healing of the perforation.

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

Hadj Amor WB, Bonin EA, Vitton V, Desjeux A, Grimaud JC, Barthet M

Endoscopy. 2012;44 Suppl 2 UCTN:E277-8

[Epub 2012 Aug 29]

92

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

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

Toshniwal J et al. report about the use of the OTSC System to anchor a fully covered self-expandable metal stent to prevent stent migration. The patient underwent distal esophagectomy with gastric pull-up. The stent was placed to a postoperative 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

Toshniwal J, Zabielski M, Fry LC, Mönkemüller K

Endoscopy. 2012;44 Suppl 2 UCTN:E288-9

94

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 Dişibeyaz and co-authors, Department of Gastroenterology of Türkiye İhtisas Hospital, Ankara, report about their case series of 9 patients (age 22–65 years). Anastomotic leakage from GI surgical anastomosis was present in 5, fistula in 3 and acute perforation in 1 patient. Type “a” clips were placed in all cases. In 4 cases clip deployment was not undertaken, due to strong tissue fibrosis. In the other 5 patients the clip was successfully deployed and closed the defect without the need of further treatment. The 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) 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

Dişibeyaz S, Köksal AŞ, Parlak E, Torun S, Şaşmaz N

Clin Res Hepatol Gastroenterol. 2012 Dec;36(6):614-21

[Epub 2012 Jun 14]

83

November 2012 | First publication of Japanese experience with OTSC®

In the recent issue of the World Journal of Gastroenterology Dr. Hirohito Mori published first Japanese experiences with the OTSC System.

Two elderly patients who had suffered iatrogenic lesions in the rectum (one large rectal perforation with abscess formation and one recto-vesical fistula). Both patients were not subject to a surgical intervention for poor general condition, and thus were successfully treated with one OTSC clip each. Both interventions resulted in a dramatic improvement of the patients' status. It should be noted that both patients underwent direct endoscopic lavage before closure. This is noteworthy especially in the case with the

abscess where no pararectal drainage was inserted.

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

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

Mori H, Kobara H, Fujihara S, Nishiyama N, Kobayashi M, Masaki T, Izuishi K, Suzuki Y

World J Gastroenterol. 2012 Jun 28;18(24):3177-80

82

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

Anastomotic leaks and fistulas are a severe complication in colorectal surgery. The incidence of clinically relevant leaks is in the range of 3–6% of cases. Prof. Dr. Alberto Arezzo and colleagues, Dept of Digestive, Colorectal and Minimal Invasive Surgery, University of Turin, Italy report about a prospective case series covering 14 consecutive patients, treated between April 2008 and September 2011. Criteria for treatment with OTSC® were a wall opening of <15 mm with no extraluminal abscess and absence of stenosis. The mean defect size treated was 9.1 mm in diameter. One OTSC® clip of either size 11 or 12 was sufficient in all 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 colcutaneous fistula.

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

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

Surg Endosc. 2012 May 12. [Epub ahead of print]

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August 2012 | The interesting case: ERCP-related jejunal perforation managed by OTSC® clipping

In a recent issue of Gastrointestinal Endoscopy Dr. F. Buffoli and colleagues, Digestive Endoscopy and Gastroenterology Unit of the Hospital Institutes, Cremona, Italy presented an interesting case report on OTSC® clipping for jejunal perforation closure: An 85 y/o woman with bile obstruction due to pancreatic cancer presented with jaundice. The patient had Billroth II anatomy from gastric resection due to a peptic ulcer 35 year in the past. Cholangiography showed a bile duct stricture. An endoscope-related perforation of the jejunum with a size about 20 mm was visualized distal of the papilla. After placing a covered self-expanding stent through the biliary duct 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 jejunum was successful. Retroperitoneal fatty tissue was additionally pulled into the cap by suction and created a “retroperitoneal fat patch”. Abdominal CT revealed retroperitoneal air but no free liquids. The patient received parenteral nutrition and antibiotic treatment. The patient remained symptom-free and the jaundice disappeared. Control CT after 20 days demonstrated complete absorption of the air and the patient was discharged. ERCP has a perforation rate of approx. 0.3 to 1.3%, as described in the clinical literature. The authors conclude that for the endoscopic closure of large ERCP-related perforations OTSC® may be considered as a possible treatment.

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

Buffoli F, Grassia R, Iiritano E, Bianchi G, Dizlioli P, Staiano T

Gastrointest Endosc. 2012 May;75(5):1115-7

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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® is „promising, further clinical experience will help to identify the optimal role and indication for OTSC®s in gastrointestinal bleeding“.

Ovesco would like to add that recently Dr. T. Kratt (Endoscopy Unit, Dept. Gen. Surgery, University of Tübingen) has prospectively evaluated 60 consecutive patients with complicated GI hemorrhages with encouraging results (see Ovesco news below „June 2012 | OTSC® in emergency hemostasis: new data demonstrate superior results“). At the same time a 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 regarded 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, Hucl et al. Endoscopy 2011; 43: 01A48) that deal with animal models and prove safety and efficacy of OTSC®, the authors are referring to „an interesting German prospective study ... on snare-resection of gastric subepithelial masses (<3 cm) in 16 patients (Schlag et al. Endoscopy 2011; 43: 01A329). Although endoscopic resection was possible in 12/16 cases, perforation occurred in four patients, which was successfully treated with an OTSC® clip. The technique per se can be regarded as a step towards transgastric endoscopic surgery, and the possibility of secure closure with the OTSC® has a pivotal role providing safety of the procedure...“.

Remark from Ovesco: G. Kähler (Dept. of Surgery, 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.

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

In a second talk, Prof. Dr. Arezzo presented a case study on OTSC® closure of a double entero-cutaneous 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

http://www.eventure-online.com/eventure/welcome.do?type=public&congress=32_2012

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

Voermans et 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 gastric, 12 duodenal, and 13 colonic perforations were included and endoscopic repair was performed by using the Over-the-Scope Clip according to a standardized operating procedure. Primary end point was successful closure, which was determined as endoscopic successful closure without leakage (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

Voermans RP, Le Moine O, von Renteln D, Ponchon T, Giovannini M, Bruno M, Weusten B, Seewald S, Costamagna G, Deprez P, Fockens P; on Behalf of the CLIPPER Study Group

Clin Gastroenterol Hepatol. 2012 Jun;10(6):603-8

[Epub 2012 Feb 20]

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

The German Society for Endoscopy and Imaging Techniques (DGE-BV) held its 42nd Annual Conference in Munich, Germany, from March 22-24. Ovesco's OTSC® clip was the topic of a number of presentations in the scientific programme, as listed below. Part of these presentations were recently published on "Endoskopie heute", the official journal of the DGE-BV. Dres Faehndrich and Sandmann from Dortmund presented their 2-year experience using OTSC® in various indications.

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

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

Sandmann M, Heike M, Fährndrich M

The group of Prof. Hochberger from Hildesheim presented their results of a consecutive series of 40 OTSC® interventions.

In 85% of cases the primary therapeutic goal was reached. Dr. Wedi reported on 23 cases of upper GI bleeding which had been refractory to other therapy before being treated with OTSC® clipping. 19 patients were successfully treated, 2 patients died in spite of attempted

surgical hemostasis and 2 other patients for reasons not related to the endoscopic intervention. He also showed data of 3 perforations with a closure rate of 100%. Also 2 complications were reported. 1 new sigmoid perforation that was seen after successful closure of an EMR-related perforation in the hepatic flexure and one impingement of an endoscopic instrument with an OTSC® clip.

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

Wedi E, Menke D, Hochberger J

The group around Prof. Raithehl from Erlangen summarized their experience of 17 cases of OTSC® perforation closures in a retrospective evaluation. Dr. Hagel reported an overall success rate of 64.7%. He distinguished between cases with vital and with necrotic or inflamed tissue margins. In cases with non-vital wound margins the number of clips was greater than 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

Hagel A, Nägel A, Lindner A, Kessler H, Matzel K, Diebel H, Raithehl S, Neurath MF, Raithehl M

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

P22 Pure-NOTES-Sigmaresektion in einem Tier-Überlebensmodell

Bernhardt J, Köhler P, Fabian R, Schneider-Koriath S, Steffen H, Ludwig K, Lamadé W

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

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

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

Moreover, several posters showed results of OTSC System applications:

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

Hagel A, Nägel A, Lindner A, Kessler H, Matzel K, Diebel H, Raithehl S, Neurath MF, Raithehl M, Erlangen

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

Raithehl M, Hagel A, Neufert C, Nägel A, Neurath MF, Schiele A, Kessler H, Erlangen

December 2011 | Systematic literature review: OTSC® is a safe and uncomplicated alternative to surgery in perforation closure

The recent issue of "Endoskopie heute", the official journal of the German Society for Endoscopy (DGE-BV), publishes a systematic literature review on Ovesco's OTSC® clip. The paper, presented by Dr. A. Kirschniak 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 [OTSC-Clip System – Clinical Applications and Experimental Experiences – A Systematic Review]

Kirschniak A, Falch C, Kirschniak N, Storz P, Kratt T.

Endo heute 2011; 24: 195-200

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

OP447 BETTER OUTCOME OF ENDOSCOPIC MANAGEMENT VS SURGERY FOR UPPER GASTROINTESTINAL PERFORATION

Anne Vijverman, Belgium; Hubert Piessevaux; Tarik Aouattah; Jean-François Gigot; 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 DGAV (German society of digestive & metabolic disease and German society 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 intrathoracic anastomotic insufficiency" and "Therapeutic concept for intraabdominal anastomotic insufficiency" session participants 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 Karolinska 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 followup, a month later, the patient presented fully recovered. The second patient, a 83-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 conventional surgical treatment of peptic ulcer perforations.

Att behandla perforerade peptiska ventrikel-ulkus med endoskopi; fallrapport på två patienter

Fredrik Swahn, Lars Enochsson, Magnus Nilsson, Lars Lundell, Matthias Löhr, Urban Amelo

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

A new case series, reported by Dres Sandmann, Heike and Faehndrich, Klinikum Dortmund Mitte, Germany, was published in the German *Zeitschrift fuer Gastroenterologie*.

The authors present a series of 10 patients with penetrating defects within the digestive tract. Pathologies were fistulas (esophagotracheal, esophagopleural, gastrocutaneous and colovesical), perforations (after mucosectomy, after papillotomy and PEG misplacement) and anastomotic leakages (after gastrotomy 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, Anastomosal Leakages and Perforations within the Gastrointestinal Tract

Sandmann M, Heike M, Faehndrich M. Z Gastroenterol. 2011 Aug;49(8):981-5 [Epub 2011 Aug 2]

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August 2011 | OTSC® clip among most promising technologies for closure of perforations in the digestive tract

In the latest issue of the Spanish journal *Gastroenterologia y Hepatologia* Dr. F. Junquera and colleagues, from the Servicio de Aparato Digestivo, Corporación Parc Taulí, Sabadell, Spain, describe the OTSC® System and its use in full thickness perforations of the digestive tract. The authors conclude that OTSC® is one of the most promising technologies for closure of perforations of the gastrointestinal tract because of its efficacy, safety and rapidity. Other indications include severe gastrointestinal bleeding, fistulae, anastomotic leaks, and bariatric surgery anastomosis remodelling.

OVESCO: a promising system for endoscopic closure of gastrointestinal tract perforations (in Spanish)

Junquera F, Martinez-Bauer E, Miquel M, Fort M, Gallach M, Brullet E, Campo R. Gastroenterol Hepatol. 2011 Oct;34(8):568-72 [Epub 2011 Jul 14]

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March 2011 | The Over-The-Scope Clip (OTSC®) for the treatment of gastro-intestinal 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 preoperative marking (n = 4).

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

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

Kirschniak A, Subotova N, Zieker D, Königsrainer A, Kratt T Surg Endosc. 2011 Sep;25(9):2901-5 [Epub 2011 Mar 18]

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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 Arabellapark 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 I1+2

Komplikationsmanagement: Perforationen und post-operative Leckagen

Workshop J1 and Workshop J2

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

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 endoskopischer R1 Resektion eines low grade kolorektalen Frühkarzinoms

M Sandmann, M Heike, M Fährndrich, 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 Fährndrich, 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“ (OTSC) zum Verschluss von intestinalen Leckagen und zur Therapie der intestinalen Blutung

J Albert, M Friedrich-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)

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

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

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

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

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

“Sparing the surgeon”: clinical experience with over-the-scope clips for gastrointestinal perforation

Seebach L, Bauerfeind P, Gubler C Endoscopy 2010; 42:1108-11

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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. Eisendrath, 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?

Eisendrath P | Endoscopy 2010; 42:753-4

33

An initial case series (n=2) on endoscopic closure of postoperative esophageal leaks with the OTSC® clip is presented by Dr. J. Pohl et al., Wiesbaden, Germany. The authors conclude that OTSC® clipping is an effective endoscopic treatment of intrathoracic esophageal leaks and might be considered as a valid alternative to stent treatment in selected cases.

Endoscopic closure of postoperative esophageal leaks with a novel over-the-scope clip system

Pohl J, Borgulya M, Lorenz D, Ell C Endoscopy 2010;42:757-9

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

The leading German speaking endoscopy journal "Endoskopie heute", Official Journal of the German Society for Endoscopy (DGE-BV), reports about the OTSC® clip. Juergen Hochberger, MD, PhD, Hildesheim, Germany, and coauthors describe the state-of-the-art in technical aspects

and equipment for Endoscopic Submucosal Dissection (ESD). Perforations of the 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) Technical Aspects at the Endoscopic Submucosal Dissection (ESD)

Hochberger J, Dammer S, Menke D, Kruse E, Köhler P, Bürrig KF

Endoskopie heute 2010; 23: 24–33

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

A multicentric study performed at 2 Italian endoscopy centers (General Hospital, San Remo, and Humanitas Hospital, Milan) has investigated the use of the OTSC® clip for closure in 10 patients. Indications for digestive organ wall closure included acute perforations, fistula and anastomotic leakage. The location of the leak was gastric (n=2), duodenal (n=2) and colonic (n=6). The leak diameter ranged from 7 to 20 mm.

After closure with the OTSC® clip, patients received followup 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 Bianchi, M Conio

Gastrointest Endosc. 2010 Oct; 72(4):881-6

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

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

Kratt T, Stüker D, Küper M, v. Feilitzsch M, Königsrainer A, Kirschniak A

There were two more reports on successful application of Ovesco's OTSC® System:

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

Kratt T, Stüker D, Brücher B, Heininger A, Miller S, Königsrainer A

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

Kratt T, Kramer M, v. Feilitzsch M, Strese C, Küper M, Schenk M, Greiner T, Lange J, Kirschniak A, Minkley L,

Schröppel K, v. Weyhern CH, Königsrainer A

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

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

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

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

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

The primary endpoint was successful closure, defined as macroscopic adequate closure and no leakage on water soluble contrast X-ray within 24 hours without additional interventions. He reported on 24 of 36 planned consecutive patients in the participating centers. Primary closure could be achieved in 22 of 24 patients. One patient suffered other complications before the clip could be applied, and one patient failed adequate placement of the clip. Only one 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.

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 „effectiveness“, leading to the highest overall score of all systems.

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

Arezzo A, Morino M.

Surgical Endoscopy 2010 24:2; 298-303

March 2010 | Tuebingen University starts clinical NOTES trial on diagnostic laparoscopy. Successful closure of gastric NOTES access

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

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

Prof. Won Young Cho et al. from the Dept. of Gastroenterology (Director: Prof. Ju Young Cho) at the College of Medicine, Sooncheonhyang University, Korea, refer to the OTSC® clip as an endoscopic device for treating postinterventional bleeding or organ wall lesions in the chapter on Endoscopic Submucosal Dissection (ESD) of the recently published book „Endoscopic Treatment of Gastric Cancer“. Prof. Won Young Cho and his colleagues are leading users of Ovesco's OTSC® in South Korea.

Endoscopic Treatment of Gastric Cancer

Won Young Cho, Tae Hee Lee, Yoon Seon Park, Ju Young Cho

Endoscopic Submucosal Dissection (ESD), pp 16-52; Jin Publishing Co. Ltd. Seoul, Korea, 2009
ISBN 978-89-90698-48-3

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

At this year's EndoClubNord at the Congress Center Hamburg Ovesco's OTSC® (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 transmural endoscopic cutting of the muscular layer. The stomach was closed through the flexible endoscope with two OTSC® gc clips, was re-inflated thereafter and proved to be tight. The surgical team then closed the outer of the stomach 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

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

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

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

Closure of chronic lesions

September 2015 | OTSC as effective treatment of GI fistulae: abscess drainage increases healing rates to 88%

Dr. P. Mercky, Dr. J.-M. Gonzalez, Dr. E. Aimore Bonin, Dr. O. Emungania, Dr. J. Brunet, Dr. J.-C. Grimaud and Dr. M. Barthet of the Departments of Gastroenterology and Digestive Surgery, North Hospital, Méditerranée University, Marseille, France, presented the results of a retrospective study in two teaching hospital centers.

The study encompassed 30 patients (12 male, 18 female) of 23 to 75 years of age (mean age: 48) suffering from GI fistulae (upper GI: 24; lower GI: 6). 60% of fistulae (18 patients) occurred after laparoscopic sleeve gastrectomy (LSG), the other 12 patients suffered from fistula at mixed locations (rectovaginal, urethrorectal, rectovesical, gastrogastric, gastrocutaneous, esophagojejunal fistulae and one colorectal anastomotic leak). Fistula orifice sizes ranged from 3 mm to 20 mm (mean: 7.2 mm) and mean time between fistula diagnosis and OTSC placement was 12.4 months (8 days to 10 years). 18 patients (60%) had previously undergone endoscopic or surgical treatment attempts of their fistula in another center.

The OTSC clip was placed successfully in all cases and 16 patients (53%) recovered without further intervention. Others required secondary treatment. Overall final success rate in the whole group was 70%.

Regarding efficacy, the paper notes several points:

In patients with a previously drained abscess, the success rate was significantly higher (88.2% healing vs. 53.8%). The highest primary efficacy, however, could be reported for fistulae related solely to LSG (88.9%).

Efficacy was related to operator experience since the overall success rate of the high-volume center was higher than that of the low-volume center (74% vs. 60%).

The authors note that OTSC placement allows closure of much larger fistulae (<30 mm) in a single procedure than standard clips, and that the procedure is similar to the well-established technique of band ligation, which helps the operators' learning curve. They also state that it enables treatment of difficult-to-treat fistulae, e.g. those at the lower extremity of the staple line after LSG. Judging from the eight patients who did not benefit from OTSC placement, the authors speculate that previous radiotherapy (and resulting microvascular lesions) as well as cardiovascular risk factors might impede fistula closure with OTSC. Overall, they deem the OTSC system a safe and effective treatment for GI fistulae, both as a primary and secondary option. They also emphasize that the treatment of serious and difficult-to-treat leakages after LSG especially benefitted from the use of OTSC.

Usefulness of over-the-scope clipping system for closing digestive fistulas.

Mercky, P, Gonzalez, JM, Aimore Bonin E, Emungania O, Brunet J, Grimaud JC, Barthet M.
Dig Endosc. 2015 Jan;27(1):18-24.
doi: 10.1111/den.12295.

185 | 238

January 2015 | OTSC clip for closure of pancreatico-colonic fistulas – new case studies

J. Ito, Y. Igarashi, T. Mimura et al., Division of Gastroenterology and Hepatology, Toho University Omori Medical Center, Tokyo, Japan, published a case study on the successful OTSC closure of a colonic fistula complicating severe pancreatitis. Dr. E.C. Gorospe, Dr. S. Desai, Dr. B. Al-Bawardy et al., Division of Gastroenterology and Hepatology, Mayo Clinic, Rochester, Minnesota, USA, describe the clip closure of a pancreatico-colonic fistula caused by severe necrotizing pancreatitis. Y. Koike, T. Kudo, T. Shigesawa et al., Department of Gastroenterology, Sapporo City General Hospital, Sapporo, Japan, presented the closure of a colonic fistula complicating a pancreatic pseudocyst.

The Tokyo case was a 44-year-old male with hyperlipidemic acute pancreatitis including an abscess in the left abdominal cavity and immense peripancreatic fluid collection. Conservative treatment resulted in middling success. A disruption on the tail of the main pancreatic

duct was suspected and confirmed after 90 days and treated with an ENPD tube and a pancreatic stent, which proved ineffective. After conservative management options had been exhausted, surgical therapy was considered, but postponed due to presence of E. coli and MRSA in abscess culture. Finally, an OTSC clip was used on day 148 to endoscopically seal the fistula. A follow-up indicated complete sealing of the leak and improved healing. After the patient had been upgraded to a full diet, an endoscopic pancreatic stent was placed to deal with increased percutaneous drainage. Several follow-ups showed the success of the procedure with improvement of the abscess, clip in situ and healed perforation site with no signs of inflammation, ulceration or pancreatic duct disruption. Patient is well and now receives outpatient care for hyperlipidemia.

The Mayo Clinic reported the case of a 69-year-old female with necrotizing pancreatitis, who had had 3 previous transgastric necrosectomies. When she was hospitalized 3 weeks after her last necrosectomy, there was reflux of fecal-like material into the debrided cavity as well as a sigmoid structure, likely caused by pancreatic necrosis and pancreatic secretions directly into the colon through fistulae. Two fistulae were located and closed from a colonic approach using OTSC clips. Closure was confirmed fluoroscopically and endoscopically. After 7 months, the patient remained asymptomatic.

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

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

Ito K, Igarashi Y, Mimura T, Kishimoto Y, Kamata I, Kobayashi S, Yoshimoto K, Okano N

Case Rep Gastroenterol. 2013 Jul 23;7(2):314-21

Print 2013 May

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Over-the-scope clip closure of pancreaticocolonic fistula caused by severe necrotizing pancreatitis

Gorospe EC, Desai S, Al-Bawardy B, Baron TH, Buttar NS, Wong Kee Song LM

Gastrointest Endosc. 2014 May;79(5):71

Epub 2013 Dec 12

158

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

Koike Y, Kudo T, Shigesawa T, Fujita Y, Endo A, Ono Y, Nakamura M, Nagasaka A, Nishikawa S

Endoscopy. 2014;46 Suppl 1 UCTN:E178-9

Epub 2014 Apr 22

191

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

Dr. T. H. Kothari and Dr. G. Haber, Division of Gastroenterology, Lenox Hill Hospital, New York, USA published a three-case series on closure of fistulas in the alimentary tract, while Dr. T. Meister, Dr. J. Kuhlitz and Dr. M. Floer, Helios-Albert-Schweitzer-Klinik, Northeim, Germany published a case report on closure of a postoperative entero-cutaneous fistula.

The first New York case was an 80-year-old female with dysphagia, history of aortic valve regurgitation, esophageal perforation due to TEE, repair with feeding jejunostomy and venting gastrostomy. Healing resulted in a gastrocutaneous fistula, which persisted for 9 months despite PPI therapy. Tissue was grasped with OTSC Anchor and pulled into the cap, then an OTSC clip was successfully deployed. Follow-up after 3 months showed that the fistula had fully healed.

The second case was a 36-year-old female with a history of diverticulosis, presenting with passage of feculent

material from her vaginal canal and recurrent urinary tract infections. CT scan revealed a fistula between sigmoid colon and vagina, but locating it gastroscopically was difficult. The OTSC clip was deployed, resulting in good tissue entrapment. The patient was symptom-free for several weeks. When symptoms recurred, surgery revealed an abscess communicating with the colovaginal fistula, which prevented healing.

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

The German case report was about a 48-year-old female suffering from an enterocutaneous fistula for four months, leading to malnourishment. Prior attempts to close the fistula with fibrin glue had failed. The OTSC clip was placed onto the fistula opening under continuous suction and successfully deployed. Follow-up after 12 months showed continued success.

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

Kothari TH, Haber G, Sonpal N, Karanth N

Can J Gastroenterol. 2012 Apr;26(4):193-5

160

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

Meister T, Kuhlitz J, Floer M

Acta Chir Belg. 2014 Jan-Feb;114(1):87-9

186

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

Dr. Vijay Jayaraman and colleagues, Cedars Sinai Medical Center, Los Angeles, recently presented a retrospective study on their experience with the OTSC System in the treatment of GI bleeding, fistula and perforation. Their case series consisted of 24 consecutive patients treated between January 2011 and April 2012 (mean age 70 years) included the following indications for OTSC placement (28 clips): postsurgical enterocutaneous fistula (n=10), spontaneous perforation (n=1), anastomotic leak (n=4), perforation after mucosal resection (n=3), prophylactic closure of mucosal defect after EMR (n=1), postpolypectomy bleeding (n=2), postendoscopic perforation (n=2), tracheoesophageal fistula (n=1) and leakage from a percutaneous jejunostomy site (n=1). Instruments or modalities used to grasp the tissue were dedicated devices (OTSC Twin Grasper and OTSC Anchor) in 16 and nondedicated devices (rat tooth/alligator forceps or suction alone) in 15. Median follow-up time was 2.9 months; mean defect size 10 mm (range 5–2 mm). The overall success rate was 61%. In their experience the success rate of closure of an acute defect is higher compared to chronic fistula. 9 out of 24 lesions were chronic (> 1 month) in this series which might explain the lower overall success rate in comparison to the literature (72–100%).

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

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

Clinical Application and Outcomes of Over the Scope Clip Device: Initial US Experience in Humans

Jayaraman V, Hammerle C, Lo SK, Jamil L, Gupta K

Diagn Ther Endosc. 2013;2013:381873

doi: 10.1155/2013/381873

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June 2014 | Three case reports on surgery-sparing uses of the OTSC clip in multiple

indications

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

The first case report describes the use of the OTSC System in the management of a Dieulafoy lesion. A 74-year old man suffered from a recurrent, obscure, life-threatening gastro-intestinal bleeding. EGD revealed a non-bleeding Dieulafoy lesion at the lesser gastric curvature. Due to the large size and difficult position of the lesion, conventional through-the-scope clips were not used, but an OTSC clip was successfully deployed.

In another case report a 61-year old woman presented for EGD for evaluation of dysphagia. Four arteriovenous malformations were found in the duodenum, which were cauterized. On withdrawing the endoscope, a 2-cm gastric perforation was identified on the lesser curvature. Using the suction technique an OTSC clip was applied to close the defect.

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

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

Gómez V, Kyanam Kabir Baig KR, Lukens FJ, Woodward T

Endoscopy. 2013;45 Suppl 2 UCTN:E71.

doi: 10.1055/s-0032-1326073

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

Singhal S, Atluri S, Changela K, Gupta SS, Krishnaiah M, Anand S

Gastrointest Endosc. 2014 Jan;79(1):23.

doi: 10.1016/j.gie.2013.07.050

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

Albert JG | Video Journal and Encyclopedia of GI Endoscopy. 2013 June, pages 219–20

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April 2014 | Multipurpose use of the OTSC System to treat endoluminal gastrointestinal disorders

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

The range of indications included gastrointestinal bleeding (n=6), gastrocutaneous fistulas (n=3), esophagotracheal and/or esophagopleural fistulae (n=3), resection of submucosal tumor (n=2), stent fixation (n=1), and anastomotic leak after esophagectomy (n=1). The overall per case success rate was 70% (14 of 20 applications). Mean follow-up was 10 months (range 1-10). There were no complications (0%) related to endoscopy, sedation or application of the clipping device.

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

Comment Ovesco: especially in cases where the

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

In essence the authors draw a very positive conclusion stating "that the OTSC device is ideally suited to treat soft tissue leaks or fistulizing lesions and high-risk bleeding lesions such as ulcers in the posterior duodenum or Dieulafoy's lesions" with the main underlying mechanism being compressing the surrounding tissue around the vessel. They continue "...The OTSC device may become a better device to treat bleeding ulcers located in difficult positions because of its barrel-shaped transparent cap design which allows it to suction the bleeding lesion. It is well known that these bleeding ulcers and lesions are of a higher risk and also more difficult to treat because of their awkward location and/or position...". This statement is followed by an elaborate discussion of the shortcomings of alternative devices. It is important to underline also that the authors support "... multiple OTSC applications in a single session..." as sometimes being useful and allowing approximation of tissue to facilitate subsequent closure. "Interestingly, the device does not tear tissue, as it snaps it together. So far, there have been no reports of GI wall tearing..."

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

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

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

Mönkemüller K, Peter S, Toshniwal J, Popa D, Zabielski M, Stahl RD, Ramesh J, Wilcox CM

Dig Endosc. 2014 May;26(3):350-7

doi: 10.1111/den.12145 | Epub 2013 Jul 16

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March 2014 | OTSC@FISMAD, Naples, Italy: 77% success in anastomotic leak treatment

At the 20th National Congress of Digestive Diseases, Napoli, Italy, March 19-22, MA Bonino and colleagues, Department of Surgery, Turin University reported about a consecutive series of 26 patients treated with OTSC for postsurgical colorectal leaks.

The mean defect size was 8.7 mm. In 10 cases there were acute and in 16 cases chronic leaks (fistula). 4 cases were complicated by recto-vaginal, 3 by recto-vesical and 7 by colo-cutaneous fistula. In 3 cases OTSC was used to complete earlier vacuum sponge therapy. The overall success rate was 77% (20/26), 90% in acute (9/19) and 69% (11/16) in chronic cases. There were no OTSC-related complications, additional surgery was needed in 2 cases.

Anastomotic leakage is a serious and non infrequent complication in colorectal surgery. Incidence rate in the literature range from 1 to 39%. Clinically relevant leaks are commonly seen in 3-6% of the cases. OTSC closure of colorectal post-surgical leaks and fistula is a safe technique with a high success rate.

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

Efficacy of the Over-The-Scope Clip (OTSC) for treatment of colorectal postsurgical leaks and fistulas

Bonino MA, Verra M, Salvai A, Bullano A, Rapetti L, Arezzo A, Morino M

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

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

Their case series consisted of 23 consecutive patients treated between November 2011 and September 2012 (mean age 77 years) included the following indications for OTSC placement: stopping GI bleeding (n=9), closing perforation (n=10), closing chronic fistula (n=4) and prevention of post endoscopic submucosal dissection (ESD) duodenal artificial ulcer perforation (n=1). One patient had a perforation that formed a fistula.

Lesions were located in the esophagus (n=1), the stomach (n=10), the duodenum (n=5), the sigmoid colon (n=3) and in the rectum (n=4). In 8 patients other therapies preceded OTSC application (e.g. conventional hemostatic clips, local injections, hemostatic coagulation forceps). Median follow-up time was 67 days. The primary technical success rate was 91.3% (21/23). In two cases application of the OTSC clip was not possible due to stiff, fibrotic lesion edges. The overall clinical success rate (complete closure by using only OTSC clips) was 82.6%. Major contributing factors for OTSC failure were a large lesion size (greater than 20 mm) and a delayed diagnosis (more than 1 week). No patient reported any complications associated with OTSC placement. In conclusion, the OTSC is an interesting and novel device that enhances the armamentarium of therapeutic gastroenterologists.

Efficacy and safety of over-the-scope clip: including complications after endoscopic submucosal dissection

Nishiyama N, Mori H, Kobara H, Rafiq K, Fujihara S, Kobayashi M, Oryu M, Masaki T

World J Gastroenterol. 2013 May 14;19(18):2752-60

doi: 10.3748/wjg.v19.i18.2752

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January 2014 | OTSC in mucosal flap closure after peroral endoscopic myotomy (POEM)

Maintaining the integrity of the mucosal flap and the reliable closure of mucosal entry during peroral endoscopic myotomy (POEM) is paramount in preventing leakage of esophageal contents into the mediastinal space. In a recently published case series (n=2) Payal Saxena, MD and colleagues, Dept. of Medicine and Div. of Gastroenterology and Hepatology, Johns Hopkins Medical Institutions, Baltimore, Maryland, USA describe their positive experience with the application of the OTSC System for reliable and easy flap closure after POEM.

Both patients presented with dysphagia and regurgitation and were diagnosed with achalasia. It was decided to proceed with POEM. After myotomy of the inner circular muscle bundles it was noted that the mucosal incision had elongated from 2 cm to 4 cm in one case. Whereas the distal part of the mucosal entry was successfully closed with conventional hemostatic clips (Resolution Clip, Boston Scientific) in both cases, closure of the proximal half was not possible even with different clips. As the clips were noted to slip to one side of the mucosal incision, there was a risk of displacing clips into the submucosal tunnel. Hence, all partially attached clips were removed with a biopsy forceps.

Finally, complete closure of the mucosal incision was performed with the OTSC clip and the OTSC TwinGrasper in both cases. Contrast swallow of the esophagus the following day revealed no leaks in either patient.

The authors state that the OTSC clip provides more durable closure than standard hemostatic clips and full-thickness closure is achievable due to greater compressive force. Considering that failure of closure risks serious adverse events, like mediastinitis and sepsis, these features of the OTSC clip appear even more attractive.

An alternative method for mucosal flap closure during peroral endoscopic myotomy using an over-the-scope clipping device

Saxena P, Chavez YH, Kord Valeshabad A, Kalloo AN, Khashab MA
Endoscopy. 2013 Jul;45(7):579-81 doi: 10.1055/s-0032-1326398 122

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

Iatrogenic gastric fistulas after bariatric surgery are a potentially dangerous situation as they can lead to severe complications, such as peritonitis and abscess formation. Two case reports recently published by Dr. Victoria Gómez and colleagues, Dept. of Gastroenterology and Hepatology, Mayo Clinic, Jacksonville, USA, and Dr. Hany Shehab et al., Dept. of Gastroenterology, Dar Al Fouad Hospital Giza, Egypt, respectively, describe the closure of gastric fistulas with the OTSC System after laparoscopic bariatric surgery.

Dr. Gómez reports on a 45-year old woman who was hospitalized for management of complications from a prior sleeve gastrectomy. Postoperatively the patient developed fever and abdominal pain. A CT scan showed a fluid collection in the region of the right liver lobe, free intraperitoneal air and an abscess in the postsurgical bed of the stomach. The results of a barium contrast study were consistent with a significant leak in the proximal third of the gastric sleeve. EGD revealed a gastric fistula 4 centimeters below the esophago-gastric junction. As an initial treatment with an esophageal stent and abdominal drains had failed to seal the leak, the stent was removed and a fully covered esophageal stent was applied. A second stent had to be deployed to bridge the prior stent. Since there was no improvement of the fistula, the stents were again removed. As next treatment approach the fistula was grasped with the OTSC Twin Grasper and closed by application of an OTSC clip. A follow-up radiograph showed no extravasation of contrast.

Dr. Shehab presents the case of a 36-year old man who had undergone a Roux-en-Y gastric bypass for morbid obesity. Postoperatively an anastomotic leak was found. Two attempts of surgical repair failed as well as a conservative approach with drainage and insertion of a feeding jejunostomy. 5 months after the first surgery an EGD revealed a well-epithelialized fistula with a wide lumen. It was decided to close the fistula by OTSC-clipping. To remove the epithelium at the fistula orifice, argon plasma coagulation was applied to the proximal lumen of the fistula. Then the OTSC Twin Grasper was used to approximate the edges of the fistula orifice followed by the application of the OTSC clip. After 10 months there was no evidence of a fistula recurrence.

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

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

Gómez V, Lukens FJ, Woodward TA
Surg Obes Relat Dis. 2013 Mar-Apr;9(2):e31-3
doi: 10.1016/j.soard.2012.09.004 99

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

Shehab HM, Elasmr HM
Surg Endosc. 2013 Aug;27(8):2967-70
doi: 10.1007/s00464-013-2839-1 Epub 2013 Feb 23 119

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

Dr. Rudolf Mennigen and colleagues, Dept. of General and Visceral Surgery, University Hospital of Muenster, Germany, recently presented a study on efficacy and safety of the OTSC System in endoscopic closure of postoperative gastrointestinal leakages and fistulas,

concluding that the OTSC System dramatically increases the possibilities of defect closure by endoscopic clipping as opposed to conventional endoclips.

Their case series of 14 consecutive patients (May 2011–November 2012) included patients with anastomotic leakage (n=6) e.g. after gastrectomy, perforation after fundoplication (n=1) and post-operative fistulas (n=7, colocolic, enterocolic, gastrobronchial, rectourethral, rectocutaneous, gastropleural). 11 of the 14 lesions were chronic (treated by OTSC later than postoperative day 14) and in 9 patients other therapies preceded OTSC application (e.g. covered stent application, fibrin glue injection). Median follow-up time was 5.5 months.

The primary procedural success rate was 100%. 3/14 patients (21%) required further treatment during follow-up. Reasons for OTSC failure were massive fibrosis of the fistula and application in an actively inflamed bowel segment in Crohn's disease. However, unsuccessful OTSC treatment did not impair subsequent surgical therapies. Complete and clinically durable closure of the defects was achieved in 79%, indicating from the authors' point of view that the OTSC will play an important role in the therapy of post-operative leakages.

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

Mennigen R, Colombo-Benkmann M, Senninger N, Laukoetter M
Gastrointest Surg. 2013 Jun;17(6):1058-65
doi: 10.1007/s11605-013-2156-y 115

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

Current guidance has advocated surgery for delayed presentations of Boerhaave's syndrome with evidence of mediastinal contamination. However, Dr. Eamon Ramhamadany and colleagues, Dept. of General Surgery, University Hospital Coventry and Warwickshire, UK, present the successful management of Boerhaave's syndrome in a 69-year-old man by means of the OTSC System, sparing the patient surgery and possible associated complications. The man presented to hospital with an episode of forceful vomiting. A chest radiograph was performed revealing a pleural effusion. After several days without improvement a CT chest showed an oesophageal perforation with mediastinitis. Because of the size of the defect and the delay in presentation, it was decided not to perform surgery, but to apply the OTSC clip for endoscopic repair. A contrast swallow confirmed the correct placement of the clip and the successful closure of the leak. After a total parenteral nutrition for 3 days, the patient was fed via a naso-jejunal tube. Intravenous antibiotics and bilateral chest drains led to a resolving mediastinitis. The whole procedure resulted in a favourable outcome without the need for surgery.

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

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

Ramhamadany E, Mohamed S, Jaunoo S, Baker T, Mannath J, Harding J, Menon V
J. surg. case rep. (2013) 2013 (5): rjt020.
doi: 10.1093/jscr/rjt020 120

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

Postoperative leaks after total gastrectomy are among the most common early complications. Dr. C. N. Ferreira and colleagues, Serviço de Gastrenterologia e Hepatologia, Hospital de Santa Maria, Lisbon, Portugal report on a 78-year old woman presenting with melena. She was diagnosed with gastric adenocarcinoma and treated with total gastrectomy and esophagojejunal Roux-en-Y anastomosis.

On the fifth postoperative day she developed a septic condition caused by a fistulous orifice just above the intact anastomosis. Due to her poor general condition a surgical intervention was unfeasible. Thus, it was decided to treat the fistula endoscopically by means of the OTSC clip. By using the OTSC Twin Grasper to approximate the edges of the fistula and application of an OTSC clip the orifice was effectively closed. The patient was discharged in stable condition two weeks later. In a commentary to this publication Dr. David Robbins, Assistant Editor of the Journal Gastrointestinal Endoscopy emphasizes the significantly higher strength of the OTSC clip for hemostasis and closure of GI tract wall in comparison to conventional endoscopic clips.

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

Noronha Ferreira C, Ribeiro LC, Velosa J, Ferreira J, Ferreira C, Freire JP, Marques J, Ruivo A, Bicha Castelo H
Gastrointest Endosc. 2013 Mar;77(3):497-8 ; 112
doi:10.1016/j.gie.2012.10.031. [Epub 2013 Jan 4]

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

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

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

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

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

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

Initial Experience with an Innovative Endoscopic Clipping System

Coker AM, Jacobsen GR, Acosta G, Talamini MA, Savides TJ, Horgan S
Surg Technol Int. 2012 Dec;22:39-43 [Epub ahead of print] 111

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

Dr. Alberto Murino, Wolfson Unit for Endoscopy, St Mark's Hospital, London, UK, and his colleagues report on a successfully treated gastrocolic fistula using the OTSC System. A migrated PEG tube caused a gastrocolic fistula in the transverse colon in a 41 y/o male with cerebral palsy. The fistula led to extensive diarrhea and mouth odor. The CT showed an involvement of the greater curvature of the stomach.

By using the OTSC Anchor to approximate the tissue the OTSC clip was released precisely closing the fistula orifice completely. Diarrhea and mouth odor were stopped. The 3 months' follow-up revealed a complete healing of the fistula. The second case report published in the World Journal of Gastrointestinal Endoscopy by Prof. Klaus Mönkemüller and his colleagues, Division of Gastroenterology and Hepatology, Basil Hirschowitz Endoscopic Center of Excellence, University of Alabama, Birmingham, USA, describes the effective endoscopic closure of a large

gastrocolic fistula with the OTSC System in an extremely malnourished patient with complex post-surgical upper GI anatomy. The 47 y/o man presented with chronic diarrhea and severe weight loss of 32 kg in a 1-year period. He had a history of chronic pancreatitis, alcoholism and Billroth II gastrojejunostomy due to a perforated peptic ulcer. Endoscopy showed a clean based ulceration at the anastomosis and a second orifice that represented the fistula. Connecting stomach and colon, the fistula measured about 10–12 mm. Because of the patient's poor clinical status he could not benefit from a surgical intervention so an endoscopic procedure using the OTSC System was chosen. To ensure a definitive closure of the fistula the OTSC Twin Grasper was used to approximate the edges of the fistula. The application of the OTSC led to a complete closure of the gastrocolic fistula which was confirmed by an endoscopy.

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

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

Murino A, Despott EJ, Vaizey C, Bashir G, Hansmann A, Gupta A, Konieczko K, Fraser C

Gastrointest Endosc. 2012 Apr;75(4):893; discussion 894
Epub 2012 Jan 31 | doi: 10.1016/j.gie.2011

72

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

Mönkemüller K, Peter S, Alkurdi B, Ramesh J, Popa D, Wilox C

World J Gastrointest Endosc. 2013 Aug 16;5(8):402-6
doi: 10.4253/wjge.v5.i8.402

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August 2013 | The interesting case: OTSC closure of esophagobronchial fistula

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

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

In this situation closure of the fistula with the OTSC clip was decided. A 12/6/t clip was placed under endoscopic control and with the aid of the OTSC Anchor for better manipulation and targeting of the fistula orifice. Immediate technical success was achieved and verified by barium esophagogram 2 days later. The patient was discharged from the hospital after 1 week in stable condition. The clip was still found in place at 1 month follow-up by chest X-ray but passed spontaneously and uneventfully as seen in CAT scan 45 days after the procedure. Final follow-up at 3 months revealed no recurrence or postprandial cough.

Esophagobronchial fistula closure using a novel endo-scope over-the-scope clip

Zolotarevsky E, Kwon Y, Bains M, Schattner M
Ann Thorac Surg. 2012 Sep;94(3):e69-70.

doi: 10.1016/j.athoracsur.2012.02.025

96

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

Dr. Todd H. Baron and colleagues, Division of Gastroenterology & Hepatology, Mayo Clinic, Rochester MN, USA report about their experience with 45 patients and 48 OTSC clip placements from March 2011 to January 2012. Median follow-up time in this mixed cohort was 77 days (30–330 days). Indication break-down

included hemostasis (n=7), closure of chronic fistula (n=28), closure of iatrogenic perforations (n=5), closure of post-esophagectomy anastomotic leakage (n=3) and miscellaneous (n=2). Before OTSC placement 49% of the patients had undergone other therapies for their condition that had failed. The overall clinical success rate was 71%. Hemostasis was achieved in 100% of cases. Anastomotic leakage and fistula was closed in 65%. Also one case of OTSC clip removal by means of APC-cutting of a clip hinge is described. The authors conclude that the OTSC clip appears clinically effective and is a welcome addition to the therapeutic armamentarium in the closure of leaks, fistula, perforations and non-variceal bleeding.

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

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

85

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

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

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

Galizia G, Napolitano V, Castellano P, Pinto M, Zamboli A, Schettino P, Orditana M, De Vita F, Auricchio A, Mabilia A, Pezzullo A, Lieto E

J Gastrointest Surg. 2012 Aug;16(8):1585-9

[Epub 2012 Mar 7]

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November 2012 | First publication of Japanese experience with OTSC®

In the recent issue of the World Journal of Gastroenterology Dr. Hirohito Mori published first Japanese experiences with the OTSC System.

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

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

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

Mori H, Kobara H, Fujihara S, Nishiyama N, Kobayashi M, Masaki T, Izuishi K, Suzuki Y

World J Gastroenterol. 2012 Jun 28;18(24):3177-80

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November 2012 | Performance of the OTSC System in the endoscopic closure of gastrointestinal fistulae – a meta-analysis

The recent issue of "Minimally Invasive Therapy & Allied

Technologies" publishes a systematic review and meta-analysis on the challenging field of closing gastrointestinal fistulae by means of the OTSC System. The paper provides an extensive overview of relevant primary clinical research, case reports and conference abstracts published on this topic. The statistical evaluation of, in total, 19 examined articles revealed a high rate of procedural success (mean 84.6%; 95% confidence interval 66.6% to 93.8%) and durable clinical success (mean 69.0%; 95% confidence interval 51.8% to 82.2%) in OTSC-mediated closing of GI fistulae.

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

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

Weiland T, Fehlker M, Gottwald T, Schurr MO
Minim Invasive Ther Allied Technol. 2012; 21(4):249-58

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

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

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

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

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

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

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

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

Anastomotic leaks and fistulas are a severe complication in colorectal surgery. The incidence of clinically relevant leaks is in the range of 3–6% of cases. Prof. Dr. Alberto Arezzo and colleagues, Dept of Digestive, Colorectal and Minimal Invasive Surgery, University of Turin, Italy report about a prospective case series covering 14 consecutive patients, treated between April 2008 and September 2011. Criteria for treatment with OTSC® were a wall opening of <15 mm with no extraluminal abscess and absence of stenosis. The mean defect size treated was 9.1 mm in diameter. One OTSC® clip of either size 11 or 12 was sufficient in all 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 colocolic fistula.

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

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

Surg Endosc. 2012 May 12. [Epub ahead of print]

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July 2012 | First North American literature report on OTSC®

In a recent issue of the Canadian Journal of Gastroentero-

logy, Dr. T.H. Kothari, Dr. G. Haber and colleagues from the Dept. of Gastroenterology at Lenox Hill Hospital, New York City, reported about their initial experience using Ovesco's OTSC® clip.

They report about the application of OTSC® in the treatment of gastrocutaneous fistula. A case report describes the use of OTSC® in a patient with a persistent gastrocutaneous 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 gastroscopic 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 gastrocutaneous fistula.

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

Kothari TH, Haber G, Sonpal N, Karanth N
Can J Gastroenterol. 2012 Apr; 26(4):193-5

75

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 publish an interesting clinical case report of Dr. Alberto Arezzo from the University of Torino, Italy, of a double anastomotic fistula to the skin after right hemicolectomy, both treated by OTSC®.

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

Alberto Arezzo, Rossella Reddavid, Mauro Verra, Francesca Cravero, Marco Augusto Bonino, Mario Morino
Caso Clinico proposto da Alberto Arezzo. Pubblicato il: 11/05/2012

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

Click here to view the video:

http://www.siedwebtv.it/index.php?option=com_k2&view=item&id=83:trattamento-di-duplice-fistola-anastomotica-enterocutanea-dopo-emicolectomia-destra-mediante-over-the-scope-clip-otsc&Itemid=105

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

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

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

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

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

Sandmann M, Heike M, Fährndrich M

The group of Prof. Hochberger from Hildesheim presented their results of a consecutive series of 40 OTSC® interventions. In 85% of cases the primary therapeutic goal was reached. Dr. Wedi reported on 23 cases of upper GI bleeding which had been refractory to other therapy before being treated with OTSC® clipping. 19 patients were successfully treated, 2 patients died in spite of attempted surgical hemostasis and 2 other patients for

reasons not related to the endoscopic intervention. He also showed data of 3 perforations with a closure rate of 100%. Also 2 complications were reported. 1 new sigmoid perforation that was seen after successful closure of an EMR-related perforation in the hepatic flexure and one impingement of an endoscopic instrument with an OTSC® clip.

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

Wedi E, Menke D, Hochberger J

The group around Prof. Raithel from Erlangen summarized their experience of 17 cases of OTSC® perforation closures in a retrospective evaluation. Dr. Hagel reported an overall success rate of 64.7%. He distinguished between cases with vital and with necrotic or inflamed tissue margins. In cases with non-vital wound margins the number of clips was greater than 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

Hagel A, Nägel A, Lindner A, Kessler H, Matzel K, Diebel H, Raithel S, Neurath MF, Raithel M

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

P22 Pure-NOTES-Sigmaresektion in einem Tier-Überlebensmodell

Bernhardt J, Köhler P, Fabian R, Schneider-Koriath S, Steffen H, Ludwig K, Lamadé W

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

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

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

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

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

Hagel A, Nägel A, Lindner A, Kessler H, Matzel K, Diebel H, Raithel S, Neurath MF, Raithel M, Erlangen

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

Raithel M, Hagel A, Neufert C, Nägel A, Neurath MF, Schiele A, Kessler H, Erlangen

March 2012 | OTSC® closure of esophago-pericardial 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 esophageo-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 esophagopericardial fistula with an over-the-scope clip

C Gubler, P Bauerfeind

Endoscopy 2012; 44:E1-E2

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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 transcutaneous drainage had failed. Radiographic studies revealed a fistula of the descending colon leading to the abscess 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 repeat dye installation. Subsequently the transcutaneous 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]

[Endoscopic closure of a chronic colonic fistula using the over-the-scope clip (OTSC)]

Grossmann J, Diening C, Althoff C

Dtsch Med Wochenschr. 2011 Nov;136(44):2245-8.

[Epub 2011 Oct 25]

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

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

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

P0003 A NEW VALUABLE TOOL FOR THE ENDOSCOPIST: THE OVER-THE-SCOPE CLIP (OTSC) – CLINICAL EXPERIENCE IN THE TREATMENT OF GASTROINTESTINAL LEAKS, BLEEDINGS AND FISTULAS IN 24 PATIENTS

Edris Wedi, Germany; Detlev Menke; Elena Kruse; Jürgen Hochberger

Marc Barthelet, 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. Barthelet 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 Barthelet

Paper published in GIE:

Endoscopic management of GI fistulae with the over-the-scope clip system (with video)

Surace M, Mercky P, Demarquay JF, Gonzalez JM, Dumas R, Ah-Soune P, Vitton V, Grimaud J, Barthet M
Gastrointest Endosc. 2011 Dec;74(6):1416-9 **63**

Daniel v. Renteln from the Hamburg (Germany) group of Thomas Rösch presented data from an animal study where they created 2-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.

OP202 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 Schachschal
Full paper: GIE 2011 Nov; 74(5): 1108 -14 **55**

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

OP204 OVER-THE-SCOPE-CLIP CLOSURE OF GASTRIC AND COLONIC ACCESS SITES IN NATURAL ORIFICE TRANSLUMINAL ENDOSCOPIC SURGERY

Tomas Hucl, Czech Republic; Marek Benes; Matej Kocik; Martin Krak; Jana Maluskova; Eva Kieslichova; Martin Oliverius; Julius Spicak

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 cured with an OTSC® clip successfully. The authors conclude that „endoscopic snare resection of gastric subepithelial masses (< 3cm) seems to be a safe and minimal invasive procedure. If perforation occurs, it can be adequately managed by placing the OTSC® clip. These results can be regarded as a further encouraging step towards transgastric endoscopic surgery.“

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

Christoph Schlag, Germany; Stefan von Delius; Hubertus Feussner; Dirk Wilhelm; Alexena Beitz; Roland M Schmid; Alexander Meining

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

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

Anders Møller Donatsky, Denmark; Luise Andersen; Ole Lerberg Nielsen; Barbara Holzknrecht; Peter Vilmann; Søren Meisner; Lars Nannestad Jørgensen; Jacob Rosenberg

Thomas Hucl 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 cases 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 NOTES ASSISTED MINI LAPAROSCOPIC TRANSGASTRIC CHOLECYSTECTOMY

Tomas Hucl, Czech Republic; Matej Kocik; Marek Benes; Martin Krak; Jana Maluskova; Eva Kieslichova; Martin Oliverius; Julius Spicak

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

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

Pierre H. Deprez, Belgium; Hubert Plessevaux

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

OP447 BETTER OUTCOME OF ENDOSCOPIC MANAGEMENT VS SURGERY FOR UPPER GASTROINTESTINAL PERFORATION

Anne Vijverman, Belgium; Hubert Plessevaux; Tarik Aouattah; Jean-François Gigot; 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 DGAV (German society of digestive & metabolic disease and German society 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 intrathoracic anastomotic insufficiency” and “Therapeutic concept for intraabdominal anastomotic insufficiency” session participants 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 | Closure rate of 90% in fistulas, anastomotic leaks and perforations treated with OTSC®: new case series published

A new case series, reported by Dres Sandmann, Heike and Faehndrich, Klinikum Dortmund Mitte, Germany, was published in the German Zeitschrift fuer Gastroenterologie. The authors present a series of 10 patients with penetrating defects within the digestive tract. Pathologies were fistulas (esophagotracheal, esophagopleural, gastrocutaneous and colovesical), perforations (after mucosectomy, after papillotomy and PEG misplacement) and anastomotic leakages (after gastrotomy 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, Anastomosal Leakages and Perforations within the Gastrointestinal Tract

Sandmann M, Heike M, Faehndrich M.

Z Gastroenterol. 2011 Aug;49(8):981-5

[Epub 2011 Aug 2]

August 2011 | OTSC® clipping for closure of gastrocutaneous fistula after surgery for peptic ulcer

Dr. G. Koukladis and colleagues from the University General Hospital of Alexandroupolis, Greece, describe a case of gastrocutaneous fistula after surgical treatment for a perforated gastric ulcer. By means of OTSC® clip placement the fistula was successfully closed. Therapeutic success was verified at the 2nd day 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.

Endoscopic treatment of a gastrocutaneous fistula using the over-the-scope clip system: a case report.

Kouklakis G, Zezos P, Liratzopoulos N, Gatopoulou A, Oikonomou A, Pitiakoudis M, Efremidou E, Simopoulos C.
Diagn Ther Endosc. 2011;2011:384143. [Epub May 29]

50

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/62/13/06409671283#fg>

In their recent report about a series of 12 consecutive patients with post-surgical or traumatic fistulas of the gastrointestinal tract treated by OTSC® clipping, R. Manta et al, Modena, Italy carried out a cost comparison. They found OTSC® therapy considerably cheaper than alternative surgical intervention (USD 1,050 vs USD 3,800 in this particular hospital setting).

Besides the cost advantage also the therapeutic results are reported as favourable: “No complications occurred, and the leaks were all healed at follow-up 1 – 3 months later. In 9 of the 11 patients, the leak was sealed within 4 days by a single application.”

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

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

Manta R, Manno M, Bertani H, Barbera C, Pigò F, Mirante V, Longinotti E, Bassotti G, Conigliaro R

Endoscopy. 2011 Jun;43(6):545-8 (Epub 2011 Mar 15)

44

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

In the April issue of the journal *Gastrointestinal Endoscopy* A. Rebelo and colleagues, Alto 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-esophageal fistula

Rebelo Ana, Mouthinho-Ribeiro Pedro, Cotter José

Gastrointestinal Endoscopy 2011;73:4 833-4

36

April 2011 | Post-surgical gastrointestinal fistulas treated with OTSC®

In the March issue of the journal *Endoscopy* R. Manta et al. report about a case series of 12 consecutive patients treated with OTSC® for closure of post-surgical gastrointestinal fistula in a tertiary referral center (S. Agostino Estense Hospital, Modena, Italy).

Fistula closure with OTSC® clipping was successful in 11 out of 12 cases. Healing 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

Manta R, Manno M, Bertani H, Barbera C, Pigò F, Mirante V, Longinotti E, Bassotti G, Conigliaro R 44
Endoscopy. 2011 Jun;43(6):545-8. [Epub 2011 Mar 15]

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 pre-operative 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

Kirschniak A, Subotova N, Zieker D, Königsrainer A, Kratt T Surg Endosc. 2011 Sep;25(9):2901-5.
[Epub 2011 Mar 18] 59

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.

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

Bini R, Coppola F, Recchia S, Fusca M, Gaia S, Leli R Surg Innov. 2011 Jan 18. [Epub ahead of print] 40

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 small residual opening was subsequently closed with cyano-acrylate injection in a second procedure. The patient was followed for approx. 10 weeks when CT showed the fistula completely closed. The authors conclude that OTSC® clipping with possible additional cyano-acrylate can be effective in the treatment of anastomotic leakage and fistula and should be considered in such cases before the patient is referred to surgery.

Endoscopic sealing of a rectovesical fistula with a combination of an over the scope clip and cyano-acrylate injection

Mangiavillano B, Pisani A, Viaggi P, Arena M, Opocher E, Mangano M, Santoro T, Masci E
J Gastrointest Oncol 2010; 1: 122-4 37

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 posttraumatic esophago-pulmonary fistula and a chronic gastrocutaneous 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 leak-proof, full-thickness closure of transmural defects.

Nevertheless, in circumstances of severe fibrosis and scarring, complete incorporation of the defect into the applicator cap and successful OTSC® application might not be possible."

Endoscopic closure of GI fistulae by using an over-the-scope clip

von Renteln D, Denzer UW, Schachschal G, Anders M, Groth S, Rösch T
Gastrointest Endosc. 2010 Dec;72(6):1289-96
[Epub 2010 Oct 16] 39

September 2010 | OTSC® for closure of rectovesical fistula after radical prostatectomy

There is growing positive clinical experience worldwide with the use of Ovesco's OTSC® clip in the treatment of chronic fistula. Dr. M. Cavina and coauthors, Reggio Emilia, Italy, report about the successful treatment of a chronic recto-vesical fistula in a male patient, subsequent to prostatectomy. The size of the chronic fistula was 4 mm and it was effectively occluded by means of a single OTSC® 12/6/a clip. The case was reported in the Italian Journal of Digestive Endoscopy.

Utilizzo della clip Ovesco nel trattamento di una fistola retto-vescicale

Maurizio Cavina, Romano Sassatelli, Francesco Azzolini, Lorenzo Camellini, Francesco Decembrino, Veronica Iori, Giuliana Sereni, Cristiana Tioi, Giuliano Bedogni Servizio di Gastroenterologia ed Endoscopia Digestive, Arcispedale „Santa Maria Nuova“ di Reggio Emilia
Giorn Ital End Dig 2010;33:147-8 31

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 chemo-radiation 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 30th National Congress of the Portuguese Society of Gastroenterology in Vilamoura, June 9-12, 2010.

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

Bruchsal, Germany, June 11, 2010. At the 21st Congress of the Southwest German Society of Gastroenterology Thomas Kratt, MD, Surgical Endoscopy, Tuebingen University Hospital, Germany, reported about a case series of 60 patients treated with OTSC® for various indications. 37 patients were treated for stopping gastrointestinal hemorrhage, 11 for closure of perforation, 8 for closure of 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

Kratt T, Stüker D, Küper M, v. Feilitzsch M, Königsrainer A, Kirschniak A

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

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

Over-the-scope clip closure of two chronic fistulas after gastric band penetration

Federico Iacopini, Nicola Di Lorenzo, Fabrizio Altorio, Marc Oliver Schurr, Agostino Scozzarro
World J Gastroenterol 2010 April 7; 16(13):1665-9 25

March 2010 | Italian gastroenterologists report successful closure of tracheo-esophageal fistula using Ovesco's OTSC® clips

In the recent issue of the journal Endoscopy, Dr. M. Traina and colleagues, Palermo, Italy, report about the closure of a chronic tracheo-esophageal fistula emerging in a patient after long-term ventilation.

The fistula was located 20 cm from the mouth. After closure with an OTSC® clip the clinical condition of the patient improved and healing of the fistula was seen at follow-up endoscopy, 2 and 4 weeks later. No complications were reported.

New endoscopic over-the-scope clip system for closure of a chronic tracheo-esophageal fistula

M Traina, G Curcio, I Tarantino, S Soresi, L Barresi, P Vitulo, B Gridelli | IsMeTT, UPMC, Palermo, Italy
Endoscopy 2010; 42:E1-E2 [UCTN] 23

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

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

Endoscopic Treatment of Gastric Cancer

Won Young Cho, Tae Hee Lee, Yoon Seon Park, Ju Young Cho
Endoscopic Submucosal Dissection (ESD), pp 16-52; Jin Publishing Co. Ltd. Seoul, Korea, 2009
ISBN 978-89-90698-48-3 10

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

Iacopini et al.

A 45-year-old woman presented with a band erosion and penetration through two large tears at the posterior wall of the gastric fundus. A subphrenic 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 fully-covered esophageal SEMS) and remained successfully closed. Both OTSC®s were spontaneously lost after 4 weeks. The authors conclude that if prospective large comparative studies with fully-covered stents and OTSC® will confirm this initial observation, the OTSC® may be the least invasive, easiest, and safest endoscopic method to close chronic small fistulas or leaks.

October 2009 | Report about OTSC® clip treatment of gastric band complications and hands-on OTSC® course at the 21st SMIT Conference, 7–9 Oct. 2009 in Sinaia, Romania

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

Dr. Agostino Scozzaro and colleagues, Rome, Italy, report about the successful closure of chronic fistula related to adjustable gastric band erosion, using OTSC® clipping.

The use of OTSC® in Natural Orifice Transluminal Endoscopic Surgery (NOTES) is presented by Prof. Dr. Alberto Arezzo, Torino, Italy, within a hands-on workshop on basic techniques in NOTES. He also shows recent data on transgastric 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 anastomosis. He recommends OTSC® clipping for suitable cases in his overview presentation on closure of fistula and chronic pelvic abscess after colorectal surgery.

A summarizing overview about global clinical experiences with the OTSC® clip is given by Prof. Dr. Marc O. Schurr, Member of the Executive Board of Ovesco Endoscopy AG.

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

November 2015 | Promising case series on novel OTSC removal device

Dr. A. Schmidt, Dr. B. Riecken, Dr. M. Damm, Dr. O. Cahyadi, Dr. M. Bauder and Dr. K. Caca, Department of Gastroenterology and Oncology, Ludwigsburg Hospital, Germany, reported the results of a case series of OTSC clip removal with a specifically developed cutting device (future trade name: remOVE, courtesy of Ovesco).

The authors note that over-the-scope clips (OTSC) have proven their efficacy in an ever-growing variety of indications. Still, there is a lack of follow-up studies on the course of the clip once it is deployed in the gastrointestinal tract. Clinical experience shows that clips usually fall off after several weeks or months, depending on the amount of tissue grasped. Since OTSC clips are fully biocompatible, they may stay in place indefinitely. However, there are a few situations which call for active removal. In these situations, clinicians have to rely on techniques that lack proof of safety and efficacy. In the case series, the prototype of a specifically developed bipolar cutting device for OTSC removal was used.

A total of 11 patients (male: 7, female: 4) between 43 and 73 (median age: 62) were treated with the device under the "compassionate use" statute. Average procedure time was 47 minutes (range: 35-75 minutes) and cutting of the clip was successful in all cases (100% success rate). Fragments were removed successfully in all but one case (91%), where a fragment was deeply grown into the duodenal wall. In a follow-up after 3 months, this fragment had not caused any complications. Indications for clip

removal included intermittent epigastric/abdominal pain, the need for a repeat biopsy at the resection site and patients' wishes.

The cutting device consists of a grasper connected to a generator. Two electrodes in the grasper tips conduct a direct current impulse, which heats up the clip and thermally cuts the material. The current has a maximum strength of 140 ampere and maximum duration of 100 milliseconds. After successful cutting, the device stops automatically, and there is no relevant current pathway through the patient's tissue.

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

The authors stress that the removal of an OTSC clip is only necessary in a minority of cases. Even if it does not fall off on its own, the clip is designed as a durable implant. The few indications for endoscopic clip removal include wrongly placed clips, accidental clipping of the retraction device to the tissue, local complications due to the clip (e.g. luminal obstruction, ulcers), scheduled removal of esophageal stents fixed with an OTSC, and the need for a repeat biopsy of the OTSC site. Additionally, patients may insist that symptoms are caused by the clip's presence.

According to the group, recommended removal times have yet to be established. However, they assume that for repeat biopsy, a good time span is 3 months, while for esophageal stent removal they favor 6-8 weeks. Longer periods of time are correlated with deep ingrowth into the intestinal wall, which impedes removal. They also caution that clips placed for perforation closure may not be removed too early to prevent re-perforation. In the case series, clips had been placed at least 4 weeks prior, while the clip in-situ for the longest time (15 months) was difficult to remove and had the longest procedure time (75 minutes). Overall, the authors see the new device for OTSC clip removal as an indispensable addition to the clinician's repertoire since it proved safe and effective in all treated patients.

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

Schmidt A, Riecken B, Damm M, Cahyadi O, Bauder M, Caca K.

Endoscopy. 2014 Sep;46:9:762-6.

doi: 10.1055/s-0034-1365493

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February 2015 | Two Studies show efficacy of anchoring esophageal SEMS (self-expanding metal stents) with OTSC

In a retrospective study of 13 patients, Dr. Irani, Dr. Gluck, Dr. Gan, Dr. Ross and Dr. Kozarek of the Department of Gastroenterology, Virginia Mason Medical Center, Seattle, Washington, together with Dr. Baron, Division of Gastroenterology & Hepatology, Mayo Clinic Rochester, Rochester, Minnesota, explored the efficacy of OTSC for securing self-expanding metal stents (SEMS) in patients who had experienced stent migration before. Indications included post-operative leaks in 4 patients (2 esophagogastric anastomotic leaks, 2 fistulae after bariatric surgery), 1 perforation, 3 benign esophageal strictures (2 peptic, 1 anastomotic), and 5 malignant esophageal strictures. The patients (8 male, 4 female) had a median age of 67 years with a range from 40 to 89 years. Before anchoring the stent with OTSC, three patients had a new SEMS deployed, in the other ten cases the migrated stent was merely repositioned. A standard upper endoscope was advanced to the proximal end of the stent and suction was applied, attempting to position tissue and stent in such a way that upon

deployment half of the OTSC would grasp the stent and the other half the esophageal wall. Clip placement was successful in all cases with a median procedure time of 3.5 minutes (range of 2 to 5.5 minutes). Cutting and OTSC/SEMS removal was 6 minutes on average. Migration occurred in two patients, both with benign esophageal strictures, at a mean of 32 days compared with a mean of 3.5 days for prior migrations without OTSC use. In 4 of 5 patients with malignant disease, the SEMSs remained in place indefinitely. Successful healing occurred in 11 of 13 patients (85%) with a median stent dwell time of 57 days (2–226 days range). Of three patients with refractory benign esophageal strictures, one recurred after stent removal.

The authors discuss several uses of esophageal stents, noting that fully covered SEMSs have high migration rates, which call for external or internal fixation. They note that in spite of improved stent fixation times from 26.4 to 12.5 minutes when using a suturing device, the use of OTSC is much more time efficient at a median of 3.5 minutes. Additionally, OTSC placement does not require the use of an overtube or double-channel upper endoscope and prevents additional costs of 700 to 800 USD for suturing. Taking into account the fact that all patients in this study had previously experienced stent migration, the reduction of stent migration from 100% to 15% through OTSC use seems promising. The authors note that prospective data is needed to define an optimal approach for OTSC use in SEMS placement.

Dr. Mudumbi, Dr. Velazquez-Aviña of the Basil I. Hirschowitz Endoscopic Center of Excellence, Division of Gastroenterology and Hepatology, University of Alabama at Birmingham, United States cooperated with Dr. Baig and Dr. Mönkemüller, Department of Medicine, University of Erlangen, Nürnberg, Germany as well as Dr. Neumann, affiliated with both institutions, in a single-center, retrospective cohort study of SEMS anchoring with OTSC and subsequent removal of clip and stent with an inject-and-resect technique. The study covered a total of 12 patients (8 male, 4 female) at a median age of 57 years (range: 45–72 years). Indications included different nonstricturing benign or malignant esophageal diseases (tracheoesophageal fistula, postoperative leaks, and esophageal perforation). Application and initial anchoring of the OTSC clip was successful in all cases, in two cases clip dislodgment and subsequent stent migration was documented during follow-up. After complete healing, stent and clip were removed in six patients, while the stent was left indefinitely in four patients to treat their underlying condition.

The authors emphasize the potential to significantly reduce stent migration rates currently at up to 40% in esophageal stent placement by using OTSC as an anchoring device. The inject-and-resect technique used for removal was successful in all cases in which the underlying condition had been healed, although the authors caution that a possible risk of perforation is connected with anchoring the clip to deeper tissue. While the group believes benefit to be greater for nonstenosing diseases, they point out that patients with malignant stricture receiving chemo-radiation may also benefit from clipping, as a reduction in the size of the tumor may also lead to stent migration. They also mention ex-vivo trials showing that sutures are most resistant to tensile forces (average of 20.4 newton needed for stent removal) compared to clip-anchored stents (16 newton on average) and un-anchored stents at 4.0 to 5.6 newton. The paper identifies clips as the least expensive device, but advises that costs associated with the possible use of multiple clips or stent migration should also be taken into account. In conclusion, the authors evaluate the use of OTSC for anchoring of fully covered SEMSs as an easy and safe avenue of treatment with the potential to significantly reduce stent migration rates and call for further studies to assess and refine the technique.

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

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

Irani S, Baron TH, Gluck M, Gan I, Ross AS, Kozarek RA
Gastrointest Endosc. 2014 May;79(5):844-51

Epub 2014 Jan 25

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

Mudumbi S, Velazquez-Aviña J, Neumann H, Kyanam Kabir Baig KR, Mönkemüller K

Endoscopy. 2014 Dec;46(12):1106-9
Epub 2014 Sep 30

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Dr. Irani et al. videos: To watch videos of the procedures performed by the group around Dr. Irani, please visit the website of Gastrointestinal Endoscopy at <http://dx.doi.org/10.1016/j.gie.2013.12.012> (behind a paywall)

January 2015 | ASGE: Over-The-Scope-Clipping device is safe and effective for management of GI defects

ASGE – The American Society for Gastrointestinal Endoscopy issued a press release concerning a publication in its GIE-Gastrointestinal Endoscopy journal:

„An international multicenter study reports that over-the-scope clip (OTSC) placement is a safe and effective therapy for the closure of gastrointestinal (GI) defects, which includes anastomotic leaks, fistulae and perforations. Clinical success was best achieved in patients undergoing closure of perforations or leaks when OTSC placement was used for primary or rescue therapy. The overall clinical success for the closure of perforations and leaks ranged between 90 percent and 73 percent; however, successful closure of fistulae was achieved in less than half of the patients. The type of defect (i.e. perforation or leak) is the best predictor of successful long-term closure. The study appears in the October issue of GIE: Gastrointestinal Endoscopy, the monthly peer-reviewed scientific journal of the American Society for Gastrointestinal Endoscopy (ASGE).“

For Immediate Release

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American Society for Gastrointestinal Endoscopy
www.asge.org | www.screen4coloncancer.org

AN OVER-THE-SCOPE CLIPPING DEVICE FOR ENDOSCOPIC MANAGEMENT OF GASTROINTESTINAL DEFECTS IS SAFE AND EFFECTIVE
DOWNERS GROVE, Ill. – October 23, 2014 –

An international multicenter study reports that over-the-scope clip (OTSC) placement is a safe and effective therapy for the closure of gastrointestinal (GI) defects, which includes anastomotic leaks, fistulae and perforations. Clinical success was best achieved in patients undergoing closure of perforations or leaks when OTSC placement was used for primary or rescue therapy. The overall clinical success for the closure of perforations and leaks ranged between 90 percent and 73 percent; however, successful closure of fistulae was achieved in less than half of the patients. The type of defect (i.e. perforation or leak) is the best predictor of successful long-term closure. The study appears in the October issue of GIE: Gastrointestinal Endoscopy, the monthly peer-reviewed scientific journal of the American Society for Gastrointestinal Endoscopy (ASGE). Conventional treatment of GI defects is with surgical management, which is associated with significant morbidity and mortality.

Technological advances in endoscopic devices have allowed for endoscopic closure of GI defects. Endoscopic therapies include placement of self-expandable metal stents (SEMSs) and application of clips and sealants, all of which have proven their utility in different clinical scenarios with varying degrees of success.

The most common endoscopic approach for treatment of GI defects before the over-the-scope clip was the use of temporary SEMSs.

A large case series reported a success rate as high as 75 percent with SEMSs; however, this practice was associated with a high rate of adverse events (46 percent). The OTSC provides more durable closure than standard clips because of its wider mouth and ability to grasp larger amounts of tissue.

In addition, full-thickness closure is achievable because of greater compressive force. The current study is the largest to-date to assess outcomes of OTSCs in the management of GI fistulae, perforations and leaks. “The primary goal of this study was to describe a large, international, multicenter experience with OTSCs for the management

of GI perforations, fistulae and anastomotic leaks and to determine the overall success of GI defect closure. Secondary goals were to determine success rate by type of defect and type of therapy, primary vs. rescue, and to determine predictors of OTSC success,” said study lead author Yamile Haito-Chavez, MD, Johns Hopkins University, Baltimore, Maryland. “Our study found that long-term success was achieved in 60.2 percent of patients. The rate of successful closure of perforations was 90 percent, closure of leaks was 73.3 percent and closure of fistulae was 42.9 percent. Long-term success was significantly higher when OTSCs were applied as a primary therapy.”

Methods A retrospective review of consecutive patients who underwent attempted OTSC placement (either as primary or rescue therapy) for the indication of GI leak, fistula or perforation at 16 academic centers in the United States, The Netherlands, Germany, Italy, and Chile was conducted between May 2006 and November 2012. Patients were identified by using endoscopic databases at each institution. Anastomotic leak was defined as disruption at a surgical anastomosis resulting in a fluid collection with or without evidence of extravasation of contrast medium on radiologic evaluation. Fistula was defined as abnormal communication between two epithelialized surfaces. Perforation was defined as an unintentional, acute iatrogenic, full-thickness defect in the GI tract. The main outcome measurement was the long-term success of the procedure.

Results A total of 188 patients (108 fistulae, 48 perforations, 32 leaks) were included. Long-term success was achieved in 60.2 percent of patients during a median follow-up of 146 days. The rate of successful closure of perforations (90 percent) and leaks (73.3 percent) was significantly higher than that of fistulae (42.9 percent). Long-term success was significantly higher when OTSCs were applied as primary therapy (primary 69.1 percent vs. rescue 46.9 percent). On multivariate analysis, patients who had OTSC placement for perforations and leaks had significantly higher long-term success compared with those who had fistulae. In an accompanying editorial, Danny Cheriyan, MB, BCh, MRCP and Robert Enns, MD, FRCP, Division of Gastroenterology, St. Paul's Hospital, University of British Columbia, Vancouver, Canada, state “The future of the OTSC in mainstream endoscopy is promising. It is arguable that these clips should be available in every well-stocked unit, and because a application and deployment are similar to those of a standard ligation bander, it would be appropriate for implementation into training and clinical practice in gastroenterology.”

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

Two case reports recently published by Dr. Tontini and colleagues, Dept. of Medicine I, University of Erlangen-Nuernberg, Germany and by Dr. Chen and colleagues, Dept. of Gastroenterology, Riverside, University of California, USA illustrate the complete closure of larger anastomotic leaks with the OTSC System when other techniques have failed or deemed unsuitable. A 69-year old man had an Ivor-Lewis esophagectomy due to esophageal carcinoma. After the development of chest pain 6 days later a CT scan revealed an anastomotic dehiscence. During an EGD a metal stent was placed but a persistent defect was found 10 days later by a CT. An additional stent was placed overlapping the first stent. Because of a continued leakage another EGD was performed demonstrating a gastric conduit fistula. After application of conventional endoscopic hemoclips the patient was discharged but presented with worsening symptoms. Another EGD showed a persistent fistula that was finally closed with an OTSC clip resulting in a complete healing.

The other patient (71-year old woman) presented with hypotension, melena and low hemoglobin level 3 weeks after a Billroth I gastroenteral anastomosis. EGD showed a oozing bleeding and as well a defect at the anastomosis. In this case the dehiscence extended over half the circumference of the anastomosis. Since other

techniques seemed inappropriate due too large leak, massive bleeding and difficult target position it was decided to use the Twin Grasper and an OTSC clip to close the defect. Complete closure was confirmed by a subsequent endoscopic examination. According to the authors, the OTSC clip should be considered as the first choice for sealing of intermediate leaks.

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

Tontini GE, Naegel A, Albrecht H, Vieth M, Vecchi M, Neurath MF, Neumann H

Endoscopy. 2013;45 Suppl 2 UCTN:E343-4
doi: 10.1055/s-0033-1344771

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

Chen AI, Lim BS, Ma JS, Chaya CT

Gastrointest Endosc. 2014 Apr;79(4):546
doi: 10.1016/j.gie.2013.10.001

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April 2014 | Conference report | 44th DGE-BV Congress, Hamburg

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

Again a significant number of both oral presentations and posters have been featured at this year's event. In summary they all reported their mostly positive experiences with the OTSC System in all main indications. In addition our products were featured in several hands-on courses alongside the conference (Chairs: Hochberger J., Maiss J., Kraus F.). Ovesco presented their new products, the DC Clip Cutter and the FTRD device which are both due to be launched later this year. The reaction of the medical world was more than promising.

• Neue Clips für Blutung und Verschlussstechniken

Caca K, Ludwigsburg, Germany

K. Caca gave a talk on “New tools for the treatment of GI-hemorrhage and perforation”. Even though also mentioning other devices he mainly elaborated on the OTSC System. In his summary of clinical cases his take home message was: “the OTSC device achieves hemostasis more quickly than all other devices and is more effective particularly regarding acute, difficult and heavy bleedings.” For the treatment of perforation OTSC was the standard choice. Also, he showed first experiences with the all new DC Clip Cutter device as an important tool for removing the OTSC which will be launched later this year.

• Update Endoskopie – meine Toppapers

Häfner M, Vienna, Austria

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

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

Manta R, Galloro G, Mangiavillano B, Conigliaro R, Pas-quale L, Arezzo A, Masci E, Bassotti G, Frazzoni M

Surg Endosc. 2013 Sep;27(9):3162-4
doi: 10.1007/s00464-013-2871-1 [Epub 2013 Feb 23]

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

Chan SM, Chiu PW, Teoh AY, Lau JY

Endoscopy. 2014 May;46(5):428-31
doi: 10.1055/s-0034-1364932 [Epub 2014 Feb 6]

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• Clip-Karussell

Groth S, Hamburg, Germany

S. Groth elaborated on the endoscopist's option once it comes to use clips. Interesting enough he exempted the OTSC from the rest of all products stating that OTSC is playing in a different league.

(Comment by Ovesco: the comparator of OTSC is surgery!)

• Techniken zum Perforationsverschluss

Fritscher-Ravens A, Kiel

A. Fritscher-Ravens underlined in her talk on techniques of perforation closure the importance and advantages of the use of the Twin Grasper. Other than that she referred to OTSC as standard treatment.

Altogether five posters were dealing with OTSC:

• **Over-the-Scope Clip System (OTSC) – One Therapy for Safety Closure**

Leonhardt K, Ohse A, Bauer B, Repp M, Altenburg, Germany report their 3.5-year experience with our system regarding the three major indications: hemorrhage, acute perforation, and chronic fistula/anastomotic leakage where they achieved a 85.7%, 84.6%, and 60% success rate. 33 patients were included in this retrospective analysis. Average age was 69 years (41–92 ys). Three patients received two clips at once. Across the GI tract the number of patients was equally distributed, except for Jejunum and Ileum with only one patient each. The authors conclude that OTSC is a useful and effective tool for the endoscopist sparing the surgeon in many cases.

• **The OTSC System in the treatment of a perforation of the colon complicated by adhesion of small bowel**

H. Albrecht et al., Erlangen, Germany presented a case report. During diagnostic colonoscopy they experienced an acute perforation which was as usual closed with an OTSC clip. After a few days the patient developed acute symptoms with free sub-diaphragmatic air which led to a sigmoidal resection and overstitch of the small bowel. The authors point out the possible risks of the use of OTSC.

Comment by Ovesco: the authors used suction only for getting colonic tissue into the cap. Already during this process small bowel was trapped in the cap and could clearly be seen between the teeth of the closed clip. The IFU of the product recommend the use of the Twin Grasper for fresh perforations. Suction may be used after the edges of a fresh perforation have clearly been identified and pulled into the cap.

Einsatz des Over-the-Scope Clips (OTSC) zur Beandlung einer Colon-Perforation verursachte eine Dünndarmfixation mit nachfolgender chirurgischer Resektion

Albrecht H, Nägel A, Hagel A, Rösler W, Förtsch T, Neurath MF, Raitheil M

• **Comparison of the OTSC and cSEMS in the treatment of gastrointestinal leakages: results of retrospective multicenter analysis**

H. Famik et al. reported in a very important paper of the interventional therapy of postoperative (73, 69%), postinterventional leakages (24, 23%), and 9 (8%) spontaneous perforations. Primary closure was done with an cSEMS in 72 patients. (69%), and with OTSC in 31 pts. (29%). Average duration of the treatment needed 45.6 days with cSEMS versus only 19.8 days in patients of the OTSC group. Treatment was complicated in 66.7% of cSEMS patients, and only in 5.9% in the OTSC group. 1.12 interventions (1.00-1.23) were needed with OTSC, 2.44 (2.12 – 2.76) in the cSEMS group. The diameter of the defect was larger in the cSEMS group (12.6 mm, 10.9-15.2) than in the OTSC group (7.1, 4.4-9.7).

	OTSC	cSEMS	P
Age (mean, years)	60.82	63.3	n.s.
Gender (m/f)	22/12	53/19	
Diameter of leakage (mean mm, 95% ci)	7.1 (4.4-9.7)	12.6 (10.9-15.2)	
Duration of defect (days)	10.97	7.96	n.s.
Local infection (n, %)	15(44%)	51(71%)	
Number of interventions (mean, 95% ci)	1.12 (1.00-1.23)	2.44 (2.12-2.76)	
Technical success (n,%)	33 (97.1%)	71 (98.6%)	n.s.
Duration of treatment	24.8	38.9	
Dislocation rate (n,%)	1 (3%)	17 (24%)	

The authors conclude in their discussion that OTSC is the preferred primary therapy of smaller post-interventional leakages. It might also be used in combination where cSEMS treatment was incomplete. They conclude that the longer treatment period with cSEMS and the higher complication rate might be due to sicker patients, but also due to the relevant dislocation rate of cSEMS.

Vergleich zwischen OTS-Klipp und cSEMS zur Indikationsstellung bei der Behandlung gastro-intestinaler Leckagen: Ergebnisse einer retrospektiven, multizentrischen Analyse

Famik H¹, Driller M¹, Kratt T², Schmidt C³, Fähndrich M⁴, Friedrich-Rust M¹, Filmann N¹, Königsrainer A², Stallmach A³, Heike M⁴, Zeuzem S¹, Albert J¹

¹Frankfurt am Main, ²Tübingen, ³Jena, ⁴Dortmund, Germany

• **Endoscopic treatment of acute bleedings with an Over-The-Scope Clip (OTSC)**

A. Braun et al. investigated the role of OTSC in the treatment of acute GI hemorrhage in an emergency. Between 2011 and 2013 they treated 16 patients (median 75.5 y/o (61-92), m=9, f=7) with OTSC for upper and lower-GI bleeding (8 each). Patients with upper-GI bleeding received high PPI-medication simultaneously. 7 patients were classified F Ia, 7 F Ib, and 2 F IIa. All patients presented with an acute decrease of hemoglobin, with hematemesis, melena, and hematochezia. The clip was applied by using a standard forceps. Technical success was achieved in all 16 patients (100%) with immediate primary hemostasis. None of the interventions took longer than 20 minutes. Only 6 patients underwent follow-up endoscopy between day 1 and 7 after clip application. All control endoscopies were uneventful and showed clinical success. 9 patients did not need any further endoscopy. None of the patients needed any further therapy for bleeding. All patients started normal oral intake from day 2.

The authors conclude that OTSC is safe and effective for the treatment of hemorrhage which reduces mortality, with short intervention times.

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

Braun A, Richter-Schrag HJ, Fischer A, Freiburg, Germany

• **Clinical experience in the treatment of perforations, leakages, and fistulas in the GI tract with the Over-the-scope clip (OTSC)**

J. Stücker et al. report their retrospective results in the standard indications of OTSC.

21 patients (Median 69 years (30–87), m=11, f=10) were treated for leakages and fistulas (n=11, 52%) due to anastomotic leaks. 5 patients had complications due to diagnostic or therapeutic endoscopy. 2 patients had fistulas due to necrotizing pancreatitis. 2 patients suffered from a persistent PEG fistula. Technical success was reported in 20/21 cases (95%). All 5 endoscopic complications could successfully be treated with OTSC. 7/11 anastomotic leaks could successfully be treated as well. One patient with duodenal leak due to acute necrotizing pancreatitis and a patient with perforated antrum died due to sepsis. The treatment of persistent PEG fistula was clinically not successful in this series.

The authors conclude that altogether the treatment of perforations, leakages, and fistulas with OTSC is very promising, and point out that this is especially true for the management of complications during endoscopy and surgical complications like anastomotic leakage.

Klinische Erfahrungen bei der Behandlung von Perforationen, Leckagen und Fistelungen im Gastrointestinaltrakt mit dem Over the scope Clip (OTSC®)

Stücker J, Probst A, Bittinger M, Scheubel R, Ebigo A,

Messmann H, Gölder S, Augsburg, Germany

doi: 10.1055/s-0032-1326398

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March 2014 | Management of esophageal perforation with the OTSC System – four new case studies by different authors report favourable results.

Spontaneous or iatrogenic esophageal perforation is a life-threatening condition that can lead to severe mediastinitis, sepsis and multiple organ failure. Endoscopic management has contributed to the decrease of morbidity and mortality associated with surgical repair. Four different case reports lately published by Dr. Alexander Braun et al., Div. of General Surgery, University of Freiburg, Germany, Dr. Davide Bona et al., Div. of General Surgery, University of Milan, Italy and Dr. Alexandre Ferreira, Dept. of Gastroenterology and

Hepatology, Hospital de Santa Maria, Lisbon, Portugal illustrate the successful closure of esophageal perforations with the OTSC System.

Two patients presented with Boerhaave's syndrome, one patient had an iatrogenic perforation and one patient suffered from a perforation caused by a fishbone. In all four cases a minimally invasive approach with the OTSC System was chosen. Two patients were treated with the OTSC clip within 12 hours. Although the two other patients were admitted to hospital not until after 48 h after an episode of vomiting, late management of the esophageal perforation with the OTSC System was successful. After complete closure of the defect, all patients were kept on antibiotic therapy and were discharged in stable condition after 10 days (patient with iatrogenic perforation), 21 days (patient with perforation caused by a fishbone) and 20 or 28 days respectively (patients with Boerhaave's syndrome). 3-month follow-up revealed a free esophageal passage and correct placement of the OTSC clip. The OTSC clip is a new, safe and effective treatment alternative for the management of esophageal perforation. Due to the endoscopic approach and shorter hospital stay, the procedure is more cost effective than conventional surgical procedures.

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

Braun A, Hopt UT, Richter-Schrag HJ

Endo heute 2013;

doi:10.1055/s-0033-1334004

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Management of Boerhaave's syndrome with an over-the-scope clip

Bona D, Aiolfi A, Rausa E, Bonavina L

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Eur J Cardiothorac Surg. 2013 Jul 18 [Epub ahead of print]

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

Ferreira AO, Lopes J, Velosa J

BMJ Case Rep. 2013 Oct 25;2013

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pii: bcr2013201614 doi: 10.1136/bcr-2013-201614

March 2014 | OTSC: easy to use with good results, decreasing morbidity and mortality in diagnostic and therapeutic endoscopy

In the quest to describe the use and the clinical applications of OTSC System in an environment where endoscopic and surgical techniques are increasingly more complex and frequent Singhal et al. have searched and analysed the literature using the key words „endoscopy“ and „over-the-scope clip“ in order to identify human studies evaluating the application of OTSC from January 2001 to August 2012.

The indication, efficacy, complications, and limitations were recorded. The overall success rates of OTSC based on the current literature are in the range of 75% to 100% for closure of iatrogenic gastrointestinal perforations, 38% to 100% for closure of gastrointestinal fistulas, 50% to 100% for anastomotic leaks, and 71% to 100% for bleeding lesions. OTSC has shown 100% success rates in managing postbariatric surgery weight gain secondary to dilation of the gastro-jejunosomy.

The authors conclude that OTSC is easy to use with good results, thus decreasing the morbidity and mortality associated with complications secondary to both diagnostic and therapeutic endoscopy and avoiding surgery in many situations.

Over the Scope Clip: Technique and Expanding Clinical Applications

Singhal S, Changela K, Papafragkakis H, Anand S, Krishnaiah M, Duddempudi S

J Clin Gastroenterol. 2013 Oct;47(9):749-56

doi: 10.1097/MCG.0b013e318296ecb9

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Further reviews by Weiland et al.:

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

Weiland T, Fehlker M, Gottwald T, Schurr MO

Surg Endoscopy. 2013; 27:2258-74

81-2

doi: 10.1007/s00464-012-2754-x Epub 2013 Jan 24

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

Weiland T, Fehlker M, Gottwald T, Schurr MO

Minim Invasive Ther Allied Technol. 2012 Jul;21(4):249-58

doi: 10.3109/13645706.2012.694367

Epub 2012 Jun 14

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January 2014 | OTSC in mucosal flap closure after peroral endoscopic myotomy (POEM)

Maintaining the integrity of the mucosal flap and the reliable closure of mucosal entry during peroral endoscopic myotomy (POEM) is paramount in preventing leakage of esophageal contents into the mediastinal space. In a recently published case series (n=2) Payal Saxena, MD and colleagues, Dept. of Medicine and Div. of Gastroenterology and Hepatology, Johns Hopkins Medical Institutions, Baltimore, Maryland, USA describe their positive experience with the application of the OTSC System for reliable and easy flap closure after POEM.

Both patients presented with dysphagia and regurgitation and were diagnosed with achalasia. It was decided to proceed with POEM. After myotomy of the inner circular muscle bundles it was noted that the mucosal incision had elongated from 2 cm to 4 cm in one case. Whereas the distal part of the mucosal entry was successfully closed with conventional hemostatic clips (Resolution Clip, Boston Scientific) in both cases, closure of the proximal half was not possible even with different clips. As the clips were noted to slip to one side of the mucosal incision, there was a risk of displacing clips into the submucosal tunnel. Hence, all partially attached clips were removed with a biopsy forceps. Finally, complete closure of the mucosal incision was performed with the OTSC clip and the OTSC Twin Grasper in both cases. Contrast swallow of the esophagus the following day revealed no leaks in either patient.

The authors state that the OTSC clip provides more durable closure than standard hemostatic clips and full-thickness closure is achievable due to greater compressive force. Considering that failure of closure risks serious adverse events, like mediastinitis and sepsis, these features of the OTSC clip appear even more attractive.

An alternative method for mucosal flap closure during peroral endoscopic myotomy using an over-the-scope clipping device

Saxena P, Chavez YH, Kord Valeshabad A, Kallou AN, Khashab MA

Endoscopy. 2013 Jul;45(7):579-81
doi: 10.1055/s-0032-1326398

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June 2013 | Report on successful removal of an OTSC Clip

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

Mönkemüller K, Toshniwal J, Zabielski M

Gastrointest Endosc. 2012 Nov;76(5):1077-8
doi: 10.1016/j.gie.2012.06.009

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

During clinical live demonstrations at endo-update which took place under the presidency of Prof. Dr. H. Messmann and Prof. Dr. H.-D. Allescher in Augsburg, Germany, a neuro-endocrine tumor (NET) in the rectum was resected with the new Full-Thickness Resection Device of Ovesco Endoscopy: the FTRD.

A 62 year old patient showed a submucosal tumor of about 9 mm diameter. Biopsy revealed a neuroendocrine tumor. Prof. Dr Thomas Rösch (University Hospital Hamburg-Eppendorf) used the FTRD to resect the lesion. The FTRD consists of an elongated OTSC cap pre-mounted with a specially designed, derivative OTSC

clip and the cap incorporates a resection snare.

Prof. Rösch grasped the lesion with a grasping forceps and pulled the target tissue into the cap in a full thickness fashion. After mobilizing the tissue into the cap, the clip was released to seal the invaginated tissue before resection.

Right afterwards the snare was closed and the tissue resected with HF current.

The resection specimen included the full thickness of the wall carrying the NET, with a safety margin. The serosa was seen in histology, confirming that the specimen was a full-thickness resection.

endo-update 2012 | 30.11.-01.12.2012

Venue: Klinikum Augsburg, Augsburg, Germany

The FTRD device is not yet commercially available.

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

OTSC was well-covered in the scientific programme of this year's German Endoscopy Conference in Munich.

Clinical presentations confirm efficacy of OTSC clipping in a range of indications

Munich, March 14-16, 2013. The 43rd German Endoscopy Congress, DGE-BV, was held under the presidency of Prof. Dr. Christoph F. Dietrich.

A significant number of presentations had clinical data of OTSC clipping as their topic and confirmed clinical efficacy and safety in the primary indications of the product, hemostasis, closure of acute lesions/perforations and closure of chronic lesions/fistula (source: www.dge-bv.de).

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

Wedi E, Menke D, and Hochberger J, Strasbourg (France) reported about a cohort of 84 patients with OTSC clipping for GI bleeding, fistula and GI wall insufficiency.

101 OTSC clips have been used in this cohort, or 1.2 clips per patient. Indications included mainly severe upper GI peptic ulcer hemorrhage (n=38) and preventive clipping to avoid re-bleeding (n=12) or secondary perforation (n=18) after large area ESD. The clinical success rate in peptic ulcer bleeding was 79%, most patients had already been treated unsuccessfully with other hemostatic techniques before OTSC clipping or had been candidates for surgical hemostasis.

2 complications were encountered: 1 inadvertent clipping of an instrument with OTSC and fixation of the instrument to the tissue and one perforation of the sigmoid with the OTSC cap. The authors state that OTSC application is an effective procedure to deal with endoscopic situations that otherwise would require a surgical approach.

Der Einsatz des OTSC-Makroclips bei 84 Patienten mit schwerer GI-Blutung, Fisteln und Insuffizienzen – ein Résumé.

E. Wedi, D. Menke, and J. Hochberger, Strasbourg

Large single center cohort on OTSC hemostasis in severe GI bleeding

Kratt T, Stüker D, Gräpler F, Küper M, Wichmann D, Königsrainer A, Tübingen, showed data from their cohort on OTSC in endoscopic hemostasis (n=85). The bleeding location was in the upper GI tract in 63% (21% peptic gastric ulcers and 40% peptic duodenal ulcers) and in the lower GI tract in 37% (mostly bleeding after polypectomy in the rectum). The characteristics of the cohort underline the severity of bleeding: life-threatening bleeding (28.4%), patient in hemorrhagic shock (31.1%), immediate blood transfusion (33.8%), patient under anti-coagulation (21.6%), Forrest I bleeding (72.3%). OTSC placement was achieved with cap-suction in 72 cases and with an OTSC Anchor in 2 cases. Technically successful hemostasis for 72 hrs was achieved in 92.8% of cases, a persistent bleeding and an early relapse bleeding (<72 hrs) were seen in 3.6%, respectively. Late relapse bleeding (>72 hrs) was observed in 3.6%. No severe complications were observed; in 3 cases mucosal esophageal lesions from device introduction were seen. In 14.5% OTSC clipping was achieved with cap-suction in an initially successful other endoscopic therapy and in 13.3% for failure of other methods in the same treatment session. In 35.1% OTSC clipping was seen as an ultima ratio and as an alternative

to surgical therapy otherwise becoming necessary. The summary of the authors is that the simple and easy to handle OTSC system is an effective treatment in severe GI bleeding and can avoid surgery in several cases.

Das OTSC-Clip-System: Klinische Erfahrungen zur Therapie der schweren GI-Blutung bei 85 Patienten

T. Kratt, D. Stüker, F. Gräpler, M. Küper, D. Wichmann, A. Königsrainer, Tübingen

OTSC to prevent migration of covered self-expanding stents

Fährdrich M, Pohl T, Rolffs S, Sandmann M, and Heike M, Dortmund, presented their technique of using OTSC to avoid migration of covered, self-expandable stents. Stent migration has an incidence of up to 30% and represents a significant clinical challenge. To prevent stent migration the authors used OTSC to fix the stent permanently to the neighboring GI wall. In 24 cases with benign indication for stent placement OTSC fixation was carried out in the following locations: esophagus, small bowel and colon. After 5-8 weeks the OTSC clips were removed by Nd:YAG laser cutting to intentionally remove the stent. In all 24 patients the procedure was technically successful. In 1 patient an undesired stent migration before intentional removal was observed. In another case the stent had to be removed after a few days due to intolerance by the patient in a location close to the upper esophageal sphincter. The authors conclude that OTSC clipping was found to be a safe and practical technique and has prevented stent migration in 96% of the cases studied.

Verwendung des Ovesco-Clips zur Verhinderung der Migration bei vollgecoverten selbstexpandierenden Stents

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

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

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

OTSC-Anwendung bei manifester GI-Perforation: 30-Tages-Mortalität, Hospitalisationsdauer und Outcome nach endoskopisch erfolgreichem und nicht-erfolgreichem Perforationsverschluss

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

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

Nietsch H, Hammelmann F, and Asperger W, Halle, summarized their initial experience with OTSC in endoscopic closure of the GI organ wall in 10 consecutive applications. Indications included: postsurgical rectal anastomotic leak (n=2), rectal ESD perforation (n=1), gastric ESD perforation (n=2), esophageal perforation after balloon dilation (n=1), Mallory-Weiss tear (n=1), perforated gastric ulcer (n=1), post-surgical duodenal leak (n=1) and post-surgical bariatric suture line leak.

All cases were successful. The authors conclude: OTSC enables a safe transmural closure of spontaneous and iatrogenic perforations. In a majority of cases target tissue handling is possible with suction only and does not require additional instruments. In well-trained endoscopy centers the learning curve for OTSC is short.

Erfahrungsbericht der ersten 10 Anwendungen des endoskopischen OTSC-Clipsystems

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

OTSC for closure of distal esophageal perforation

Braun A, Richter-Schrag H, Hopt U, Fischer A, Freiburg, showed data on OTSC in the treatment of distal esophageal perforation after vomiting (Boerhaave, n=1) and iatrogenic injury (n=1). Esophageal perforation is a life-threatening situation with a high complication and mortality rate. In both cases endoscopic closure of the esophagus was achieved within 12 hrs after the lesion. Both patients received bilateral thorax drainage and antibiotic therapy. No patient developed sepsis. Starting oral intake was without problems. Control endoscopy after 3 months revealed no stenosis and both clips were found in place. The authors summarize that the closure of esophageal perforations with OTSC is a safe and effective method and is significantly more economic than common surgical therapy requiring longer hospital stays.

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

A. Braun, H. Richter-Schrag, U. Hopt, A. Fischer, Freiburg

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

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

The overall clinical success rate in the mixed case series was 82%. No procedure took more than 30 min. As complications 1 fistula recurrence (required second OTSC procedure), 1 re-bleeding and 1 remaining perforation were seen. The authors summarize that OTSC clipping is a fast procedure with a high primary success rate and is quick to learn.

Endoskopische Interventionen mit dem OTSC-System am Klinikum Neubrandenburg

T. Thomsen, B. Berthold, M. Khiabanchain, and I. Trabandt

OTSC for stopping gastroduodenal artery bleeding in duodenal ulcer

Kratt T, Stüker D, Kirschniak A, Heininger A, Wietek B, Königsrainer A, Tübingen, showed a case series (n=7) in which OTSC was applied in upper GI emergency hemostasis to stop bleeding from the gastroduodenal artery. Gastroduodenal artery bleeding is besides aortoduodenal fistula considered the most severe bleeding complication in the digestive tract, associated with high morbidity and mortality. In many cases surgical emergency hemostasis is inevitable. In all cases reported here the gastroduodenal artery was verified as the bleeding source by angiography after successful endoscopic treatment. In all 7 patients the acute bleeding from an ulcer at the posterior duodenal wall was successfully controlled with OTSC, in 4 cases fibrin glue was additionally applied. After the initial 72 hrs, 3 patients suffered from re-bleeding, which was then controlled surgically. No mortality was encountered in this case series. The authors draw the conclusion that OTSC is effective in emergency management of gastroduodenal artery bleeding. In more than half of the cases endoscopic management was the only therapy. In the other patients OTSC was a successful "bridge to surgery" and allowed stabilizing the patient before the operation.

OTSC-basierte Notfall-Hämostase der lebensbedrohlichen A. gastroduodenalis Ulkus-Arrosionsblutung: alleinige endoskopische Therapie oder „bridge-to-surgery“

T. Kratt, D. Stüker, A. Kirschniak, A. Heininger, B. Wietek, A. Königsrainer, Tübingen

Report on Ovesco FTRD (pre-commercial device)

Kratt T, Stüker D, Gräpler F, Schnek M, Adam P, and Königsrainer A, Tübingen, presented data of their first 8 cases with FTRD, a device of Ovesco Endoscopy, not yet commercially available. It combines modified OTSC clipping with tissue resection. In 7 of the 8 cases the procedure was technically feasible; in 1 case the target lesion could not be reached. The cases treated included various indications in which FTRD was used as a device

for full-thickness tissue retrieval with the primary purpose of enhanced histological examination of an in-toto full thickness specimen. The target lesions were in the upper GI tract, melanoma metastasis (n=3), GIST (n=1) or in the lower GI tract (adenoma or early colorectal cancer, low risk histology; n=4). The presentation gave a detailed case history of an elderly patient with recurrent adenoma (high grade dysplasia, partially adenocarcinoma) of the rectum. The patient had full thickness resection with FTRD under single-shot antibiotics and was discharged the following day. As histology demonstrated complete removal of the lesion, no further therapy was done. Follow-up was uncomplicated. After 14 weeks control endoscopy revealed that the clip had detached from the tissue, normal scar formation was seen at the resection site and no signs of residual lesion or new recurrence were found.

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

T. Kratt, D. Stüker, F. Gräpler, M. Schnek, P. Adam, and A. Königsrainer, Tübingen

FTRD is not yet commercially available.

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

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

Dr. Kratt presented data of his first 8 cases with FTRD, a device of Ovesco Endoscopy, not yet commercially available. It combines modified OTSC clipping with tissue resection. In 7 of the 8 cases the procedure was technically feasible; in 1 case the target lesion could not be reached.

The cases treated included various indications in which FTRD was used as a device for full-thickness tissue retrieval with the primary purpose of enhanced histological examination of an in toto full-thickness specimen. The target lesions were in the upper GI tract, melanoma metastasis (n=3), GIST (n=1) or in the lower GI tract (adenoma or early colorectal cancer, low risk histology; n=4).

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

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

Dr. Todd H. Baron and colleagues, Division of Gastroenterology & Hepatology, Mayo Clinic, Rochester MN, USA report about their experience with 45 patients and 48 OTSC clip placements from March 2011 to January 2012. Median follow-up time in this mixed cohort was 77 days (30–330 days). Indication break-down included hemostasis (n=7), closure of chronic fistula (n=28), closure of iatrogenic perforations (n=5), closure of post-esophagectomy anastomotic leakage (n=3) and miscellaneous (n=2). Before OTSC placement 49% of the patients had undergone other therapies for their condition that had failed. The overall clinical success rate was 71%. Hemostasis was achieved in 100% of cases. Anastomotic leakage and fistula was closed in 65%. Also one case of OTSC clip removal by means of APC-cutting of a clip hinge is described. The authors conclude that the OTSC clip appears clinically effective and is a welcome addition to the therapeutic armamentarium in the closure of leaks,

fistula, perforations and non-variceal bleeding.

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

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

October 2012 | The success rates for hemostasis in severe GI bleeding, perforation closure and chronic fistula closure are 88%, 79% and 73%, respectively

The OTSC System has been described in more than 40 clinical papers in the scientific literature covering a range of indications.

In order to summarize the clinical data published so far and to evaluate the overall clinical efficacy, Ovesco Endoscopy has commissioned systematic literature research on the OTSC System.

The study was limited to clinical publications and covered the key applications of the OTSC System, hemostasis, closure of acute GI lesions (perforations) and chronic GI lesions (fistula). Only clinical reports with >4 patients were included into the survey, that was carried out by Dr. Timo Weiland, novineon CRO, a specialized contract research organization for the medical device industry (www.novineon.com).

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

http://www.ovesco.com/fileadmin/Downloads/OTSC_System_clinical_data_eng_Rev01_2012-10-22.pdf (English)

http://www.ovesco.com/fileadmin/Downloads/OTSC_System_KlinischeDaten_deu_Rev01_2012-10-22.pdf (German)

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

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

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

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

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

Sandmann M, Heike M, Fährndrich M

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

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

FV24 Der Over-The-Scope-Clip (OTSC) – Erste klinische

Erfahrung bei der Behandlung von schweren Blutungen, Perforationen und Fisteln an 40 Patienten

Wedi E, Menke D, Hochberger J

The group around Prof. Raitel from Erlangen summarized their experience of 17 cases of OTSC® perforation closures in a retrospective evaluation. Dr. Hagel reported an overall success rate of 64.7%. He distinguished between cases with vital and with necrotic or inflamed tissue margins. In cases with non-vital wound margins the number of clips was greater than 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

Hagel A, Nägel A, Lindner A, Kessler H, Matzel K, Diebel H, Raitel S, Neurath MF, Raitel M

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

P22 Pure-NOTES-Sigmaresektion in einem Tier-Überlebensmodell

Bernhardt J, Köhler P, Fabian R, Schneider-Koriath S, Steffen H, Ludwig K, Lamadé W

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

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

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

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

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

Hagel A, Nägel A, Lindner A, Kessler H, Matzel K, Diebel H, Raitel S, Neurath MF, Raitel M, Erlangen

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

Raitel M, Hagel A, Neufert C, Nägel A, Neurath MF, Schiele A, Kessler H, Erlangen

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®:

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 cured with an OTSC® clip successfully. The authors conclude that „endoscopic snare resection of gastric subepithelial masses (< 3cm) seems to be a safe and minimal invasive procedure. If perforation occurs, it can be adequately managed by placing the OTSC® clip. These results can be regarded as a further encouraging step towards transgastric endoscopic surgery.“

PF1080 ENDOSCOPIC FULL THICKNESS RESECTION OF GASTRIC SUBEPITHELIAL MASSES – A STEP TOWARDS NOTES?

Christoph Schlag, Germany; Stefan von Delius; Hubertus Feussner; Dirk Wilhelm; Analena Beitz; Roland M Schmid; Alexander Meining

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 DGAV (German society of digestive & metabolic disease and German society 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 intrathoracic anastomotic insufficiency” and “Therapeutic concept for intraabdominal anastomotic insufficiency” session participants 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 | Closure rate of 90% in fistulas, anastomotic leaks and perforations treated with OTSC®: new case series published

A new case series, reported by Dres Sandmann, Heike and Faehndrich, Klinikum Dortmund Mitte, Germany, was published in the German *Zeitschrift fuer Gastroenterologie*. The authors present a series of 10 patients with penetrating defects within the digestive tract. Pathologies were fistulas (esophagotracheal, esophagopleural, gastrocutaneous and colovesical), perforations (after mucosectomy, after papillotomy and PEG misplacement) and anastomotic leakages (after gastrotomy 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, Anastomosal Leakages and Perforations within the Gastrointestinal Tract

Sandmann M, Heike M, Faehndrich M.
Z Gastroenterol. 2011 Aug;49(8):981-5
[Epub 2011 Aug 2]

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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 3/7 patients requiring further treatment afterwards. The overall success rate regarding leaks was 66% (ranging from closure of stomach perforation due to necrotising pancreatitis to gastro-cutaneous fistulas and postoperative leaks). The follow-up time ranged from 6 to 68 weeks.

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

Albert JG, Friedrich-Rust M, Woeste G, Strey C, Bechstein WO, Zeuzem S, Sarrazin C.
Gastrointest Endosc. 2011 Aug;74(2):389-97
[Epub 2011 May 25]

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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 oesophagodiaphragmatic 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]

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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 preoperative marking (n = 4).

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

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

Kirschniak A, Subotova N, Zieker D, Königsrainer A, Kratt T
Surg Endosc. 2011 Sep;25(9):2901-5 [Epub 2011 Mar 18]

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

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

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

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

Dr. Martin Fähndrich and Dr. Marcel Sandmann of the Department of Gastroenterology, Klinikum Dortmund, Germany for the fourth time successfully used the OTSC® System in a full wall resection for early colon cancer.

The tumor was secured within the resection cap of the system, the clip then released, and the target tissue eventually resected safely. The procedure was broadcasted by Germany's largest public broadcasting company WDR, Cologne. Audience ratings indicated almost 1 million viewers of the transmission.

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

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

Effective:

- Anastomotic failure
- Fistula
- Anastomotic correction

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

Kratt T, Stüker D, Küper M, v. Feilitzsch M, Königsrainer A, Kirschniak A

There were two more reports on successful application of Ovesco's OTSC® System:

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

Kratt T, Stüker D, Brücher B, Heining A, Miller S, Königsrainer A

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

Kratt T, Kramer M, v. Feilitzsch M, Strese C, Küper M, Schenk M, Greiner T, Lange J, Kirschniak A, Minkley L, Schröppel K, v. Weyhern CH, 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 monofilament snare through the other. The tissue 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, it required two maneuvers in one case. One gastric wall perforation occurred. The authors conclude that grasp-and-snare EMR is feasible with the OTSC® Anchor.

Endoscopic mucosal resection using a grasp-and-snare technique

von Renteln D, Schmidt A, Vassiliou MC, Rudolph HU, Caca K

Endoscopy 2010 Jun;42(6):475-80

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September 2009 | Ovesco's OTSC® System applied in live demos at 43rd Erlangen Symposium for Practical Gastroenterology and Hepatology, Erlangen University, 18–19 Sept 2009

Future prospects in complication management are a major topic of this meeting (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. Raitel.

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

Bariatric**January 2014 | Avoiding Surgery: Minimally invasive endoscopic management of an iatrogenic colon perforation**

Iatrogenic lesions of GI organs are a significant complication of diagnostic or interventional endoscopic procedures. Dr. Pilar Díez-Redondo and colleagues, Dept. of Gastroenterology, Hospital Universitario, Río Hortega, Valladolid, Spain present a case report on OTSC clipping for colon perforation closure: For assessment of iron deficiency an 82-year old woman was referred to the endoscopic unit. A gastroscopy confirmed a hiatal hernia.

Colonoscopy revealed no abnormalities. 18 cm proximal to the anus an iatrogenic perforation with a size of 12 mm occurred. To close the perforation endoscopically an 11/a OTSC clip was chosen. The target tissue and a piece of omentum were pulled into the applicator cap by suction and the clip released successfully, approximating the edges of the lesion. A small residual recess was closed with two conventional, endoscopic clips. The patient was discharged 10 days after the intervention. A 7-month follow-up confirmed the correct placement of the OTSC.

Iatrogenic colon perforations can cause severe complications and often require surgery, as the major drawback of an endoscopic approach with conventional clips is the limited ability of these clips to achieve sufficient apposition of the mucosa and submucosa to ensure tight sealing of the perforation. With the advent of the larger and more powerful OTSC clips, surgery can be avoided and perforations managed in a minimally invasive, endoscopic way. For that reason the authors suggest that the OTSC System should be available to all endoscopy units as a bail-out device.

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

Diez-Redondo P, Blanco JJ, Lorenzo-Pelayo S, Dela-Serna-Higuera C, Gil-Simón P, Alcaide-Suárez N, Pérez-Miranda M Rev Esp Enferm Dig. 2012 Oct-Nov;104(10):550-2

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

From June 18 to 20 the 30th GEEW – Gastroenterology and Endotherapy European Workshop – took place in Brussels, Belgium, under the directorship of Prof. Dr. Jacques Devière and colleagues.

The use of Ovesco's OTSC® clip was presented in a live procedure for the treatment of weight regain after Roux-en-Y gastric bypass.

The procedure was performed by Prof. Dr. J. Devière, Brussels, supported by Prof. Dr. G. Costamagna, Rome. The gastrojejunal pouch anastomosis that had enlarged over time, leading to weight-regain, was reduced in size by means of the placement of 2 OTSC® clips. A variation of the original technique described by Dr. A. Heylen was applied. The procedure took about 15 min. Prof. Dr. Devière also mentioned that he is currently running a study on 20 patients and that he treated 3 patients so far with satisfactory weight loss.

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

Heylen AM, Jacobs A, Lybeer M, Proßt RL Obesity surgery 2011 Oct;21(10):1629-33

www.live-endoscopy.com

November 2010 | Successful use of the OTSC® Clip in Revisional 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, where they report on 94 obese patients who had undergone Fobi pouch gastric bypass, and because of a dilation of the gastro-jejunosomy suffered a marked but unintended weight gain.

An endoscopic over-the-scope clip was used to narrow the pouch-outlet. The OTSC® application was safe and efficient to reduce the pouch-outlet in all cases. Best clinical results were obtained by narrowing the gastro-jejunosomy by placing two clips at opposite sites, hence reducing the outlet of more than 80%. Preferably, the clip approximated the whole thickness of the wall to avoid further dilatation of the anastomosis.

Between surgery and OTSC® application the mean BMI dropped from 45.8 (+/-3.6) to 32.8 (+/-1.9).

3 months (mean 118 days, +/-46 days) after OTSC® application the mean BMI was 29.7 (+/-1.8). At the second follow-up about 1 year (mean 352 days, +/-66 days) after OTSC® application the mean BMI was 27.4 (+/-3.8).

The authors conclude: „The OTSC® clip for revisional

endoscopy 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 Revisional Endoscopy Against Weight Gain After Bariatric Gastric Bypass Surgery

Heylen AM, Jacobs A, Lybeer M, Proßt RL

Obes Surg. 2011 Oct; 21(10):1629-33

[Epub 2010 Sept 3]

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

Dr. F. Iacopini published a case report on the use of OTSC to treat complications of gastric banding in the World Journal of Gastroenterology. Ovesco's OTSC clip was used to close full thickness stomach erosions resulting from long-term gastric band implantation. Two patients were successfully treated.

Over-the-scope clip closure of two chronic fistulas after gastric band penetration

Federico Iacopini, Nicola Di Lorenzo, Fabrizio Altorio, Marc Oliver Schurr, Agostino Scozzaro

World J Gastroenterol 2010 April 7; 16(13):1665-9

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Anorectal fistula closure**December 2014 | Full-thickness resection of adenoma in colonic diverticulum using Ovesco FTRD System**

PV Valli, M Kaufmann and P Bauerfeind, Dept of Gastroenterology and Hepatology, University Hospital Zurich and B Vrugt, Institute of Pathology, University Hospital Zurich in Switzerland published the first case where colonic adenoma located from a diverticulum, a rare finding, was treated using the FTRD full-thickness resection device.

The patient was a 66 year old woman with extensive diverticulosis in the entire colon. Colonoscopy revealed a 10 mm lesion (pathological size: 13 mm) inside a diverticulum in the ascending colon. Using a standard colonoscope with Indian ink injection and a hemoclip, the diverticulum was marked before a therapeutic colonoscope, fitted with the FTRD System, was introduced and advanced to the adenoma, located 10 cm proximal to the hepatic flexure. Adenoma and inverted diverticulum were mobilized into the cap of the FTRD with grasping forceps and additional suction before the FTRD clip was placed. Then resection was performed above the clip with the electrical snare integrated in the FTRD device. Histopathology showed successful full-thickness resection of a tubular adenoma with low-grade dysplasia and the resected diverticulum. The patient received single-shot peri-interventional antibiotic prophylaxis and was kept overnight for observation. Free of pain, the patient was discharged the next day, and no signs of complication arose over a 3 month follow-up period. The authors consider the new FTRD System as a secure treatment option for the resection of high-risk polyps without the risk of leakage of bowel content into the peritoneal cavity and see potential for use in an outpatient setting.

To watch a video of the procedure, please visit the website of Gastroenterology journal at

dx.doi.org/10.1053/j.gastro.2014.07.053

Endoscopic Resection of a Diverticulum-Arisen Colonic Adenoma Using a Full-Thickness Resection Device

Valli PV, Kaufmann M, Vrugt B, Bauerfeind P

Gastroenterology 2014, 147.5:969-71

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April 2014 | Efficacy and safety of OTSC Proctology confirmed by clinical data at two major German conferences**40th Congress of the German Society for Coloproctology, April 3–5, 2014 in Munich under the presidency of Prof. Dr. Dr. h.c. W. Hohenberger**

Prospective multicentric trial shows 90% success rate for OTSC Proctology in anal fistula closure

R. Prosst and co-authors, Stuttgart and Mannheim, Germany, presented data from a prospective multicentric trial including 20 patients treated with OTSC Proctology for anal fistula. 18 of 20 patients (90%) reached the treatment success defined as clinical healing of the anal fistula and

absence of recurrence at 6-month post-operative period. The authors conclude that OTSC Proctology is a new minimally invasive device for the treatment of anorectal fistula which is procedurally simple and time efficient. The risk profile is favourable, without relevant risk of fecal incontinence.

Anorektaler Fistelverschluss mittels OTSC Proctology: Ergebnisse einer prospektiven Beobachtungsstudie

R. Proßt, A. Joos, A. Herold, D Bussen, W. Ehni

Proktologisches Institut Stuttgart & Enddarmzentrum Mannheim

The 131st Congress of the German Society for Surgery, March 25–28, 2014 in Berlin under the presidency of Prof. Dr. J. Jaehne

OTSC Proctology in retrospective analysis of mixed case series: efficacy and safety confirmed

S. Dango and colleagues, Kassel and Goettingen, Germany presented their experience using OTSC Proctology in the treatment of transsphincteric anal fistula. They conclude that OTSC placement is a promising sphincter-preserving minimally invasive method with considerably less complications than in more invasive types of surgical fistula treatment.

Efficacy and safety of the over-the-scope clip in the treatment of anal trans-sphincteric fistula

S. Dango, D. Schrader, M. Ghadimi, F. Antonakis, R. Hesterberg

Dept. of General and Visceral Surgery, Rotes Kreuz Krankenhaus, Kassel and Dept. of General and Visceral Surgery, University Hospital, Goettingen

R. Mennigen et al., Muenster, Germany report about their first experience with OTSC Proctology fistula closure in patients who had recurrence after fistula surgery. 9 consecutive patients were included into the trial. The authors conclude that OTSC is a safe and effective procedure for closing recurrent anal fistula even in more complex cases with Crohn's disease or multiple surgical pretreatments.

Verschluss analer Rezidivfisteln mit dem OTSC Proctology System

R. Mennigen, M. Laukoetter, N. Senninger, E. Rijken

Klinik für Allgemein- und Viszeralchirurgie, University Hospital, Muenster

For more detailed information on the studies see reports in a pdf file on www.ovesco.com.

follow-up (6 months), 7 patients were still followed. In patients who had already completed the trial, mean follow-up was 10.8 months (6–15 months).

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

In his presentation PD Dr. R. Prosst, Stuttgart, coordinator of the trial, summarized that data were encouraging but completion of the trial had to be awaited. The trial is expected to close in 2013.

February 2013 | OTSC Proctology – description of operative technique in MITAT

PD Dr. R Prosst and Dr. W Ehni, Stuttgart Proctology Institute, Stuttgart, Germany, pioneers in the application of Ovesco's OTSC Proctology system, recently described their preferred technique for anal fistula closure with the device.

The procedure consists of 3 steps: local removal of the anoderm around the inner orifice of the fistula, debridement of the fistula tract and clip closure of the fistula.

They also present an indicative case study of a 54-year old female patient suffering from a high transsphincteric anal fistula and recurrence after unsuccessful prior surgery. After transanal clip release from the OTSC Proctology applicator, the internal fistula opening was adequately closed by the clip. Eight months after clip closure the fistula had permanently healed. The authors conclude fistula closure using the OTSC Proctology system represents a promising sphincter-preserving minimally invasive procedure.

The OTSC Proctology clip system for anorectal fistula closure: the „Anal Fistula Claw“: Case report

Prosst RL, Ehni W

Minim Invasive Ther Allied Technol.

2012 Jul;21(4):307-12 [Epub 2012 Jun 4]

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

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

Neue Techniken bei der Therapie der Analfistel

Herold A.

Chirurgische Allgemeine (2013); 14: 99–102

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

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

The trial presented an interim analysis on the first 15 patients. Inclusion criteria are supra-, extra- or high-trans-sphincteric anal fistula, including first recurrence but excluding patients with IBD.

Mean follow-up was 6.9 months (1–15 months) after OTSC placement. 8 patients had already completed

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